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 District Court for the Northern District of New York
The Honorable David N. Hurd (No. 1:21-CV-1066)

Brief of *Amicus Curiae* Open Markets Institute in Support of Plaintiff-Appellant

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INTEREST OF *AMICUS CURIAE*[1]

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INTRODUCTION

This case concerns a critical question in many antitrust matters—how to define the product market in which businesses compete. Elementary concepts in antitrust such as market power and monopoly power are only meaningful in relation to a specific market. Many antitrust cases turn on the fact-intensive inquiry on market definition. Accordingly, courts recognize the importance of permitting parties to develop the factual record, evaluating the evidence, and properly drawing the product and geographic boundaries of the relevant market. The consequences of courts ignoring the factual evidence and incorrectly identifying market

[1] The Plaintiff-Appellant consented to the filing of this brief, while the Defendants-Appellees did not object to its filing. *Amicus curiae* has moved for leave to file this brief. No counsel for any party authored this brief in whole or part. Apart from *amicus curiae*, no person contributed money intended to fund the brief's preparation and submission.

boundaries are serious. Such mistakes can let corporate wrongdoers avoid accountability. For example, a monopolist accused of unfair competitive practices can escape antitrust liability if a court draws the product market boundary too broadly and concludes that the firm faces effective rivalry even though, in reality, it does not.

Regeneron is a pharmaceutical company that makes EYLEA to treat macular degeneration and other serious eye conditions. Regeneron competes against Novartis' LUCENTIS.[2] Historically, these drugs, which are called anti-vascular endothelial growth factor therapies (or anti-VEGF therapies), were distributed in vial form. Physicians and other health care practitioners had to transfer the vial contents into a syringe before they could administer anti-VEGF therapies to patients.

In recent years, anti-VEGF therapies have been sold in prefilled syringes that practitioners can directly administer without any transfer. The elimination of this step for practitioners saves time, increases ease of use, and reduces the risk of contamination and serious adverse effects for patients. Novartis introduced LUCENTIS as a prefilled syringe in 2017, while Regeneron started marketing

[2] Novartis granted commercialization rights and a patent license to Genentech to sell Lucentis in North America. Novartis also owns a 33% stake in Genentech's parent corporation.

EYLEA as a prefilled syringe on a commercial scale in February 2020. From its launch as a prefilled syringe in 2017 until the launch of EYLEA as a prefilled syringe in February 2020, Novartis' LUCENTIS had a monopolistic position in the market for prefilled syringes of anti-VEGF therapies. Vetter is the leading provider of the service of prefilling syringes and has collaborated with both Regeneron and Novartis in developing prefilled syringe versions of EYLEA and LUCENTIS, respectively.

Regeneron has charged that Novartis, instead of competing by lowering the price and improving the safety and efficacy of LUCENTIS, resorted to unfair and illegal competitive tactics to thwart Regeneron's entry and to preserve its monopoly. In January 2013, Novartis filed a patent application to cover a prefilled syringe containing any Food and Drug Administration (FDA) approved anti-VEGF therapy, an invention developed jointly by employees of Novartis and Vetter. Novartis struggled to secure a patent on this invention, with examiners at the Patent and Trademark Office (PTO) issuing a series of non-final rejections of Novartis' original and amended applications. According to Regeneron, Novartis in December 2015 finally obtained a patent through strategic omissions of material facts in its application. In its successful application to the PTO, Novartis allegedly withheld material information on the prior art and did not identify Vetter as a co-inventor. If these facts had been disclosed, Regeneron has argued that the PTO

would have categorically rejected Novartis' patent application. Instead, Novartis obtained a powerful—but unjustified—competitive weapon in its rivalry with Regeneron. Following the launch of EYLEA as a prefilled syringe, Novartis in June 2020 accused Regeneron of patent infringement, seeking damages and injunctive relief in federal court and an order from the International Trade Commission prohibiting the importation of certain components of the prefilled syringe version of EYLEA.

