No. 22-0427

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

REGENERON PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

NOVARTIS PHARMA AG, NOVARTIS TECHNOLOGY LLC, NOVARTIS PHARMACEUTICALS CORPORATION, VETTER PHARMA INTERNATIONAL GMBH,

Defendants-Appellees.

On Appeal from the United States District Court for the Northern District of New York, No. 1:21-cv-1066, Hon. David N. Hurd

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BRIEF FOR THE AMERICAN ANTITRUST INSTITUTE AS AMICUS CURIAE IN SUPPORT OF PLAINTIFF-APPELLANT

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June 17, 2022

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INTEREST OF AMICUS CURIAE[1]

The American Antitrust Institute ("AAI") is an independent nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. It serves the public through research, education, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. AAI enjoys the input of an Advisory Board that consists of over 130 prominent antitrust lawyers, law professors, economists, and business leaders. *See* http://www.antitrustinstitute.org.[2] AAI submits this brief because the district court's opinion undermines patent and antitrust policy by distorting and biasing an objective analytical methodology. If the opinion is not overturned, fraud perpetrators who intentionally thwart competition and the progress of science and the useful arts will be wrongly shielded from scrutiny and liability.

INTRODUCTION

This appeal turns on the burden of pleading market definition when a plaintiff otherwise plausibly alleges *Walker Process* fraud. Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") alleges that Defendants Novartis Pharma AG,

[1] All parties consent to the filing of this amicus brief. No counsel for a party has authored this brief in whole or in part, and no party, party's counsel, or any other person—other than amicus curiae or its counsel—has contributed money that was intended to fund preparing or submitting this brief.

[2] Individual views of members of AAI's Board of Directors or Advisory Board may differ from AAI's positions.

Novartis Technology LLC, and Novartis Pharmaceuticals Corporation (collectively, "Novartis") fraudulently induced the U.S. Patent and Trademark Office ("PTO") to issue an invalid patent (the "'631 Patent") covering doctors' preferred method of administering a class of ophthalmic drugs that inhibit the production of vascular endothelial growth factor ("anti-VEGF drugs") to treat degenerative eye disease. Regeneron alleges Novartis deliberately lied to the PTO by falsely claiming to have pioneered the use of pre-filled syringes ("PFS") to administer anti-VEGF drugs, and that it attempted to monopolize a relevant product market for FDA-approved anti-VEGF PFS by procuring and asserting the '631 Patent.

Regeneron's proposed relevant market is premised in part on an allegation that competition among anti-VEGF PFS is not disciplined by competition from products that rely on the previous method of administering anti-VEGF drugs, which involved vials. A-418 (¶ 196). It alleges that 80-90% of doctors have switched their patients from vials to PFS, and that Novartis has conceded in a federal court filing that Regeneron's introduction of an anti-VEGF PFS caused its own anti-VEGF PFS to experience "'price erosion.'" A-365 (¶ 88); A-425 (¶ 215) (internal citation omitted).

In *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, the U.S. Supreme Court held that the enforcement of an invalid patent procured by a knowing and deliberate fraud on the PTO may be the basis of an action under § 2 of the

Sherman Act, provided the other elements of a § 2 case have been satisfied. 382 U.S. 172, 174 (1965). The district court did not question whether Regeneron plausibly pleaded invalidity and the required threshold showing of knowing and deliberate fraud. *See Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG*, No. 1:21-CV-1066, slip op. at 22 (N.D.N.Y. Jan. 31, 2022) [hereinafter "Op."]; *see also* Pl.'s Br. at 17 (citing International Trade Commission Staff proposed findings that Regeneron showed invalidity by clear and convincing evidence and that Novartis failed to disclose a co-inventor and withheld prior art from the PTO). Instead, it dismissed Regeneron's complaint on grounds that Regeneron failed to adequately allege a relevant product market.

According to the district court, Regeneron "bore the burden of alleging" that "there really is no fitting substitute" for anti-VEGF PFS. Op. at 27. It held that, where a plaintiff proposes to "limit the scope of the relevant product market to the scope of a patent," the plaintiff's burden is to plead that "the relevant product market would have to be constrained to the patented product." *Id*. at 26, 27. Here, the district court held, Regeneron pleaded a relevant market for anti-VEGF PFS that is "identical to the protection afforded to Novartis by the '631 Patent" without showing "why consumers would not be…free to choose between a vial or PFS." *Id*. at 24, 27. Accordingly, the district court reasoned, "Regeneron's proposed market fails." *Id*. at 28.

