UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

ELECTRICAL MEDICAL TRUST and PLUMBERS LOCAL UNION NO. 68 WELFARE FUND, Plaintiffs, v. U.S. ANESTHESIA PARTNERS, INC., WELSH, CARSON, ANDERSON & STOWE XI, L.P., WCAS ASSOCIATES XI, LLC, WELSH, CARSON, ANDERSON & STOWE XII, L.P., WCAS ASSOCIATES XII, LLC, WCAS MANAGEMENT CORPORATION, WCAS MANAGEMENT, L.P., and WCAS MANAGEMENT, LLC, Defendants.	Civil Case No. 4:23-cv-04398 **PLAINTIFFS' NOTICE OF SUPPLEMENTAL AUTHORITY** Hon. Alfred H. Bennett

Plaintiffs provide the Court with this notice of supplemental authority relevant to Defendants' Motions to Dismiss the Complaint: the Second Circuit's decision in *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG*, --- F.4th ---, 2024 WL 1145340 (2d Cir. Mar. 18, 2024) (a copy of which is attached as **Exhibit A**). There, the Second Circuit reversed the lower court's determination that the plaintiff failed to plead an adequate relevant market. *Id.* at *6.

The court wrote of the standard for evaluating market definition on a motion to dismiss:

> "[M]arket definition is a deeply fact-intensive inquiry," and [] courts therefore "hesitate to grant motions to dismiss for failure to plead a relevant product market." Motions to dismiss should generally not be granted in such cases except "[w]here the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products."

Id. at *7 (citations omitted). The Second Circuit found that the district court "placed improper weight on the functional, rather than economic, similarities between" certain medicines sold in prefilled syringes—which the plaintiff alleged form a distinct relevant market—and the same medicines sold in vials. *Id.* at *6. The Second Circuit reasoned:

> Where a plaintiff pleads facts plausibly showing that two products should be considered part of distinct antitrust markets, those proposed markets are *not* to be rejected simply because a court believes the plaintiff is unintuitively separating products that might have real-world functional similarities into different relevant markets. Rather, the applicable analysis is whether or not the products are *economic* substitutes, not whether they appear to be functionally similar. This analysis turns on economic differences, such as a lack of cross-elasticity of demand or reasonable interchangeability among products. In dismissing [plaintiff] Regeneron's proposed PFS-only market, the district court erred by focusing too heavily on the functional similarities between anti-VEGF vials and PFSs, rather than on the extent to which consumers are willing to substitute one for the other.

Id. at *8-9 (citations omitted).

Dated: March 25, 2024 Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that the foregoing was duly served upon all Counsel of record via the Court's CM/ECF system on March 25, 2024.

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EXHIBIT A

2024 WL 1145340
Only the Westlaw citation is currently available.
United States Court of Appeals, Second Circuit.

REGENERON PHARMACEUTICALS, INC., Plaintiff-Appellant,

v.

NOVARTIS PHARMA AG, Novartis Technology LLC, Novartis Pharmaceuticals Corporation, Vetter Pharma International GmbH, Defendants-Appellees.

No. 22-0427-cv
|
August Term 2023
|
Argued: October 11, 2023
|
Decided: March 18, 2024

Synopsis

Background: Pharmaceutical company filed suit claiming violation of Sherman Act by attempted monopolization and unreasonable restraint of trade, as well as tortious interference with contract in violation of New York law, by competitor and contractor that entered agreement with company to collaborate on prefilled syringe (PFS) version of company's prescription medication for treating overproduction of vascular endothelial growth factor (VEGF), rather than its vial version, and agreed that company had ownership interest in any patent conceived or reduced to practice by company or contractor related to PFS version of company's anti-VEGF drug, but contractor allegedly also had confidentially entered similar agreement with competitor to produce competing anti-VEGF PFS and fraudulently concealed contractor's contributions to competitor's patent for anti-VEGF PFS to fraudulently obtain patent, after which both competitor and contractor took steps to keep company out of anti-VEGF PFS market for years until company finally released its own PFS version. Case was transferred from Southern District of New York to Northern District of New York, where competitor's patent infringement action against company was pending. The United States District Court for the Northern District of New York, David N. Hurd, J., 582 F.Supp.3d 26, granted competitor's and contractor's motion to dismiss for failure to state claim. Company appealed.

Holdings: The Court of Appeals, Parker, Circuit Judge, held that:

company plausibly alleged anti-VEGF PFS market distinct from vials;

company plausibly alleged attempted monopolization claims;

company plausibly alleged tortious interference claim; and

company's allegations were sufficient to equitably estop competitor from invoking statute of limitations as defense to tortious interference claim.

Reversed and remanded.

Procedural Posture(s): On Appeal; Motion to Dismiss for Failure to State a Claim.

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

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Before: Parker, Lee, and Merriam, Circuit Judges.

Opinion

Barrington D. Parker, Circuit Judge:

***1** The resolution of this appeal turns on the definition of the relevant antitrust product market. The products in question are prescription medications used to treat the overproduction of vascular endothelial growth factor ("VEGF"), a naturally occurring protein that, if overproduced, can lead to various eye disorders and, in some cases, to permanent blindness. Both Plaintiff-Appellant Regeneron Pharmaceuticals, Inc. ("Regeneron") and Defendant-Appellees Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation (collectively, "Novartis") produce "anti-VEGF" medications to combat the overproduction of VEGF. Regeneron produces EYLEA, while Novartis produces LUCENTIS.

For several years after they were first introduced, anti-VEGF medications were packaged into vials and administered in a two-step process. A doctor would first fill a syringe with medicine from an anti-VEGF vial and then inject the drug into a patient's eye. The newer versions of the medications are sold in prefilled syringes ("PFSs") and administered in one step. PFSs contain the same medication as vials but are injected directly into the patient's eye. This simpler process carries a significantly lower risk of complications and infections and is now the preferred way of administering anti-VEGF medications. The pivotal issue in this appeal is whether anti-VEGF medications in vials and PFSs compete in the same or in different product markets.