Novartis further successfully induced Vetter to radically revise its longstanding relationship with Regeneron. After Novartis and Vetter entered a collusive and exclusionary licensing arrangement regarding Novartis' pending patent application, Vetter in late 2013, in an unexpected about-face, gave Regeneron two options: 1) continue working with Vetter on extremely restrictive terms, or 2) find another partner for filling prefilled syringes. Given the extremely one-sided offer from Vetter, Regeneron chose the latter option and, as a result, had to find another provider of filling services and delay the launch of EYLEA as a prefilled syringe.

In July 2020, Regeneron filed an antitrust complaint against Novartis and Vetter in federal district court in New York alleging attempted monopolization and restraint of trade and seeking damages and injunctive relief. The defendants moved to dismiss Regeneron's complaint. Despite the evidence presented by Regeneron

that prefilled syringes have important functional advantages over vials, the district court held that a patented product cannot be its own product market and included vials in the product market as well. Accordingly, the court concluded that Regeneron's alleged product market—prefilled syringes with anti-VEGF therapies—is too narrow because it is covered by Novartis' patent. Finding Regeneron's alleged product market deficient, the district court dismissed the complaint. Regeneron now appeals the dismissal of its complaint.

SUMMARY OF ARGUMENT

Market definition is a key—and often decisive—inquiry in antitrust cases. The courts have held that the analytical framework for a range of business practices is the rule of reason and similar fact-intensive standards. When applying these legal tests, antitrust enforcers and courts ordinarily must identify a relevant product and geographic market to determine whether the defendant has market or monopoly power. Drawing appropriate market boundaries is critical: "Taken together, the product and geographic components illuminate the relevant market analysis, which is essential for assessing the potential harm to competition from the defendants' alleged misconduct." *Concord Assocs., L.P. v. Ent. Props. Tr.*, 817 F.3d 46, 53 (2d Cir. 2016) (quoting *Mathias v. Daily News, L.P.*, 152 F. Supp. 2d 465, 481 (S.D.N.Y. 2001)).

At present, fact-intensive tests such as the rule of reason are the prevailing legal standard for most claims under the Sherman Act. In a 1997 decision concerning Section 1 of the Sherman Act, the Supreme Court stated:

> [M]ost antitrust claims are analyzed under a "rule of reason," according to which the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.

State Oil Co. v. Khan, 522 U.S. 3, 10 (1997). In monopolization cases under Section 2, courts apply a similar fact-intensive inquiry. There, plaintiffs must prove "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

In rule of reason and monopolization cases, antitrust enforcers typically try to show that the defendant has market or monopoly power in a relevant market based on market share and that the challenged restraint injured customers,

suppliers, or workers. *See Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). For example, in a case decided last term, the Supreme Court affirmed a district court decision that the NCAA's limits on education-related compensation to college basketball and football players injured these athletes and violated the rule of reason. *NCAA v. Alston*, 141 S. Ct. 2141 (2021).

Given the prevailing legal standards, market definition is an important inquiry in many Sherman Act cases. As one court wrote in a Section 1 case, "[t]he determination of the relevant market is a 'necessary predicate' to analyzing antitrust claims under the rule of reason." *N. Am. Soccer League, LLC v. United Soccer Fed'n, Inc.*, 296 F. Supp. 3d 442, 470 (E.D.N.Y. 2017), *aff'd*, 883 F.3d 32 (2d Cir. 2018) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957)). In defining product and geographic markets, courts aim to identify the "area of effective competition." *Standard Oil of Cal. v. United States*, 337 U.S. 293, 299 n.5 (1949). Courts must usually define relevant markets before they can determine whether a firm has market power or monopoly power. Correctly drawing the boundaries of the geographic and product market is essential and can decide the outcome of an antitrust lawsuit. Mistakenly identifying the scope of the market may lead to courts supplying incorrect answers to key questions such as whether a defendant has sufficient share to possess market power or monopoly power.

