PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 11-3602

ETHYPHARM S.A. FRANCE,
Appellant

v.

ABBOTT LABORATORIES

On Appeal from the United States District Court
for the District of Delaware
(D.C. No. 08-cv-00126)
District Judge: Hon. Sue L. Robinson

Argued
September 25, 2012

Before: McKEE, *Chief Judge*, JORDAN, and VANASKIE,
Circuit Judges.

(Filed: January 23, 2013)

Carlos T. Angulo, Esq.
Dwight P. Bostwick, Esq. [ARGUED]
Zuckerman Spaeder
1800 M Street, NW – Ste. 1000
Washington, DC 20036

Austen C. Endersby, Esq.
Gregory B. Williams, Esq.
Fox Rothschild
919 North Market Street – Ste. 1300
Wilmington, DE 19801
Counsel for Appellant

Sean M. Brennecke, Esq.
Klehr Harrison Harvey Branzburg
919 North Market Street – Ste. 1000
Wilmington, DE 19803

William F. Cavanaugh, Jr., Esq. [ARGUED]
Chad J. Peterman, Esq.
Thomas W. Pippert, Esq.
Edward R. Tempesta, Esq.
Timothy Waters, Esq.
Patterson, Belknap, Webb & Tyler
1133 Avenue of the Americas
New York, NY 10036

David J. Margules, Esq.
Bouchard, Margules & Friedlander
222 Delaware Avenue - #1400
Wilmington, DE 19801

Stuart N. Senator, Esq.
Jeffrey I. Weinberger, Esq.
Munger, Tolles & Olson
355 S. Grand Avenue – 35th Fl.
Los Angeles, CA 90071
Counsel for Appellee

OPINION OF THE COURT

JORDAN, *Circuit Judge*.

Ethypharm S.A. France ("Ethypharm") appeals the judgment of the United States District Court for the District of Delaware granting Abbott Laboratories ("Abbott") summary judgment on Ethypharm's antitrust and state law claims. Although the District Court ruled in Abbott's favor, it had earlier denied Abbott's motion to dismiss, a motion premised on the assertion that Ethypharm lacked standing to bring antitrust claims under §§ 1 and 2 of the Sherman Antitrust Act. Abbott has pressed its standing argument on appeal, and we conclude that the District Court erred in holding there is antitrust standing in this case. Because Ethypharm's state law claims have not been argued on appeal, the District Court's judgment on those claims will remain undisturbed, but we will vacate the District Court's grant of summary judgment as to the federal claims and will remand with directions that they be dismissed for Ethypharm's lack of standing.

I. Background

A. *Facts*[1]

Ethypharm is a privately held French corporation that develops and manufactures pharmaceutical drug products. The drug at issue in this case is a fenofibrate[2] developed and manufactured by Ethypharm and carrying the brand name Antara®. Because, as Ethypharm observes, entry into the United States pharmaceutical market requires "substantial time and resources," it does not sell Antara directly in the United States. (J.A. at 122.) Instead, its business model was to "enter into a license and distribution agreement with a company in the United States." (J.A. at 122.) Thus, in 2001,

---

[1] Because we are primarily reviewing the District Court's denial of Abbott's motion to dismiss for lack of antitrust standing, we take as true all the factual allegations in the complaint and the reasonable inferences that can be drawn from those facts. *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 262 n.27 (3d Cir. 2010); *see also In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 398-99 (3d Cir. 2000) (applying Rule 12(b)(6) on motion to dismiss for lack of antitrust standing). To the extent we recount facts outside of the complaint, we do so for informational purposes only and do not rest our decision on those facts.

[2] "Fenofibric acid, the active metabolite of fenofibrate, produces reductions in total cholesterol, LDL cholesterol, apolipoprotein B, total triglycerides and triglyceride rich lipoprotein (VLDL) in treated patients." *Physicians' Desk Reference* 565 (66th ed. 2012).

it entered into a Development, License, and Supply Agreement ("DLS") with Reliant Pharmaceuticals, Inc. ("Reliant"), an American company, pursuant to which Reliant would sell Antara in this country. The DLS stated that Ethypharm would provide Reliant with the finished pharmaceutical product, or, at Reliant's option, the drug in bulk, which could then be encapsulated.

Reliant "was responsible for obtaining regulatory approval for the drug, preparing appropriate packaging material, and then marketing the drug through the efforts of a large, motivated, and experienced sales force." (J.A. at 122.) To that end, the DLS granted exclusive rights to Reliant in the United States and allowed it to seek approval with the U.S. Food and Drug Administration ("FDA") to market and sell Antara.[3] Ethypharm explains in its Complaint[4] that Reliant's role in exclusively marketing, selling, and obtaining FDA approval for Antara was critical because, without the "mechanism of the license and distribution agreement, Ethypharm would be foreclosed from the United States market." (J.A. at 122.) Thus, without Reliant's, or some similar distributor's, willingness to take on the risk and expense of gaining FDA approval and marketing Antara, the drug could never have reached the United States market.

---

[3] The DLS also gave Ethypharm a right of first refusal should Reliant seek to divest its rights in Antara.

