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, VETTER PHARMA INTERNATIONAL GMBH

Defendants-Appellees

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

BRIEF FOR THE COMMITTEE TO SUPPORT THE ANTITRUST LAWS AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Committee to Support the Antitrust Laws states that it is a nonprofit corporation and no entity has any ownership interest in it.

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INTEREST OF AMICUS

The Committee to Support the Antitrust Laws ("COSAL")[1] is an independent, nonprofit corporation devoted to preventing, remediating, and deterring anticompetitive conduct since its founding in 1986. *See* COSAL, https://www.cosal.org/about. COSAL advocates for the enactment, preservation, and enforcement of a strong body of antitrust laws, which it accomplishes through legislative efforts, public policy debates, and by serving as *amicus curiae*.

Private enforcement of the antitrust laws "is an integral part of the congressional plan for protecting competition." *California v. Am. Stores Co.*, 495 U.S. 271, 284 (1990); *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 745 (1977) (recognizing "the longstanding policy of encouraging vigorous private enforcement of the antitrust laws"). "Antitrust laws in general, and the Sherman Act in particular, are the Magna Carta of free enterprise. They are as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the

[1] All parties consent to the filing of this brief. Amicus COSAL states that no counsel for any party has authored this brief in whole or in part and no party, party's counsel, or any other person or entity—other than COSAL—has contributed money to fund its preparation or submission.

protection of our fundamental personal freedoms." *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972).

The federal government cannot prosecute every violation of federal antitrust laws. Nor has the federal government traditionally seen its role as compensative of the victims of antitrust violations. Private enforcement fills these significant gaps, buttressing public enforcers' limited budgets and saving competition (and taxpayers) in the process.[2]

The District Court committed legal error by misconstruing or ignoring Plaintiff-Appellant Regeneron Pharmaceuticals, Inc.'s ("Regeneron") well-pled allegations of market definition, failing to draw all reasonable inferences in the light most favorable to Regeneron, and imposing a heightened standard to plead market definition to dismiss with prejudice Regeneron's First Amended Complaint ("FAC"). The District Court's holding is not only contrary to the general pleading

[2] *See* Lande, Robert H. & Davis, Joshua P., Benefits From Private Antitrust Enforcement: An Analysis of Forty Cases, 42 U.S.F. L. Rev. 879, 897, 906 (2008) (reviewing 40 successful private antitrust cases and finding that of the $18-19.6 billion recovered for victims in those cases, almost half of the total recovery came from 15 cases that did not follow government actions); Baxter, William F., Separation of Powers, Prosecutorial Discretion, and the "Common Law" Nature of Antitrust Law, 60 Tex. L. Rev. 661, 690-91 (1982) (same from the assistant A.G. in charge of the DOJ Antitrust Division during the Reagan administration).

requirements set force in Fed. R. Civ. P. 8, *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), but also issue-precedent from the Supreme Court and this Circuit holding that market definition is a deeply fact intensive inquiry that—absent two unique circumstances not present here—can only be determined after discovery and a factual inquiry into commercial market realities. *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451 (1992). Not only did Regeneron's FAC at a minimum plead a plausible market definition relying on the "practical indicia" announced in the Supreme Court's *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962), but Regeneron far surpassed the pleading standard by explaining why each alternative product that Defendants identified is not reasonably interchangeable with the products in Regeneron's well-defined market.

The District Court's heightened pleading standard cannot be squared with binding precedent providing that, in all but the rarest circumstances (not present here), questions about the contours of the relevant market should be decided with the benefit of discovery. If the District Court's heightened pleading standard for market definition is allowed to stand, private enforcement of the nation's antitrust laws could

be seriously undermined by requiring antitrust plaintiffs to *prove* their market definition at the pleading stage, a task that is often impossible given the unavailability of sufficient public data to offer as proof. COSAL, as a proponent of robust private enforcement of our nation's antitrust laws, thus has a strong interest in the outcome of this important appeal.