SUMMARY OF ARGUMENT

The district court created a special pleading rule and applied faulty logic. An antitrust plaintiff does not have to prove a relevant market "in the same way the corpus delicti must be proved to establish a crime." *United States v. Pabst Brewing Co.*, 384 U.S. 546, 549 (1966). At the pleading stage, a plaintiff's burden is to allege market boundaries using plausible fact allegations that (1) "bear a 'rational relation to the methodology courts prescribe to define a market for antitrust purposes," *Todd v. Exxon Corp*., 275 F.3d 191, 202–03 (2d Cir. 2001) (Sotomayor, J.) (citations omitted), and (2) "reference" demand substitution and thereby permit "inferences" that can (and must) be granted in the plaintiff's favor. *Chapman v. N.Y. State Div. for Youth*, 546 F.3d 230, 238 (2d Cir. 2008).

Despite numerous fact allegations that bear a rational relation to demand substitution, *see* Pl.'s Br. at 29–33, the district court found it implausible that firms vying to win the market for anti-VEGF PFS could generate "effective competition"—*i.e.* competition that leads to beneficial market effects such as lower prices or reduced output—so long as patients are permitted to switch back to vials. *Tampa Elec. Co. v. Nashville Coal Co*., 365 U.S. 320, 328, (1961) ("[T]he relevant market" describes the "area of effective competition."). But even if the district court were correct, its conclusion could never follow from the fact that anti-VEGF PFS are the subject of a patent claim. An "area of effective competition" cannot be

determined by reference to the scope of a patent grant; it requires an analysis of customer behavior.

I. The district court's reasoning is contrary to antitrust law, patent law, basic market definition principles, and good sense. Neither the fact of a patent grant, nor its scope, can substitute for the iterative analytical exercise of market definition in an antitrust case. The market definition inquiry delineates relevant markets according to the magnitude of buyer substitution among differentiated products. That a product may be differentiated by patented features instead of unpatented features is incapable of saying anything relevant about whether buyers would substitute away to alterative products if the patented product's price were to increase.

The district court wrongly relied on a version of the "scope of the patent test" that the Supreme Court has rejected. The scope of the patent test has been condemned by scholars and courts because it fails to account for the high risk of patent invalidity and strikes the wrong balance between patent and antitrust policy. Empirically, the PTO issues an excess of invalid patents, and litigation is an essential corrective to ferret out mistakes. Antitrust litigation is particularly valuable because it focuses attention on the most harmful invalid patents and carries no offsetting social risk when it targets invalid patents procured by intentional fraud.

II. The district court's holding also fails because it would prevent plaintiffs from pleading a required element of a *Walker Process* claim. The district court

held that if a plaintiff's *Walker Process* allegations "limit the scope of the relevant product market to the scope of a patent," then the pleading necessarily "fail[s] because [it] would allow any patented product to be a unique market by itself." Op. at 25. But to establish monopolization by patent fraud, courts require plaintiffs to plead that the fraudulent patent, in and of itself, constitutes the source of the patentee's monopoly power. *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 265 (7th Cir. 1984) (Posner, J.) (The patent must have "enough value to enable the patentee to drive all or most substitutes from the market."). A patent that does not have enough power to establish a distinct relevant market but that does have enough power to confer monopoly status is a contradiction in terms. The district court's rule would turn *Walker Process* pleading into an absurd Schrödinger's Cat exercise, whereby the plaintiff would have to allege that the fraudulent patent both confers monopoly power and not.[3]

III. The district court's fears about collapsing the integrity of *Walker Process* claims whenever the relevant market is coterminous with the scope of a patent claim are confused and mistaken. Op. at 26. The district court wrongly conflates lawful and unlawful monopoly. Its analysis fails, and its decision should be reversed.

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[3] "Schrödinger's Cat" is a thought experiment in quantum physics positing a hypothetical cat that, because of a paradox in quantum mechanical theory, "may be considered simultaneously both alive and dead." *Schrödinger's Cat*, Wikipedia, http://en.wikipedia.org/wiki/Schr%C3%B6dinger's_cat.

ARGUMENT

I. THE SCOPE OF A PATENT DOES NOT LIMIT THE RANGE OF PERMISSIBLE MARKET-DEFINITION INFERENCES IN A *WALKER PROCESS* CASE

The "far-reaching social and economic consequences" of patent grants "give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud[.]" *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). The U.S. Supreme Court protects this interest and balances it against the patent system's incentives to promote investments in innovation by permitting antitrust lawsuits against PTO applicants who fraudulently procure patent monopolies despite knowingly contributing nothing inventive to the public domain. *Walker Process*, 382 U.S. at 179 (Harlan, J., concurring) ("[T]his decision" is "aimed of course at achieving a suitable accommodation in this area between the differing policies of the patent and antitrust laws."); *see Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) ("The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'") (quoting U.S. Const., Art. I, § 8, cl. 8).

A *Walker Process* plaintiff, like any Section 2 plaintiff, must satisfy the remaining elements of a monopolization offense. Part of the necessary proof is to show that the patent monopoly amounts to a market monopoly under antitrust law.