[4] Ethypharm filed its initial complaint on March 3, 2008. After Abbott filed a motion to dismiss that complaint, Ethypharm filed its Amended Complaint, the operative pleading, on July 2, 2008. For simplicity, we refer to the Amended Complaint as the Complaint.

Consistent with the DLS, Reliant sought FDA approval of Antara pursuant to § 505(b)(2) of the Food, Drug, and Cosmetics Act ("FDCA"). 21 U.S.C. § 355(b)(2). Reliant thus began the process of complying with the complex regulatory regime that governs how pharmaceuticals come to market in the United States. Before a drug can be released, it must be approved by the FDA pursuant to the FDCA, 21 U.S.C. §§ 301 *et seq*. The manufacturer of a new branded drug must submit detailed safety and efficacy data for the drug to the FDA in a New Drug Application ("NDA"). *Id.* § 355(a), (b)(1). The NDA must also list "the patent number and the expiration date of any patent which claims the drug … or which claims a method of using such drug." *Id.* § 355(b)(1). After approval, information about the branded drug, including patent information, is published by the FDA in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally called the "Orange Book," after the color of its cover. *See generally* FDA Electronic Orange Book, http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm (last visited Dec. 3, 2012).

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), codified at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§ 156, 271, 282, provides a framework for the introduction of generic versions of previously approved branded drugs. Under that framework, a generic manufacturer may submit an Abbreviated New Drug Application ("ANDA") to the FDA. 21 U.S.C. § 355(j). The ANDA process allows the generic manufacturer to incorporate efficacy and safety data submitted to the FDA in the NDA for a branded drug, as long

as the generic drug is shown to be bioequivalent to that branded drug. *Id.* § 355(j)(2)(A).

There is also a third kind of application that a drug manufacturer may use to obtain FDA approval, and that is the route Reliant chose for Antara. Under § 505(b)(2) of the FDCA, a drug manufacturer may file an NDA for a drug that is not entirely new but is not simply a generic version of a branded drug. For drugs that have changes from a branded drug, such that an ANDA application is unavailable, but whose changes are so slight that a manufacturer may rightly rely on the "full reports of investigations," 21 U.S.C. § 355(b)(1), of the original drug to establish the new drug's safety and efficacy, an NDA may be filed pursuant to § 505(b)(2), even though those investigations "were not conducted by or for the applicant and … the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted," *id.* § 355(b)(2). The § 505(b)(2) applicant must submit additional data to the FDA that demonstrates that any differences between the original drug and the § 505(b)(2) drug will not affect the § 505(b)(2) drug's safety and efficacy. *See* 21 C.F.R. § 314.54(a) (providing that § 505(b)(2) applications must provide data that supports any modification of the drug from the relied upon NDA). But, having done that, a § 505(b)(2) applicant can avoid preclinical and certain human studies necessary in full NDA applications.

Finally, much as when filing an ANDA application, a § 505(b)(2) applicant must certify whether its drug will infringe any patents listed in the Orange Book. 21 U.S.C. § 355(b)(2)(A). Those certifications are as follows: "(i) that such patent information has not been filed (ii) that such patent

has expired, (iii) of the date on which such patent will expire, or (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted … ." *Id.* § 355(b)(2)(A)(i)-(iv).

Rather than conducting its own clinical studies, Reliant depended on the data of another, already approved, fenofibrate drug called TriCor®, which was developed by a French company named Laboratories Fournier ("Fournier") and distributed by Abbott in the United States.[5] Antara received FDA approval in November 2004, and Reliant began marketing the drug in February 2005. Reliant chose not to make a certification under § 505(b)(2)(A)(iv) that Antara did not infringe any patents in the Orange Book or that those patents were invalid, but elected to market Antara immediately after gaining FDA approval.[6] That marketing exposed Reliant to a possible infringement suit from Abbott,

[5] Fournier granted Abbott an exclusive license to manufacture and sell TriCor in the United States. Abbott listed the patents for TriCor in the Orange Book.

[6] As explained above, a § 505(b)(2) applicant must make a certification pursuant to 21 U.S.C. § 355(b)(2)(A). Although Ethypharm admits in its Complaint that Reliant did not make a Paragraph IV certification, it also states in that Complaint that "Reliant provided notice of a regulatory filing and certification to Abbott in February 2004." (J.A. at 137.) The record is unclear what certification Reliant made, and it is also unclear what the consequences of not making a certification would have been for Reliant. Neither party contends that such failure is relevant here.

making Reliant's launch of Antara "at risk."[7] In a prophylactic maneuver, Reliant filed a declaratory judgment action in the United States District Court for the District of Delaware in June 2004, seeking a declaration of non-infringement with respect to four of Abbott's fenofibrate patents, U.S. Patent Nos. 6,074,670 (the "'670 patent"), 6,277,405 (the "'405 patent"), 6,589,552 (the "'552 patent"), and 6,652,881 (the "'881 patent"). Reliant also argued that the patents were unenforceable due to inequitable conduct. Abbott counterclaimed for infringement of two of the four patents. Despite that lawsuit, Antara's net sales in 2005 were $23.5 million, and for the first half of 2006 they were $18.9 million.

