No. 22-427

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,
and VETTER PHARMA INTERNATIONAL GMBH,
Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of New York
1:21-cv-1066 (Hon. David N. Hurd)

BRIEF FOR THE UNITED STATES AND
THE FEDERAL TRADE COMMISSION AS *AMICI CURIAE*
IN SUPPORT OF NEITHER PARTY

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INTEREST OF THE AMICI

The Department of Justice and the Federal Trade Commission enforce the federal antitrust laws and have a strong interest in their correct interpretation and application. We file this brief under Federal Rule of Appellate Procedure 29(a) to address several legal errors in the district court's analysis of whether the plaintiff's antitrust complaint adequately pleaded a relevant product market. We take no position as to whether the complaint adequately pleads a relevant antitrust market or states an antitrust claim.[1]

INTRODUCTION

A central issue in this appeal is the definition of the relevant antitrust product market. The products at issue here are a group of prescription medications that are injected into the eye to treat several serious diseases. They are sold in two dosage forms: vials (from which a doctor fills a syringe) and prefilled syringes. The complaint alleges that either form can be used to deliver the same medication, but that prefilled syringes are easier to use and to present a lower risk of infection and other complications. The fundamental question on appeal is whether prefilled

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[1] The United States has a pending action against Regeneron alleging violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A), for alleged conduct by Regeneron to subsidize the cost of Eylea that was ultimately reimbursed by Medicare. *See United States v. Regeneron*, Complaint, No. 1:20-cv-11217 (Filed June 24, 2020, D. Mass). This amicus brief is wholly unrelated to that pending action. This brief takes no position on any facts and is limited to a discussion of the correct legal principles for defining the relevant market in antitrust cases.

syringes can plausibly constitute an antitrust product market on their own or whether the relevant market must also include the vial dosage forms. We take no position on that ultimate question, but file this amicus solely to state the applicable antitrust standards for determining its answer, which the district court did not properly consider.

Plaintiff Regeneron Pharmaceuticals, Inc., alleges that the relevant market is limited to prefilled syringe products. It accuses defendant Novartis (which holds a patent on prefilled syringe products) of attempting to monopolize that market and of conspiring with one of its manufacturing partners, defendant Vetter Pharma International GmbH, to restrain trade in that market.[2] The district court dismissed Regeneron's complaint on the grounds that the relevant market could not be limited to prefilled syringes. In so holding, the district court made two distinct errors in its legal analysis that this Court should correct on appeal.

First, the court improperly concluded that the relevant product market must include both vials and prefilled syringes simply because they are *functional* substitutes for each other—*i.e.*, they contain the same medicines and are used for the same purpose. The proper question is whether the products are reasonably interchangeable from the standpoint of the relevant consumers, which typically

[2] "Novartis" refers collectively to defendants Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation.

means that there is a high enough cross-elasticity of demand between them (in economists' terms) that the price of one sufficiently constrains the price that can be charged for the other. *See, e.g.*, *Todd v. Exxon Corp.*, 275 F.3d 191, 201-02 (2d Cir. 2001). This Court has held, in another case involving pharmaceuticals, that even products that are exact functional substitutes, containing the same medication in the same form, may be in separate markets for purposes of antitrust analysis. *See Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496-500 (2d Cir. 2004). Rather than focusing on functional substitutability, the district court should have assessed the product market allegations using one of the well-established methodologies the complaint invokes for determining whether products are sufficiently interchangeable that they must be included in the same market. The complaint includes allegations relevant to two established frameworks for market definition—the "practical indicia" identified by the Supreme Court in *Brown Shoe Co., Inc. v. United States*, 370 U.S. 294 (1962), and the "hypothetical monopolist" test endorsed by this Court and others—but the district court did not address either of them.

Second, the district court compounded its error by adopting a new rule, never recognized by any other court, that absent extraordinary circumstances, a relevant product market for antitrust purposes cannot be limited to the products covered by a patent. That holding reflects a fundamental misunderstanding of the

relationship between patent law and antitrust law and cannot be squared with governing legal principles of antitrust market definition.

ISSUE PRESENTED

Did the district court apply incorrect legal principles in analyzing whether the complaint adequately pleaded a relevant product market?

STATEMENT

1. Overview. We take the facts stated here from the operative complaint (ECF No. 87). This case involves a class of medications known as anti-VEGF agents that are administered by injection into the eye.[3] When first introduced, the drugs were packaged in vials, from which a doctor (or other clinician) would fill a syringe at the time of injection. Newer versions—the products at issue here—come in prefilled syringes (or "PFS"), which contain the same medicine but are easier to administer and have a lower risk of infection and other complications.