INTRODUCTION

This case presents the question of whether the District Court improperly imposed a heighted pleading standard to dismiss a federal antitrust complaint for failure to prove the product market at the pleading stage. Regeneron alleges that Defendants-Appellees Novartis Pharma AG, Novartis Technology LLC, Novartis Pharmaceuticals Corporation, and Vetter Pharma International GMBH (collectively, "Defendants") acted to restrain competition in the United States market for anti-vascular endothelial growth factor ("anti-VEGF") drugs in prefilled syringes ("PFS") approved by the FDA for the treatment of certain ophthalmic diseases. Anti-VEGFs drugs are publicly recognized in the medical community as the standard of care for treating ophthalmic disorders (i.e., those affecting principally the eye), including Wet Age-

Related Macular Degeneration, Diabetic Retinopathy, Diabetic Macular Edema, and Macular Edema following Retinal Vein Occlusion.

Regeneron pled a product market consisting of anti-VEGF PFS as distinct from analogous drugs delivered through less effective vial delivery systems. Delivery via vial was time consuming, burdensome and problematic because the practitioner had to follow a series of steps to first extract the correct quantity of medication from the vial, switch needles, and inject the medication into a patient's eye. Regeneron's EYLEA product and Novartis's licensed-LUCENTIS product were historically sold only in this vial form; however, more recently, physicians have converted from vial to PFS in massive quantities, based on PFS' unique characteristics and benefits, including ease of administration and lower risk of complications. Due to the superiority of the PFS product, practitioners have widely switched to prescribe anti-VEGF drugs in PFS form.

Regeneron's antitrust complaint explained in detail how the market for anti-VEGF is distinct from and does not include vials, and Regeneron specifically alleged a lack of cross-elasticity or reasonable

interchangeability between PFS and vials with the following substantial allegations as merely exemplars:

- PFS appeal to consumers as they are more accurate and more convenient than vials (*e.g.*, A336 (¶ 6), A414 (¶¶ 76-87), A417-418 (¶¶ 196-97));
- PFS require separate regulatory approvals and specialized production from vials (*e.g.*, A419 (¶ 199));
- 80% of patients on vials switched to PFS for both LUCENTIS and EYLEA within months of their respective launches (*e.g.*, A360-363 (¶¶ 76-84), A419-420 (¶¶191-200), A425 (¶ 215), A428 (¶ 225), A431 (¶¶ 236), A438 (¶253)), indicating that a small but significant increase in price for PFSs would not cause mass defection back to vials so as to render it unprofitable, satisfying the "hypothetical monopolist" test;
- Industry participants, including retinal specialists, recognize the significant advantages of PFS over vials: "Using syringes prefilled with the soluble anti-VEGF agents will protect patients from the disastrous consequences of endophthalmitis, assure the most efficient manner of precise dosing, and assist

with patient flow in growing, busy clinics." Similarly, a third-party survey shows that a significant number of doctors have indicated that they will increase their prescribing of EYLEA due to the availability of PFS. And Genentech and Novartis have publicly touted the benefits of LUCENTIS PFS compared to LUCENTIS vial (*e.g.*, A419 ¶198).

- Every purported substitute identified by Defendants is not reasonably interchangeable with PFS for antitrust purposes, and thus outside the relevant market. [3]

Notwithstanding the above factual allegations and ignoring precedent on which it must follow, on January 31, 2022, the District

[3] *See e.g.*, A415-420 (¶¶ 191-202) ("[A]nti-VEGF PFS treatments do not meaningfully compete with anti-VEGF vials given that they each have particular characteristics and uses. As a result of their method of administration, anti-VEGF PFS have distinct advantages in terms of accuracy and convenience, which differentiates them from anti-VEGFs approved by the FDA in vial form-even those containing the same active drug ingredient"); ("Drugs used 'off-label' for the treatment of ophthalmic diseases are also not reasonably interchangeable with FDA-approved anti-VEGFs. These off-label treatments have distinct characteristics and uses based upon their FDA-approved indications . . . [D]rugs like Avastin need to be repackaged by third parties before they can be administered intravitreally to patients. Due to concerns with dosing accuracy and sterilization, many ophthalmologists and retinal specialists are unwilling to prescribe Avastin off-label . . . Off-label drugs also have shown to be less effective at treating certain ophthalmic diseases.").