In identifying a product market, courts determine its "outer boundaries . . . by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). Judges and juries consider "such practical indicia as industry or public recognition of the submarket 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." *Id.* "[I]nterchangeability is largely gauged by the purchase of competing products for similar uses considering the price, characteristics and adaptability of the competing commodities." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 380 (1956). Courts identify "the line of commerce, i.e., the type of goods, wares, or merchandise, etc., . . . on *the basis of the facts peculiar to the case*." *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961) (emphasis added).

Due to market definition being "a deeply fact-intensive inquiry," *Todd v. Exxon Corp.*, 275 F.3d 191, 199 (2d Cir. 2001), courts are averse to applying bright-line rules when defining markets. Market definition is case-specific and often driven by industry peculiarities. *See, e.g., du Pont*, 353 U.S. at 593-94. Accordingly, the Supreme Court has warned against applying rigid rules and categories when defining markets. In drawing market boundaries, courts should

reject "formalistic distinctions" and examine "actual market realities." *See Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 466 (1992). When defining markets, the Supreme Court "has examined closely the economic reality of the market at issue." *Id.* at 467.

The Supreme Court specifically rejected formalistic market definitions for patented products. In a 2006 decision, the Court reversed the presumption of market power for patented products. *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 46 (2006). Tellingly, the Court declined to adopt the opposite presumption that a patent *cannot* confer market power. Instead, the Court adopted a functional approach, holding that plaintiffs must establish that the patentee possesses market power in a relevant market. The Court said that the respondent "should be given a fair opportunity to develop and introduce evidence" on the relevant market and the petitioners' possession of power in that market. *Id.* at 46.

The fact-intensive character of market definition underscores the importance of courts generally permitting plaintiffs to take discovery. This Court has been clear that district courts should ordinarily not grant motions to dismiss a complaint due to purported defects in the plaintiff's alleged product market. In an opinion by then-Judge (now-Justice) Sotomayor, the Court wrote, "Because market definition is a deeply fact-intensive inquiry, courts hesitate to grant motions to dismiss for failure to plead a relevant product market." *Todd*, 275 F.3d at 199-200. So long as

a plaintiff's product market is "plausible," its complaint should survive a motion to dismiss. *See Concord Assocs.* 817 F.3d at 53. In a similar spirit, the Supreme Court held that "[t]he proper market definition in this case can be determined only *after* a factual inquiry into the 'commercial realities' faced by consumers." *Kodak*, 504 U.S. at 453 (emphasis added) (quoting *Grinnell*, 384 U.S. at 572). At the pleading stage, courts ordinarily have not had the opportunity to engage in such a factual inquiry.

The district court disregarded the directions this Court and the Supreme Court have given on market definition and employed a formalistic rule on what constitutes a proper product market. In adopting a strong presumption against a patented item constituting its own product market, the district court applied a rigid rule that the Supreme Court and this Court warned against employing. The court, in lieu of considering the evidence before it, applied a practically conclusive presumption that patented products cannot be their own market.

In formulating this false choice, the district court ignored the holding and rationale of *Illinois Tool Works*. The Supreme Court held that a patent does not always or even generally grant market power to the patent holder. *Ill. Tool Works*, 547 U.S. at 45-46. The Court, however, did not adopt the opposite proposition that a patent can never confer market power or that a patented good can never be its own product market. Plaintiffs can still show on a case-by-case basis that a patent

does confer market power. *See id.* at 43 (concluding that plaintiffs must show "proof of power in the relevant market" even for patented products). Rather than following the Supreme Court's directives and emphasis on examining the factual record on a case-by-case basis, the district court assumed it had to adopt one of two categorical rules and opted to employ the rule that patented goods can almost *never* be their own product market.

