UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Thurgood Marshall U.S. Courthouse 40 Foley Square, New York, NY 10007 Telephone: 212-857-8500

MOTION INFORMATION STATEMENT

Docket Number(s): 22-0427-cv

Caption [use short title]

Regeneron Pharms. v. Novartis Pharma AG

Motion for: Leave to File Brief as Amicus Curiae in Support of Appellant

Set forth below precise, complete statement of relief sought:

Leave to file brief as amicus curiae in support of Appellant

MOVING PARTY: Identified in Addendum A **OPPOSING PARTY:**

☐ Plaintiff ☐ Defendant

☐ Appellant/Petitioner ☐ Appellee/Respondent

MOVING ATTORNEY: Ankur Kapoor **OPPOSING ATTORNEY:**

[name of attorney, with firm, address, phone number and e-mail]

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Court- Judge/ Agency appealed from: Hon. David N. Hurd, District Judge, Northern District of New York

Please check appropriate boxes:

Has movant notified opposing counsel (required by Local Rule 27.1):
☑ Yes ☐ No (explain):

Opposing counsel's position on motion:
☑ Unopposed ☐ Opposed ☐ Don't Know

Does opposing counsel intend to file a response:
☐ Yes ☐ No ☑ Don't Know

FOR EMERGENCY MOTIONS, MOTIONS FOR STAYS AND INJUCTIONS PENDING APPEAL:

Has this request for relief been made below? ☐ Yes ☐ No

Has this relief been previously sought in this court? ☐ Yes ☐ No

Requested return date and explanation of emergency:

Is oral argument on motion requested? ☐ Yes ☑ No (requests for oral argument will not necessarily be granted)

Has argument date of appeal been set? ☐ Yes ☑ No If yes, enter date:

Signature of Moving Attorney:

s/ Ankur Kapoor **Date:** June 17, 2022 Service by: ☑ CM/ECF ☐ Other [Attach proof of service]

22-0427-cv

United States Court of Appeals

for the

Second Circuit

REGENERON PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

- V. –

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

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

MOTION OF 46 PROFESSORS OF LAW, ECONOMICS, BUSINESS, AND MEDICINE FOR LEAVE TO FILE AS *AMICI CURIAE* IN SUPPORT OF APPELLANT

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Attorneys for Amici

Per Federal Rule of Appellate Procedure 29(a)(3), Movants (46 professors of law, economics, business, and medicine identified in Addendum A to the attached brief) request leave to file the attached brief as amici curiae. Movants all have an interest in the proper interpretation and enforcement of antitrust law and submit this brief because they believe the district court erroneously dismissed Appellant's antitrust case. The court's opinion rested on a misunderstanding of the principles of market definition and, if sustained, would undermine future antitrust enforcement. Amici's proposed brief discusses the legal and economic principles of market definition, the purpose of market definition in antitrust cases, and how courts should identify the relevant market in this case.

Counsel for Appellant has consented to Movants filing their brief. Counsel for Appellees have stated that they do not object to Movants' brief.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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Dated: New York, New York
June 17, 2022

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Rules

Other Authorities

INTEREST OF AMICI CURIAE

The undersigned amici curiae are professors of antitrust law, economics, business, and medicine with an interest in the proper interpretation and enforcement of antitrust law. (A list of the signatories is attached as Addendum A.) We submit this brief because we believe the district court erroneously dismissed the plaintiff's antitrust case, which alleged that the defendant attempted to exclude the plaintiff from the relevant market—and preserve its monopoly—by asserting a patent procured by fraud and conspiring with a key supplier to raise the plaintiff's costs. If the court's decision is upheld, patients and physicians may be deprived of the plaintiff's superior treatment for vision loss. Moreover, the court's opinion rested on a misunderstanding of the principles of market definition and, if sustained, would undermine future antitrust enforcement.[1]

INTRODUCTION

The plaintiff, Regeneron Pharmaceuticals, Inc. ("Regeneron"), developed an improved method for treating eye diseases that "can cause vision loss and even blindness" and from which "many millions of patients suffer." First Amended

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[1] No party's counsel has authored this brief in whole or in part; no party's counsel has contributed money intended to fund preparing or submitting the brief; and no person other than the amici curiae or their counsel have contributed money that was intended to fund preparing or submitting the brief.