Court dismissed with prejudice the four antitrust claims solely for failure to define a relevant product market. The Supreme Court's decision in *Eastman Kodak*, 504 U.S. at 482, explicitly held that the market definition in antitrust cases "can be determined only after a factual inquiry into the commercial realities faced by consumers." And it is established law in this Circuit that courts should hesitate to grant motions to dismiss for failure to plead a relevant product market because it is a *"deeply fact-intensive inquiry"*. *See, e.g.*, *Todd v. Exxon Corp.*, 275 F.3d 191, 199 (2d Cir. 2001) (reversing dismissal); *US Airways Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 68 (2d Cir. 2019). Dismissal on the pleading for failure to plead a market definition is appropriate only in two instances: (1) a failed attempt to limit a product market to a single brand; or (2) failure to attempt a plausible explanation as to why a market should be limited in a particular way. *Todd*, 275 F.3d at 200. Regeneron's proposed market satisfies neither exception because the market includes both EYLEA and LUCENTIS products (*i.e.*, it is not limited to a single brand) and the complaint explains in detail why demand for vials is not cross-elastic with demand for PFS, such that Anti-VEGF PFS make up their own product market. A363-64 (¶¶ 84-86),

A417-18 (¶¶ 196-198). These detailed allegations do not merely pass muster under the low pleading burden applicable to market definition, Regeneron far surpasses the pleading requirements. If such pleadings do not easily surpass market definition pleading standards, private plaintiffs, without the benefit of discovery, may rarely have publicly available data sufficient to do so.

Amicus curiae COSAL respectfully requests that this panel reverse the District Court's opinion dismissing Regeneron's FAC because there is no heightened pleading standard for antitrust cases generally, and certainly not for the fact-driven issue of market definition. If the allegations in Regeneron's FAC, including explaining why every alternative product does not belong in the definition, do not easily surpass market definition pleading standards, private plaintiffs, without the benefit of discovery, may rarely have publicly available data sufficient to do so.

SUMMARY OF ARGUMENT

At the pleading stage, one way[4] a plaintiff bringing a claim under Sections 1 or 2 of the Sherman Act can show market power is to allege a relevant geographic[5] and product market in which trade was unreasonably restrained or monopolized. *Heerwagen v. Clear Channel Comm'ns*, 435 F.3d 219, 227 (2d Cir. 2006) (citations omitted); *Global Discount Travel Servs., LLC v. Trans World Airlines, Inc.*, 960 F. Supp. 701, 704 (S.D.N.Y. 1997). Guiding an antitrust plaintiff through the market definition analysis (and all antitrust analyses) is the Supreme Court's admonition that there is no heightened standard for antitrust pleadings and under *Twombly and Iqbal,* all that is required at the pleading stage is for plaintiffs to plead facts to "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct," and the court must accept as true all-well pled facts and draw all

[4] Plaintiffs can either prove market power "indirectly," by defining a relevant product and geographic market and alleging the defendant (or defendants collectively) possess a sufficiently powerful share of that market, or they may proceed "directly," by showing "proof of actual detrimental effects, such as a reduction in output." *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 460-61 (1986) (quotation omitted). At the pleading stage, plaintiffs often must rely on indirect proof, as they lack the facts necessary to prove anticompetitive effects.

[5] The relevant geographic market is not disputed.

reasonable inferences in the light more favorable to Plaintiffs. *Iqbal*, 556 U.S. at 663.