To do so, the plaintiff must ordinarily define a relevant market in which the fraudulent and invalid patent had a "market effect and economic consequences." *Walker Process*, 382 U.S. at 178. "Without a definition of that market there is no way to measure [the patentee's] ability to lessen or destroy competition." *Id*.

A. The District Court Fundamentally Misunderstood Basic Market Definition Principles

The antitrust market definition exercise that measures a patentee's ability to lessen or destroy competition requires reference to the economic phenomenon of demand substitution. *United States v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377, 380 (1956) ("[T]he relevant market depends upon the availability of alternative commodities for buyers."); *see* U.S. Dep't of Just. & Fed. Trade Comm'n, Horizontal Merger Guidelines § 4, at 7 (2010) ("Market definition focuses solely on demand substitution factors[.]"). If the relevant market is not the result of this "autonomous method of analysis" but rather is "reverse engineered" by reference to extrinsic factors like the scope of a patent, then the market-definition exercise is a charade. Jonathan B. Baker, *Stepping Out in an Old* Brown Shoe*: In Qualified Praise of Submarkets*, 68 Antitrust L.J. 203, 214–15 (2000) (When markets are defined by factors others than demand substitution, market definition becomes an "an expositional tool" rather than "an analytic tool" and the "market definition and market concentration are conclusory."); *see Todd*, 275 F.3d at 202–03 (market def-

inition involves a prescribed "methodology" that requires an "analysis of interchangeability of use or cross-elasticity of demand.") (internal quotation omitted).[4]

In *Walker Process*, the Supreme Court explicitly recognized that the same core factual determinations about empirical buyer behavior that are required in other cases are required in cases involving patent grants. 382 U.S. at 177. It explained that "the exclusionary power of the illegal patent claim in terms of the relevant market" is "a matter of proof." *Id*. at 177–78. And it remanded the case because the trial court had not yet "analyzed any economic data" to conduct an "examination of market effect and economic consequences." *Id*. at 178.

Here, the district court did not base its market definition decision on an any analysis of the revealed preferences of buyers. It substituted a formalism—the scope of a patent grant—for the economic question of whether effective competition has been thwarted by an act of fraud. The district court ignored direct evidentiary allegations of demand substitution among anti-VEGF PFS and rested its opinion on an intuition that an alleged relevant market is suspect if it happens to be coterminous with the scope of a patent grant. Op. at 24.

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[4] Courts may also consider supply responses in addition to demand responses if a hypothetical monopolist would be constrained "by actual or potential competitors capable of providing new competition quickly with little sunk costs." *Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 499 (2d Cir. 2004); *see FTC v. Rag-Stiftung*, 436 F. Supp. 3d 278, 293 (D.D.C. 2020); *but see* Jonathan B. Baker, *Market Definition: An Analytical Overview*, 74 Antitrust L.J. 129, 132-38 (2007) (arguing that supply substitution is better addressed at subsequent stages of the analysis).

The district court's reliance on the scope of the patent rather than an empirical inquiry into demand substitution is erroneous, dangerous, and irreconcilable with *Walker Process*'s insistence on economic proof to define markets. Moreover, there is nothing unusual or suspicious about a relevant product market that proves to be coterminous with the scope of a patent grant after an analysis of buyer switching behavior. Indeed, it is *required* that the plaintiff allege the challenged patent is the patentee's source of monopoly power in a *Walker Process* case. *See infra* **II**.

To be sure, a relevant market that is coterminous with a patent grant is suspect if the patent is offered as the *only basis* for market definition. *See Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337, 1352 (Fed. Cir. 2011) (rejecting a "naked assertion that non-infringing goods are not an adequate substitute for a patented product" in the absence of "some allegation that, if proved, would define the market or the submarket with reference to consumer demand"); *Unitherm Food Sys. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1365 (Fed. Cir. 2004), *overruled on other grounds*, 546 U.S. 394 (2006) (market definition that "defined the scope of the…patent as coterminous with a relevant antitrust market" failed where expert "inferred market power from the possession of a patent" and "failed to present any economic evidence"). But that is precisely because a patent itself says nothing whatsoever about customer switching behavior, which is the relevant

market-definition metric. Relying on patent rights to reject a relevant market *despite* customer switching allegations, as the district court did here, is just as erroneous as relying on patent rights to define a market.

The court got off on the wrong foot by mischaracterizing "the relevant market Regeneron claims" and the scope of "the protection afforded to Novartis by the '631 Patent" as "identical." Op. at 24. By the district court's own reading, Regeneron's claimed relevant market covers only anti-VEGF PFS that are FDA-approved, yet the '631 Patent covers "a PFS containing any anti-VEGF." *Id*. The patent claim therefore is broader than the alleged relevant market, and Regeneron distinguishes the two based on a demand substitution factor: Doctors may not switch their patients from an FDA-approved anti-VEGF PFS to an unapproved anti-VEGF PFS notwithstanding that both are within the scope of the '631 Patent. *See also* Pl.'s Br. at 14, n.17.