Novartis owns United States Patent 9,220,631 (the '631 Patent), which broadly claims anti-VEGF agents in prefilled syringes. Compl. ¶ 9. Its licensee, Genentech, Inc., markets one such drug in the United States under the brand name Lucentis. When Regeneron began selling a version of its competing drug, Eylea, in prefilled syringes, Novartis sued Regeneron for patent infringement. Regeneron in

[3] VEGF stands for vascular endothelial growth factor—a naturally-occurring protein that may cause disease if overproduced.

turn sued Novartis and Vetter (which provides syringe-filling services for Genentech) for antitrust violations.

The parties dispute the relevant product market for Regeneron's antitrust claims (apparently agreeing that the relevant geographic market is the United States). Regeneron contends that the relevant product market consists of anti-VEGF agents in prefilled syringes—*i.e.*, that it is coextensive with the scope of Novartis's patent. Defendants contend that the relevant market must also include anti-VEGF agents in vials.

2. Anti-VEGF Agents in the U.S. Market. According to the complaint, there are three main anti-VEGF agents on the U.S. market approved by the Food and Drug Administration for treatment of eye diseases: Lucentis, Eylea, and Beovu. Compl. ¶¶ 2, 47.

Lucentis was developed jointly by Novartis and Genentech and is marketed in the United States by Genentech.[4] *Id.* ¶ 48. The FDA approved Lucentis in vials in 2006 and in prefilled syringes in 2016. *Id.* ¶ 49. Following the launch of the prefilled syringes in early 2017, Genentech reported that more than 80% of patients switched to the newer dosage form. *Id.* ¶ 85. Today, prefilled syringes account for nearly all Lucentis sales in the United States. *Id.* ¶ 49.

[4] When the complaint was filed, Novartis held a significant financial stake in Genentech's parent company. Compl. ¶ 2.

Eylea, which is made and sold by Regeneron, was approved by the FDA in in vials in 2011 and in prefilled syringes in 2019. *Id*. ¶¶ 58, 62. As with Lucentis, most patients switched to the prefilled syringes, which now account for approximately 80% of Eylea sales. *Id.* ¶ 62. Within a few months of the launch of Eylea prefilled syringes, market share shifted away from Lucentis prefilled syringes to Eylea. *Id.* ¶ 63.

Beovu, which is marketed by Novartis, was approved by the FDA in 2019 and launched thereafter. *Id.* ¶ 64. When the complaint was filed, Beovu was approved only in vials, but Novartis was planning to seek approval for a prefilled syringe version. *Id*. ¶ 65

3. Regeneron's Antitrust Claims. Regeneron's complaint asserts four antitrust claims: three counts of attempted monopolization (in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2) against Novartis alone, and one of count of unreasonable restraint of trade (in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1) against Novartis and Vetter. [5]

Two of the attempted monopolization claims are based on *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), which held that a patent owner may face antitrust liability for enforcing a patent

[5] Regeneron also alleges tortious interference under state law, which the district court also dismissed and which we do not address.

with knowledge that it was obtained by "knowingly and willfully misrepresenting facts to the Patent Office." *Id.* at 177 & n.5.[6] A *Walker Process* claim involves two steps: the plaintiff must first prove fraud and knowing enforcement, and then separately prove the elements of monopolization or attempted monopolization. *See, e.g.*, *TransWeb, LLC v. 3M Innovative Prop. Co.*, 812 F.3d 1295, 1306 (Fed. Cir. 2016). Regeneron alleges that Novartis defrauded the Patent Office by deliberately failing to disclose "prior art" (*i.e.*, earlier inventions) that would have doomed its patent application, *see* 35 U.S.C. § 102, and by failing to name all the actual inventors as required by the patent laws, *see id.* § 116(a). Compl. ¶¶ 219-221, 277-282. It further alleges the elements of attempted monopolization—*i.e.*, that Novartis engaged in anticompetitive conduct by enforcing the fraudulently obtained patent, that it had the specific intent to monopolize the prefilled syringe market, and that there is a dangerous probability it will succeed in doing so. Compl. ¶¶ 229; 244-45; *see generally Spectrum Sports v. McQuillan*, 506 U.S. 447, 456 (1993) (attempted monopolization requires proof "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power").