Starting around 2005, Regeneron recognized the comparative advantages of PFSs over vials and, for approximately the next fifteen years, sought to develop and obtain FDA approval for an anti-VEGF PFS treatment. At the beginning of this development process, Regeneron contracted with Defendant-Appellee Vetter Pharma International GmbH ("Vetter") to collaborate on a PFS version of its EYLEA drug. At that time, Vetter was already providing non-exclusive "filling" services for Regeneron's vial version of EYLEA. Unbeknownst to Regeneron, however, Vetter allegedly entered into a similar agreement with Novartis in 2009 to produce a competing PFS version of Novartis's drug, LUCENTIS.

Regeneron alleges that from 2009 to 2015, Novartis and Vetter fraudulently concealed Vetter's contributions to a patent that Novartis obtained in 2015 for a PFS version of LUCENTIS. Then, after unlawfully obtaining the patent, Novartis and Vetter allegedly took steps to keep Regeneron out of the anti-VEGF PFS market until 2019, when Regeneron finally released its own PFS version of EYLEA. Regeneron argues that these steps delayed the release of its anti-VEGF PFS by several years and enabled Novartis to increase its market share during this period.

In July 2020, Regeneron sued Novartis and Vetter in the United States District Court for the Southern District of New York, which transferred the case to the Northern District. The Amended Complaint asserts five claims: two claims against Novartis of attempted monopolization under *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965), in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2; one claim against Novartis of non-*Walker Process* attempted monopolization in violation of Section 2; one claim against Novartis and Vetter of unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1; and one claim against Novartis of tortious interference with contract in violation of New York law.

***2** Novartis and Vetter moved under Fed. R. Civ. P. 12(b)(6) to dismiss the Amended Complaint, and the district court (Hurd, *J.*) granted the motion. As to the antitrust claims, the court reasoned that Regeneron failed to allege plausibly that the relevant antitrust market is properly limited to anti-VEGF PFSs, to the exclusion of vials. The district court focused on the functional similarities between the PFS and vial versions of Regeneron's and Novartis's respective anti-VEGF treatments and concluded that, because of those similarities, both versions compete in the same relevant market. The court further concluded that Regeneron could not state a Sherman Act claim under *Walker Process* because a proposed relevant market cannot be coextensive with the bounds of a patent. Additionally, the district court dismissed Regeneron's tortious interference claim as untimely, holding that Regeneron's pleadings failed to establish that Novartis should be equitably estopped from invoking the statute of limitations.

On appeal, Regeneron argues that the district court improperly dismissed its antitrust claims both because it plausibly alleged that anti-VEGF PFSs constitute their own product market—distinct from the market for vials—and because the district court applied an improper standard to its claims under *Walker Process*. Regeneron also argues that the district court improperly rejected its equitable estoppel argument because Novartis and Vetter took steps to prevent Regeneron from learning of Novartis's tortious interference until after the limitations period had expired. We agree with Regeneron. We therefore **REVERSE** the judgment of the district court and **REMAND** for further proceedings consistent with this opinion.

BACKGROUND [1]

I. Factual Background

Regeneron and Novartis are biotechnology and pharmaceutical companies that produce drugs that treat the overproduction of VEGF. Vetter, a supplier of drug "filling" services, has contracted with both Regeneron and Novartis to fill vials and PFSs with their anti-VEGF treatments.

The overproduction of VEGF, if left untreated, can cause patients to "see the world as if through distorted lenses: straight lines may appear bent, central vision may be reduced, colors may be dulled, and patients may see haziness." J. App'x at 349 (Am. Cmplt. ¶ 38). Patients may also "experience a well-defined blurry or blind spot in their central field of vision," or even suffer permanent blindness. *Id.* (Am. Cmplt. ¶¶ 38-39).

EYLEA and LUCENTIS, produced by Regeneron and Novartis, respectively, are the primary anti-VEGF drugs approved by the FDA. Vetter has historically provided drug filling services to both Regeneron and Novartis, filling vials and PFSs with the anti-VEGF medicines they produce.

While anti-VEGF vials and PFSs contain the same active ingredients and are used to combat the same condition, their differing formats have significant implications for how physicians treat patients. When delivered in vials, the treatments come "with multiple components, including the vialed biologic, two separate needles, and a plastic syringe." J. App'x at 360 (Am. Complt. ¶ 76). Doctors using the vials must, under sterile conditions, "use the filter needle to withdraw the correct amount of the anti-VEGF from the vial and then switch to an injection needle before injecting the properly measured dosage into the patient's eye." *Id.* This process is cumbersome and, if handled incorrectly, introduces a heightened risk of endophthalmitis—a harmful inflammation of the interior of the eye.

PFSs, on the other hand, are easier to administer and, according to the parties, "permit more safe, effective and efficient injections of VEGF-antagonists into the eye." J. App'x at 362 (Am. Cmplt. ¶ 82) (quoting Novartis's patent infringement complaint). PFSs enable physicians to administer the required dose more precisely and with a lower risk of foreign particles entering the eye, thereby increasing dose accuracy and clinical efficiency. *See id.* at 361-62 (Am. Cmplt. ¶¶ 79, 81). Accordingly, Regeneron asserts that PFSs have been recognized as a "boon to patients" and that physicians treating patients with EYLEA and LUCENTIS converted between 80 and 100 percent of their patients from vials to PFSs once PFS versions of the drugs became available. *Id.* at 361 (Am. Complt. ¶ 78).

***3** Recognizing the comparative advantages offered by anti-VEGF PFSs over vials, Regeneron entered into an agreement in 2005 with Vetter to collaborate on a PFS version of EYLEA (the "2005 Agreement"). Regeneron alleges that this agreement granted it an ownership interest "in any patent conceived or reduced to practice by Regeneron *or* Vetter related to EYLEA PFS." Appellant's Br. at 11; J. App'x at 394 (Am. Cmplt. ¶ 148).