Complaint ("FAC") ¶ 5.[2] Traditionally, doctors treated these diseases by injecting the eye of a patient with an "anti-VEGF" drug drawn from a vial. Recently, Novartis and Regeneron each developed syringes prefilled with the drugs. Regeneron's allegations demonstrate in detail why the prefilled syringe ("PFS") method of administration is superior to the traditional vial method and why, as a result, physicians and patients would not switch back to vials if the price of PFSs increased significantly.

Administering anti-VEGFs with pre-filled syringes reduces the risk of contamination inherent in drawing anti-VEGFs out of vials—contamination which itself can cause vision loss. FAC ¶ 6. PFSs also improve dosage accuracy and shorten the time necessary to administer the drug. *Id.* Accordingly, as Regeneron pleaded, there is substantial physician preference for anti-VEGF PFSs, to the point where PFSs have already replaced vials as the standard of care.

Novartis was the first to launch an anti-VEGF PFS in the U.S., and for three years from its introduction of Lucentis PFS to Regeneron's launch of Eylea PFS, Novartis had virtually 100% of the market. *See* FAC ¶ 86. Novartis had no intention of giving up this monopoly position. When Regeneron entered in late 2019 and early

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[2] This brief treats all pleaded facts as true, as required under Federal Rule of Civil Procedure 12(b)(6). Amici take no position on whether the allegations are true. Regeneron would have to prove them at trial.

2020, Novartis brought patent infringement actions in both the International Trade Commission and the Northern District of New York. *See id.* ¶ 188.[3] If those actions are successful, they would impose substantial harm on patients and physicians. The plaintiff has alleged that Eylea PFS is an improvement over Novartis' Lucentis PFS because patients need fewer injections of Eylea and Eylea is more effective against vision loss for certain patients. *See id.* ¶ 56. Moreover, Eylea PFS's entry led to a significant reduction in Lucentis' price. Thus, if Eylea PFS were excluded from the marketplace, patients and physicians would be deprived of both a better treatment and lower prices.

Regeneron responded to Novartis' patent actions by filing this antitrust action. Regeneron's complaint alleged that Novartis had procured the '631 Patent through fraud on the Patent Office. Regeneron further alleged that Novartis conspired with a common supplier, Vetter Pharma International GmbH ("Vetter"), the leading PFS filler, to delay and raise the cost of Regeneron's entry. Regeneron asserted that Novartis' patent fraud was an attempt to monopolize the relevant market in violation of Section 2 of the Sherman Act and that its pact with Vetter constituted a conspiracy in restraint of trade in violation of Section 1.

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[3] Novartis, the holder of the '631 Patent, sells Lucentis through a marketing agreement with Genentech, a wholly-owned subsidiary of Roche. Novartis owned 33% of Roche during the relevant period. For ease of reference, we refer to Novartis, Roche, and Genentech as "Novartis."

SUMMARY OF ARGUMENT

To establish its claims, Regeneron must plead either market or monopoly power or direct evidence of anticompetitive effects. Market or monopoly power can be shown via direct evidence of power over price or power to exclude competition, or it can be inferred from high market shares. The latter method requires defining a relevant market.[4] In its First Amended Complaint ("FAC"), Regeneron alleged that the relevant product market consisted of therapeutic drugs ("anti-VEGFs") sold in pre-filled syringes ("PFSs").[5]

The district court rejected Regeneron's market definition. Noting that Regeneron's alleged market is coextensive with the scope of Novartis' patent, the court stated that if Regeneron's position were accepted, it would mean that every patent confers monopoly power. It is true that not every patent confers monopoly power in a relevant antitrust market. It is also true that patent-based monopolies,

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[4] Regeneron not only defined a relevant market but alleged that Novartis' conspiracy with Vetter caused actual anticompetitive effects. Regeneron asserted that the conspiracy delayed its launch of Eyelea PFS for years, FAC ¶ 175, and thus deprived physicians and patients of a better product and lower prices for a substantial period of time. These anticompetitive effects, if established at trial, would allow Regeneron to challenge the conspiracy without defining a relevant market. *See* John B. Kirkwood, *Market Power and Antitrust Enforcement*, 98 B.U. L. Rev. 1169, 1195 n.148 (2018) (citing numerous cases).