More fundamentally, the district court erred by conflating patent monopoly and antitrust monopoly conceptually. The district court opined that "[t]he purpose behind granting a patent" is to incentivize innovation "by granting 'a statutory right to exclude' other competitors." Op. at 20 (citation omitted). But the court's statement begs the key question in this case: exclude from what?

"[P]atent rights are not *legal monopolies* in the antitrust sense of that word." *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1367 (Fed. Cir.

1984) (emphasis in original), *abrogated in part on other grounds*, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011). Patents confer the right to exclude competitors from making, using or selling an invention for a period of years, but they do not inherently or necessarily grant the right to exclude other competitors from *markets* during that time. A temporary antitrust immunity that may happen to follow as an incidence of a patent grant is a second-order by-product that is contingent on buyers' willingness to substitute. The "immunity" arises only if and when an invention over which a patentee holds exclusive rights proves to be sufficiently differentiated from comparable products in the minds of consumers.

The district court thought "commercial advantage" is embodied in "a patent's very nature," Op. at 20, but "a patent does not necessarily confer market power." *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 44 (2006). To assume that patent rights necessarily do confer market power is to commit an "elementary" analytical error. Edmund W. Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 Vand. L. Rev. 1727, 1729–1731 (2000); Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law § 1733b (4th & 5th eds. 2022) ("[E]quating the statutory 'patent monopoly' with substantial market power" is "careless[].").

A patent distinguishes one product from another on grounds that it contains an inventive element, but absent market power, that distinction has no antitrust significance. The invention may convey (1) no commercial advantage whatsoever, (2) a minor commercial "advantage" in the sense that it differentiates the product, but not in the sense that customers would be unwilling to switch to alternatives, or (3) a significant commercial advantage that "creates its own market" with concomitant monopoly power. Op. at 25. Accordingly, in a *Walker Process* case, the degree of market power the patent conveys can only be determined by an empirical inquiry into whether and how consumers substitute in relation to the patented product; it cannot be determined by reference to the fact of the patent grant or its scope. Mark A. Lemley & Mark P. McKenna, *Is Pepsi Really a Substitute for Coke? Market Definition in Antitrust and IP*, 100 Geo. L.J. 2055, 2088 (2012) (There are numerous industries where patents "suffice to make their [owners'] products somewhat distinctive in a product differentiated market," including "automobiles, vacuum cleaners, cleansers, and pharmaceuticals," but "[f]or antitrust law, the question is how distinctive those products are."). Jonathan B. Baker, *Market Definition: An Analytical Overview*, 74 Antitrust L.J. 129, 138 (2007) [hereinafter "Baker, *Analytical Overview*"] ("Market definition for antitrust purposes requires, first and foremost, an assessment of the *magnitude* of the economic force of buyer substitution.") (emphasis added).

Importantly, the empirical market definition inquiry into consumer switching behavior often generates results that are quite surprising. Judges cannot go with their gut and base market definition on what "strikes the court as plausible," Op. at 22, because "consumers' beliefs about products can drive purchasing behavior even if those beliefs are not based in reality." Lemley & McKenna, *supra*, at 2084 ("It might seem odd that two functionally identical products are in separate markets. But that is because markets aren't always about function."). Unpredictable switching is what makes market definition a "fact-intensive inquiry" and why "[t]he emphasis always is on the actual dynamics of the market." *Geneva Pharm. Tech. Corp. v. Barr Labs*., Inc., 386 F.3d 485, 496 (2d Cir. 2004).

In *Geneva*, for example, this Court recognized that "it might seem paradoxical" to suspect a significant group of patients presented with the choice between functionally identical branded and generic versions of the same drug—which have been certified by the FDA as therapeutically equivalent—would choose the former when the latter were offered "at about 70 percent" of the price. *Id*. at 496. Yet, the Court correctly defined separate markets for the branded and generic versions of the drug because the facts showed that consumers did not actually behave in ways that accorded with what function and price would predict. *Id*. at 497 ("a substantial customer base" counterintuitively remained loyal to the brand "despite conspicuously high prices" more than three years later); *see also, e.g., FTC v. Staples*,

970 F. Supp. 1066, 1075, 1078 (1997) (It was "difficult to overcome the first blush or initial gut reaction" that "the sale of consumable office supplies through office superstores" could form a distinct relevant product market, but the facts showed "certain consumers do not go elsewhere for their supplies" despite a "high degree of functional interchangeability" with supplies sold through other retailers.).