The District Court, however, improperly crafted a heightened pleading standard and prematurely imposed the burden on Regeneron to prove the relevant market at the pleading stage. In fact, instead of accepting Regeneron's well-pled facts as true and drawing all reasonable inferences in the light most favorable to it, the District Court instead improperly chose to draw inferences *in favor of the Defendants*, finding their competing version of the facts was correct. Such a decision is not proper. *Anderson News, LLC. v. Am. Media, Inc.,* 680 F.3d 162, 185 (2d Cir. 2012) ("The choice between two plausible inferences that may be drawn from factual allegations is not a choice to be made by the court on a Rule 12(b)(6) motion.").

The Supreme Court has explicitly held that the market definition in antitrust cases "can be determined only after a factual inquiry into the 'commercial realities' faced by consumers." *Eastman Kodak*, 504 U.S. at 482.[6] As a result, this Circuit has consistently held that courts should

[6] As discussed above, there are two exceptions to this general prohibition,: (1) an attempt to limit a product market to a single brand without adequate justification; or (2) the failure to even attempt a

hesitate to grant motions to dismiss for failure to plead a relevant product market because it is a *"deeply fact-intensive inquiry." Todd,* 275 F.3d at 199; *Mereith Corp. v. SESAC LLC*, 1 F. Suppp. 3d 180, 219 (S.D.N.Y. 2014) ("[M]arket definition 'is a highly factual one best allocated to the trier of fact.'") (internal citation omitted). One practical reason that Courts in fact hesitate to grant motions to dismiss for failure to plead a relevant market is because market definition is often the topic of economist expert discovery. *See E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.,* 637 F.3d 435, 443 (4th Cir. 2011) (holding market definition is a highly fact-based analysis that generally requires discovery); *Dial Corp v. News Corp.*, 165 F. Supp. 3d 25, 34-35 (S.D.N.Y. 2016) ("Market definition 'is a highly factual one best allocated to the trier of fact.'") (citing *Meredith Corp.* v. SESAC LLC 1 F. Supp. 3d 180, 219 (S.D.N.Y. 2014).

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plausible explanation as to why a market should be defined in a particular way. *Todd*, 275 F.3d at 200. Regeneron's proposed market satisfies neither exception as it is not limited to a single brand and it explains in detail why non-PFS products are outside the relevant market's borders. A417-417 (¶¶ 196-198).

To satisfy pleading standards before the plaintiff can use the discovery phase of the litigation to learn and submit its fact and empirical evidence, market definitions need only "bear a rational relation to the methodology courts prescribe to define a market for antitrust purposes" and include a plausible explanation as to why a market should be limited to exclude possible substitutes. *Todd*, 275 F.3d at 200 (internal quotes and citations omitted).

The heightened pleading standard incorrectly imposed by the District Court would leave fewer avenues for private plaintiffs to prove market definition, as they would be forced to proceed without the benefit of fact and expert discovery. Such a result is underscored here because the District Court dismissed this case *even though* Regeneron went so far as to explain why every alternative product that Defendants identify—including anti-VEGF vials—is not reasonably interchangeable and thus outside of the relevant market, satisfying the low "rational relationship" test imposed by *Todd* and its progeny. A415-420 (¶¶ 191-202). If such detailed pleadings do not easily surpass the pleading standards, private enforcement could be curtailed in cases where sufficient public data does not exist to prove up this aspect of a claim. And while no industry merits

special, heightened pleading standards in antitrust cases, it is especially inappropriate in the healthcare industry, where preserving competition is not just a matter of economic liberty—it causes broader societal harm on patients and their families who might be unable to afford treatment at inflated prices. The District Court should be reversed, and this case remanded.