In April 2006, Abbott and Reliant settled their patent dispute. Fournier, TriCor's developer, was also a party to the settlement. The three entered into a Settlement Term Sheet ("STS") providing that Abbott and Fournier would grant a non-exclusive license to Reliant for the patents that were the subject of the lawsuit, along with U.S. Patent No. 4,895,726 (the "'726 patent"), another fenofibrate patent. (*See* J.A. at 247 ("Abbott and Fournier would grant Reliant a non-exclusive license … under the [patents] to exploit [Antara[8]] in

---

[7] In its Complaint, Ethypharm says that "Abbott responded in writing [to Reliant's regulatory filings] with a thinly-veiled threat to bring suit." (J.A. at 137.)

[8] The STS also provided for a specific set of products that could be manufactured by Reliant:

> [T]he 43 mg, 87 mg and 130 mg fenofibrate capsule products that are the subject of Reliant's New Drug Application 21–695, as

the United States … .").) In exchange, "Reliant would make quarterly royalty payments to Abbott and Fournier in the total amount of 7% of Net Sales."[9] (J.A. at 248.) If, however, Reliant was acquired or it sold off the Antara portion of its business,[10] the new owner would not receive the benefit of a 7

> supplemented and/or amended from time to time. Reliant Products do not include (i) any pharmaceutical products where fenofibrate is not the sole active ingredient, (ii) any combination therapy products or (iii) any products in a form other than a 43 mg, 87 mg or 130 mg fenofibrate capsule.

(J.A. at 246.) Thus, the STS would not allow Reliant to create new doses or combination drugs that would be covered by the non-exclusive license.

[9] The STS defines Net Sales as "the gross invoiced sales of the Reliant Products in the Territory under the License Agreement … ." (J.A. at 244.) The STS defines the Reliant Products to be "the 43 mg, 87 mg and 130 mg fenofibrate capsule products that are the subject of Reliant's New Drug Application 21-695 … ." (J.A. at 246.)

[10] The STS referred to this as a "Change of Control," which was to include "the sale, lease, exchange, license or other disposition of all or substantially all of such Reliant['s] assets related to … [Antara] and … Reliant['s] other assets … ."; "a merger, consolidation, share exchange or similar corporate transaction as a result of which the holders of" Reliant's stock no longer owned the company; or "the acquisition" of Reliant by any person or company. (J.A. at 249.)

percent royalty; instead, "the License Fee … would increase to 10% of Net Sales." (*Id*.) Relevant here, § 8 of the STS (the "Restricted Entity provision") provided that:

> The license would contain additional customary terms and conditions including, without limitation, the following: … (ii) no assignment, sublicense or other transfer of any rights relating to the Reliant Products (including the right to market and promote the Reliant Products) except: … (e) to acquirers … of any portion of Reliant [or its business] relating to the Reliant Products other than pursuant to a Change of Control, provided that any assignment, sublicense or other transfer of rights granted pursuant to Section 8(ii)(e), (A) to a Restricted Entity or Affiliate thereof, shall require the prior written consent of Abbott and (B) to any entity other than a Restricted Entity or Affiliate thereof shall be limited to [the '726, '670, '405, '552 and '881 patents] unless Abbott consents to the assignment, sublicense or other transfer (in which case, Reliant's rights to [the patents and their continuations] may be included).

(J.A. at 255-56.) That provision effectively foreclosed Reliant from assigning its rights in Antara to any "Restricted Entity" or partnering with such an entity to market Antara in the United States. The term "Restricted Entity" was defined to include, as the District Court summarized it, "about 20 large pharmaceutical companies, 10 generic companies[,] and a few specialty pharmaceutical companies." (J.A. at 10.)

In April 2006, Abbott and Reliant entered a stipulation of dismissal of the patent litigation in accordance with the STS. A few months later, in July 2006, Reliant sold to Oscient Pharmaceutical Company ("Oscient") the exclusive rights to market and sell Antara in the United States. Oscient, a business that did not appear on the Restricted Entity list, paid Reliant $78 million for the exclusive rights to Antara, plus the cost of Reliant's remaining Antara inventory.[11] Ethypharm had a right of first refusal under the DLS, pursuant to which it could "acquire all rights in relation with [Antara] and the relevant Intellectual Property and Confidential Information belonging to RELIANT … ." (J.A. at 320.) But it declined to exercise that right and instead approved the sale to Oscient. Abbott, however, exercising its rights under the DLS, did not give its approval. As a result, Reliant was only able to assign its license to the five Abbott patents contained in the STS and not any future continuation

[11] Although called a "New Drug Application," an approved NDA is no longer an "application" in the commonly understood sense of the word. It is, rather, the approval to participate in the United States pharmaceutical market. *See* 21 C.F.R. § 314.105(a) (explaining that once notice of an approved application is received by letter, marketing of the drug may begin, unless the FDA or some other provision of law has delayed that effective date). The rights to an NDA are readily transferrable between owners, so long as the new owners comply with certain regulatory requirements. *See id.* § 314.72(a) ("An applicant may transfer ownership of its application."); *id.* § 314.72(b) ("The new owner shall advise FDA about any change in the conditions in the approved application under § 314.70 … .").

or divisional applications. (*See* J.A. at 255 (noting that an assignment of Reliant's license from Abbott "to any entity other than a Restricted Entity or Affiliate thereof shall be limited to [the '726, '670, '405, '552 and '881 patents] unless Abbott consents to the assignment, sublicense or other transfer (in which case, Reliant's rights to [the patents and their continuations] may be included).").)