Notwithstanding this arrangement, Regeneron alleges that in 2009, Vetter confidentially entered into a similar agreement with Novartis to develop and commercialize a PFS version of LUCENTIS. According to Regeneron, the agreement between Vetter and Novartis resulted in their cooperation on a patent application for a PFS containing anti-VEGF treatments. In December 2015, after several years of this allegedly secret collaboration, Novartis obtained U.S. Patent No. 9,220,631 (the "'631 Patent"), which specifically identifies EYLEA as the "preferred" anti-VEGF for use with the invention. Appellant's Br. at 11. Regeneron alleges that in doing so, Novartis and Vetter "sabotage[d] Regeneron's ownership rights" to the '631 Patent under the 2005 Agreement.[2] J. App'x at 339 (Am. Cmplt. ¶ 10).

Regeneron asserts that because of (1) Vetter's secret collaboration with Novartis, (2) Novartis's fraudulent acquisition of the '631 Patent, and (3) subsequent anti-competitive steps taken by both companies to keep Regeneron out of the anti-VEGF PFS market, Regeneron's development of an EYLEA PFS was significantly compromised. This in turn forced Regeneron to delay the release of a competing EYLEA PFS by several years, until 2019. Regeneron's antitrust allegations center on Novartis's and Vetter's conduct between 2009 and 2017.

First, Regeneron alleges that prior to the issuance of the '631 Patent in 2015, it "specifically and repeatedly asked Vetter about the nature of its agreement with Novartis," yet Vetter refused to disclose the details of this agreement. Appellant's Br. at 51; *see also* J. App'x at 410, 447 (Am. Cmplt. ¶¶ 179, 273). Meanwhile, in October 2013, Vetter, allegedly acting at Novartis's behest, demanded several modifications to its 2005 Agreement with Regeneron. For example, Vetter allegedly demanded that Regeneron take out a license on a hypothetical, not-yet-issued PFS patent, agree in advance not to challenge the patent once it issued, and commit to using Vetter as its exclusive PFS filler for the life of the patent without a guaranteed supply commitment from Vetter. *See* J. App'x 404-06 (Am. Cmplt. ¶¶ 166-70). These steps, Regeneron alleges, were intended to monopolize the market by freezing out competitors.

Regeneron alleges that it refused to accede to these demands—"even though it knew doing so would delay the launch of EYLEA PFS and cost Regeneron millions of dollars"—because it believed they would "compromise the competitiveness of EYLEA PFS." *Id.* at 408 (Am. Cmplt. ¶ 174). When Regeneron rejected Vetter's demands, however, Novartis and Vetter allegedly agreed to exclude Regeneron from Vetter's filling services, a step that they knew would force Regeneron "to invest significant time, money, and effort to establish a new, reliable supply chain for EYLEA PFS" and delay its launch by several years. *Id.* (Am. Cmplt. ¶175).

***4** Second, Regeneron alleges that Novartis fraudulently procured the '631 Patent both by failing to name Vetter as a co-inventor in its application to the U.S. Patent and Trademark Office ("USPTO"), as required by law,[3] and by knowingly withholding material prior art from that Office.

Specifically, relying on confidential discovery obtained in a separate patent litigation, Regeneron alleges that Novartis explicitly but confidentially recognized Vetter's contributions to the LUCENTIS PFS in a September 2013 amendment to the development agreement between Novartis and Vetter. Regeneron further alleges that during this period Novartis knew the 2005 Agreement vested Regeneron with ownership rights in any patent that arose from Novartis's collaboration with Vetter. That knowledge allegedly caused Novartis to omit Vetter's contributions to the LUCENTIS PFS from the '631 Patent application and to secure Vetter's assent to the deception by granting Vetter a co-exclusive license over the '631 Patent. J. App'x at 403-04 (Am. Cmplt. ¶ 165). As a result, the USPTO—and by extension Regeneron—did not learn about Vetter's involvement.

Regeneron additionally alleges that, by knowingly withholding material prior art from the USPTO, Novartis fraudulently obtained the '631 Patent. Specifically, Novartis allegedly narrowed its application to claim a patent only for a "terminally sterilized" PFS yet failed to disclose numerous prior art references regarding terminal sterilization—despite knowing that they were material and that the USPTO had previously discussed them in a separate PFS-related patent application by Novartis. J. App'x at 377 (Am. Cmplt. ¶ 112). That omission, according to Regeneron, enabled Novartis to obtain the '631 Patent when it otherwise would have been denied. [4]

Finally, Regeneron points to Novartis's and Vetter's conduct after Novartis obtained the '631 Patent as evincing anti-competitive behavior. Having already rejected Vetter's October 2013 proposed conditions, Regeneron continued to negotiate with Vetter, hoping to come to an agreement on PFS filling terms. Yet, when the parties revisited terms in October 2017, Vetter allegedly continued its anti-competitive behavior by insisting that it would not work with Regeneron on an EYLEA PFS unless Regeneron agreed to a long-term exclusivity agreement and not to challenge the '631 Patent. Regeneron again refused to agree to these terms. While these negotiations were ongoing, Novartis received FDA approval for LUCENTIS PFS and subsequently launched it in the United States, through Genentech, in early 2017.

Regeneron alleges that following the launch of LUCENTIS PFS, 80% of LUCENTIS users switched from vials to PFSs. Genentech, having licensed the '631 Patent from Novartis for North American sales, saw dramatically increased demand for LUCENTIS PFSs. Through 2018, LUCENTIS PFS sales continued to grow markedly, with Genentech's parent company touting " 'increas[ed] market shares in all approved indications' due to LUCENTIS PFS' 'competitive advantage.' " J. App'x at 364 (Am. Cmplt. ¶ 85) (quotation marks omitted). Since the launch of LUCENTIS PFS, nearly all of LUCENTIS's sales have been in PFSs.