ARGUMENT

I. PRIVATE ENFORCEMENT OF THE ANTITRUST LAWS COULD BE DIMINISHED IF A HEIGHTENED MARKET DEFINITION PLEADING STANDING IS ADOPTED

The Supreme Court has repeatedly held that the private right of action provisions in the antitrust laws serve two purposes: compensation to victims and deterrence of potential violators. *See*, *e.g.*, *Pfizer, Inc. v. Gov't of India*, 434 U.S. 308, 314 (1978) (stating that "[the Clayton Act] has two purposes: to deter violator and deprive them of 'the fruits of their illegality,' and "to compensate victims of antitrust violations for their injuries") (citations omitted); *Am. Soc. of Mech. Eng'rs v. Hydrolevel Corp.*, 456 U.S. 556, 575–76 (1982) (asserting that "treble damages serve as a means of deterring antitrust violations and of compensating

victims").[7] While public federal agencies, including the U.S. Department of Justice and the Federal Trade Commission have authority to enforce antitrust laws, they cannot prosecute all unlawful conduct due to insufficient resources. Private litigants step in to fill that void and help protect competition without overburdening the taxpayer. In fact, private antitrust actions have become much more prominent, and in turn vital, form of enforcing the Sherman Act.[8] And these increased filings have led to tremendous results for victims of anticompetitive conduct, with over $29.3 billion in compensation being recovered *in private antitrust class actions alone* between the years 2009 through 2021.[9] Beyond providing compensation to the victims of antitrust schemes, the "treble-damages

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[7] S*ee*, *e.g.*, Antitrust Modernization Commission, Report and Recommendations, 246–47 (2007), http://govinfo.library.unt.edu/amc/report_recommendation/amc_final_report.pdf (last visited June 17, 2022).

[8] Fed. Judicial Caseload Statistics, Table C-2: *U.S. District Courts—Civil Cases Commenced, by Basis of Jurisdiction and Nature of Suit, During 12-Month Periods Ending March 31, 2020 and 2021*, https://www.uscourts.gov/statistics-reports/federal-judicial-caseload-statistics-2021-tables (last visited June 17, 2022) (indicating that out of 589 antitrust cases in federal courts 565 were private actions).

[9] *See*, American Antitrust Report: The Critical Role of Private Antitrust Enforcement in the United States, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4117930 (last visited June 17, 2022).

provision wielded by the private litigant is a chief tool in the antitrust enforcement scheme," because the fear of treble damages creates "a crucial deterrent to potential violators." *Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc.*, 473 U.S. 614, 635 (1985) (citations omitted).

Alleged antitrust violations in the pharmaceutical industry are especially egregious because they affect the nation's healthcare as a whole and could mean life or death for any U.S. citizen who is required to purchase a certain drug or treatment at a supracompetitive price to combat a health disease. Following the Supreme Court's decision in *Federal Trade Commission v Actavis*, 570 U.S. 136 (2013), private antitrust litigation in the pharmaceutical industry remains robust, with individual suits and class actions alike serving to challenge unlawful behavior.

Two areas of pharmaceutical antitrust litigation have been especially prevalent in recent years: "reverse payment" or "pay for delay" litigation and alleged "product hopping." Generally, in reverse payment litigations it is alleged that a pharmaceutical company provided compensation in some form to its potential generic competitor to induce that competitor to refrain from marketing the generic version of a

branded drug after the expiration of the drug's patent. In product hopping cases, plaintiffs challenge brand manufacturers' introduction of so-called "new" versions of existing drugs by filing sham patents that do nothing more than attempt to extend the product's patent protection without improving efficacy. Those suits claim that brand manufacturers introduce "new" versions and discontinuing "older" versions of brand drugs as an attempt to work around patent expiry to thwart generic competition. In product hopping patent cases especially, the parties are likely to dispute the relevant market in which the Defendant allegedly has market power, and whether reasonable substitutes exist.