The district court may be forgiven for having gut instincts, but not for crediting them over fact allegations. The brand loyalist phenomenon in *Geneva* should have belied the district court's supposition that only price can spur demand substitution. Op. at 28, n.6 (80-90% switch rate not plausibly suggestive of demand substitution because "patients switched…at current price points"); *see* Baker, *Analytical Overview*, *supra*, at 147 n.65 ("[A] price increase is simply a measurable proxy for any small change (whether on a price or nonprice dimension) that makes what is sold in the candidate market less attractive to buyers."). Moreover, precedent in this Court recognizes the well-known "price disconnect" in the pharmaceutical industry, whereby "the doctor may not know or even care about the price and generally has no incentive to take the price into account" when writing patient prescriptions. *New York v. Actavis PLC*, 787 F.3d 638, 646 (2d Cir. 2015)

(citing AAI amicus brief). The district court's assumption that *patients* would switch exclusively according to "price points" was thus doubly mistaken.[5]

B. The District Court Applied a Defunct and Misguided Test that Generates Perverse Results

The district court purported to ground its analysis and holding in the need to protect patent owners from antitrust nuisance suits, as a matter of sound patent policy. Op. at 25–28. But it forgot that *Walker Process* cases "deal only with a special class of patents, *i.e.* those procured by intentional fraud." *Walker Process*, 382 U.S. at 176. That distinction "must be remembered." *Id*. Permitting recovery under the Sherman Act for "monopolization knowingly practiced under the guise of a patent procured by deliberate fraud cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure." *Id.* at 179–80 (Harlan, J., concurring).

The district court's rationale for deferring to patent rights irrespective of fraudulent procurement and invalidity has been definitively rejected as an analytical mistake. Scholars have given the rationale a proper burial and assigned it an epitaph: the "scope of the patent test." Michael A. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 Stan. Tech. L. Rev. 1, 1–2 (2012) [hereinafter "Carrier, *Why the Scope*"]. The "scope of the pa-

[5] Regeneron repeatedly alleges that doctors switch their patients, not vice versa. A-345 (¶ 21); A-365 (¶ 88); A-415 (¶ 190); A-418 (¶ 196); A-419-20 (¶ 200).

tent test" had its day in court, and lost, in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

In *Actavis*, the parties to an anticompetitive patent-infringement settlement agreement defended the agreement on grounds that its exclusionary effects did not exceed the scope of the patent grant. The Supreme Court did not agree that the fact that the "'anticompetitive effects fall within the scope of the exclusionary potential of the patent'" can "immunize the agreement from antitrust attack." *Id*. at 147 (citation omitted). It rejected the test and held that "patent and antitrust policies are both relevant in determining the scope of the patent monopoly—and consequently antitrust law immunity—that is conferred by a patent." *Id*. at 148; *accord New York v. Actavis*, 787 F.3d at 659.

As Professor Hovenkamp has explained, the scope of the patent test wrongly "perpetuate[d] the idea of the patent as a walled garden whose insides are largely free of scrutiny[.]" Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 Ohio St. L.J. 467, 476 (2015). The idea "was essentially that a patent is a type of monopoly defined by boundaries, identified by its written description and claims." *Id*. at 477. But as relevant in antitrust cases like this one:

> [T]he 'scope' question concerns the *location* of a patent's boundaries…. As in the law of real property, the owner's 'scope' defines what he or she may do as a matter of property law, such as evicting trespassers, but it says virtually nothing about anticompetitive uses that are reachable under antitrust law."

Id. at 478 (emphasis added).

The problem with the scope of the patent test is that it is "based on the crucial assumption that the relevant patent is valid." Carrier, *Why the Scope, supra*, at 5. The test breaks down whenever the patent is invalid. Obviously, "[i]f…the patent is not valid, then it does not have any scope at all." *Id.* at 6; *Actavis*, 570 U.S. at 147 ("'a *valid* patent excludes all except its owner from the use of the protected process or product," but "an *invalidated* patent carries with it no such right.") (emphases in original); *In re Cipro Cases I & II*, 61 Cal. 4th 116, 144 (2015) ("The scope of the patent test is flawed precisely because it assumes away whatever level of uncertainty a given patent…may be subject to."); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (3d Cir. 2012) (same).

The Court in *Actavis* recognized that "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy." 570 U.S. at 148. Citing *Walker Process* specifically, the Court held that, "to refer, as the [lower court] referred, simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent here may or may not be valid[.]" *Id*. at 147 (citing 382 U.S. at 174).

The assumption of substantive patent validity under the scope of the patent test is particularly unsound given the proportion of patents that prove, after litiga-

tion, to be invalid.[6] Experts believe that structural flaws in the U.S. patent system—particularly an excessive influx and backlog of patent applications—lead to "errors that result in a large number of invalid patents being issued." Michael D. Frakes & Melissa F. Wasserman, *Decreasing the Patent Office's Incentives to Grant Invalid Patents* 5, Brookings Inst., Hamilton Project (Dec. 2017), https://tinyurl.com/3n9wvwfa; *see* Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Perspectives 75, 78–79 (2005) (listing factors and incentives contributing to granting of invalid patents).