[6] A *Walker Process* claim may also be based on the applicant's knowing and willful failure to disclose material facts to the Patent Office. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069-70 (Fed. Cir. 1998).

The third attempted monopolization claim alleges that Novartis sought to achieve a monopoly through other alleged anticompetitive conduct, including efforts to use its patent rights to coerce Regeneron into entering into an exclusive agreement with Vetter to provide syringe-filling services and the filing of "bogus patent infringement lawsuits" to delay Regeneron's entry into the prefilled syringe market. Compl. ¶¶ 241, 243. The Section 1 claim alleges that Novartis and Vetter entered into a series of agreements intended to frustrate and delay Regeneron's entry into the prefilled syringe market. Compl. ¶¶ 256-65.

4. Product Market Allegations. Regeneron contends that the relevant product market for all the antitrust claims consists of FDA-approved anti-VEGF agents in prefilled syringes. *Id.* ¶¶ 191, 201, 223, 234, 252. The complaint alleges that prefilled syringes do not "meaningfully compete" with products in vials because the prefilled syringes have "distinct advantages in terms of accuracy and convenience" and are "quicker and easier to use than vials." *Id.* ¶¶ 196, 197. As a result, physicians have a "strong preference" for prefilled syringes over vials. *Id.* ¶ 200.

The complaint alleges that these benefits have been recognized by industry participants and by Novartis and Genentech themselves. *Id.* ¶¶ 196-98. It further alleges that manufacturing and selling anti-VEGF agents in prefilled syringes requires production facilities and capabilities different from those needed for

producing vials. *Id*. ¶ 199. It also alleges that the rapid switch of most patients from vials to prefilled syringes supports treating them as distinct markets. *Id*. ¶ 200. The complaint further asserts that "a small, but significant, price increase in the PFS version would not cause physicians to substitute the vial version for PFS (even if they contain the same underlying anti-VEGF)." *Id*. ¶ 200.

5. The District Court Decision. The district court held that Regeneron had not adequately alleged a relevant product market and dismissed the complaint for failure to state a claim. The court acknowledged that market definition is a "deeply fact-intensive inquiry," but held that a complaint may nonetheless be dismissed at the pleading stage if "a plaintiff's market definition does not include 'all products reasonably interchangeable by consumers for the same purpose.'" Op. 23 (quoting *City of New York v. Group Health Inc.*, 649 F.3d 151, 155 (2d Cir. 2011)). The court found it "strange" that a product market could be "limited to anti-VEGFs in a PFS when the same product comes in a vial." Op. 24. It held that Regeneron's asserted justifications for the more limited market—that prefilled syringes have performance based advantages over vials, that the products have different manufacturing facilities, and that the physicians would not switch back to vials even in the face of a small but significant price increase for prefilled syringes—"failed to meaningfully explain why anti-VEGF vials are not a reasonable substitute for an anti-VEGF PFS." Op. 26, 27.

The district court also found Regeneron's proposed market deficient because it was "identical to the protection afforded to Novartis by the '631 Patent." Op. 24. In the court's view, accepting Regeneron's proposed market would mean that "all patents would immediately confer complete monopoly power to the inventor." Op. 25-26. The court viewed the improvements described in the patent as a sufficient reason why customers would prefer prefilled syringes to vials and a justification for any price differential. It reasoned that "most any patent" will improve a product's efficacy "enough to merit some heightened costs," and held that such a commercial advantage is "a sacrifice the law is willing to make to spur technical and technological advancement." Op. 25.

The court suggested that the commercial advantages conferred by a patent would "evaporate" if a relevant product market could be limited to what the patent claims. "[I]f a patent allows its owner to exclude other firms from producing products covered by its terms, and an antitrust plaintiff can define a market so narrowly that the patent itself creates its own market," the court stated, "then plaintiffs could never fail to plead out an antitrust claim against a patent owner as long as they raised a colorable challenge to the patent's validity." Op. 25-26.

The district court expressed concern that a product market limited to the scope of the patent's claims would be especially problematic when it comes to *Walker Process* claims because it would mean that "each of the three elements of

an attempted monopolization claim"—*i.e.*, predatory or anticompetitive conduct, specific intent to monopolize, and a dangerous probability of achieving monopoly power—"would be met as a matter of course." Op. 26. It reasoned that "[t]he patent would exclude other firms from participating in the market, which is the definition of anticompetitive conduct," that seeking a patent would "evince[] a clear intent to monopolize because a patent is itself a lawful monopoly," and that the grant of 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." *Id.* Thus, the court concluded, a market limited to the patent scope would "collapse" the *Walker Process* inquiry by effectively eliminating any requirement that the plaintiff prove the elements of a monopolization claim, such that "every claim of patent fraud would give rise to an antitrust claim by definition." *Id.* at 26-27.