As articulated by the District Court, the gist of a *Walker Process* claim, as Regeneron pled, is that an unlawfully obtained patent should be stripped of its usual immunity from antitrust liability. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). There are two global requirements to a *Walker Process* claim: (1) "that the antitrust-defendant obtained the patent by knowing and willful fraud on the patent office and maintained and enforced the patent with knowledge of the fraudulent procurement;" and (2) all other elements of a Sherman Act monopolization claim, including (i) market

power, (ii) anticompetitive effects or antitrust "impact," (iii) resulting damages and (iv) a lack of offsetting procompetitive justifications are also met. *Transweb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1307 (Fed. Cir. 2016).

The District Court committed reversible error when it held that if a relevant market were the same as what a patent claims, then "every instance of patent fraud would give rise to an antitrust claim by definition." SPA25-27.[10] To support this holding, the District Court rejected the standard tools of market definition, including reasonable interchangeability of use, cross-elasticity of demand, and the "small but significant non-transitory increase in price" test, and substituted a new rule that prevents an antitrust market from being concomitant with a patent unless the products are "so novel that there really is no fitting substitute." *Id.* Neither the Defendants nor the Court cited precedent for this novel test that would put a heightened burden on the plaintiff, at

[10] Even if one credited the conclusion that finding a patent concomitant with a relevant market's borders then *ipso facto* the relevant market inquiry was complete, it still does not mean, as the District Court concludes, that there is a "antitrust claim by definition" in "every instance of patent fraud" as the claimant *must still prove the remaining elements of their Section 2 claim* to succeed.

least those pursuing *Walker Process* claims. Instead, the law is clear and explicit: there are no special rules for market definition. *See FTC v. Actavis,* 570 U.S. at 149 ("this Court answered the antitrust question by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents"); *U.S. Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 64 (2d Cir. 2019) (quoting *Brown Shoe*, 370 U.S. at 325); *Todd*, 275 F.3d at 201-02; *United States v. American Express Co.*, 838 F.3d 179, 195-200 (2d Cir. 2016).

The traditional market tools, therefore, apply regardless of whether the asserted market is concomitant with what a patent claims. If a plaintiff pleads, as Regeneron did here, that a proposed market satisfies the reasonable interchangeability of use or the cross-elasticity of demand, it is a properly pled antitrust market, regardless of whether the proposed market is concomitant with a patent. *See Walker Process Equip. Inc. v. Food Machinery and Chem. Corp.*, 382 U.S. 172, 177-78 (1965) (traditional market definition tools applied where asserted market was coextensive with patent); *Transweb,* 812 F.3d at 1307 (affirming jury

verdict in a *Walker Process* case based on traditional market analysis tools where the product was manufactured by only two firms (like Novartis and Regeneron, here) and where the product market was coextensive with the patent).

Contrary to the District Court's conclusion, application of the well-settled market definition principles to a patent does not mean the Plaintiff presumptively has a claim. There are other requirements of an antitrust claim that provide the necessary check and balance between encouraging innovation and protecting competition. *See supra* at p.18-19 and note 10. Here, Regeneron did not plead the bare conclusion that the patent itself defined the market. Instead, Regeneron pled the commercial realities for anti-VEGF PFS separate from patent protection. The flawed rationale that antitrust markets preemptively fail when they are coexistent with patent claims is contrary to decades of precedent (*see* Section II, *infra*) and if allowed to stand on appeal would incentivize anticompetitive activity in the critically important pharmaceutical industry by encouraging sham patent filings and anticompetitive product hopping strategy. In a similar vein, the Defendants' claim that a relevant market must include every product that treats the same condition

ignores that in the pharmaceutical context, something more than mere therapeutic equivalency is required to define the relevant antitrust product market, *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496-98 (2d Cir. 2004),[11] and more generally, antitrust markets are often limited despite the literal possibility of some substitution.[12] Finding to the contrary could have demeritorious effects on private enforcement not just in *Walker Process* actions, but potentially in antitrust cases more broadly.