[5] In short, anti-VEGF PFSs. The parties agree that the relevant geographic market is the United States.

lawfully obtained, do not violate the antitrust laws. But the district court asserted that a relevant market can *never* be coextensive with the scope of a patent. That is a fundamental error of law. *See* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 518a (2021) ("Of course, a patented product and the relevant market may be coterminous."); *FTC v. Actavis Inc.*, 570 U.S. 136, 157 (2013) ("An important patent itself helps to assure . . . the power to charge prices higher than the competitive level."); *id.* at 158 (a patent may "generate[] monopoly profits"); *Rambus Inc. v. FTC*, 522 F.3d 456, 463 (D.C. Cir. 2008) (Rambus' patented technologies gave it monopoly power in four relevant markets that consisted of "technologies covered by" its patents). Moreover, the court's ruling would seriously impede antitrust enforcement: it would prevent challenges to patents procured by fraud whenever the patent and the relevant market are coterminous.

A relevant market in antitrust law is a product or group of products over which market or monopoly power can be exercised. Such a market is of antitrust concern because anticompetitive conduct in that market could raise prices above the competitive level or harm innovation. Accordingly, the Supreme Court has defined a relevant market as "'the area of effective competition,'" *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018). That means, in the simplest case, that products within the relevant market constrain each other's pricing and products outside the relevant market do not. More generally and more precisely, Product B supplies effective

competition to Product A if a small but significant increase in the price of Product A would cause so many buyers to switch to Product B that the increase would be unprofitable. If that condition is met, Product B constrains the pricing of Product A and belongs in the same relevant market. Product B is a close substitute for Product A. Inversely, if that condition is not met, Product B does not provide effective competition to Product A, is not a close substitute, and does not belong in the relevant market.

The district court concluded that the relevant market should include anti-VEGFs in vials. But vials should be included in the relevant market only if they supply effective competition to pre-filled syringes. Specifically, vials should be included only if a small but significant price increase on PFSs would cause such a large number of physicians and patients to switch to vials that the price increase would not be profitable. Regeneron alleges that this test is *not* met, and that anti-VEGF PFSs therefore constitute a relevant antitrust market in which market or monopoly power could be exercised.[6]

In its First Amended Complaint, Regeneron set forth multiple factual allegations in support of the conclusion that vials and PFSs are significantly differentiated from the perspectives of safety, convenience, and cost. FAC ¶ 196. As

[6] In the related patent actions, Novartis argued that anti-VEGF PFSs are so superior to vials as to warrant the issuance and enforcement of a patent.

a result, a small but significant price increase on PFSs would not cause substantial numbers of physicians to substitute vials. *Id.* ¶ 200. Regeneron alleged:

- Administering anti-VEGFs in vials is complicated. A physician must use one sterile needle to withdraw the correct dosage from the vial, switch the head of the syringe to a sterile injectable needle, and then inject the serum directly into the patient's eye. *Id.* ¶ 76. By comparison, administering anti-VEGFs by PFS eliminates all but the final step, significantly reducing the opportunities for improper dosing or contamination. *Id.* ¶¶ 77, 81-82.
- Use of PFSs reduces the chances for endophthalmitis, a serious inflammation of the interior of the eye that can cause blindness, by 50%. *Id.* ¶ 197.
- Administering anti-VEGFs by PFSs is considerably faster, reducing prep time by 40%. This allows physicians to treat more patients. *Id.* ¶ 80.
- When Lucentis PFS launched in 2017, more than 80% of physicians switched to PFS from vials. *Id.* ¶ 85. Studies show that once a PFS version launches, physicians convert 80-90% of their patients to the PFS version. *Id.* ¶ 88.
- Today, anti-VEGF PFS have become the standard treatment for ophthalmic diseases, replacing vials. *Id.*

