22-427

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

_____

REGENERON PHARMACEUTICALS, INC.

Plaintiff-Appellant,

v.

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

Defendants-Appellees,

_____

On Appeal from the United States District Court
for the Northern District of New York

No. 1:21-CV-1066, Hon. David N. Hurd, U.S. District Judge

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BRIEF OF AMICI CURIAE NEVADA, DISTRICT OF COLUMBIA, ILLINOIS, LOUISIANA, MINNESOTA, AND NEW MEXICO AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANT, REGENERON PHARMACEUTICALS, INC.

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INTERESTS OF AMICI CURIAE

Amici States of Nevada, District of Columbia, Illinois, Louisiana, Minnesota, and New Mexico submit this brief, pursuant to Federal Rule of Appellate Procedure 29(a)(2), in support of plaintiff-appellant, Regeneron Pharmaceuticals, Inc ("Regeneron").

Regeneron brought suit against its competitor Novartis for Novartis' conduct in the market for anti-vascular endothelial growth factor ("anti-VEGF") medications. Anti-VEGF medications are used to treat severe eye diseases affecting elderly persons and persons suffering from diabetes. These medications are administered by ophthalmologists via syringe with an injection near the retina in the back of the eye. The medication is sold to ophthalmologists in vials and or pre-filled syringes ("PFS"). One of the diseases treated with anti-VEGF is Wet Age-Related Macular Degeneration ("AMD"), the leading cause of blindness among older Americans. Approximately 11 million elderly persons across the United States suffer from some form of AMD, with wet-AMD being the advanced form of the disease, causing rapid and progressive vision loss. Anti-VEGF medications are also used to treat diabetic retinopathy, the most common diabetic eye disease. Diabetes is the leading cause of new cases of blindness in persons 20-74 years of age in the United States. Diabetic retinopathy affects approximately 5% of the overall United States population over age 50 and approximately 10% of the overall population over

age 75. Hispanic Americans are particularly affected by diabetic retinopathy, with 8% of the population above age 50 affected, increasing to 20% above the age of 75.

Regeneron's antitrust suit followed Novartis' patent infringement complaints against Regeneron in district court and before the International Trade Commission ("ITC"). While Novartis' district court patent infringement complaint is still pending, the ITC Complaint was withdrawn after the Staff of the ITC opined that Novartis' asserted patent was invalid based on incorrect inventorship and obviousness. Regeneron's antitrust lawsuit before the Northern District of New York was dismissed for failure to state a claim. Dismissal was made without consideration of Regeneron's allegations concerning market conditions, the standard method for defining a product market established by Supreme Court precedent.

The Attorneys General of the *Amici* States are authorized by Congress to bring federal antitrust actions to protect their citizens from the harmful effects of anticompetitive conduct. 15 U.S.C. § 15c. *Amici* States thus have a strong interest in ensuring that federal courts apply clear and effective standards for liability under the Sherman Act, so that they may effectively enforce antitrust laws in all aspects of the economy, including in the anti-VEGF therapeutics market. This market, estimated at 12 billion dollars annually, affects the wellbeing of a significant portion of the U.S. population, including some of the nation's most vulnerable populations.

SUMMARY OF THE ARGUMENT

The *Amici* States do not take a position on the parties' contract or patent infringement claims beyond recognizing the opinion of the ITC Staff and Novartis' subsequent withdrawal of its patent infringement action before that agency. In this brief, the States focus on two reasons supporting reversal of the district court's decision:

First, proper disposition of product market definition should be left to the trier of fact considering the plausible explanations for market definition identified in *Brown Shoe Co. v. United States,* 370 US. 294 (1962). Instead of following precedent, the district court substituted its judgment for that of the trier of fact. In making its decision, the district court did not consider Regeneron's allegations regarding reasonable interchangeability based on cross-elasticity of demand, the product's peculiar characteristics and uses, unique production facilities, and specialized vendors to be plausible explanations for market definition.

Second, instead of considering product market definition under *Brown Shoe,* the court based its dismissal on its confusion between patent exclusivity and antitrust market power. This confusion stemmed from the court's incorrect assumptions that all patents are monetizable and that products covered by the scope of a patent may never create separate markets for antitrust purposes.