Oscient had some initial success with Antara. Sales in 2007 and 2008 were approximately $53.6 million and $73.8 million respectively, up from $42.5 million in 2006. But sales stagnated in 2009, with Oscient losing market share to generic fenofibrate manufacturers. By the summer of 2009, Oscient had discontinued its promotion of Antara and filed for bankruptcy. Lupin, a manufacturer of generic pharmaceuticals, purchased the rights to Antara for $38 million from Oscient's bankruptcy estate, and, although Lupin is currently attempting to grow the market for the drug, its CEO testified that it is a difficult task because Abbott had solidified its place in the market while Oscient was floundering. To that end, as of 2010, Antara's market share was only 2 to 4 percent, a far cry from the 25 to 33 percent Reliant initially hoped to capture when it launched Antara, but in line with the 2.2 and 3.4 percent market share Reliant had actually captured in 2005 and 2006, respectively.

B. *Procedural History*

Believing that the failure of Antara to compete with TriCor was a direct result of Abbott's patent suit against Reliant and of the resulting STS, particularly the Restricted Entity provision, Ethypharm filed this action against Abbott. The Complaint features antitrust and sham litigation claims

under §§ 1 and 2 of the Sherman Act. *See* 15 U.S.C. § 1 ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."); *id*. § 2 ("Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony … ."), as well as a number of state law claims, including unfair competition, tortious interference with contract, tortious interference with prospective economic advantage, and common law restraint of trade. According to Ethypharm, the STS was designed to make sure that Antara would be put in the hands of a company with "limited resources and a relatively small sales force," so that it could not effectively compete with TriCor. (J.A. at 11.)

In addition to citing the allegedly anticompetitive nature of the Restricted Entity provision, Ethypharm averred that the 7 percent royalty payment Reliant owed to Abbott restrained Ethypharm's ability to compete because, by collecting a royalty from Ethypharm's exclusive distributor, Abbott weakened Antara's profitability. Ethypharm also claimed that the provisions of the STS preventing Oscient from developing new combination drugs or different doses of Antara further restricted the ability of Antara to compete against TriCor.

Abbott initially moved to dismiss the Complaint for lack of antitrust standing, but the District Court denied that motion, holding that Ethypharm had the necessary standing to sue. The Court determined that "a foreign name-brand

manufacturer, which does not itself market and distribute its product in the United States but does so through an exclusive United States distributor, is entitled to avail itself of the protection of the antitrust laws for the purpose of challenging the conduct of a manufacturer of a competing brand name drug." (J.A. at 11, 35.)[12]

Following discovery, Abbott moved for summary judgment. The District Court granted that motion, determining that Ethypharm had not presented enough evidence from which a reasonable jury could find a causal connection between the alleged antitrust injury and the damage it suffered. Specifically, the Court concluded there was insufficient evidence that Abbott's allegedly anticompetitive conduct caused Antara's failure in the market and, therefore, Ethypharm's antitrust claim was untenable. (*See* J.A. at 20 ("Put simply, there are many market influences that may have contributed to Oscient's failure with Antara.").)[13]

---

[12] The District Court did grant Abbott's motion to dismiss Ethypharm's "unlawful restraint of trade" claim. Specifically, Abbott contended that Delaware's Antitrust Act, which codified a restraint of trade claim, *see* Del. Code Ann. tit. 6, § 2103, preempted a common law restraint of trade claim. Ethypharm failed to respond to that argument, and the Court concluded that that failure doomed the claim. (*See* J.A. at 43 (dismissing Ethypharm's restraint of trade claim because it failed to "articulate in some manner how its pleading meets the legal requirements of its claims").

[13] The District Court also granted summary judgment in favor of Abbott on Ethypharm's sham litigation claims. Ethypharm does not dispute that determination on appeal.

Ethypharm timely appealed.

In addition, the District Court granted summary judgment in favor of Abbott on Ethypharm's state law claims. With respect to those claims, Ethypharm says, in a footnote at the close of its Opening Brief before us, that the District Court dismissed its state law claims without articulating a basis for that ruling. (*See* Appellant's Opening Br. at 61 n.27 ("The district court's decision did not separately address Ethypharm's three remaining state common law claims for unfair competition.").) In response, Abbott states it "is clear [as to why] the district court decided to dismiss the state law claims: Ethypharm cannot prove injury in fact." (Appellee's Br. at 58-59; J.A. at 20.) We have consistently held that "[a]n issue is waived unless a party raises it in its opening brief, and for those purposes a passing reference to an issue ... will not suffice to bring that issue before this court." *Laborers' Int'l Union of N. Am., AFL-CIO v. Foster Wheeler Energy Corp.*, 26 F.3d 375, 398 (3d Cir. 1994) (internal quotation marks omitted); *see John Wyeth & Bro. Ltd. v. CIGNA Int'l Corp.*, 119 F.3d 1070, 1076 (3d Cir. 1997) ("[A]rguments raised in passing (such as, in a footnote), but not squarely argued, are considered waived."); *see also SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 n.6 (Fed. Cir. 2006) ("[A]rguments raised in footnotes are not preserved."). Thus, Ethypharm waived its appeal of its state law claims. And because of Ethypharm's waiver, and because the District Court had diversity jurisdiction over those state law claims, *see infra* note 14, we will not disturb the District Court's grant of summary judgment for Abbott with respect to Ethypharm's state law claims.