***5** In August 2019, Regeneron received FDA approval for its EYLEA PFS. In December 2019, having arranged for a new filling supply chain, Regeneron finally launched EYLEA PFS in the United States. Less than two weeks later, Vetter transferred sole enforcement rights over the '631 Patent to Novartis. The purpose of this transfer, Regeneron alleges, was to allow Novartis to sue Regeneron for infringing the '631 Patent without naming Vetter as a co-plaintiff. Within six months of EYLEA PFS' launch, 80% of anti-VEGF patients using EYLEA, like LUCENTIS, switched from vials to PFSs.

II. Patent-Related Litigation

In June 2020, shortly after EYLEA PFS launched, patent-related litigation began. First, Novartis sued Regeneron in the United States District Court for the Northern District of New York [5] and then before the International Trade Commission ("ITC"), alleging that Regeneron's EYLEA PFS infringed the '631 Patent.

During discovery in the ITC suit, Regeneron obtained a copy of a confidential 2013 amendment to the agreement between Novartis and Vetter, which documented their cooperation on the '631 Patent. Regeneron alleges that, from this document, it learned for the first time about Vetter's role in inventing and developing key features of the LUCENTIS PFS. However, because of a protective order in the ITC proceedings, Regeneron was unable to make use of this newly-discovered information immediately.

In March 2021, the ITC's independent Office of Unfair Import Investigations filed a brief concluding that Novartis's '631 Patent was invalid because Novartis had failed to disclose Vetter's inventorship and material prior art. *See* J. App'x at 619-701. After this brief was sent to Regeneron and Novartis, but before the case went to trial, Novartis terminated the ITC action.

In October 2021, the Patent Trial and Appeals Board ("PTAB") instituted *inter partes* review of the '631 Patent. In October 2022, after the briefing in this appeal was completed, the PTAB issued a final written decision finding the '631 Patent invalid. The following month, Novartis's patent case was again stayed in the Northern District pending Novartis's appeal of the PTAB's decision to the Federal Circuit. The patent case remains stayed as of this writing.

III. Procedural History & District Court Decision

Regeneron initiated this suit against Novartis and Vetter in the United States District Court for the Southern District of New York in July 2020. That court (Nathan, *J.*) transferred the case to the Northern District of New York, where the patent litigation was already pending.

As noted, Regeneron's Amended Complaint asserts four antitrust claims and a tortious interference with contract claim. In support of its Section 1 and Section 2 antitrust claims, Regeneron alleged—and reiterates on appeal—that "[t]he relevant product market is anti-VEGFs in prefilled syringes that are approved by the FDA for the treatment of certain ophthalmic diseases," which it emphasizes is distinct from the markets for just anti-VEGF vials or for all anti-VEGF treatments. [6] J. App'x at 415-16 (Am. Cmplt. ¶ 191); *see also* Appellant's Br. at 19.

***6** The district court disagreed. It concluded that Regeneron's proposed market was not plausible and dismissed the antitrust claims without leave to amend. *See Novartis Pharma AG v. Regeneron Pharms., Inc.*, 582 F. Supp. 3d 26, 46 (N.D.N.Y. 2022). The court also dismissed Regeneron's tortious interference with contract claim as time-barred.

In dismissing the antitrust claims, the district court relied on two distinct, albeit related, rationales. First, the court concluded that anti-VEGF vials and PFSs compete in the same, not separate, markets because they contain the same medicines and are used to treat the same condition. The district court further concluded that Regeneron failed plausibly to allege why, given these significant functional similarities, consumers would not consider them interchangeable. *Id.* at 41-42.

Second, the court concluded that Regeneron's proposed anti-VEGF PFS market could not support its antitrust claims because, absent extraordinary circumstances "where the subject of a patent is so novel that there really is no fitting substitute," a proposed antitrust market cannot be coextensive with the bounds of a patent. *Id.* at 42. Having created this new standard, the district court held that Regeneron failed to satisfy it because the proposed market was "identical to the protection afforded to Novartis by the '631 Patent." *Id.* at 41.

Finally, the district court dismissed without leave to amend Regeneron's tortious interference with contract claim against Novartis as untimely, rejecting Regeneron's argument that Novartis was equitably estopped from raising a statute of limitations defense. The court reasoned that Regeneron could not claim estoppel because, to the extent Novartis and Vetter sought to conceal their cooperation on an anti-VEGF PFS, this constituted a deception directed to the general public and not to Regeneron specifically. *See id.* at 45. Moreover, the court concluded that Regeneron failed to adequately investigate whether it had a viable tortious interference claim before the statute of limitations lapsed. Regeneron then timely appealed the district court's dismissal of its claims.

DISCUSSION [7]

This appeal presents two issues: first, whether Regeneron stated any plausible antitrust claims against Novartis and Vetter based on the existence of a PFS-only market; and second, whether Regeneron's tortious interference claim against Novartis was untimely, notwithstanding its equitable estoppel arguments.

We hold that the district court erred on both issues and that Regeneron properly stated antitrust and tortious interference claims. First, the district court improperly concluded that Regeneron failed to plead adequately the existence of a distinct anti-VEGF PFS market because it (1) placed improper weight on the functional, rather than economic, similarities between anti-VEGF PFSs and vials and (2) misconstrued the relationship between a patent and a proposed antitrust market. Second, the district court improperly rejected Regeneron's equitable estoppel argument in support of its tortious interference claim. Regeneron has satisfactorily alleged, at this stage in the litigation, that Novartis prevented Regeneron from learning about its contractual interference until after the limitations period expired. We consider the two issues in turn.