Despite the elevated burden of proof that challengers face in court, empirical studies show that 46% of all granted patents that are challenged and litigated to a final decision prove to be invalid. Lemley & Shapiro, *supra*, at 80. Indeed, pharmaceutical "follow-on" patents, like the method of administration patent in this case, fare even worse. Fed. Trade Comm'n, Generic Drug Entry Prior to Patent

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[6] The presumption of substantive patent validity under the scope test should not be confused with the *procedural* presumption of validity under the Patent Act. 35 U.S.C. § 282 (2006); *Am. Hoist & Derrick Co.*, 725 F.2d at 1360. The statutory presumption gives the alleged infringer a heightened standard of proof in rebutting validity, but it does not bear upon the legal substance of the patent claim. *See Microsoft Corp. v. i4i LLP*, 564 U.S. 91, 100, n.4 (2011); *id*. at 114 (Breyer, J., concurring) ("[I]n this area of law as in others the evidentiary standard of proof applies to questions of fact and not to questions of law…. Where the ultimate question of patent validity turns on the correct answer to legal questions…today's strict standard of proof has no application."); *Reckendorfer v. Faber*, 92 U.S. 347, 355 (1875) (patent is "a prima facie right only . . . subject to an examination by the courts"); *see also In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985); *Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1534 (Fed. Cir. 1983).

Expiration: An FTC Study 16 (2002), https://tinyurl.com/2tdxuhyj (generic firms prevailed in 73% of challenges to drug patents); *see* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. of Health Econ. 327, 334 (2012) (generics challenge 75% of non-active-ingredient patents and only 29% of active ingredient patents).

Despite these exorbitant invalidity rates, the PTO issues patents on "the overwhelming majority of patent applications in the United States, perhaps 85 percent." Lemley & Shapiro, *supra*, at 79. Consequently, there is widespread recognition among experts that "invalid patents are unnecessarily reducing consumer welfare, stunting productive research, and discouraging innovation." Frakes & Wasserman, *supra*, at 5.

C. No Interest of Patent Policy Is Served by Artificially Limiting Invalidity Challenges Against Patents Plausibly Procured by Intentional Fraud

Litigation plays an essential role in the patent system by ferreting out fraudulent and invalid patents. Without litigation, the patent system could not adequately deter fraud against the PTO, because the punishment is generally nothing more than the "loss" of the invalid patent. Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 Minn. L. Rev. 101, 172–73 (2006).

Consequently, patent policy not only permits legal challenges to weak patents; it affirmatively encourages them. *See, e.g., MedImmune, Inc. v. Genentech,*

Inc., 549 U.S. 118, 137 (2007) (licensees have standing to challenge patent validity or infringement without repudiating their licenses); *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973) (licensee in antitrust suit "may attack the validity of the patent under which he is licensed even though he has agreed not to do so in his license"); *Blonder-Tongue Labs. v. Univ. of Illinois Found.*, 402 U.S. 313, 349–50 (1971) (allowing alleged infringer to claim estoppel where patent previously declared invalid).

Antitrust litigation under Section 2 of the Sherman Act is particularly useful because it focuses attention on, and threatens with treble damages, only "those invalid patents that are actually causing harm, or are most likely to cause harm." Leslie, *supra*, at 172. At the same time, once knowing and deliberate fraud has been established, antitrust litigation carries very little social cost, because protecting a fraud perpetrator's right to enforce an invalid patent will never increase social welfare more than the enhanced market competition that antitrust law promotes. Arthur C. Pigou, The Economics of Welfare pt. II ch. IX § 17 (4th ed. 1932) ("As a rule . . . the social net product of any dose of resources invested in a deceptive activity is negative."). Accordingly, "as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play." *Walker Process*, 382 U.S. at 180 (Harlan, J., concurring).

The district court elided this calculus and simply assumed away the anti-competitive potential of the '631 Patent at the pleading stage, as though *Novartis* had already litigated the fraud dispute and won. It ignored this Court's "especially clear" admonition "that the economic incentives provided by the patent laws were intended to benefit only those persons who lawfully acquire the rights granted under our patent system." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) (citing *Walker Process*). Obviously, fraudulent procurers of invalid patents are not among those persons. Under the circumstances, the district court's "blind deference to the patent laws" was analytically indefensible. Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. Pa. L. Rev. 761, 764 (2002) [hereinafter "Carrier, *Unraveling*"].