II. Discussion[14]

Abbott argues that the District Court erred in concluding that Ethypharm had standing to bring its antitrust claims. Specifically, Abbott says that Ethypharm does not compete with it because Ethypharm is not a supplier of Antara in the United States and, therefore, it cannot claim to

[14] The District Court had jurisdiction over the federal antitrust claims pursuant to 28 U.S.C. § 1331 and over the state law claims both as pendent claims pursuant to § 1367, and under diversity jurisdiction pursuant to § 1332 because Ethypharm is a French company, Abbott is an Illinois corporation, and the amount in controversy exceeds $75,000. We have jurisdiction under 28 U.S.C. § 1291.

Our review of the District Court's denial of Abbott's motion to dismiss for lack of standing is plenary. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 206 (3d Cir. 2009). We take as true all the factual allegations in the Complaint and the reasonable inferences that can be drawn from those facts, *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 262 n.27 (3d Cir. 2010), but we disregard legal conclusions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "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." *Sheridan*, 609 F.3d at 262 n.27 (internal quotation marks omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (internal quotation marks omitted).

have been harmed by any anticompetitive conduct here. In short, it lacks antitrust standing.[15]

Standing is a threshold requirement in all actions in federal court. It is moored in the constitutional principle that the judiciary's power only extends to cases or controversies. *See* U.S. Const. art. III, § 2; *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Constitutional standing is "augmented by consideration of prudential limitations." *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 264 (3d Cir. 1998). For plaintiffs suing under federal antitrust laws,[16] one of the prudential limitations is the requirement of

---

[15]Although Abbott did not file a cross-appeal, its standing argument is properly before us because it is "well established that an appellee may, without taking a cross-appeal, support the judgment as entered through any matter appearing in the record, though his argument may attack the lower court's reasoning or bring forth a matter overlooked or ignored by the court." *EF Operating Corp. v. Am. Bldgs.*, 993 F.2d 1046, 1048 (3d Cir. 1993). We have held that antitrust standing "is simply another element of proof for an antitrust claim, rather than a predicate for asserting a claim in the first place." *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 307 (3d Cir. 2011) (en banc), *cert. denied*, 132 S. Ct. 1876 (2012). Thus, by that reasoning, failure to establish antitrust standing is a merits issue properly before us.

[16] Section 4 of the Clayton Act provides the statutory authorization for a private antitrust suit: "[A]ny person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws" may maintain a private action for treble damages." 15 U.S.C. § 15.

"antitrust standing." *W. Penn Power Co.*, 147 F.3d at 264.[17] It does not affect the subject matter jurisdiction of the court, as Article III standing does, but prevents a plaintiff from recovering under the antitrust laws. *Gerlinger v. Amazon.com Inc.*, 526 F.3d 1253, 1256 (9th Cir. 2008).

---

[17] Although not free from debate, we have explained that antitrust standing is based on prudential principles. *See W. Penn Power Co.*, 147 F.3d at 264 ("Thus, the crux of the issue in this case is whether the City satisfies the 'prudential' requirements of standing; that is, does the City have 'antitrust standing,' and is the plaintiff a proper party to bring a private antitrust action?"); *see also Palmyra Park Hosp. Inc. v. Phoebe Putney Mem'l Hosp.*, 604 F.3d 1291, 1299 (11th Cir. 2010) ("To have antitrust standing, a party must do more than meet the basic 'case or controversy' requirement that would satisfy constitutional standing; instead, the party must show that it satisfies a number of prudential considerations aimed at preserving the effective enforcement of the antitrust laws." (internal quotation marks omitted)); *cf.* Erwin Chemerinski, *Federal Jurisdiction* § 2.3.6 (5th ed. 2007) (explaining prudential standing requirement that a plaintiff be within the zone of interest protected by a statute). We have also indicated, however, that, at least in a state law context, antitrust standing is a kind of "statutory standing." *Sullivan*, 667 F.3d at 307 (characterizing state law antitrust claims as involving "statutory standing"). In this case, whether the standing inquiry is characterized as "prudential" or "statutory" makes no difference because neither deprives us of Article III jurisdiction and both bar a plaintiff's ability to recover.