I. Regeneron's Proposed Relevant Market

A. Functional vs. Economic Similarities Between anti-VEGF PFSs and Vials

***7** To state a claim under either Section 1 or Section 2 of the Sherman Act, a plaintiff must plausibly allege that the defendants' anticompetitive conduct restricted competition within a relevant market. Our Court defines the relevant market as "all products reasonably interchangeable by consumers for the same purposes." *United States v. Am. Express Co.*, 838 F.3d 179, 196 (2d Cir. 2016) (citation and quotation marks omitted); *see also United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395, 76 S.Ct. 994, 100 L.Ed. 1264 (1956). At the motion-to-dismiss stage, a plaintiff's proposed relevant market must "bear a rational relation to the methodology courts prescribe to define a market" and include a "plausible explanation as to why a market should be limited" to exclude possible substitutes. *Todd v. Exxon Corp.*, 275 F.3d 191, 200 (2d Cir. 2001) (citation and quotation marks omitted). This is a relatively permissive pleading standard.

To determine the boundaries of a product market, we look to "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, 82 S.Ct. 1502, 8 L.Ed.2d 510 (1962). Two products are reasonably interchangeable where there is "sufficient cross-elasticity of demand"—that is, where "consumers would respond to a slight increase in the price of one product by switching to another product." *Todd*, 275 F.3d at 201-02 (quoting *AD/SAT v. Associated Press*, 181 F.3d 216, 227 (2d Cir. 1999)); *see also US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 64 (2d Cir. 2019).

Our Court has evaluated interchangeability by, for instance, "imagining that a hypothetical monopolist has imposed a small but significant non-transitory increase in price ('SSNIP') within the proposed market." *Am. Express*, 838 F.3d at 199. If the hypothetical monopolist can impose a SSNIP without losing so many sales to other products as to render the SSNIP unprofitable, then the proposed market is the relevant market. *Id.* Courts also often look to "practical indicia" of market boundaries to identify whether two products are economic substitutes and compete within the same antitrust market. *Brown Shoe*, 370 U.S. at 325, 82 S.Ct. 1502. These indicia can include "industry or public recognition of the [ ]market as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Id.* (setting forth the "*Brown Shoe* factors"); *see also US Airways*, 938 F.3d at 64-65 (enumerating and applying the *Brown Shoe* factors); *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496-99 (2d Cir. 2004) (applying *Brown Shoe* factors, including different distribution chains, industry recognition, and lack of supply substitution, to determine the bounds of an antitrust market); *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 106-07 (2d Cir. 2002) (same).

The Supreme Court has cautioned that identifying the scope of a relevant market requires resolving empirical questions that "can be determined only after a factual inquiry into the commercial realities faced by consumers." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482, 112 S.Ct. 2072, 119 L.Ed.2d 265 (1992) (citation and quotation marks omitted). Accordingly, we have recognized that "market definition is a deeply fact-intensive inquiry," and that courts therefore "hesitate to grant motions

to dismiss for failure to plead a relevant product market." *Chapman v. New York State Div. for Youth*, 546 F.3d 230, 238 (2d Cir. 2008) (citation and quotation marks omitted). Motions to dismiss should generally not be granted in such cases except "[w]here the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products." *Id.* (alteration in original) (quoting *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997)).

***8** Where a plaintiff pleads facts plausibly showing that two products should be considered part of distinct antitrust markets, those proposed markets are *not* to be rejected simply because a court believes the plaintiff is unintuitively separating products that might have real-world functional similarities into different relevant markets. Rather, the applicable analysis is whether or not the products are *economic* substitutes, not whether they appear to be functionally similar. This analysis turns on economic differences, such as a lack of cross-elasticity of demand or reasonable interchangeability among products. *See Todd*, 275 F.3d at 201-02; *Brown Shoe*, 370 U.S. at 325, 82 S.Ct. 1502.

In dismissing Regeneron's proposed PFS-only market, the district court erred by focusing too heavily on the functional similarities between anti-VEGF vials and PFSs, rather than on the extent to which consumers are willing to substitute one for the other.

The district court posited that it would be "strange" to limit the relevant market to anti-VEGF PFSs "when the same drug comes in a vial as well." *Novartis Pharma AG*, 582 F. Supp. 3d at 41. Accordingly, it rejected Regeneron's proposed market for three reasons. First, the court concluded that PFSs are only "marginally superior" to vials and rejected Regeneron's allegations that PFSs have performance-based and safety advantages over vials. *Id.* at 42. Second, it concluded that differences in the equipment required to produce PFSs and vials "say[ ] nothing about whether a consumer would find a vial and PFS interchangeable." *Id.* at 41. And third, it concluded that Regeneron's allegations that a SSNIP in anti-VEGF PFSs would not cause consumers to substitute PFSs for vials could not establish the proposed relevant market because a "small boost in usefulness will often be valuable enough to merit some heightened costs." *Id.* These considerations led the court to conclude that Regeneron had not "meaningfully explain[ed]" why anti-VEGF vials are not reasonable substitutes for anti-VEGF PFSs. *Id.* at 42.

We disagree with these conclusions. The fact that vials and PFSs contain the same medicines and treat the same condition does not automatically mean that they compete in the same market. In *Geneva Pharmaceuticals*, we held that a drug manufacturer plausibly alleged that the market for the generic version of a blood-thinning drug was distinct from the market for the name-brand version of the drug—even though the two were functionally the same. 386 F.3d at 496. We explained that while functional interchangeability is a *prima facie* indication that two products may be in the same antitrust market, other economic factors may nonetheless restrict the cross-elasticity of demand between two products and confine them to different product markets. *Id.* at 496-97; *cf. FTC v. AbbVie Inc.*, 976 F.3d 327, 372-73 (3d Cir. 2020) (same). For instance, the substantially higher prices for the name-brand version of the drug in that case, we concluded showed customer allegiance and inelastic demand, even in the face of a generic alternative. *Geneva Pharms.*, 386 F.3d at 497. We also relied on several additional differences between the name-brand and generic versions—for example, the fact that risk sensitive patients tended to prefer the name-brand version and the different supply chains used for distribution of the name-brand and generic versions—to conclude that they were part of distinct markets. *Id.* at 497-98. The same principles apply in this case.