The court acknowledged that "one can imagine a circumstance where the subject of a patent is so novel that there really is no fitting substitute, and the relevant market would have to be constrained to the patented product," but concluded that Regeneron had not alleged such circumstances. *Id.* It held that "[i]nstead of explaining why consumers would not be so free to choose between a vial or PFS delivery system for an anti-VEGF as to create a separate market," Regeneron had merely alleged that prefilled syringes were "like all patented

products, at least marginally superior to the vial," and that this was not enough. *Id.* at 27-28. The court dismissed the antitrust claims with prejudice. *Id.* at 35.

ARGUMENT

The district court's decision departs from well-settled principles of market definition that have been consistently applied by this Court and many others. In particular, the district court erred by improperly focusing on the functional similarities between vials and prefilled syringes, rather than on the extent to which consumers are willing to substitute one for the other. And it compounded this error by applying a new and erroneous rule that an antitrust product market generally cannot be coextensive with the claims of a patent.

I. PRODUCT MARKET DEFINITION IN ANTITRUST CASES

Determining the relevant market is an important step in many kinds of antitrust cases. Market definition is not a goal in itself but rather a tool to assess whether a defendant can exercise market power or monopoly power.[7] The goal is to "identify the market participants and competitive pressures that restrain an

[7] The Supreme Court has defined monopoly power as "the power to control prices or exclude competition," *United States v. E. I. Du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956), and market power as the ability "to force a purchaser to do something that [it] would not do in a competitive market," *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 14 (1984), including "the ability to raise prices above those that would be charged in a competitive market," *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents*, 468 U.S. 85, 109 n.38 (1984). The difference between monopoly power and market power is one of degree. *See, e.g.*, *Reazin v. Blue Cross & Blue Shield, Inc.*, 899 F.2d 951, 967 (10th Cir. 1990).

individual firm's ability to raise prices or restrict output." *Geneva Pharms.*, 386 F.3d at 496. Antitrust law speaks of a "relevant" market because the task before a court is to identify the grouping of products or services that is "relevant to the particular legal issue being litigated." Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 533c (4th ed. 2015).

The key question in determining whether a group of products constitutes a distinct market for antitrust purposes is whether they have "reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered." *Todd*, 275 F.3d at 201. But the fact that there is some degree of substitutability between two products does not necessarily mean that they are "reasonably interchangeable" in the antitrust sense, such that they belong in the same antitrust product market. As the Supreme Court long ago explained, "[f]or every product, substitutes exist. But a relevant market cannot meaningfully encompass that infinite range. The circle must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn." *Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 612 n.31 (1953).

To draw this line, courts generally utilize the economic concept of cross-elasticity of demand. Thus in *Times-Picayune*, the Court held that the relevant market should "exclude … products whose 'cross-elasticities of demand' are

small." *Id.* This Court has similarly held that "products or services are reasonably interchangeable where there is sufficient cross-elasticity of demand," which "exists if consumers would respond to a slight increase in the price of one product by switching to another product." *Todd*, 275 F.3d at 201-02; *see also AD/SAT, Div. of Skylight, Inc. v. Associated Press*, 181 F.3d 216, 227 (2d Cir. 1999).[8]

Cross-elasticity of demand need not be precisely quantified and there is no fixed threshold for what constitutes a sufficiently "high" level of cross-elasticity to determine that products are in the same market. 1 Am. Bar Ass'n, *Antitrust Law Developments* § 6B-1-b n.46 (2022); *see also Knutson v. Daily Rev., Inc.*, 548 F.2d 795, 804 (9th Cir. 1976) (plaintiffs did not have to "produce a numerical value of the cross-elasticity of demand"). The key question is ultimately whether "the ability of consumers to switch to a substitute restrains a firm's ability to raise prices above the competitive level." *Geneva Pharms.*, 386 F.3d at 496.[9]

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[8] In certain markets, such as those in which products do not have a price, reasonable interchangeability and cross-elasticity of demand may be assessed using other metrics, such as product quality. *See, e.g.*, *Community Publ'rs, Inc. v. Donrey Corp.*, 892 F. Supp, 1146, 1153, 1158-59 (W.D. Ark. 1995) (where daily local newspapers competed for readers and advertisers, court assessed whether changes in quality constrained ability to exercise market power); *Antitrust Law Developments*, *supra*, § 6B-1-b n.46 (noting that cross-elasticity of demand "may also be applied to a change in quality").