In applying a formalistic approach to product market definition, the district court disregarded the evidence that Regeneron had presented in its complaint. Regeneron did not assert that a patent automatically conferred market power on LUCENTIS or Food and Drug Administration (FDA) approved anti-VEGF therapies in prefilled syringes or that a patented item always constitutes its own product market. Instead, Regeneron relied on product features and health care practice to distinguish FDA approved anti-VEGF therapies in prefilled syringes from anti-VEGF therapies in vials. Specifically, it presented evidence, including a third-party survey, on the functional advantages of—and practitioners' strong preference—for prefilled syringes over vials. Regeneron identified the greater ease of use, time savings, and lower risk of serious adverse effects of prefilled syringes, relative to vials. Due to these critical advantages, Regeneron contended that prefilled syringes have become the standard of care among ophthalmologists, with vials generally viewed as an obsolete method of administration. With this evidence

in its complaint, Regeneron presented more than a plausible basis for limiting the product market to FDA approved anti-VEGF therapies in prefilled syringes and proceeding to discovery.

ARGUMENT

I. Defining the Relevant Market(s) Is a Critical Inquiry in Many Antitrust Cases

Market definition is a key—and often dispositive inquiry—in antitrust cases. The courts have held that the analytical framework for a range of business practices is the rule of reason and similar fact-intensive standards. When applying these inquiries, antitrust enforcers and courts ordinarily must identify a relevant product and geographic market to determine whether the defendant has market or monopoly power. Drawing appropriate market boundaries is critical: "Taken together, the product and geographic components illuminate the relevant market analysis, which is essential for assessing the potential harm to competition from the defendants' alleged misconduct." *Concord Assoc., L.P. v. Ent. Props. Tr.*, 817 F.3d 46, 53 (2d Cir. 2016) (quoting *Mathias v. Daily News, L.P.*, 152 F. Supp. 2d 465, 481 (S.D.N.Y. 2001)). For example, by drawing the market too broadly, courts risk exonerating corporations that possess market or monopoly power in the actual market in which they participate.

At present, the rule of reason is the prevailing legal standard for claims under Section 1 of the Sherman Act. In a 1997 decision, the Supreme Court stated:

> [M]ost antitrust claims are analyzed under a "rule of reason," according to which the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.

State Oil Co. v. Khan, 522 U.S. 3, 10 (1997). The rule of reason stands in contrast to per se rules and quick-look tests under which a defendant is conclusively or presumptively liable for certain practices without a showing of harmful effects on consumers or other market participants. *See Cal. Dental Ass'n. v. FTC*, 526 U.S. 756, 779 (1999) (identifying three principal legal tests but acknowledging that "categories of analysis . . . are less fixed than terms like 'per se,' 'quick look,' and 'rule of reason' tend to make them appear."). While price fixing and market allocation among competitors are per se illegal practices, *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 48-50 (1990) (per curiam), resale price maintenance and territorial restraints between manufacturers and distributors of their goods are subject to the rule of reason under Section 1.

Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877 (2007); *Cont'l T.V., Inc., v. GTE Sylvania Inc.*, 433 U.S. 36 (1977).

In monopolization cases, courts apply a similar fact-intensive inquiry. Plaintiffs must make two showings. "The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). The monopoly power element of the two-part test "may be inferred from one firm's large percentage share of the relevant market." *Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 98 (2d Cir. 1998).

In rule of reason and monopolization cases, antitrust enforcers have two paths for establishing the defendant's power. First, they can use direct evidence, such as the firm's pricing power or the challenged restraint's contribution to higher prices or diminished product quality, to establish market power and even illegality. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460 (1986). In theory, "proof of actual detrimental effects, such as a reduction of output, can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects." *Id.* at 460-61 (quotations omitted). Ordinarily though, plaintiffs do not have the requisite "direct proof" of the defendant's market power, *United States v.*

Microsoft Corp., 253 F.3d 34, 51 (D.C. Cir. 2001), or of the effects of the challenged practice because the quantitative data either do not exist or are proprietary and not publicly available.