Despite these allegations, the district court rejected Regeneron's proposed market. In so doing, the court disregarded precedent in this Circuit that "market definition is a deeply fact intensive inquiry," and courts "hesitate to grant motions to

dismiss for failure to plead a relevant product market." *Todd v. Exxon Corp.*, 275 F.3d 191, 199-200 (2d Cir. 2001) (Sotomayor, J.) (reversing dismissal); *US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 64 (2d Cir. 2019) (same).

The district court ultimately acknowledged that a product market could be "constrained to the patented product," Op. 27, but when the court examined Regeneron's specific allegations, it ruled that they were inadequate to establish a separate anti-VEGF PFS market. The court could only reach this result, however, by overlooking many of Regeneron's well-pleaded allegations. For example, the court asserted that Regeneron merely claimed that PFSs are "at least marginally superior to the vial," which "is not enough." Op. 28. But in fact, Regeneron alleged that physicians have a "strong preference" for PFSs, FAC ¶ 200, and that PFSs are "an important . . . advance," *id.* ¶ 196—to the point that PFSs have supplanted vials as the standard of care. *Id.* ¶ 88.

Similarly, the district court brushed aside the allegation that patients shifted rapidly from vials to PFSs because patients might switch back if the price of PFSs rose significantly. Op. 28 n. 6. But Regeneron expressly alleged that "a small, but significant, price increase in the PFS version would *not* cause physicians to substitute the vial version for PFS," FAC ¶ 200 (emphasis added). In short, the district court contravened Rule 12(b)(6) by failing to credit all of Regeneron's

allegations regarding the lack of substitutability between vials and pre-filled syringes.

Publicly available sales and pricing data corroborate Regeneron's proposed market. Sales figures from Novartis and Regeneron indicate that when Eylea was introduced in PFS form (years after Eylea was introduced in vials), Eylea begin to gain market share at Lucentis PFS's expense. Moreover, pricing data from the Centers for Medicare and Medicaid Services ("CMS") show that Novartis responded to the launch of Eylea in PFS form by significantly reducing the discounted price of Lucentis PFS. Novartis made no similar effort to reduce the price of its vials when Eylea was launched in vial form. Novartis saw Eylea PFS as a much more direct threat to its business than Eylea in vials. Likewise, two drug companies just announced the launch of the first biosimilar anti-VEGF. They are only offering it in vial form, however, and are pricing it at a 40% discount off the list price of Lucentis PFS. This enormous price differential is striking evidence that vials are not in the same relevant market as pre-filled syringes.

In short, Regeneron's factual allegations, supported by independently generated public data, are more than sufficient to establish a plausible relevant market which the district court should have accepted at the motion-to-dismiss stage.

ARGUMENT

A. Market definition determines the ability of firms to exercise market power by identifying the area of effective competition.

In antitrust cases brought under the rule of reason, proof of market power is a fundamental element. Market power "is central to antitrust because it distinguishes firms that can harm competition and consumers from those that cannot. A firm with market power can deviate from the competitive result and force consumers to pay higher prices." Kirkwood, *Market Power and Antitrust Enforcement*, 98 B.U. L. Rev. at 1173.

Market definition is a tool for assessing market power. "The ordinary way that courts determine market power is by defining a relevant market and calculating the defendant's market share." John B. Kirkwood, *Antitrust and Two-Sided Platforms: The Failure of* American Express, 41 Cardozo L. Rev. 1805, 1838 (2020). Market share, however, is but "'one factor' relevant to market power analysis," and this Circuit has "decline[d] to establish any strict threshold of market share sufficient to establish" an antitrust violation. *United States v. Am. Express Co.*, 838 F.3d 179, 200 n.47 (2d Cir. 2016) ("*U.S. v. Amex*"), *aff'd sub nom. Ohio v. Am. Express Co.*, 138 S. Ct. 2272 (2018) ("*Ohio v. Amex*"). The ultimate question is market *power*—whether the defendant has "the ability to raise prices above those that would be charged in a competitive market." *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 109 n.38 (1984).