[9] Sometimes the competitive price level is the current price level, but not always. For example, in a monopolization case, current prices may already be supracompetitive, *i.e.*, higher than they would be in a competitive market.

A properly defined product market can be a subset of a larger market. For example, there may be a market for apples (if their prices are not sufficiently constrained by other fruit), and at the same time a distinct market for organic apples (if their prices are not sufficiently constrained by conventional apples). *Cf. FTC v. Whole Foods Mkt.*, 548 F.3d 1028, 1038-1041 (D.C. Cir. 2008) (premium, natural, and organic supermarkets could be distinct market from supermarkets generally). Which market is the *relevant* market turns on the particular antitrust question at issue. If a court is assessing whether the merger of organic apple growers will have anticompetitive effects, and conventional apples do not sufficiently constrain the price of organic apples, the relevant market is likely to be organic apples and not apples generally.

In every case, market definition turns on "the actual dynamics of the market rather than rote application of any formula," *Geneva Pharms.*, 386 F.3d at 496, and "there is no requirement to use any specific methodology," *Optronic Techs., Inc. v. Ningbo Sunny Elec. Co*., 20 F.4th 466, 482 (9th Cir. 2021). Which analytical method is most appropriate in any given case turns on factors such as the nature of the industry, the products at issue, and the availability of data.

One well-established framework that courts have employed to assess the relevant market derives from the Supreme Court's *Brown Shoe* decision. That approach examines "practical indicia" to define a relevant market, including

"industry or public recognition of the []market as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Brown Shoe*, 370 U.S. at 325; *see also Geneva Pharms.*, 386 F.3d at 496-500 (applying *Brown Shoe* factors).[10]

Another commonly used approach to market definition that this Court has endorsed is known as the "hypothetical monopolist test" or "HMT." *See United States v. Am. Express Co.*, 838 F.3d 179, 198 (2d Cir. 2016) ("*Amex*") ((noting that this Court "often applies" HMT), *aff'd sub nom. Ohio v. Am. Express Co.*, 138 S. Ct. 2274 (2018).[11] In its usual form, this test assesses whether a single profit-maximizing firm controlling all of the proposed market (a "hypothetical monopolist") likely would raise prices by a small but significant amount (*e.g.*, 5%) over a sustained period.[12] For example, if such a price increase would not be

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[10] *Brown Shoe* speaks of defining "submarkets" within a larger market, but as this Court has observed, that terminology is "somewhat of a misnomer, since the 'submarket' analysis simply clarifies whether two products are in fact 'reasonable' substitutes and are therefore part of the same market." *Geneva Pharms.*, 386 F.3d at 496. The inquiry is better framed as a search for a relevant market.

[11] The Court has sometimes referred to a "hypothetical cartel" test rather than a "hypothetical monopolist," *see, e.g.*, *Todd*, 275 F.3d at 201-02, but the difference in terminology is immaterial for purposes of this brief.

[12] Different antitrust contexts may call for variations on the test. For example, in the case of monopsony or oligopsony, the factors courts look at are reversed because that situation involves the "'mirror image' of the traditional seller-side

profitable because too many consumers would switch to substitute products (i.e., cross-elasticity of demand is sufficiently high), then the proposed market is too narrow. But if customers would pay the higher price in sufficient numbers to make the increase profitable then the proposed market can be a distinct antitrust market. *See Amex*, 838 F.3d at 198-200; U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 4.1 (2010) (describing hypothetical monopolist test in detail), at https://www.justice.gov/atr/horizontal-merger-guidelines-08192010.[13] The hypothetical monopolist test may overlap with the *Brown Shoe* framework, since some of the same evidence will often be considered under either approach.

II. THE DISTRICT COURT COMMITTED LEGAL ERRORS WHEN ANALYZING THE PRODUCT MARKET ALLEGATIONS.

The district court misapplied the foregoing principles in assessing the sufficiency of Regeneron's product market allegations.

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market analysis." *Todd,* 275 F.3d at 202. And in a case involving an alleged existing monopolist, the test could ask whether a small but significantly *lower price* (or a small but significantly *higher quality*) would prevail if there were more than one major firm supplying the candidate product, since in that case the current price might be the monopoly price rather than a competitive price.