ARGUMENT

I. Product Market Definition Should be Left To The Trier Of Fact.

A. Dismissal as a Matter of Law is Rarely Warranted, and Was Not Proper in This Case.

The district court dismissed Regeneron's antitrust claim as a matter of law despite being offered plausible explanations for limiting the market. Product market definition is a fact-intensive inquiry that generally requires discovery. *Todd v. Exxon Corp.,* 275 F.3d 191, 199-200 (2d Cir. 2001) (Sotomayor, J.) (citing *Eastman Kodak Co. v. Image Tech. Servs., Inc.,* 504 U.S. 451, 482(1992)). Accordingly, "[t]o survive a Rule 12(b)(6) motion to dismiss, an alleged product market must bear a rational relation to the methodology courts prescribe to define a market for antitrust purposes—analysis of the interchangeability of use or the cross-elasticity of demand, and it must be plausible." *Id.* (internal citation and quotation marks omitted). "[I]n most cases, proper market definition can be determined only after a factual inquiry into the commercial realities faced by consumers." *Eastman Kodak Co.*, 504 U.S. at 482. Product market definition is a basis for dismissal based on failure to state a claim where the plaintiff fails to define a market with reference to reasonable interchangeability and cross-elasticity of demand, or alleges a proposed product market that does not include all interchangeable substitutes when all factual inferences are drawn in the plaintiff's favor. *Chapman v. New York State Div. for*

Youth, 546 F.3d 230, 237-38 (citing *Todd*, 275 F.3d at 199-200). As the Second Circuit explained, "[c]ases in which dismissal on the pleadings is appropriate frequently involve either (1) failed attempts to limit a product market to a single brand, franchise institution, or comparable entity that competes with potential substitutes or (2) failure even to attempt a plausible explanation as to why a market should be limited in a particular way." *Todd,* 275 F.3d at 200.

In defining the market for anti-VEGF pre-filled syringes ("PFS"), Regeneron offered plausible explanations for product market definition. Product market definition includes consideration of "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." *Brown Shoe*, 370 U.S. at 325. Regeneron asserted that there was inelastic demand by purchasers in response to a small but significant nontransitory increase in price ("SSNIP"), *i.e.*, a reference to reasonable interchangeability and cross-elasticity of demand. Regeneron alleged that purchasers showed an overwhelming preference for the use of PFS over vials due to greater patient safety, greater precision in dosing, and increased efficiency of use. Regeneron further alleged that anti-VEGF PFS had become the standard treatment for ophthalmic disease, and that filling PFS required

specialty vendors and unique production facilities, all of which the court did not deem plausible explanations for product market definition.

B. Regeneron Presented Plausible Explanations for Excluding Vials Containing Anti-VEGF Medications From the Market.

Regeneron posited plausible explanations for excluding vials containing anti-VEGF medications from its product market definition. Regeneron alleges in its Complaint that PFS's are "quicker, easier and safer" to use than vials, that manufacturing vials uses different equipment than PFS, and that a SSNIP would not cause physicians to substitute the vial version for PFS. The district court, however, rejected these distinctions, concluding that "[n]one of those three reasons plausibly justifies Regeneron's narrow market."

The purpose to which a product is put "sketches the boundaries of a market, but there may also be cognizable submarkets which themselves constitute the appropriate market for antitrust analysis." *Geneva Pharm. Tech. Corp. v. Barr Labs, Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (citing *Brown Shoe,* 370 US. at 325). For example, in *Geneva Pharmaceuticals,* the Second Circuit defined the product market to include the generic but not the chemically-identical brand-name version of a particular drug. 386 F.3d at 496-500. "Products are not reasonably interchangeable merely because they share similar forms or functions, but rather, "such limits are drawn according to the cross-elasticity of demand for the product in question – the

extent to which purchasers will accept substitute products in instances of price fluctuations and other changes." *In re Loestrin 24 Fe Antitrust Litigation,* 261 F. Supp. 3d 307, 327 (D. R.I. 2017).

In its analysis, the district court failed to consider Regeneron's allegation of inelastic demand in light of a SSNIP supporting the definition of a submarket. "In economists' terms, two products or services are reasonably interchangeable where there is sufficient cross-elasticity of demand. Cross-elasticity of demand exists if consumers would respond to a slight increase in the price of one product by switching to another product." *Id.* at 201-02 (quoting *AD/SAT v. Associated Press*, 181 F.3d 216, 227 (2d Cir. 1999); *City of New York v. Grp. Health Inc.*, 649 F.3d 151, 155 (2d Cir. 2011)). Products are interchangeable where consumers retain the ability to switch to a substitute product such that a firm cannot raise price above a competitive level. *City of New York v. Grp. Health Inc.,* 649 F.3d 151, 155 (2d Cir. 2011).