The Supreme Court, in *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519 (1983), articulated several factors to be considered when deciding whether a complainant has antitrust standing. We have organized those factors (the "*AGC* factors") into the following multifactor test:

> (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1165-66 (3d Cir. 1993). The second factor, antitrust injury, "is a necessary but insufficient condition of antitrust standing." *Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 182 (3d Cir. 1997). If it is lacking, we need not address the remaining *AGC factors.*

Generally, antitrust injury – that is, "injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants' acts unlawful,"

Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977) – "is limited to consumers and competitors in the restrained market and to those whose injuries are the means by which the defendants seek to achieve their anticompetitive ends," *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 102 (3d Cir. 2010). Ethypharm, of course, does not claim to be a consumer. Therefore, for Ethypharm to have standing it must be either a competitor in the defined relevant market or it must have suffered such injuries as "are the means by which the defendant[] seek[s] to achieve [its] anticompetitive ends." *Id.*

Abbott contends that Ethypharm fits neither qualification. First, Abbott argues that Ethypharm is not a supplier of Antara in the United States but only an offerer of intellectual property licenses and raw materials, which are not interchangeable with the drug that Abbott offers. Second, Abbott contends that "Ethypharm's alleged injury is not the 'means' by which Abbott" allegedly restrained competition. (Appellee's Br. at 43.) Abbott reasons that it effectuated its allegedly illegal restraint of trade without any need to affect Ethypharm because Abbott needed only to place restrictions on Reliant, the sole United States distributor of Antara.

Ethypharm counters that it produces not just raw materials but a finished drug that directly competes with Abbott's product. According to Ethypharm, the fact that it markets and sells Antara through an exclusive distributor to bring that product to the United States is irrelevant. Thus, Ethypharm argues, its "offering of the manufactured product is reasonably interchangeable with Abbott's offering of TriCor." (Appellant's Reply Br. at 17 (internal quotation marks omitted).) Ethypharm also contends that even if it did

not directly compete with Abbott, it has suffered antitrust injury because the harm caused by Abbott to Ethypharm is "inextricably intertwined with Abbott's alleged wrongdoing." (*Id.* (internal quotation marks omitted).)

In making their arguments about whether Ethypharm and Abbott are competitors in the relevant market, the parties focus on two of our precedents in particular, *Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178 (3d Cir. 1997), and *Carpet Group International v. Oriental Rug Importers Association, Inc.*, 227 F.3d 62 (3d Cir. 2000), *abrogated on other grounds by Animal Sci. Prods., Inc. v. China Minmetals Corp.*, 654 F.3d 462 (3d Cir. 2011).[18] In *Barton & Pittinos*, we determined that a drug marketing company did not have antitrust standing to sue a drug manufacturer after the manufacturer chose to sever its relationship with the marketer. Barton & Pittinos had entered into an agreement with SmithKline to market SmithKline's hepatitis-B vaccine to nursing homes. Barton & Pittinos would solicit orders from nursing homes and pass those orders on to a third party, General Injectables and Vaccines, Inc. ("GIV"), "which would buy the vaccine from [SmithKline] and then resell it to the nursing homes." *Barton & Pittinos*, 118 F.3d at 179. Previously, pharmacists had supplied nursing homes with SmithKline's vaccine, and those

[18]Abbott's argument relies heavily on our non-precedential opinion in *SigmaPharm, Inc. v. Mutual Pharm. Co.*, 454 F. App'x 64 (3d Cir. 2011). We do not address that case, *see* 3d Cir. I.O.P. 5.7 (2010) ("The court by tradition does not cite to its not precedential opinions as authority."), but instead look to the case upon which *SigmaPharm* rests its reasoning, our precedential opinion in *Barton & Pittinos.*

pharmacists complained to SmithKline about the arrangement with Barton & Pittinos. In response to those complaints, SmithKline terminated its arrangement with Barton & Pittinos. Barton & Pittinos then brought suit contending that SmithKline had conspired with the pharmacists to restrain competition in the distribution of the vaccine, in violation of § 1 of the Sherman Act.

We held that Barton & Pittinos had no standing to avail itself of the antitrust laws because it was not a competitor in the market and, accordingly, could not suffer antitrust injury. Speaking for the court, then-Judge Alito reasoned that Barton & Pittinos was essentially an advertiser and not a competitor in the relevant drug market. *Id*. at 182. We first defined the proper market, as Barton & Pittinos had, as "all hepatitis-B vaccine *sold* to nursing homes in the United States." *Id.* at 182 (internal quotation marks omitted). Then, we considered whether Barton & Pittinos was a competitor by determining if there was cross-elasticity of demand between the pharmacists' offerings and Barton & Pittinos's offerings. In analyzing that question, we focused not on the overall marketing program devised by SmithKline, but on what Barton & Pittinos itself offered. That is, Barton & Pittinos offered marketing services but did not have direct access to the vaccine and could not supply the vaccine to nursing homes without GIV. The pharmacists, in contrast, could supply nursing homes directly with the vaccine. Because nursing homes only had indirect access to the vaccine through Barton & Pittinos, "there was no cross-elasticity of demand as between the pharmacists' offerings and [Barton & Pittinos's] offerings; no matter how much the pharmacists raised the price of the package of the goods and

services that they offered, the nursing homes could not have switched to [Barton & Pittinos]." *Id.* at 183.

We concluded that Barton & Pittinos's position as an advertiser made its injury different from the type of injury that the antitrust laws were designed to redress. *See id.* at 184 ("Because [Barton & Pittinos] was thus not a competitor or consumer in the market in which trade was allegedly restrained by the antitrust violations pled by [Barton & Pittinos], we hold that [its] alleged injury is not 'antitrust injury,' meaning injury 'of the type that the antitrust statute was intended to forestall.'" (quoting *Associated Gen. Contractors*, 459 U.S. at 540)). Barton & Pittinos thus lacked antitrust standing.