[13] The hypothetical monopolist test may also be used to assess the geographic boundaries of relevant markets. *See, e.g.*, *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 338 (3d Cir. 2016).

A. The Court Improperly Focused Solely on Functional Substitutability.

The district court erred in its product market analysis by focusing on whether prefilled syringes and vials are *functionally* interchangeable, rather than on whether there is sufficient cross-elasticity of demand between the two forms to make them reasonably interchangeable in the antitrust sense. The court found it "strange" that the market could be "limited to anti-VEGFs in a PFS when the same drug comes in a vial as well," and concluded that Regeneron had not "meaningfully explain[ed] why anti-VEGF vials are not a reasonable substitute for an anti-VEGF PFS." Op. 24. 27. In other words, it concluded that because vials and prefilled syringes contain the same medicines, they must be in the same market for antitrust purposes.

That analysis rests on the very same error committed by the district court in *Geneva Pharmaceuticals*. In that case, a drug manufacturer accused its competitors of monopolizing and restraining trade in a market for the generic version of a blood-thinning drug. The district court held that the relevant market must include not just the generics, but also the brand-name version of the drug, which was an exact functional equivalent: it contained the same dose of the same medication in the same form as the generics, and was FDA approved for the same treatment. 386 F.3d at 494, 496. This Court reversed, explaining that while it might seem "paradoxical" for two functionally equivalent products to be in separate markets, a

proper antitrust analysis using the *Brown Shoe* factors compelled that conclusion. *Id.* at 496. Among other things, the Court noted that the branded drug fetched a consistently higher price than the generics and that the price of the brand drug did not drop when additional generic competitors entered the market. *Id.* at 496-97.

The Third Circuit likewise recognized in the pharmaceutical context that functional substitutability does not necessarily mean that products are part of the same market in *FTC v. AbbVie Inc.*, 976 F.3d 327 (3d Cir. 2020). Like this case, *AbbVie* involved different delivery methods for the same underlying drug—there, testosterone, which can be administered either by injection (typically in a doctor's office) or through application of a topical gel (which can be done at home). The products were functional substitutes because they contained the same drug used to treat the same conditions. But the Third Circuit upheld the district court's determination that they were not in the same market because there was "little cross-elasticity of demand" between the gels and the injectables and there was testimony from the defendant's employees that its gel did not compete against injectables. *Id.* at 372-373.

Rather than focusing on functional substitutability, the district court should have examined whether Regeneron adequately alleged that prefilled syringes constitute a distinct market under established legal frameworks. Regeneron's complaint plainly invokes both the *Brown Shoe* factors and the hypothetical

monopolist test. With respect to *Brown Shoe*, the complaint refers multiple times to "practical indicia" and discusses several specific factors that the Supreme Court identified as relevant to market definition, including "industry recognition," "particular characteristics and uses," and "unique production facilities." Compl. ¶¶ 195-199, 224, 235, 253. With respect to the hypothetical monopolist test, the complaint alleges that physicians have a "strong preference" for prefilled syringes and that "a small, but significant, price increase in the PFS version would not cause physicians to substitute the vial version for PFS (even if they contain the same underlying anti-VEGF agent)." Compl. ¶ 200. The district court, however, did not address either *Brown Shoe* or the hypothetical monopolist test, and it discounted the factual allegations relevant to these frameworks based on its view that vials and prefilled syringes must be in the same market because they are functionally interchangeable. Op. 24-25.

The district court's only discussion of price constraints and cross-elasticity of demand appears in a footnote dismissing Regeneron's allegation that 80% of vial users switched to prefilled syringes when they became available. Op. 28 n.6. The court stated that this allegation "does not suggest that if Novartis attempted to raise prices beyond a 'small' discrepancy that those patients would not simply switch back to the vials." *Id.* The logic is flawed for multiple reasons.

First, as noted above, Regeneron specifically alleges that a small but significant increase in the price of prefilled syringes would not cause physicians to switch back to vials. Compl. ¶ 200. The district court either did not credit that allegation or failed to recognize its significance. *See Todd*, 275 F.3d at 197 ("On a motion to dismiss for failure to state a claim, we construe the complaint in the light most favorable to the plaintiff, accepting the complaint's allegations as true.").