Market definition is thus guided by the central question it seeks to answer: can the defendant raise prices above the competitive level? Accordingly, "the relevant market is defined as 'the area of effective competition.'" *Ohio v. Amex*, 138 S. Ct. at 2285, and effective competition exists when competition prevents a producer from increasing its prices significantly above the competitive level. To determine whether that is the case, courts and enforcement agencies look at the substitutability between products. *See id.* (quoting Phillip E. Areeda & Herbert Hovenkamp, *Fundamentals of Antitrust Law* § 5.02 (4th ed. 2017) (The relevant market is "the 'arena within which significant substitution in consumption or production occurs.'"). Accordingly, courts and agencies ask whether a substantial number of buyers would substitute Product B for Product A in response to a significant increase in the price of Product A. If such a large number of buyers would switch to Product B that an increase in the price of Product A would not be profitable, then Product B provides effective competition to Product A, and both products should be included in the relevant market.

Market definition is not merely a process of identifying *functional substitutes*—products that can be used for the same purpose (like landline phones and mobile phones). Rather, market definition seeks to identify products that are *economic substitutes*—products that are not only functional substitutes but also exhibit significant consumer switching when their relative prices change. Market

definition seeks to identify that set of products to which consumers will turn in the event of a "small but significant non-transitory increase in price" (or "SSNIP" in antitrust parlance).[7]

"'[M]arket definition is a deeply fact-intensive inquiry' because its purpose is 'to identify the market participants and competitive pressures that restrain an individual firm's ability to raise prices or restrict output." *U.S. v. Amex*, 838 F.3d at 196-97 (quoting *Todd v. Exxon Corp.*, 275 F.3d 191, 199 (2d Cir. 2001) (Sotomayor, J.), and *Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004)). Drawing market boundaries may be difficult in industries composed of differentiated products, like most pharmaceutical and biotech products. *See* Kirkwood, *Market Power and Antitrust Enforcement*, 98 B.U. L. Rev. at 1177. In such industries, market definition provides the framework for analysis, not an electoral map. *See Geneva Pharms.*, 386 F.3d at 496. "The emphasis always is on the actual dynamics of the market rather than rote application of any formula." *Id.*

This Court's opinion in *Geneva Pharmaceuticals* provides an instructive example of the fact-specific inquiry required. There, the Court reasoned that generic versions of the blood-thinner Coumadin® (warfarin sodium)—which contain the same active ingredient as, and are therapeutically equivalent to, the brand-name

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[7] U.S. Dep't of Justice and Fed. Trade Comm'n, Horizontal Merger Guidelines § 4, available at https://www.justice.gov/atr/horizontal-merger-guidelines-08192010.

drug—by themselves constituted a relevant market that did *not* include Coumadin®. 386 F.3d at 496. The Court noted that while that may seem "paradoxical," the market reality was that the lone manufacturer of generic warfarin, Barr, could raise price unconstrained by Coumadin's® price. *Id.* at 496. Yet "[w]hen other generic competitors entered the market, Barr's prices dropped substantially." *Id.* at 497.

In evaluating a proposed merger, the federal antitrust enforcement agencies similarly define markets in order to assess the merger's likely competitive effects; market definition "is not an end in itself."[8] If evidence of competitive effects is directly observable, then that informs the relevant-market inquiry.[9] "For example, evidence that a reduction in the number of significant rivals offering a group of products causes prices for those products to rise significantly can itself establish that those products form a relevant market."[10] Likewise, the evidence that the entry of Eylea began to impact the price and market share of Lucentis when Eylea was introduced in PFS form, not when Eylea entered the market in vial form, suggests that the relevant market should include PFSs but not vials.