II. DISCOUNTING *WALKER PROCESS* CLAIMS WHEN THE RELEVANT MARKET IS IDENTICAL TO THE PATENT SCOPE MAKES NO SENSE

The district court's reasoning falters for the additional reason that it prohibits plaintiffs from pleading an element of a *Walker Process* claim that they are required to prove. By holding that the plaintiff's claim fails in cases where it pleads a relevant market that is identical to the scope of a patent grant, the court necessarily holds that the plaintiff's claim fails if it alleges the defendant derives its monopoly power from the patent grant in such cases. Op. at 25; *see, e.g., United States v. Grinnell Corp.*, 384 U.S. 563, 576 (1966) (explaining that the relevant market de-

termines whether the defendant has monopoly power.). Yet, the failure to plead this very fact dooms a *Walker Process* claim. The district court's new pleading rule thus produces the absurd result that the plaintiff's complaint is damned if it alleges the coterminous patent confers monopoly power and damned if it does not.

The requirement that a *Walker Process* claimant must allege that the fraudulent patent is itself a source of monopoly power comes directly from *Walker Process*. 382 U.S. at 177. It is well recognized in this Circuit and elsewhere. *See, e.g., Christen, Inc. v. BNS Indus.*, 517 F. Supp. 521, 525–26 (S.D.N.Y. 1981) ("[I]n the absence of an allegation that these sales were derived from products within the scope of the illegal patent, [Plaintiff] fails to state a claim under Walker Process.") (internal citation omitted); *see also Brunswick Corp.*, 752 F.2d at 265 ("For a patent fraud actually to create or threaten to create monopoly power, and hence violate section 2, … [t]he patent must dominate a real market."); *Abbott Labs., Inc. v. Curtis Labs., Inc.*, 597 F.2d 1312, 1314 (9th Cir. 1979) ("[T]he claims of the illegal patent, in and of themselves, must provide the monopoly power proscribed by Section 2."); *see also Fishman v. Estate of Wirtz*, 807 F.2d 520, 564 (7th Cir. 1986) (Easterbrook, J., dissenting in part) ("[B]usiness torts violate the antitrust laws only if they produce injury to consumers by monopolizing a market that is otherwise competitive.").

The district court thought it "strange" that Regeneron alleged a pharmaceutical market based on a differentiated method of administering "the same drug." Op. at 24. But it is strange that the district court thought this strange. If Novartis' and Regeneron's customers would simply switch back to vials in response to an increase in the price of PFS, that would mean the '631 Patent does not confer monopoly power. Not only would the *Walker Process* claim be a losing proposition, but Regeneron would be foolishly wasting its time and money by bothering to assert it. Novartis, too, would be making the same mistake in asserting the extant infringement claims. *See* Op. at 12. The more reasonable inference, instead, is that both parties are rational actors who are litigating because they recognize that a patent on anti-VEGF PFS conveys meaningful market power. *Oetiker v. Jurid Werke*, 556 F.2d 1, 9 (1977) ("'[C]ertainly an attempt to enforce a fraudulently obtained patent would justify taking the bad actor at the full value of its own judgment and imposing monopolization liability.'") (internal citation omitted).

The district court should have recognized that it is *only* when the patent itself promises to confer meaningful market power that it becomes worth enforcing and/or challenging. *See* Lemley & Shapiro, *supra*, at 81 ("Many patents are virtually worthless, either because they cover technology that is not commercially important, because they are impossible to enforce effectively, or because they are very unlikely to hold up if litigated and thus cannot be asserted effectively."); Car-

rier, *Unraveling*, 150 U. Pa. L. Rev. at 791, n.22 (discussing Gallini & Trebilcock study showing that "'in a survey of [patent] licensors, there were no close substitutes [for the patented product] in only 27 percent of cases; whereas in over 29 percent of cases, they had more than 10 competitors.'") (internal citation omitted).

Indeed, patent applications have been likened to "lottery tickets" insofar as only 1.5 percent of all patents are ever litigated, and only 0.1 percent litigated to trial—the ones "important enough commercially to justify the costs of litigation." Lemley & Shapiro, *supra*, at 79, 81. At the pleading stage, the fact that a patent is plausibly alleged to have been fraudulently procured and enforced therefore is itself circumstantial evidence that the patent confers meaningful market power. It "'reflects the judgment of the firm that some commercial gain can be reaped from the effort.'" *Oetiker*, 556 F.2d at 8 (internal citation omitted).

Where, as here, the challenged patent has been enforced against a *rival*, there is little left for the market definition inquiry even to accomplish. Market definition's only purpose is "to determine whether an arrangement has the potential" to create or enhance monopoly power, *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460 (1986), and monopoly power is defined as "the power to control prices or exclude competition." *E. I. du Pont de Nemours & Co*., 351 U.S. at 391. Once it is clear an asserted patent threatens to exclude actual or perceived competition, there is no analytical need to pursue market definition any further, particularly at the

pleading stage. For all practical purposes, "[t]he fact of exclusion (or its attempt) defines the market." Ariel Katz, *Making Sense of Nonsense: Intellectual Property, Antitrust, and Market Power*, 49 Ariz. L. Rev. 837, 901 (2007); *see Ind. Fed'n of Dentists*, 476 U.S. at 460–61 ("[P]roof of actual detrimental effects…can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects.").