The district court here should have focused on whether Regeneron alleges that the PFSs and vials are not *economic* substitutes under established legal frameworks such as the "hypothetical monopolist" test or the *Brown Shoe* factors. [8] *See Am. Express*, 838 F.3d at 199; *Brown Shoe*, 370 U.S. at 325, 82 S.Ct. 1502. Regeneron plainly does so.

***9** As to the hypothetical monopolist test, the Amended Complaint alleges that physicians have a "strong preference" for PFSs and that a "small, but significant, price increase in the PFS version would not cause physicians to substitute the vial version for PFS (even if they contain the same underlying anti-VEGF)." J. App'x at 419-20 (Am. Cmplt. ¶ 200). Regeneron supports this contention by pleading that more than 80% of patients on anti-VEGF treatment courses transitioned from vials to PFSs due to their superiority. *Id.* at 414 (Am. Cmplt. ¶ 188). These allegations indicate an inelasticity of demand for PFSs vis-à-vis

vials. Indeed, at this stage of the litigation, like in *Geneva Pharmaceuticals*, Regeneron's allegations plausibly establish that anti-VEGF PFSs compete in a wholly separate market from vials. Regeneron alleges that the ability of patients or physicians to switch from PFSs to vials does not "restrain a [PFS] firm's ability to raise prices above the competitive level" because PFSs and vials are not viewed as economic substitutes—even if they are functional substitutes. *Geneva Pharms.*, 386 F.3d at 496. The district court did not properly credit these allegations.

As to the *Brown Shoe* factors, Regeneron's Amended Complaint includes several references to the "practical indicia" identified by the Supreme Court as relevant to a proposed market definition. *See Brown Shoe*, 370 U.S. at 325, 82 S.Ct. 1502. For example, Regeneron alleges that anti-VEGF PFSs require "unique production facilities and capabilities that are distinct from those required to manufacture anti-VEGF vials." J. App'x at 419 (Am. Cmplt. ¶ 199). Regeneron also alleges that "industry recognition" and "particular characteristics and uses"—such as methods of administration, accuracy, and convenience—differentiate anti-VEGF PFSs from vials. *Id.* at 417, 427-28, 431, 438 (Am. Cmplt. ¶¶ 96, 224, 235, 253). These allegations, particularly when combined with those relating to SSNIP, convince us that Regeneron has provided a plausible explanation as to why the relevant market should be limited to anti-VEGF PFSs.

B. Effect of a Patent on a Proposed Antitrust Market

The district court also justified dismissal of Regeneron's Section 2 *Walker Process* claims based on the overlap between Regeneron's proposed market and the protections afforded to Novartis by the '631 Patent.[9] It concluded that an antitrust market cannot be coextensive with a patent because this would mean that "all patents would immediately confer complete monopoly power." *Novartis Pharma AG*, 582 F. Supp. 3d at 42. The court therefore held Regeneron to a heightened pleading standard, requiring it to show that "the subject of [the] patent is so novel that there really is no fitting substitute." *Id.* This reasoning was flawed.

The appropriate inquiry into whether a patent confers monopoly power is whether there are "effective substitutes for the [product] which do not infringe the patent." *Walker Process*, 382 U.S. at 178, 86 S.Ct. 347. Whether and to what extent a patent confers monopoly power is "a matter of proof" that must be assessed using the same principles that courts typically apply in antitrust cases. *Id.*; *see Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45, 126 S.Ct. 1281, 164 L.Ed.2d 26 (2006) ("[A] patent does not necessarily confer market power upon the patentee."). As discussed above, this is a "deeply fact-intensive" inquiry that requires consideration of the factors that might affect the cross-elasticity of demand and reasonable interchangeability between two products. *Todd*, 275 F.3d at 199; *see also US Airways*, 938 F.3d at 64. Regeneron's allegations plausibly demonstrate that anti-VEGF PFSs and vials are not reasonably interchangeable and are consequently not part of the same product market.

***10** The district court reasoned that if a relevant market were coextensive with the scope of a patent, then each of the three elements of an attempted monopolization claim—anticompetitive conduct, specific intent to monopolize, and a dangerous probability of achieving monopoly power—"would be met as a matter of course." *Novartis Pharma AG*, 582 F. Supp. 3d at 42. However, where, as here, an antitrust plaintiff alleges that a patent was fraudulently obtained and the patent holder garnered monopoly power as a result of that fraud, a court must "appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved." *Walker Process*, 382 U.S. at 177, 86 S.Ct. 347. In other words, once an antitrust plaintiff has demonstrated that a patent was obtained through fraud, it must separately explain how the fraudulently obtained patent enabled the defendants to achieve market power within the relevant market. "Without a definition of that market there is no way to measure [the defendant's] ability to lessen or destroy competition." *Id.*

Under this framework, the district court should have considered (1) whether Regeneron adequately pleaded that the '631 Patent was fraudulently obtained; and (2) whether Novartis's and Vetter's use of that patent conferred monopoly power in the relevant market. At the motion-to-dismiss stage, Regeneron's allegations meet these requirements.

First, the Amended Complaint alleges that the '631 Patent was fraudulently obtained. Regeneron alleges that in order to avoid triggering Regeneron's rights under the 2005 Agreement with Vetter, Novartis and Vetter concealed Vetter's role as a co-inventor from the USPTO—despite being obligated to disclose that role. *See* J. App'x at 434 (Am. Cmplt. ¶ 240); *see* 35 U.S.C. § 116; 37 C.F.R. §§ 1.56, 1.63. Regeneron alleges that this "deception was successful, as the USPTO, unaware of the contributions of the Vetter employee(s) to the inventions claimed in the '631 Patent, allowed the patent to issue with only the Novartis employees identified as the named inventors." J. App'x at 433-34 (Am. Cmplt. ¶ 240). Regeneron further asserts that in prosecuting the '631 Patent, Novartis, acting "with an intent to deceive," "deliberately withheld ... prior art and other determinations by the USPTO." *Id.* at 375-76 (Am. Cmplt. ¶ 110). Specifically, Regeneron alleges that the '631 Patent would not have been granted had the patent examiner been aware of this undisclosed material prior art. *Id.* at 376.