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8 Horizontal Merger Guidelines § 4.

9 *Id.*

10 *Id.*

In sum, courts and antitrust enforcement agencies look to the competitive pressures facing market participants to identify "'the area of effective competition.'" *Ohio v. Amex*, 138 S. Ct. at 2285. In defining a relevant market, as in other aspects of antitrust analysis, the outcome "depends on a careful analysis of market realities." *NCAA v. Alston*, 141 S. Ct. 2141, 2158 (2021).

B. Regeneron alleged a plausible market definition.

Regeneron contended that the relevant product market was composed solely of anti-VEGF PFSs, and supported that contention with numerous specific factual allegations showing that vials did not constrain the prices of PFSs and therefore were not part of "'the area of effective competition.'" *Ohio v. Amex*, 138 S. Ct. at 2285.

Because of the advantages of pre-filled syringes, summarized above, their introduction has caused a rapid change in the standard of care for anti-VEGF administration. More than 80% of physicians switched from vials to PFSs shortly after the first PFS, Novartis' Lucentis PFS, entered the market. FAC ¶ 85. Today, nearly all Lucentis sales are in PFS rather than vial form. *Id.* Likewise, virtually all of Regeneron's Eylea is, or will soon be, dispensed in PFSs. *Id.* ¶¶ 62, 196.[11] Given

[11] Vials and PFSs also require different "production facilities and capabilities." FAC ¶ 199. Anti-VEGFs in PFSs need "specialized equipment and filling lines" and "separate regulatory approval" *Id.* Such distinct production and regulatory requirements limit substitution in supply, which buttresses Regeneron's proposed market. *See* Areeda & Hovenkamp, *Antitrust Law* ¶ 530a ("a market is the arena in

the rapid uptake of PFSs and their clear advantages over vials, Regeneron alleged that physicians would not switch back to vials if Novartis became the sole seller of PFSs and raised their price by a small but significant amount. *Id.* ¶ 200.

C. The fact that Regeneron's proposed market is coextensive with the scope of Novartis' asserted patent does not make the market implausible.

Accepting Regeneron's allegations as true, it is reasonable to believe that a sole seller of anti-VEGF PFSs could exercise monopoly power. It could "control prices or exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). It could "raise price profitability by restricting output." *Ohio v. Amex,* 138 S. Ct. at 2288 (emphasis omitted). It could charge "prices substantially above the competitive level." *United States v. Microsoft Corp.*, 253 F.3d. 34, 51 (D.C. Cir. 2001); *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1070 (10th Cir. 2013) (Gorsuch, J.) (same); Kirkwood, *Market Power and Antitrust Enforcement,* 98 B.U. L. Rev. at 1173.[12]

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which significant substitution in consumption *or production* occurs") (emphasis added).

[12] "Monopoly power under § 2 requires . . . something greater than market power under § 1." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 481 (1992). Many courts and scholars express this difference by saying that monopoly power demands a "substantial" or "high degree" of market power. *See* Kirkwood, 98 B.U. L. Rev. at 1173 & n.14. The leading antitrust treatise takes another approach: it maintains that both types of power require the ability to increase price "significantly," but what constitutes a "significant" price increase depends on the violation charged, among other factors. *See* Areeda & Hovenkamp, *Antitrust*

The district court rejected Regeneron's proposed relevant market on the grounds that it was coextensive with Novartis' patent.[13] The court stated that if it "accepts Regeneron's proposed market, then all patents would immediately confer complete monopoly power to the inventor." Op. 26. The court is correct that market power cannot be inferred from the existence of a patent. *See Illinois Tool Works, Inc., v. Indep. Ink, Inc.* 547 U.S. 28, 43-46 (2006). But a finding that Novartis' patent would create monopoly power would not mean that any other patent, much less every other patent, likewise confers monopoly power. Regeneron's pleadings plausibly allege only that the '631 Patent would allow Novartis to exercise monopoly power.[14] The district court's misreading of Regeneron's allegations is a fundamental error of law.