In contrast to *Barton & Pittinos*, we concluded in *Carpet Group International* that a plaintiff did have antitrust standing. *Carpet Grp. Int'l*, 227 F.3d at 78. In that case, Carpet Group International sought to provide a direct link between oriental rug manufacturers and domestic retailers, cutting out middlemen wholesalers, who were united by a trade group, the Oriental Rug Importers Association. Carpet Group International bypassed the wholesalers by inviting manufacturers and retailers to trade shows where the retailers could buy directly from the manufacturers. Carpet Group International also organized buying trips where the retailers could go abroad to see and directly purchase rugs. Oriental Rug Importers responded by, among other tactics, threatening not to buy from any manufacturer who attended a trade show or sold directly to a retailer during a buying trip. Those actions prompted Carpet Group International to bring an antitrust action.

Oriental Rug Importers relied on *Barton & Pittinos* to argue that Carpet Group International did not have antitrust standing. We noted, however, that Carpet Group International's role in the oriental rug market was different from Barton & Pittinos's role in the relevant drug market. Barton & Pittinos, as an unlicensed entity, could not supply drugs to consumers, but, in contrast, Carpet Group International and Oriental Rug Importers could and did offer the exact same service to consumers – a way to procure rugs from manufacturers. "In other words, there [was] a cross-elasticity of demand between the plaintiffs' offering and the defendants' offering." *Id.* at 77; *see id.* ("If the wholesaler/importers raised the prices at which they sold oriental rugs to domestic retailers, those retailers could go to [Carpet Group International's] trade shows and purchase rugs there directly from manufacturers."). Thus, the injury that Carpet Group International claimed to have suffered was an antitrust injury.

As one might expect, Abbott contends that this case is controlled by *Barton & Pittinos*, and Ethypharm says it is not and that *Carpet Group* is the pertinent authority. Although this is a closer case than *Barton & Pittinos* because Ethypharm does manufacture a product ultimately sold in the relevant market, we think Abbott has the better of the arguments. Ethypharm is not a competitor because, in the highly regulated pharmaceutical market in this country, there is no cross-elasticity of demand between Ethypharm's offerings and Abbott's offerings. In this case, as in *Barton & Pittinos*, customers in the United States cannot purchase the drug at issue from Ethypharm. Ethypharm structured its business in a way that assured that only Reliant or someone to whom Reliant sold the rights to Antara could supply the drug.

Ethypharm has chosen, for reasons sufficient to itself, not to seek the necessary approval to sell pharmaceuticals in the United States.[19] It is thus forbidden to compete in the relevant market. Because of its choice to leave to an exclusive licensee the responsibility of obtaining FDA approval for Antara and of selling and marketing that drug in the United States, there is no cross-elasticity of demand between what Ethypharm can lawfully offer, *i.e.*, bulk drug sales from outside the United States to an FDA-approved entity, and what Abbott offers, a finished pharmaceutical product within the United States.

Indeed, Ethypharm's own Complaint defines the relevant market in this case as the sale of fenofibrate products in the United States. (J.A. at 143 ("For purposes of this Complaint, the relevant geographic market is the United States. The relevant product market is products containing fenofibrate.").) When looking through that market lens, Ethypharm does not and cannot compete with Abbott. Similar to Barton & Pittinos, Ethypharm, on its own, cannot directly supply the United States market with the drug in question. *See Barton & Pittinos*, 118 F.3d at 180 (recognizing that Barton & Pittinos "lacked the required [regulatory] license to … sell the vaccine"). It did not enter the United States market and receive the required FDA approval to market Antara; Reliant alone obtained that approval. *Cf.* 21 U.S.C. § 355(a) (requiring pharmaceutical

[19] Not only did Ethypharm choose not to initially enter the United States market with Antara, it passed on a second opportunity to do so when it declined to exercise its right of first refusal at the time Reliant transferred its rights in Antara, complete with the approved NDA.

companies to obtain FDA approval before marketing prescription drugs). In fact, as Ethypharm explained in its Complaint, that was its entire business plan:

> While Ethypharm develops, formulates, and manufactures its fenofibrate product for sale in the United States, it does not directly sell and distribute this product in this country. Instead, Ethypharm sought a business partner who would enter into an agreement to: license Ethypharm's underlying patent and intellectual property rights; obtain U.S. regulatory approval for the product; and market the product in the U.S.

(J.A. at 113.) And without a license of its own, Ethypharm admits that it "would be foreclosed from the United States market." (J.A. at 122.) Therefore, just like the pharmacists' ability to raise prices of the vaccine in *Barton & Pittinos* and the nursing homes' inability to procure that vaccine directly from Barton & Pittinos, Abbott could raise the price of TriCor and consumers could not turn to Ethypharm for Antara.