Second, Regeneron alleges that Novartis and Vetter sought to control the supply of all anti-VEGF PFS treatments both before and after obtaining the '631 Patent by "jointly agree[ing] to leverage Novartis's fraudulently procured '631 Patent to try to coerce Regeneron... into long-term exclusive PFS filling relationships." *Id.* at 406 (Am. Cmplt. ¶ 171). Regeneron alleges that Novartis and Vetter insisted on onerous modifications to Vetter's 2005 Agreement with Regeneron after obtaining the '631 Patent in order to give Vetter total control over the supply of EYLEA PFS and to enable Novartis to control the supply of "effectively all FDA-approved anti-VEGF PFS treatments." *Id.* at 407 (Am. Cmplt. ¶ 173). Regeneron further alleges that after it refused these demands, Novartis and Vetter "jointly agreed to cut off Regeneron entirely" from Vetter's PFS filling services. *Id.* at 408 (Am. Cmplt. ¶ 175). According to the Amended Complaint, these actions allegedly delayed the release of Regeneron's EYLEA PFS to 2019 and enabled Novartis to accumulate market power. Accordingly, we conclude that these allegations plausibly state claims for Section 2 *Walker Process* attempted monopolization violations.

II. Tortious Interference with Contract

In addition to its antitrust claims, Regeneron asserts a tortious interference claim against Novartis under New York law. The district court dismissed this claim as untimely, and we reverse. Regeneron's pleadings adequately establish that Novartis was estopped from asserting a statute of limitations defense because Novartis and Vetter prevented Regeneron from learning of their secret arrangement until after the limitations period expired.

***11** Under New York law, a plaintiff claiming tortious interference with contract must plead (1) "the existence of a valid contract between the plaintiff and a third party"; (2) the "defendant's knowledge of that contract"; (3) the "defendant's intentional procurement of the third-party's breach of the contract without justification"; (4) "actual breach of the contract"; and (5) "damages resulting therefrom." *Rich v. Fox News Network, LLC*, 939 F.3d 112, 126-27 (2d Cir. 2019) (quoting *Lama Holding Co. v. Smith Barney Inc.*, 88 N.Y.2d 413, 424, 646 N.Y.S.2d 76, 668 N.E.2d 1370 (1996)). Additionally, the "plaintiff must allege that the contract would not have been breached but for the defendant's conduct." *Id.* (quoting *Burrowes v. Combs*, 25 A.D.3d 370, 808 N.Y.S.2d 50, 53 (1st Dep't 2006)).

Regeneron alleges that Novartis tortiously interfered in its contract with Vetter by covertly working with Vetter to fraudulently procure the '631 Patent and by preventing Regeneron from obtaining the ownership rights in the Patent promised to it by the 2005 Agreement. J. App'x at 451-55 (Am. Cmplt. ¶¶ 285-94). Knowing about this preexisting contract and seeking to circumvent it, Novartis allegedly "fraudulently conceal[ed] Vetter employees' inventorship from the USPTO in order to sabotage Regeneron's ownership rights." *Id.* (Am. Cmplt. ¶ 288). Regeneron claims that Novartis "intentionally procured Vetter's breach" and injured Regeneron by depriving it of its intellectual property ownership rights under the 2005 Agreement. *Id.* at 453-54 (Am. Cmplt. ¶¶ 290, 293). As a consequence, Regeneron was required to spend money and divert resources to develop a new, alternative supply of EYLEA PFS using a different filler and different assembly processes. *See id.* at 454 (Am. Cmplt. ¶ 293).

New York provides for a three-year statute of limitations for tortious interference claims. A plaintiff's claim accrues "when all elements of the tort can be truthfully alleged in a complaint." *IDT Corp. v. Morgan Stanley Dean Witter & Co.*, 12 N.Y.3d 132, 140, 879 N.Y.S.2d 355, 907 N.E.2d 268 (2009). Novartis and Vetter argue that Regeneron was required to bring its tortious interference claim by 2016 because the Amended Complaint alleges that Regeneron first suffered contractual injury in late 2013 (when Vetter allegedly cut Regeneron off from its filling services, forcing it "to invest significant time, money, and effort" to

find an alternative filler). Appellees' Br. at 59 (quoting J. App'x at 404, 408 (Am. Cmplt. ¶¶ 166, 175)). Regeneron did not commence this action until July 2020.

Notwithstanding the three-year limitations period, New York law recognizes that a defendant may be equitably estopped from invoking the statute of limitations "where [the] plaintiff was induced by fraud, misrepresentations or deception to refrain from filing a timely action." *Zumpano v. Quinn*, 6 N.Y.3d 666, 674, 816 N.Y.S.2d 703, 849 N.E.2d 926 (2006) (citation and quotation marks omitted). The doctrine applies if the plaintiff can show "some conduct on the part of the defendant after the initial wrongdoing" to conceal the fraud. *Ross v. Louise Wise Servs.*, 8 N.Y.3d 478, 491, 836 N.Y.S.2d 509, 868 N.E.2d 189 (2007); *see also Matter of Steyer*, 70 N.Y.2d 990, 993, 526 N.Y.S.2d 422, 521 N.E.2d 429 (1988) (equitable estoppel applies when a defendant refuses to respond to a plaintiff's efforts "to elicit the facts"). The plaintiff bears the burden of establishing that the claim was brought within a reasonable time after the deception came to light. *See Simcuski v. Saeli*, 44 N.Y.2d 442, 450, 406 N.Y.S.2d 259, 377 N.E.2d 713 (1978).