II. MARKET DEFINITION IS TYPICALLY A QUESTION OF FACT

Antitrust precedent from the Supreme Court, this Court, and numerous other courts holds that market definition is a deeply fact-intensive inquiry that "can be determined only after a factual inquiry into

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[11] *E.g.*, *Geneva Pharm.*, 386 F.3d 496 (holding therapeutically equivalent branded and generic drugs are separate product markets).

[12] *E.g., Am. Needle, Inc. v. New Orleans La. Saints*, No. 04-cv-7806, 2014 WL 1364022 at *3 (N.D. Ill. Apr. 4, 2014) (finding that NFL team hats are in a distinct market from hats bearing logos of teams from other sports); *Jamsports & Entm't, LLC v. Paradama Prods., Inc.*, Case No. 02 C 2298, 2003 WL 1873563 at *1 (N.D. Ill. Apr. 15, 2003) (finding supercross plausible market distinct from motorcycle racing or motor sports generally); *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 52-60 (D.D.C. 2011) (relevant product market consisted of digital do-it-yourself tax preparation products, such as TurboTax, but not "pen and paper" tax returns or "assisted preparation."

the commercial realities faced by consumers." *Eastman Kodak Co.*, 504 U.S. at 482 (internal quotation marks and citation omitted); *see Todd,* 275 F. 3d at 199 ("[M]arket definition is a deeply fact-intensive inquiry[.]").[13]

Because of the fact-intensive nature of market definition, "courts hesitate to grant motions to dismiss for failure to plead a relevant product market." *Todd* 275 F.3d at 199-200. At the pleading stage, and absent two rare occasions not present here, *see supra* at p. 9 and note 6, "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

[13] The Circuit Courts are in harmony on this uncontroversial point. *See, e.g.*, *McWane, Inc. v. F.T.C.*, 783 F.3d 814, 825 (11th Cir. 2015) ("[O]ur caselaw makes clear that '[t]he definition of the relevant market is essentially a factual question.'") (citation omitted); *Telecor Commc'ns, Inc. v. Sw. Bell Tel. Co.*, 305 F.3d 1124, 1131 (10th Cir. 2002) ("It is well settled that defining the relevant market is an issue of fact[.]"); *Oltz v. St. Peter's Cmty. Hosp.*, 861 F.2d 1440, 1446 (9th Cir. 1988) ("Defining the relevant market is a factual inquiry ordinarily reserved for the jury."); *Gen. Indus. Corp. v. Hartz Mountain Corp.*, 810 F.2d 795, 805 (8th Cir. 1987) ("[D]etermining the relevant product market is a factual issue which is reserved to the jury[.]"); *Weiss v. York Hosp.*, 745 F.2d 786, 825 (3d Cir. 1984) ("Market definition is a question of fact[.]"); *Hayden Pub. Co. Inc. v. Cox Broad. Corp.,* 730 F.2d 64, 70 n.8 (2d Cir. 1984) ("It frequently has been observed that '[a] pronouncement as to market definition is not one of law, but of fact . . . .'") (citation omitted).

must be plausible." *Id.* at 200 (internal quotation marks and citation omitted). Dismissal for failure to define a market is appropriate only where the pleadings contain no more than "bare and conclusory allegations" devoid of any development. *In re Crude Oil Commodity Futures Litig.*, 913 F. Supp. 2d 41, 52 (S.D.N.Y. 2012) (citation omitted).

This result holds because courts—before and after *Twombly*—recognize that plaintiffs often need discovery to demonstrate the relevant market. *See E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.,* 637 F.3d 435, 443 (4th Cir. 2011) (holding market definition is a highly fact-based analysis that generally requires discovery); *Alternative Electrodes, LLC v. Empi, Inc.,* 597 F. Supp. 2d 322, 333 (E.D.N.Y. 2009) ("[D]etermining the relevant market requires a fact-intensive inquiry that is best served by allowing the parties discovery.").[14] For example, in *Crude Oil*, the