Second, the district court erred in asking what would happen if the price of prefilled syringes was raised *beyond* a small amount. A sufficiently large price increase will always cause some customers to switch to the next best alternative, which is why the market definition analysis properly considers "reasonable variations in price," *Times-Picayune*, 345 U.S. at 612 n.31, or in the language of the hypothetical monopolist test, a "small but significant non-transitory increase in price." *Amex*, 838 F.3d at 199.

Finally, the district court's focus on whether "patients" would switch back to vials in response to a price increase fails to recognize that in a case involving pharmaceuticals, "there is not just one relevant customer group." *Geneva Pharms.*, 386 F.3d at 496. The court may need to consider the roles played by doctors, patients, and third-party payers, among others. *Id.* For example, in many cases, the decision to prescribe a particular drug may be made by the doctor, who "may not know or even care about the price and generally has no incentive to take the price

into account," with at least some of the cost being borne by a third-party insurer. *New York v. Actavis PLC*, 787 F.3d 638, 646 (2d Cir. 2015).[14]

B. The Court Erred in Holding That a Product Market Cannot Be Coextensive With Patent Claims Absent Extraordinary Circumstances.

The district court also held that the product market could not be limited to anti-VEGF agents in prefilled syringes because that is what Novartis's patent covers. Op. 25-28. In the district court's view, defining the product market as the products covered by a patent would mean "all patents would immediately confer monopoly power" such that "every instance of patent fraud would give rise to an antitrust claim by definition." Op. 26-27. This holding is incorrect. There is no reason why a relevant market cannot be limited to the products covered by a patent, whether an antitrust claim is based on *Walker Process* (*i.e.*, enforcement of a patent obtained through fraud) or another legal theory.

The district court's analysis reflects a basic misunderstanding of the relationship between patents and antitrust law. While courts sometimes refer to

[14] For drugs that are administered by a physician in a clinical setting, the physician typically purchases the product and receives reimbursement from the patient or their health insurance. *See, e.g.*, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 35-37 (D. Mass. 2007), *aff'd*, 582 F.3d 156 (1st Cir. 2009); U.S. Gov. Accountability Office, GAO-16-780R, *Physician-Administered Drugs: Comparison of Payer Payment Methodologies* (2016), available at https://www.gao.gov/assets/gao-16-780r.pdf (Table 1).

patents as a kind of "lawful monopoly" (as the district court did here), it is well established that "a patent does not necessarily confer market power upon the patentee." *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 46 (2006). A valid patent merely confers certain exclusionary rights, including the right to exclude others from making, using, or selling the patented invention. 35 U.S.C. § 271(a). "Neither ownership of the right nor the power to exclude conveys monopoly power unless the right in question dominates a properly defined relevant market." Areeda & Hovenkamp, *supra*, ¶ 704.[15]

Whether a patent confers monopoly power in the antitrust sense depends on whether there are "effective substitutes … that do not infringe the patent," *Walker Process*, 382 U.S. at 178, and whether such substitutes are reasonably interchangeable with the patented products. This is a "deeply fact-intensive" question. *Todd*, 275 F.3d at 199. Accordingly, the district court was wrong to hold that an antitrust product market generally cannot be coextensive with the claims of a patent, and equally wrong to suggest that a contrary rule would make every patent owner a monopolist. Whether and to what extent a patent confers market

[15] *See also* U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (Jan. 12, 2017) ("Although the intellectual property right confers the power to exclude with respect to the specific product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power.")

power or monopoly power is "a matter of proof," *Walker Process*, 382 U.S. at 178, which must be assessed using the same principles that apply generally in antitrust cases.

The district court noted that patented products often will command higher prices than unpatented substitutes, and described this as "a sacrifice that the law is willing to make to spur technical and technological advancement." Op. 25. It is true that the exclusionary rights conferred by a valid patent "may permit the patent owner to charge a higher-than-competitive price for the patented product." *FTC v. Actavis, Inc.*, 570 U.S. 136, 147 (2013). But a patent does not confer blanket immunity from the antitrust laws. *See id.* at 148-151 (summarizing case law where improper use of a patent violated antitrust laws). Where a plaintiff alleges antitrust violations through the improper use or procurement of a patent, it may be necessary to determine whether the patented products (or some subset of them) constitute a relevant antitrust market, applying ordinary principles of antitrust analysis. Again, this is a fact-intensive question. Courts should not simply presume the patented products are—or are not—a relevant market.