Due to the difficulty of using direct evidence to establish the requisite power or illegality, plaintiffs usually pursue the second option. They attempt to show that the defendant has market or monopoly power in a relevant market and that the challenged restraint injured customers, suppliers, or workers. *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). For example, in a case decided last term, the Supreme Court affirmed a district court decision that the National Collegiate Athletic Association's collusive limits on education-related compensation to college basketball and football players injured these athletes and violated the rule of reason. *NCAA v. Alston*, 141 S. Ct. 2141 (2021). The players demonstrated the NCAA had power in the market for college athletes' services and that its restraints depressed compensation tied to education. *Id.* at 2156-57.

Given the prevailing legal standards, market definition is an important inquiry in many Sherman Act cases. As one court wrote in a Section 1 case, "the determination of the relevant market is a 'necessary predicate' to analyzing antitrust claims under the rule of reason." *N. Am. Soccer League, LLC v. United Soccer Fed'n*, Inc., 296 F. Supp. 3d 442, 470 (E.D.N.Y. 2017), *aff'd,* 883 F.3d 32 (2d Cir. 2018) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S.

586, 593 (1957))). Courts must define relevant markets before they can determine whether a firm has market power or monopoly power. Resolving this question is important and can be dispositive. By way of example: In the absence of a showing of monopoly power, an enforcer typically loses as a matter of law in a monopolization case. *See, e.g.*, *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 109 (2d Cir. 2002) (affirming district court's granting of summary judgment in favor of Coca-Cola on PepsiCo's Section 2 claims because Pepsi failed to show Coca-Cola has monopoly power in an appropriate relevant market). Conversely, for certain claims, showing power in a market can be sufficient to establish the defendant's liability. In suits challenging the improper tying of separate goods or services, establishing that a defendant has market power in the sale of one product can be sufficient to trigger liability. *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 477-78 (1992).[3]

[3] In interpreting and applying Section 7 of the Clayton Act, the Supreme Court established a structural presumption against mergers among rivals that "threaten undue concentration," with a post-merger firm with a 30 percent share of a relevant market presenting such a threat. *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 364 (1963); *see, e.g.*, *Consolidated Gold Fields PLC v. Minorco, S.A.*, 871 F.2d 252, 260 (2d Cir. 1989) ("A post-acquisition Minorco would give Anglo and the Oppenheimer family control of 32.3% of that market. That percentage is above the 30% held by the Supreme Court to trigger a presumption of illegality in *Philadelphia Nat'l Bank*. It is certainly sufficient to satisfy appellees' burden of showing likelihood of success on the merits.")

Correctly drawing the boundaries of the geographic and product market is essential and can decide the outcome of an antitrust lawsuit. Mistakenly identifying the scope of the market can lead to courts supplying incorrect answers to key questions such as whether a defendant has sufficient share to possess market power or monopoly power. For example, if a court draws the product market boundaries too widely, a firm that does not face effective competition may be deemed *not* to possess monopoly power and escape liability for otherwise illegal competitive practices. When defining markets, "[t]he 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 Publ'g Co. v. United States*, 345 U.S. 594, 612 n.31 (1953). Accordingly, enforcers and courts devote substantial time and effort to determining the relevant market in many antitrust cases.

II. Market Definition is a Fact-Intensive Question

In defining geographic and product markets, courts aim to identify the "area of effective competition." *Standard Oil of Cal. V. United States*, 337 U.S. 293, 299 n.5 (1949). Courts need to identify which goods and services effectively compete against each other and the geographic area in which competition occurs. To offer concrete examples, they seek to answer questions such as whether orange juice and orange-flavored soda are in the same product market and whether a hospital and a clinic ten miles away are in the same geographic market. Because "market

definition is a question of fact," *Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196 (1st Cir. 1996) (quotation omitted), the inquiries are market- and case-specific and not conducive to the application of bright-line rules.

In defining relevant markets, courts consider a range of factors. In identifying a product market, they determine its "outer boundaries . . . by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). Courts consider "such practical indicia as industry or public recognition of the submarket 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." *Id.* "[I]nterchangeability is largely gauged by the purchase of competing products for similar uses considering the price, characteristics and adaptability of the competing commodities." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 380 (1956). Courts identify "the line of commerce, i.e., the type of goods, wares, or merchandise, etc. . . ., on *the basis of facts peculiar to the case*." *See Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961) (emphasis added). To be in the same product market, two commodities or services must be "reasonable substitutes." *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 239 (2d Cir. 2003).