Ethypharm argues, and the District Court appeared to agree, that "Reliant's role as the holder of the Antara NDA makes no difference" with respect to the antitrust injury inquiry. (Appellant's Reply Br. at 17.) We disagree; Ethypharm's inability to participate in the United States fenofibrate market makes all the difference. Contrary to Ethypharm's contention, Reliant was not a mere conduit in bringing Antara to market. Reliant was the entity that took the risk and bore the expense of filing the NDA and gaining FDA approval. The FDA carefully regulates the

pharmaceutical industry and imposes stringent requirements on entities seeking to sell drugs in the United States. *See generally* 21 U.S.C. § 355 (describing requirements for NDA approvals); *id.* § 393 (establishing the FDA and providing its scope). It is that high legal barrier to entry, specific to the United States pharmaceutical market, that differentiates this case from others in which a manufacturer has a legal right to sell a good in the United States but chooses to utilize an exclusive distributor.

Ethypharm wants to have it both ways: it wants to pass on to a licensee the expense and risk of qualifying to compete in the United States pharmaceutical market, but, when that arrangement fails to achieve success, Ethypharm seeks to avail itself of the United States laws protecting fair competition. The rules of antitrust standing do not permit that tactic. We stress that it is not the general arrangement of manufacturer and distributor that is problematic; it is the fact that Ethypharm cannot sell Antara in the United States because of legal barriers particular to the pharmaceutical market, barriers that Ethypharm chose not to surmount. Ethypharm is literally not a lawful competitor in the United States fenofibrate market, and so it cannot be considered a competitor for purposes of antitrust injury.[20]

---

[20] Ethypharm cites a district court case, *Chemi SpA v. GlaxoSmithKline*, 356 F. Supp. 2d 495 (E.D. Pa. 2005), in support of its position that it has antitrust standing. That decision, however, fails to consider *Barton & Pittinos* under the antitrust injury prong of antitrust standing. It also appears to rest its decision on the "inextricably intertwined" theory of antitrust injury, which we conclude is lacking in this case, *see infra*. In addition, the plaintiff in that case, a foreign drug manufacturer, filed a Drug Master File with the FDA and "set

Ethypharm also argues that even if it is not a competitor in the United States fenofibrate market, it suffered antitrust injury because its injury is "inextricably intertwined" with Abbott's conduct such that Ethypharm's "injuries are the means by which the defendants seek to achieve their anticompetitive ends." *W. Penn Allegheny Health*, 627 F.3d at 102. In *Gulfstream III Associates, Inc. v. Gulfstream Aerospace Corp.*, we recognized the "inextricably intertwined" exception to the usual requirement that an antitrust plaintiff be either a competitor or consumer. 995 F.2d 425, 429 (3d Cir. 1993).[21] There, we stated that antitrust

---

forth other required information for FDA approval" of its drug. *Id.* at 497. Therefore, the plaintiff's involvement in the FDA approval process distinguishes *ChemiSpA* from this case.

[21] The "inextricably intertwined" antitrust injury originated in *Blue Shield of Virginia v. McCready*, 457 U.S. 465 (1982). There, the Court recognized that antitrust injury may be suffered by those other than competitors when the "injury alleged is so integral an aspect" of the alleged anticompetitive conduct that "the loss was precisely the type of loss that the claimed violations ... would be likely to cause." *Id.* at 479 (omission in original) (internal quotation marks omitted). It went on to conclude that that test had been met because "the injury [the plaintiff] suffered was inextricably intertwined with the injury the conspirators sought to inflict." *Id.* at 484. Thus, an "inextricably intertwined" antitrust injury is limited to plaintiffs "whose injuries are the essential means by which defendants' illegal conduct brings about its ultimate injury to the marketplace."

injury occurs if "there exists a 'significant causal connection' such that the harm to the plaintiff can be said to be 'inextricably intertwined' with the antitrust conspiracy." *Id.* at 429; *see also Carpet Group*, 227 F.3d at 77 (concluding there was antitrust injury because of inextricable intertwinement). Since that time, however, we have not extended the "'inextricably intertwined' exception beyond cases in which both plaintiffs and defendants are in the business of selling goods or services *in the same relevant market*," though they may not directly compete against each other. *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 320-21 (3d Cir. 2007) (emphasis added). Thus, Ethypharm's argument that its injuries are inextricably intertwined with Abbott's conduct – that is, the "injuries are the means by which [Abbott] seek[s] to achieve [its] anticompetitive ends," *W. Penn Allegheny Health*, 627 F.3d at 102 – fails for the same reason its argument that it is a competitor fails: Ethypharm itself, by its own choice, is not in the United States fenofibrate market.

Accordingly, we conclude that Ethypharm did not suffer antitrust injury because it does not and indeed cannot compete in the United States fenofibrate market, unless and until it acquires the required FDA approval to do so. As a result, Ethypharm lacks antitrust standing to sue Abbott.[22]

IIA Philip E. Areeda, *et al.*, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 339, at 123 (3d ed. 2007).

[22] Because we conclude that Ethypharm did not suffer antitrust injury, we do not address any of the other *AGC* factors in the antitrust standing analysis. Nor do we reach the

IV. Conclusion

For the reasons above, we will vacate the grant of summary judgment as to Ethypharm's federal claims, leave undisturbed the grant of summary judgment as to Ethypharm's state law claims, and remand the case to the District Court to dismiss the federal claims for lack of standing.

---

issue of whether the District Court erred in its analysis of the merit of Abbott's motion for summary judgment.