Similarly, it was improper to conclude that if Regeneron's proposed market

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Law ¶ 537 ("'Significant' Price Increase Required and Defined"). Regeneron follows the treatise's approach, alleging that a sole seller of anti-VEGF PFSs could impose "a small, but significant, price increase." FAC ¶ 200. At the same time, Regeneron's allegations make clear that if Novartis once again became the sole seller of anti-VEGF PFSs, its monopoly position would impose substantial harm on physicians and patients, depriving them of both lower prices and Regeneron's superior product.

[13] "[T]he relevant market that Regeneron claims is identical to the protection afforded to Novartis by the '631 Patent." Op. 24.

[14] Thus, a finding that the '631 Patent gave monopoly power to Novartis would be necessarily and properly limited to the facts of this case.

were accepted, a firm would always violate the Sherman Act when it procured a patent by fraud. *See* Op. 26-27 ("By extension, every instance of patent fraud would give rise to an antitrust claim"). Regeneron did not take that position, nor could it under *Illinois Tool Works* or *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965), which requires proof of *both* fraud on the Patent Office *and* monopoly power.

The district court's error would turn *Illinois Tool Works* on its head. *Illinois Tool Works* held that a patent does not *automatically* create monopoly power; the district court's reasoning implies that a patent *never* creates monopoly power. That is an error of law that would largely insulate from antitrust challenge patents procured by fraud and other anticompetitive conduct involving patented products and technologies.

D. The propriety of a relevant market cannot be determined without examining all of a plaintiff's allegations.

The district court ultimately acknowledged that some patents may in fact confer monopoly power. Op. 27 ("Of course, one can imagine a circumstance where the subject of a patent is so novel that there really is no fitting substitute, and the relevant product market would have to be constrained to the patented product."). As a result, the district court had to examine Regeneron's specific allegations to determine whether vials were close substitutes for PFSs. But when the court did so, it either missed the point of Regeneron's allegations or ignored allegations that

answered the court's objections.

The district court devoted only a single paragraph of text and two footnotes to the adequacy of Regeneron's product-market allegations. In text, the court rejected Regeneron's allegations that anti-VEGFs in PFSs are superior in quality to anti-VEGFs in vials because "Regeneron merely explained that the PFS is, like all valuable patented products, at least marginally superior to the vial. That is not enough." Op. 27-28 (citation omitted). But Regeneron did not allege that PFSs are only *marginally* superior to vials. As explained above, Regeneron alleged that physicians have a "substantial" preference for PFSs because they save physician time, improve dosage accuracy, and reduce contaminants. Regeneron also buttressed its allegations of product superiority with repeated allegations that physicians and patients switched overwhelmingly to PFSs once they were introduced. FAC ¶¶ 62, 85, 196. The complaint also quotes Novartis's own allegation that PFSs are "an important and valuable advance." *Id.* ¶ 196. Given those specific allegations, the district court's finding that Regeneron merely alleged that PFSs are "marginally superior" to vials is clearly erroneous.

In a footnote, the district court swept aside Regeneron's allegation that patients quickly shifted to PFSs because this allegation "does not suggest that if Novartis attempted to raise prices beyond a 'small' discrepancy that those patients could not or would not simply switch back to their vials." Op. 28 n.6. But an

allegation of massive and rapid shifting does suggest that patients would not switch back in response to a moderate price increase. Patients shifted because they and their physicians concluded that PFSs were a distinctly superior product; in that event, they would not easily return to an inferior product. Moreover, Regeneron *expressly* alleged that "a small, but significant, price increase in the PFS version would not cause physicians to substitute the vial version for PFS." FAC ¶ 200. That allegation directly undercuts the district court's objection to Regeneron's patient switching data.[15]

In a second footnote, the District Court dismissed Regeneron's allegation of equipment differences, stating: "that there might be a difference in the equipment required to produce a PFS as opposed to a vial says nothing about whether a consumer would find a vial and PFS interchangeable." Op. 25. But the Court missed the point of this allegation. It is about substitution in production, not substitution in consumption. Regeneron asserts that a producer of vials could not quickly switch to the production of pre-filled syringes. That difficulty is another valid reason to exclude vials from the relevant market. *See* Areeda & Hovenkamp, *Antitrust Law* ¶ 530a (a relevant market should include significant substitutes in production or

[15] Regeneron's allegation refers to physician switching, not patient switching, but patients would not substitute vials for pre-filled syringes unless physicians changed their prescriptions.

consumption).