To be sure, a significant risk of chilling legitimate IP rights would be implicated if the *fraud* element of a *Walker Process* claim were too easily pleaded and proved. But plaintiffs must already run a gauntlet of obstacles to establish threshold *Walker Process* fraud. If the plaintiff can establish invalidity by clear and convincing evidence, it must also establish that the fraud is knowing and willful—a showing of "very specific conduct that is clearly reprehensible." *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998). The conduct must "alone form the basis of an actionable wrong (e.g., the common law action for deceit.)," and the plaintiff must also show causation. *Id*. at 1069–70.

Moreover, trial courts are instructed to evaluate the invalidity and fraud questions first, meaning the remaining elements of the monopolization claim, including market definition, are often never reached. *See, e.g., Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1348–49 (Fed. Cir. 2007) ("DDI's antitrust immunity remains intact due to insufficient evidence of fraud. We therefore reach neither

DDI's argument on this point nor…the market definition issue[.]"); *Nobelpharma*, 141 F.3d at 1068 (plaintiff is required to prove fraud first); *see also Transweb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1307 (Fed. Cir. 2016) (reaching market definition only where "3M does not challenge the sufficiency of the evidence supporting the jury's Walker Process fraud finding").

Accordingly, there is no need to take the "drastic step" of "throw[ing] the baby out with the bath water" by artificially blocking plaintiffs from pleading relevant product markets when *Walker Process* fraud is otherwise plausible. *Actavis*, 570 U.S. at 157. The onerous requirements for the fraud element ensure that the types of acts that are reachable under *Walker Process* are "hardly the types of conduct that we should worry about chilling." Leslie, *supra*, at 175.

III. THE DISTRICT COURT'S "COLLAPSE" THEORY IS WRONG

The district court maintained that the integrity of *Walker Process* claims would "collapse" if plaintiffs are permitted to plead a relevant market that is coterminous with the scope of a patent grant. Op. at 26. The district court is wrong and confused.

First, the district court worried that in every *Walker Process* case, "[t]he patent would exclude other firms from participating in the market, which is the definition of anticompetitive conduct." *Id*. But in every *Walker Process* case, the patent has either been (1) procured by fraud, in which case it does not carry any le-

gitimate exclusionary power under patent law, or (2) procured lawfully, in which case it is not anticompetitive under antitrust law even if it is later invalidated. *ZF Meritor, LLC v. Eaton Corp*., 696 F.3d 254, 278 (3d Cir. 2012) (*Walker Process* claims are premised on the "enforcement of a *legal* monopoly provided by a patent procured through fraud."); *see SCM Corp*, 645 F.2d at 1204 ("No court has ever held" that a patentee must forfeit his patent "the instant his patent monopoly affords him monopoly power"); *Walker Process*, 382 U.S. at 177 ("technical fraud" owing to "honest mistake" is a "complete defense"). The district court therefore posited a fact pattern that cannot possibly exist as a matter of patent or antitrust law.

Second, the district court said, "the mere act of seeking the patent evinces a clear intent to monopolize because a patent is itself a lawful monopoly." Op. at 26. This is wrong, and incoherent, for the same reason. An intent to obtain a lawful monopoly cannot be an intent to "monopolize," because the latter is an intent to do something illegal. *Walker Process*, 382 U.S. at 177 ("good faith" is a "complete defense"); *New York v. Actavis*, 787 F.3d at 652 ("specific intent" requires "willfully" acquiring monopoly power "as distinguished from 'growth or development as a consequence of a superior product, business acumen, or historic accident'") (quoting *Grinnell*, 384 U.S. at 576; internal citation omitted); Leslie, *supra*, at 157–58 ("Section Two…is not a strict liability offense.").

Finally, the district court said, "the patent would not only establish a dangerous probability of monopoly power, but a certainty, because no other firm could compete with the patent holder." Op. at 26. Wrong again. *Illinois Tool*, *Delano Farms* and *Unitherm* all make clear that the patent itself does not even establish a presumption of monopoly power, let alone a certainty. If the district court's only point is that a patent procured through intentional fraud that *does* confer monopoly power in a relevant market would necessarily establish a dangerous probability of successful monopolization, that is nothing more or less than the holding of *Walker Process*—binding precedent the district court should have followed.

CONCLUSION

For the foregoing reasons, the decision below should be reversed.

Respectfully submitted,

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June 17, 2022

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of June 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Second Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Randy M. Stutz

Dated: June 17, 2022

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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