The district court also wrongly held that allowing a plaintiff to plead that the products covered by a patent constitute a relevant market would be inconsistent with *Walker Process*. It reasoned that "if a plaintiff could limit the scope of the relevant product market to the scope of a patent, then each of the elements of an

attempted monopolization claim"—anticompetitive conduct, specific intent to monopolize, and a dangerous probability of achieving monopoly power—would be established "as a matter of course," and "every instance of patent fraud would give rise to an antitrust claim by definition." Op. 26-27. But just a because a market *can* be coextensive with a patent's scope does not mean that it *must* be. As *Walker Process* explains, once an antitrust plaintiff has demonstrated that a patent was obtained through fraud and enforced with knowledge of the fraud, it must separately "appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved," because "[w]ithout a definition of that market, there is no way to measure [the defendant's] ability to lessen or destroy competition." 382 U.S. at 177. Accepting the alleged market here thus would not mean that the elements of a *Walker Process* claim would be satisfied in every case "as a matter of course." In each case, the antitrust plaintiff must adequately allege that the patented products (or some subset of them) are a relevant market, and then prove that fact at trial.[16]

[16] It is true, however, that if the patented products constitute a relevant market, proof of fraud on the Patent Office and knowing enforcement will ordinarily establish that the defendant engaged in anticompetitive activity with the specific intent necessary for attempted monopolization. For example in *TransWeb*, the defendant conceded that a showing of inequitable conduct (*i.e.*, fraud) also proved the first two elements of attempted monopolization. 812 F.3d at 1307.

Indeed, *Walker Process* itself makes clear that a relevant market may be coextensive with the claims of the patent. The Court framed the issue as whether there were effective noninfringing substitutes for the patented products ("knee action swing diffusers" used in sewage treatment systems), explaining that this was a "matter of proof." *Id.* at 177-78. In other words, the Court directly recognized that the patented products *could* constitute a relevant market, depending on the evidence presented at trial. Similarly, in *TransWeb*, which the court below also relied on, the Federal Circuit held that the product market was properly limited to the products covered by the patent (plasma-fluorinated filters for respirators) and did not have to include substitute products that did not infringe the patent. 812 F.3d at 1299-1300, 1307-08. The market thus was coextensive with the patent's coverage.

The district court's confusion is clear from its statement that "if a patent allows its owner to exclude other firms from producing products covered by its terms, and an antitrust plaintiff can define a market so narrowly that the patent itself creates its own market, then plaintiffs could never fail to plead out an antitrust claim against a patent owner as long as they raised a colorable challenge to the patent's validity." Op. 25-26. This is wrong for several reasons. First of all, *Walker Process* requires more than a "challenge to [a] patent's validity." A patent may be invalidated for numerous reasons, including if the claims were anticipated

or obvious, or the specification fails to adequately describe the invention. *See* 35 U.S.C. §§ 101, 102, 112(a) , 282(b). These types of invalidity challenges do not require a showing of intentional misconduct. *Walker Process*, by contrast, requires a showing of fraud on the Patent Office and enforcement with knowledge of that fraud. The circumstances of the fraud must be pleaded with particularity. *See* Fed. R. Civ. P. 9; *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 693 (2d Cir. 2009).

Beyond that, particularized allegations of fraud and knowing enforcement are not alone sufficient to make out a *Walker Process* claim. A complaint must also plausibly allege that the patent has enabled the defendant to achieve monopoly power within a relevant market (for actual monopolization) or created a dangerous probability that it will do so (for attempted monopolization). Thus, a *Walker Process* complaint, like any antitrust complaint, cannot simply assert in conclusory terms that the patented products constitute a relevant market. As this Court has explained, "[t]o survive a Rule 12(b)(6) motion to dismiss, an alleged product market must bear a rational relation to the methodology courts prescribe to define a market for antitrust purposes—analysis of the interchangeability of use or the cross-elasticity of demand, and it must be plausible." *Todd*, 275 F.3d at 200 (cleaned up). Thus contrary to the district court's analysis, recognizing that the relevant product market may be limited to products covered by a patent would not

transform every invalidity claim, or even every claim of improper conduct before the Patent Office, into an antitrust claim.

CONCLUSION

For the foregoing reasons, the district court committed legal error when assessing whether Regeneron adequately alleged a relevant product market. This Court should correct the district court's legal errors on market definition.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief complies with the type-volume limitation of Local Rule 29.1(c) and because it contains 6,690 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). I also certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) & (6), because it has been prepared in a proportionally spaced typeface (Times New Roman 14-point) using Microsoft Word 2010.

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