Regeneron makes four assertions in support of its equitable estoppel argument. First, it contends that Novartis "purchased Vetter's silence and complicity" by offering Vetter, among other things, a "co-extensive license over the ['631 Patent] with the right to sub-license." Appellant's Br. at 50. Second, Regeneron argues that "Vetter—acting pursuant to its anticompetitive agreement with Novartis—refused to disclose the details" of its 2013 agreement with Novartis when Regeneron asked specifically and repeatedly about the nature of the agreement. *Id.* at 51. Third, Regeneron states that "Novartis further concealed the fraud," and therefore its tortious interference, "by transferring to itself exclusive enforcement authority over the patent," which enabled Novartis to pursue patent-related litigation against Regeneron without disclosing Vetter's role as a co-inventor. *Id.* at 52. And fourth, Regeneron contends that it was able to discover Vetter's role only "because Novartis was compelled to disclose the information" in 2020, during discovery in the related patent litigation. *Id.* Regeneron then promptly brought this suit. Under New York law, these allegations are sufficient to estop Novartis from invoking the statute of limitations as a defense to Regeneron's tortious interference claim at the motion to dismiss stage. *See Ross*, 836 N.Y.S.2d at 518, 868 N.E.2d 189.

***12** In rejecting Regeneron's equitable estoppel arguments, the district court stated that "equitable estoppel is only appropriate where the plaintiff is prevented from filing an action within the applicable statute of limitations due to defendants' misconduct toward the potential plaintiff, not a community at large." *Novartis Pharma AG*, 582 F. Supp. 3d at 43 (citation and quotation marks omitted). It therefore concluded that Regeneron's arguments failed because Novartis and Vetter "sought to deceive the [USPTO] and the market at large" by concealing Vetter's inventorship—the alleged fraud was not targeted solely and directly at Regeneron. *Id.* at 45.

Our review of New York law finds no support for this proposition. The notion that a party who has been induced by fraud, misrepresentation, or deception to violate the statute of limitations cannot invoke equitable estoppel because the defendant sought to deceive other parties *in addition to the putative plaintiff* has no basis in New York law. Regeneron's allegation that it could not have known that its contractual rights were being violated within the limitations period because of Novartis's conduct is supported by detailed, plausible facts. Indeed, Regeneron alleges that it diligently sought information about the nature of Vetter's relationship with Novartis, only for Vetter to refuse to provide that information, preventing Regeneron from bringing a claim.

We conclude that these allegations were sufficient to permit Regeneron to invoke equitable estoppel and that the Amended Complaint plausibly alleges a claim for tortious interference with contract.

CONCLUSION

For the foregoing reasons, we hold that Regeneron's Amended Complaint plausibly alleges violations of Section 1 and Section 2 of the Sherman Act and tortious interference with contract. Accordingly, we **REVERSE** the judgment of the district court and **REMAND** for further proceedings consistent with this opinion.

All Citations

--- F.4th ----, 2024 WL 1145340

Footnotes

1 In this posture, we accept the well-pleaded factual allegations in the Amended Complaint as true and draw all reasonable inferences in Regeneron's favor. *Francis v. Kings Park Manor, Inc.*, 992 F.3d 67, 72 (2d Cir. 2021) (en banc).

2 Soon after obtaining the '631 Patent in 2015, Novartis worked with non-party Genentech, Inc. ("Genentech"), another pharmaceutical company, to commercialize a LUCENTIS PFS. It then licensed the '631 Patent to Genentech to market LUCENTIS PFS in North America, while Novartis maintained exclusive commercialization rights in the rest of the world. In early 2017, Novartis and Genentech officially launched LUCENTIS PFS in the United States.

3 *See* 35 U.S.C. § 116; 37 C.F.R. §§ 1.56, 1.63.

4 This conclusion, according to Regeneron, is reinforced by the fact that in October 2021, the USPTO Patent Trial and Appeal Board found that Regeneron had "established a reasonable likelihood of prevailing on its assertion that at least one of the claims [in the Patent] would have been obvious" based on this withheld prior art. J. App'x at 862.

5 Novartis's patent claims against Regeneron (and Regeneron's counterclaims against Novartis in that suit) were considered in tandem with Regeneron's antitrust suit in the Northern District. *See Novartis Pharma AG v. Regeneron Pharms., Inc*, No. 20-cv-00690 (N.D.N.Y.). In the same opinion granting Novartis's and Vetter's motions to dismiss Regeneron's antitrust and tortious interference claims, the district court also declined to reimpose a stay on the patent claims, pending further review by the USPTO. Those claims are not before us on appeal.

6 The parties agree that the relevant geographic market is the United States. J. App'x at 420 (Am. Cmplt. ¶ 201).

7 "We review *de novo* a district court's dismissal of a complaint pursuant to Rule 12(b)(6), construing the complaint liberally, accepting all factual allegations in the complaint as true, and drawing all reasonable inferences in the plaintiff's favor." *Green v. Dep't of Educ. of City of New York*, 16 F.4th 1070, 1076 (2d Cir. 2021) (quoting *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002)). To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)).

8 Our Court has emphasized that market definition turns on "the actual dynamics of the market rather than rote application of any formula." *Geneva Pharms.*, 386 F.3d at 496. Thus, so long as an antitrust plaintiff adequately references one or more of the legal frameworks we have recognized as supporting a proposed market, "there is no requirement to use any specific methodology." *Optronic Techs., Inc. v. Ningbo Sunny Elec. Co.*, 20 F.4th 466, 482 (9th Cir. 2021).

9 As our Court has explained, the Supreme Court's *Walker Process* decision enables a plaintiff to assert antitrust claims when the relevant patent giving rise to allegedly anticompetitive conduct was fraudulently procured. *See In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 685 (2d Cir. 2009) (citing *Walker Process*, 382 U.S. at 177, 86 S.Ct. 347); *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 505 (Fed. Cir. 2012) ("The Supreme Court in [*Walker Process*] held that antitrust liability may attach when a party uses a patent to obtain or preserve a monopoly if the patent was procured through intentional fraud on the Patent and Trademark Office."). Fraud in this context "requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, (4) but for which misrepresentation or

deliberate omission the patent would not have been granted." *In re DDAVP*, 585 F.3d at 685 (citing *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998)).

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