[14] *See also, e.g.*, *George Haug Co. v. Rolls Royce Motor Cars Inc.,* 148 F.3d 136, 139 (2d Cir. 1998) ("In antitrust cases in particular, the Supreme Court has stated that 'dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly.'") (internal citation omitted); *Doron Precision Sys., Inc. v. FAAC, Inc.*, 423 F. Supp. 2d 173, 180 (S.D.N.Y. 2006) ("Given the 'deeply fact-intensive' nature of the market inquiry, however, the Court cannot say at this juncture, without any discovery on the commercial realities of the bus-simulator market, that Doron's market definitions are wholly insufficient."); *Intellective, Inc. v. Massachusetts Mut. Life Ins. Co.*, 190 F. Supp. 2d 600, 612 (S.D.N.Y. 2002) ("After the fruits of the parties' discovery and

court found that the plaintiffs' market definition was "not so implausible as to warrant dismissal," especially where they pled the defendant's ability to control prices of the product at issue, West Texas Intermediate Grade (WTI) crude oil. 913 F. Supp. 2d at 54. The court noted that the defendants may have identified "fruitful areas for discovery, such as the degree to which other grades of crude oil are reasonable substitutes for WTI and whether oil on the other side of the planet is 'readily available' at Gushing." *Id.* (citation omitted). However, these arguments were not grounds for dismissal of the complaint.

Similarly, in *Meyer v. Kalanick*, 174 F. Supp. 3d 817 (S.D.N.Y. 2016), the court denied a motion to dismiss, rejecting defendants' argument that the market definition was inadequate. Plaintiffs defined the market as the "mobile app-generated ride-share service market" (e.g.,

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economic analyses are presented to me at a later stage, I may not have to accept Intellective's market definition as valid. But we have not yet reached that point."); *Cont'l Orthopedic Appliances, Inc. v. Health Ins. Plan of Greater New York, Inc.*, 40 F. Supp. 2d 109, 120 (E.D.N.Y. 1999) ("Despite the Court's reservations as to the plaintiffs' restrictive definition of the relevant product market, the Court is of the view that in this particular instance, only discovery can properly determine the commercial realities involved in the health care provider universe."); *Minpeco, S.A. v. ContiCommodity Servs.*, Inc., 552 F. Supp. 327, 331 (S.D.N.Y. 1982) ("Questions of market definition can be narrowed and determined through the discovery process.").

the Uber and Lift ride-sharing services). *Id.* at 827. Plaintiffs explained why they did not include taxis and traditional cars for hire in the market definition. *Id.* The court rejected defendants' argument that plaintiffs' explanations were inadequate, explaining that the accuracy of plaintiffs' explanations "may be tested through discovery and, if necessary, trial." *Id.*

Here, Regeneron defined a plausible market of "anti-VEGFs in prefilled syringes [PFS] that are approved by the FDA for the treatment of certain ophthalmic diseases." A415-16 (¶ 191). Regeneron explained why "anti-VEGF PFS treatments do not meaningfully compete with anti-VEGF vials given that they each have particular characteristics and uses." A417-18 (¶ 196). Regeneron addressed cross-elasticity of demand and substitutability. A196-200 (¶¶ 196-200). Nothing more is (or should be) required at the pleading stage. *See Todd*, 275 F.3d at 200.

III. CONCLUSION

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

Dated: June 21, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

United States Court of Appeals for the Second Circuit: Case No. 22-427

I, Steven N. Williams hereby certify that:

1. I am the attorney, my name appears on this brief and I am a member of the bar of this Court.
2. This document is an amicus brief and complies with word limit of Fed. R. App. P. 29(a)(5) and the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because, excluding the items exempted by Fed. R. App. P. 32(f), this brief contains 5,171 words.
3. The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6) because this document has been prepared in a proportionally spaced typeface in 14-point font.

Date: June 21, 2022

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CERTIFICATE OF SERVICE

I hereby certificate that on this 21st 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 EM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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