E. Publicly available data corroborates Regeneron's market definition.

In addition to Regeneron's well-pleaded allegations, publicly available data supports Regeneron's definition of the relevant market. Sales figures from Novartis and Regeneron, pricing information from CMS, and the recent release of a new biosimilar suggest that Regeneron's proposed market is both plausible and correct.

Sales reports from Regeneron and Novartis show that the introduction of Eyelea PFS led to a substantial shift in sales from Novartis to Regeneron. Regeneron engaged in a full-scale commercial launch of Eylea PFS in February 2020. FAC ¶ 62. From 2019, the last full year before the launch, to 2021, the latest full year for which data is available, Eylea's sales in the U.S. increased 25%, while Lucentis' U.S. sales declined 26%. See 2021 Regeneron Annual Report 6;[16] 2021 Roche Finance Report 19 (Feb. 1, 2022);[17] 2020 Roche Finance Report 21 (Feb. 1, 2021).[18] This sharp shift in business indicates that many physicians and patients preferred Eylea PFS to Lucentis PFS. It also suggests that the relevant market should be limited to PFSs. If vials were close substitutes for pre-filled syringes—if physicians

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16 Available at https://investor.regeneron.com/node/26286/html.

17 Available at https://assets.cwp.roche.com/f/126832/x/8df367bf68/fb21e.pdf.

18 Available at https://assets.cwp.roche.com/f/126832/x/db9d31e8a7/fb20e.pdf.

and patients regarded vials and PFSs as essentially identical—it is unlikely that the introduction of a single new PFS product would have caused such a major change in sales.

The introduction of Eylea PFS also led to a significant decline in the price of Lucentis. CMS data show that from the third quarter of 2019 (just before Eylea's launch) to the third quarter of 2021, the average selling price of Lucentis dropped by 11.5%. *See* https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files. This significant drop supports Regeneron's proposed market, because it suggests that Lucentis' price was more sensitive to the entry of a new PFS than to the prices of existing vials.[19]

Recently, moreover, Biogen and Samsung Bioepis announced the release of the first biosimilar anti-VEGF. They are offering it in vials rather than in pre-filled syringes and, in order to sell it, have priced it at a 40% discount off the list price of Lucentis PFS.[20] This large price differential indicates that Biogen and Samsung

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[19] The price of Lucentis in vials remained more or less constant until 2017, when Novartis launched Lucentis PFS. At that point, the average sales price of Lucentis began to fall. The decline may have occurred because Novartis wanted to preserve Lucentis' sales in the face of Regeneron's impending entry. Novartis knew as of 2017 that Regeneron had filed for regulatory approval of its own PFS product. Once Eyelea PFS was actually introduced, Novartis reduced the price of Lucentis more rapidly.

[20] *See* https://investors.biogen.com/news-releases/news-release-details/biogen-and-samsung-bioepis-byooviztm-ranibizumab-nuna-launches.

Bioepis do not believe that their new vial is a direct competitor to the existing PFSs.

The above sales and pricing data not only suggest that anti-VEGFs in vials are in a separate market from anti-VEGFs in pre-filled syringes; but they also corroborate Regeneron's claim that Novartis could exercise monopoly power if Regeneron were excluded from the market. Without Regeneron, prices would be higher and product quality would be lower because physicians and patients would be deprived of both the price competition that Eyelea PFS engendered and its superior quality. Together, these adverse consequences would represent a substantial deterioration in market performance, providing telling evidence of the existence of monopoly power.

CONCLUSION

The district court's dismissal of Regeneron's antitrust complaint should be reversed.

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