Courts evaluate a variety of evidence in defining relevant markets. As the Supreme Court wrote in a lengthy exposition on market definition in merger cases, "Congress neither adopted nor rejected specifically any particular tests for measuring the relevant markets, either as defined in terms of product or in terms of geographic locus of competition . . . ." *Brown Shoe*, 370 U.S. at 320. Parties can submit quantitative estimates of the cross-elasticity of demand between different goods and services as a method of delineating the product market. But they are not required to introduce such estimates and can use other types of quantitative or qualitative evidence as well. The aim for courts is to ensure "the accuracy of the broad picture presented." *Id.* at 341 n.69.

Given this flexible inquiry, courts often rely on a variety of qualitative evidence. They have looked to the businesses' internal communications as one source of guidance in defining relevant markets. *See, e.g.*, *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 52 (D.D.C. 2011) ("When determining the relevant product market, courts often pay close attention to the defendants' ordinary course of business documents."). Industry recognition is also well established as a factor that courts consider in defining a market. *Todd v. Exxon Corp.*, 275 F.3d 191, 205 (2d Cir. 2001) (Sotomayor, J.). Judges treat perception and opinions among other market participants as informative too. *See, e.g.*, *United States v. SunGard Data Sys., Inc.*, 172 F. Supp. 2d. 172, 189 (D.D.C. 2001) (citing "industry recognition"

as support for a particular product market definition). Annual reports and filings to the Securities and Exchange Commission, in which firms are obliged to be honest with their investors, can also help define markets. Courts review these filings to determine the boundaries of the market and to verify claims made by the parties on market definition. *See, e.g., FTC v. Swedish Match N. Am., Inc.*, 131 F. Supp. 2d 151, 164 (D.D.C. 2000).

Due to market definition being "a deeply fact-intensive inquiry," *Todd*, 275 F.3d at 199, courts are averse to applying bright-line rules when defining markets. Market definition is case-specific and often driven by industry peculiarities. *See, e.g.*, *du Pont*, 353 U.S. at 593-94 (noting that "automotive finishes and fabrics have sufficient peculiar characteristics and uses" to differentiate them "from all other finishes and fabrics"). Accordingly, the Supreme Court has warned against formalism when defining markets. In drawing market boundaries, courts should reject "formalistic distinctions" and review "actual market realities." *See Kodak*, 504 U.S. at 466. When defining markets, the Supreme Court "has examined closely the economic reality of the market at issue." *Id.* at 467.

The Supreme Court specifically rejected formalistic market definitions for patented products. In a 2006 decision, the Court reversed the longstanding rule that a patentee can be presumed to possess market power. *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 46 (2006). In overturning a nearly sixty-year-old precedent,

the high court followed a functional approach to defining markets. Tellingly, the Court declined to adopt the opposite categorical rule that a patent *cannot* confer market power on the holder. Instead, the Court held that plaintiffs had to establish that the patentee possesses market power in a relevant market. The Court said that the respondent "should be given a fair opportunity to develop and introduce evidence" on the relevant market and the petitioners' possession of power in that market. *Id.* at 46.

III. Given the Fact-Intensive Nature of Market Definition, Courts Ordinarily Decline to Decide this Question at the Pleading Stage

Market definition is an inquiry ill-suited for a dispositive decision on the pleadings. Given its fact-intensive character, this Court has directed district judges to strongly disfavor granting defendants' motion to dismiss based on market definition. Instead, courts should give plaintiffs a real opportunity to develop the evidentiary record to support their proffered product and geographic markets.