The court also failed to consider Regeneron's allegation that physicians would not switch from the use of anti-VEGF PFS in response to a SSNIP. The purchasers of anti-VEGF PFS and vials are ophthalmologists. Regeneron alleged that these physician purchasers do not switch from anti-VEGF PFS to vials in light of a SSNIP. This failure to switch in light of a SSNIP demonstrates inelastic demand for anti-

VEGF PFS, i.e., low cross-elasticity of demand, and vials are therefore not properly part of the relevant product market.

Next, the court failed to recognize that performance-based factors may form a plausible basis for product market definition. "A relevant product market consists of 'products that have reasonable interchangeability for the purposes for which they are produced – *price, use and qualities considered*.'" *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 105 (2d Cir. 2002) (emphasis added) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1965)).

A good or service which is of greatly superior quality, while having the same use, may not be in the same product market. The contours of a market are defined as containing reasonably interchangeable products "where consumers treat them as 'acceptable substitutes.'" *PepsiCo, Inc.,* 315 F.3d at 105 (quoting *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 46 (D.D.C. 1998)). Thus, two goods which have the same purpose may not be in the same market where one is superior to the other. For example, championship boxing contests were found to be in a separate market from nonchampionship programs because the former were the 'cream' of the boxing business, *i.e.*, had sufficient superior quality to justify a higher price point and constitute a separate part of the market. *Int'l Boxing Club of N.Y., Inc. v. United States*, 358 U.S. 242, 251-52 (1959). Likewise, carpet and resilient floor coverings are viewed as being in different markets; while both have the same purpose –

covering floors – resilient floor coverings have different characteristics from carpets – cushioning and springing-back – and are thus in a different product market. *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 199-200 (3d Cir. 1992). Regeneron alleged that PFS are far superior to vials based on safety, efficiency and quality, facts which were not considered by the district court here to be plausible explanations for product market definition.

Where customers make purchasing decisions based on a method of distribution, the method may create a plausible submarket. For example, in *United Food & Com. Workers Local 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA,* 296 F. Supp. 3d 1142 (N.D. Cal. 2017), the appropriate market was limited to lidocaine 5% patches. In support of a broader definition, defendants argued that an entire slew of pharmaceuticals delivered through various means used to treat pain should be included within the relevant market because these were therapeutic equivalents; however, the court disagreed due to the lack of evidence put forward concerning cross-elasticity of demand between these products. *Id.* at 1172-73. In reaching its decision, the *Teikoku* court took into account the safety, efficacy and convenience associated with the method of administration of the drug. *Id.* at 1173.

Here, the district court disregarded the particular characteristics alleged by Regeneron to be similar performance-based differentiating factors. Regeneron

alleged that the method of distribution was determinative because PFS presented a more accurate and convenient method of administration. Filling vials in a physician's office carries a higher risk of introducing foreign particles into the eye, which can cause severe complications. This type of evidence should have been considered in defining the product market, as was done in *Teikoku.*

The district court did not consider other plausible explanations for market definition alleged such as industry or public recognition of differences in products. Regeneron alleged that, "[i]ndustry participants, including retinal specialists, recognize the significant advantages of PFS over vial[s]." *Regeneron Complaint* ¶ 163; *see also Todd*, 275 F.3d at 205–06 (holding that industry recognition was "one factor to consider in the subtle, fact-specific inquiry which focuses on the ultimate issue of cross-elasticity and interchangeability"). Regeneron also alleged that PFS had become the industry standard for treatment. Regeneron further alleged that filling PFS required unique production facilities and capabilities—specifically, "specialized equipment and filling lines possessed by a limited number of firms, as well as separate regulatory approval." *Regeneron Complaint*, ¶ 164; *see also Brown Shoe*, 370 U.S. at 325 ("The boundaries of such a submarket may be determined by examining such practical indicia as . . . unique production facilities . . . and specialized vendors.").

Contrary to the district court's conclusions, these are all plausible explanations for finding a separate product market.