The fact-intensive character of market definition underscores the importance of courts generally permitting plaintiffs to conduct discovery. Consider how courts identify relevant product markets: The answer "is largely gauged by the purchase of competing products for similar uses considering the price, characteristics and adaptability of the competing commodities." *United States v. E.I. du Pont de Nemours de Nemours & Co.*, 351 U.S. 377, 380-81 (1956). Examining such

"market realities" typically cannot be done on the pleadings alone. *See Kodak*, 504 U.S. at 466-67. Courts cannot appreciate the "facts peculiar to the case" on the sparse factual record that generally exists at the pleading stage. *Tampa Electric*, 365 U.S. at 327. As a district court in a landmark monopolization suit wrote, "[T]he problem of defining a market turns on discovering patterns of trade which are followed in practice." *United States v. United Shoe Machinery Corp.*, 110 F. Supp. 295, 303 (D. Mass. 1953), *aff'd per curiam*, 347 U.S. 521 (1954).

This Court has been clear that district courts should ordinarily not grant motions to dismiss a complaint due to purported defects in the plaintiff's alleged product market. In an opinion by then-Judge (now-Justice) Sotomayor, the Court wrote that "[b]ecause market definition is a deeply fact-intensive inquiry, courts hesitate to grant motions to dismiss for failure to plead a relevant product market." *Todd*, 275 F.3d at 199-200. So long as a plaintiff's product market is "plausible," its complaint should survive a motion to dismiss. *See Concord Assocs.*, 817 F.3d at 53.

This Court's reluctance to decide market definition at the pleadings stage is consistent with the approach of other courts of appeals. Recognizing the fact-intensive character of market definition, the Third Circuit stated that, absent manifest defects in a plaintiff's alleged market definition, "courts are cautious before dismissing for failure to define a relevant market." *LifeWatch Servs. Inc. v.*

Highmark Inc., 902 F.3d 323, 337 (3d Cir. 2018). In a similar spirit, the Fourth Circuit stated that "dismissal of an antitrust claim for failure to adequately plead the relevant market can be problematic." *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 443 (4th Cir. 2011). At the pleading stage, a plaintiff does "not have to provide empirical or statistical evidence that would define the market with precision." *Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337, 1352 (Fed. Cir. 2011). *See also Found. for Interior Design Educ. Research v. Savannah Coll. of Art & Design*, 244 F.3d 521, 531 (6th Cir. 2001) ("Market definition is a highly fact-based analysis that generally requires discovery."); *Double D Spotting Serv., Inc. v. Supervalu, Inc.*, 136 F.3d 554, 560 (8th Cir. 1998) ("[C]ourts are hesitant to dismiss antitrust actions before the parties have had an opportunity for discovery . . . .").

The Supreme Court implicitly stated that granting motions to dismiss on market definition grounds should be disfavored. It held that "[t]he proper market definition in this case can be determined only *after* a factual inquiry into the 'commercial realities' faced by consumers." *Kodak*, 504 U.S. at 453 (emphasis added) (quoting *Grinnell*, 384 U.S. at 572). Market definition requires "careful consideration based upon the entire record." *United States v. Cont'l Can Co.*, 378 U.S. 441, 449 (1964). At the pleading stage, courts ordinarily have not had the opportunity to engage in such a factual inquiry.

IV. The District Court Ignored the Directives of this Court and the Supreme Court on Not to Ordinarily Decide Market Definition at the Pleading Stage

In granting the appellees' motion to dismiss, the district court made multiple critical errors. The district court disregarded the directives this Court and the Supreme Court on developing and evaluating the factual record on market definition and instead applied a rigid rule. In applying a strong presumption against a patented item constituting its own product market, the district court followed a formalistic approach that the Supreme Court and this Court admonished district courts not to use. The court, in lieu of considering the evidence before it, applied a practically conclusive presumption that patented products cannot be their own market.

The district court incorrectly applied a strong presumption on product market definition. The court held that as a general matter a patented item cannot be its own product market. In addition to ignoring the evidence introduced by Regeneron, the court embraced the formalism that the Supreme Court had directed the lower courts to reject on market definition questions. Rather than examine the particulars of the market in front of it and the extensive evidence presented by Regeneron in its complaint, the district court elevated "formalistic distinctions" over "actual market realities." *Kodak*, 504 U.S. at 466. Further, the court failed to

follow the established principle and practice of "courts hesitat[ing] to grant motions to dismiss for failure to plead a relevant product market." *Todd*, 275 F.3d at 199-200.

In its formalistic decision, the court failed to recognize the nuance involved when defining product markets that include patented goods. In analyzing Regeneron's allegations and ultimately dismissing its complaint, the court described the choice before it as a false binary rule: patented products are either always their own product market or never their own product market. The court reasoned that the former would mean that every patent constitutes a walking antitrust violation and all fraud on the Patent Office is an antitrust offense.[4] Accordingly, it adopted and applied a near-conclusive presumption that a patented product cannot be its own product market.

[4] In certain passages in its order, the district court suggested that establishing the defendant's monopoly power is sufficient to establish an antitrust violation. This is incorrect. Monopoly power alone is not enough to violate the law: "The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Grinnell*, 384 U.S. at 570-71. *See also New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 651 (2d Cir. 2015) ("To establish monopolization in violation of § 2, a plaintiff must prove not only that the defendant possessed monopoly power in the relevant market, but that it willfully acquired or maintained that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." (quotations omitted)).

In formulating this false choice, the district court ignored the holding and rationale of *Illinois Tool Works*. There, the Supreme Court held that a patent does not always or even generally grant market power to the patent holder. *Illinois Tool Works*, 547 U.S. at 44. The Court followed the lead of policymakers and scholars, stating that "Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee." *Id.* at 45.

The *Illinois Tool Works* Court, however, did not adopt the opposite proposition that a patent can never confer market power or that a patented good can never be its own product market. Plaintiffs can still show on a case-by-case basis that a patent does confer market power. *Id.* at 43 (concluding that plaintiffs must show "proof of power in the relevant market" even for patented products). Rather than following the Supreme Court's teaching and emphasis on examining the factual record, the district court here assumed it had to adopt one of two categorical rules and opted to apply the rule that patented goods can effectively *never* be their own product market.

In following a formalistic approach to product market definition, the district court disregarded the evidence that Regeneron presented in its complaint. Regeneron did not allege that a patent automatically conferred market power on Novartis or that a patented item always constitutes its own product market. Instead,

Regeneron relied on product features and health care practice to distinguish FDA approved anti-vascular endothelial growth factor therapies (anti-VEGF therapies) in prefilled syringes from anti-VEGF therapies distributed in vials. Specifically, it presented evidence, such as a third-party survey and statements of market participants, on the functional advantages of—and practitioners' strong preference for—prefilled syringes over vials. Regeneron identified the greater ease of use, time savings, and lower risk of contamination and serious adverse effects of prefilled syringes for patients, relative to vials. Due to these critical advantages, Regeneron observed that prefilled syringes have become the standard of care among practitioners, with vials generally being viewed as an obsolete method of administration.

With this evidence in its complaint, Regeneron presented more than a plausible basis for limiting the product market to FDA approved anti-VEGF therapies in prefilled syringes. Regeneron described the "actual market realities" in its complaint. *Kodak*, 504 U.S. at 466. It examined the "reasonable interchangeability of use" of prefilled syringes and vials, presented important differences between the two, and explained why they are *not* reasonably interchangeable in practice. *Brown Shoe*, 370 U.S. at 325. Even putting aside this Court's general directive not to grant motions to dismiss due to defects in product

market definitions, *Todd*, 275 F.3d at 199-200, Regeneron's complaint included more than enough factual material to proceed to discovery.

CONCLUSION

For the foregoing reasons, the decision of the district court should be reversed.

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June 17, 2022

CERTIFICATE OF SERVICE

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

/s/ Jason Rathod

Dated: June 17, 2022

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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I am the attorney of *amicus curiae* Open Markets Institute.

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