II. The Court Confused Patent Monopoly and Antitrust Market Power.

A. The Court Based Its Decision on the Incorrect Assumption that All Patent Owners Enjoy Antitrust Market Power.

The Court dismissed Regeneron's complaint based on the faulty assumption that all patent owners enjoy antitrust market power. The district court stated that any innovation which renders a product "quicker, easier, safer" would "allow any patented product to be a unique market by itself because any patent will carry efficacy improvements and make the product valuable enough to merit some heightened costs." Based on this assumption, the district court then found that necessarily every patent would give rise to a separate product market where the patent owner held a monopoly. The district court continued, "a patent allows its owner to exclude other firms from producing products covered by its terms and an antitrust plaintiff can [then] define a market so narrowly that a patent itself creates its own market." Based on its assumption that every patent owner holds a monopoly for antitrust purposes, the district court then reasoned that any allegation of invalidity would necessarily give rise to an antitrust violation. However, the district court noted that such a scenario would run afoul of its incorrect presumption that no product market can be limited to the scope of a single patent.

In these statements, the district court demonstrates confusion between patent exclusivity and market power for antitrust purposes. The presumption that a patent creates market power for antitrust purposes was overturned in *Illinois Tool Works Inc. v. Independent Ink, Inc.,* 547 U.S. 28, 45-46 (2006). There, the Supreme Court concluded that "a patent does not necessarily confer market power upon the patentee." *Illinois Tool Works*, 547 U.S. at 45-46. Most patents are neither monetizable nor monetized sufficiently to create market exclusion, regardless of the exclusive rights granted patentees. "Most IP rights are too narrow to confer much in the way of market power . . . . The power of IP rights is 'boundary exclusion' but only rarely 'market exclusion.'" Herbert J. Hovencamp, *Markets in IP and Antitrust* 100 Georgetown L.J. 2133, 2139 (2011).

Patent exclusivity exists in harmony with antitrust law. A patent delineates the metes and bounds of the property held by the patent owner, and the patent "monopoly" is the patent owner's right to exclude during the patent term. *See, e.g.*, *SCM Corp. v. Xerox Corp.,* 645 F.2d 1195, 1203-04 (2d Cir. 1981). The right to exclude afforded by the patent laws only benefit those who lawfully acquire such rights. Antitrust claims may arise where exclusion occurs based on unlawfully acquired patents. *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.,* 382 U.S. 172(1965). The district court's categorical statement that limiting a market to the scope of the claims of a patent would result in all allegations of patent

invalidity giving rise to antitrust liability is inaccurate. Rather, patent invalidity *may* give rise to an antitrust claim, e.g., where a patent holder attempts to enforce a patent which it knows to be invalid.

B. The Court Also Incorrectly Assumed that the Scope of a Relevant Product Market May Never Be Limited to the Scope of a Patent.

Finally, the Court's assumption in the Order that a relevant product market may not be limited to the scope of a patent is incorrect. Patent claim or not, the question is whether antitrust market power exists within the confines of a market shown through reasonable interchangeability based on cross-elasticity of demand. *See, e.g.*, *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 307, 315 (3rd Cir. 2007). While infrequent, a relevant product market may comprise only those products which fall within the scope of a patent. For example, the success of Xerox's patented products permitted it to evolve the patented products into a separate economic market for plain-paper copying. *SCM Corp.,* 645 F.2d at 1203. Another example is *Broadcom Corp*, 501 F.3d at 315, where the Third Circuit found that the market for Qualcomm's WCDMA technology was congruent with the scope of its patents. This finding was made despite Qualcomm's argument that such narrow market definition would result in every patent holder being condemned as a monopolist.

CONCLUSION

For the foregoing reasons, this court should reverse the decision of the district court dismissing the claim and leave the decision of product market definition to the trier of fact.

Dated: June 17, 2022

Respectfully submitted,

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CERTIFICATION OF SERVICE

I hereby certify that on June 17, 2022, a true and correct copy of the foregoing brief was timely filed electronically with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. I certify that all participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

/s/ *Heidi Parry Stern*
Heidi Parry Stern

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Local Rule 29.1(c) and Local Rule 32.1(a)(4)(A) because it contains 2,979 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5)-(6). The brief was prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s/ *Heidi Parry Stern*
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Dated: June 17, 2022