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TAKING A STAND ON STANDING: THE THIRD CIRCUIT WIDENS THE CIRCUIT SPLIT BY NARROWING PRIVATE ANTITRUST STANDING UNDER THE "CONSUMER-OR-COMPETITOR" TEST

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"Every violation of the antitrust laws is a blow to the free-enterprise system envisaged by Congress. This system depends on strong competition for its health and vigor, and strong competition depends, in turn, on compliance with antitrust legislation. In enacting these laws, Congress had many means at its disposal to penalize violators. . . . [but] Congress chose to permit all persons to sue to recover three times their actual damages every time they were injured in their business or property by an antitrust violation."[1]

I. INTRODUCTION: THE ABOLISHMENT OF ANTICOMPETITIVE BEHAVIOR VIA ANTITRUST LAWS

One of the founding principles of the United States has been the promotion of a strong, competitive market.[2] To accomplish this goal, Congress enacted the Sherman Antitrust Act and the Clayton Act in 1890 and 1914, respectively.[3] Under Section 4 of the Clayton Act, private parties who have been harmed by another's anticompetitive behavior may sue

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1. Hawaii v. Stand. Oil Co., 405 U.S. 251, 262 (1972) (citation omitted).

2. *See id. See generally* THOMAS D. MORGAN, CASES AND MATERIALS ON MODERN ANTITRUST LAW AND ITS ORIGINS 9–18 (5th ed. 2014) (discussing how truly competitive market will result in goods being produced at highest quality and lowest cost possible, thus benefiting consumers).

3. *See* Sherman Antitrust Act, ch. 647, 26 Stat. 209 (codified as amended at 15 U.S.C. §§ 1–7 (2012)); Clayton Act, ch. 323, § 7, 38 Stat. 730 (current version at 15 U.S.C. §§ 12–27, 29 U.S.C. §§ 52–53 (2012)). The Sherman Antitrust Act decrees, "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." Sherman Antitrust Act § 1. The congressional intent of the Sherman Act is shrouded with uncertainty because, at the time of its enactment, members of Congress held differing opinions as to its necessity. *See* MORGAN, *supra* note 2, at 25–28 (discussing various theories concerning congressional intent of Sherman Act). A significant number of congressmen, including Senator Sherman, viewed the Sherman Act as an attempt to protect consumers. *See id.* at 26 (quoting Congressman Sherman who stated that Sherman Act sought to "prevent . . . combinations made with a view . . . to increase the profits of the producer at the cost of the consumer" (internal quotation marks omitted)).

for treble damages.[4] Because the plain language of Section 4 states "*any* person who shall be injured . . . shall recover," seemingly the only qualification imposed by the statute itself is that a party seeking recovery must have actually been injured.[5] However, the Supreme Court and the federal appellate courts have read implicit limitations into Section 4, holding that only certain injured parties have the proper standing to obtain recompense.[6]

The road to determining which private parties have standing to bring a claim pursuant to the Clayton Act has been fraught with uncertainty, as the circuit courts have employed a variety of incongruous tests.[7] Notably, the Third Circuit has adopted a comparatively strict and relatively inflexible "consumer-or-competitor" standard for evaluating antitrust standing.[8] Recently, the Third Circuit once again narrowed this already restrictive standard in *Ethypharm S.A. France v. Abbott Laboratories*,[9] where the court held that a manufacturer of a fenofibrate drug did not have standing to bring suit against a dual manufacturer and distributor of a similar fenofibrate drug.[10] The decision is representative of the Third Circuit's inflexible and constricted approach to standing issues and has further widened the circuit split over the appropriate test for antitrust standing.[11]

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4. Clayton Act, 15 U.S.C. § 15(a) (emphasis added) ("[A]ny person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue . . . and shall recover threefold the damages by him sustained . . . .").

5. *See id.* The right to privately enforce antitrust violations, which is provided by the Clayton Act, is highly significant. *See* David Gregory Mayhan, Note, *More Trouble with Treble: The Effects of* McCready *and* Associated General Contractors *on the Antitrust Standing Opinions of the Federal Courts of Appeals*, 10 J. CORP. L. 463, 464 (1985) (explaining that in 1982, United States government filed 111 antitrust actions, while private parties filed 1,037 antitrust cases).

6. Blue Shield v. McCready, 457 U.S. 465, 477 (1982) (explaining limit to Clayton Act violator's liability notwithstanding "broad" language of Section 4 (internal quotation marks omitted)). The Supreme Court has interpreted Section 4 of the Clayton Act to mean that the right to treble damages does not extend to people "tangentially affected by an antitrust violation" in order to reduce the "risk of duplicative recovery." *See id.* at 474–77 (summarizing Supreme Court precedent concerning boundaries of Section 4 standing).

7. For a discussion of the development of antitrust standing and the varying tests that the Supreme Court and federal circuits have historically used, see *infra* notes 22–41 and accompanying text.

8. *See, e.g.*, C. Douglas Floyd, *Antitrust Victims Without Antitrust Remedies: The Narrowing of Standing in Private Antitrust Actions*, 82 MINN. L. REV. 1, 26 (1997) (describing consumer-or-competitor approach as much "too narrow" interpretation of standing).

9. 707 F.3d 223 (3d Cir. 2013) (*Ethypharm III*).

10. For a discussion on the Third Circuit's most recent antitrust standing analysis, see *infra* notes 64–93 and accompanying text.

11. *See, e.g.*, Petition for a Writ of Certiorari at 14, SigmaPharm, Inc. v. Mut. Pharm. Co., 454 F. App'x 64 (3d Cir. 2011) [hereinafter SigmaPharm Cert. Petition], 2012 WL 1419939, at *15, 23, *cert. denied*, 133 S. Ct. 110 (2012) (No. 11-1275) (stating that there is "long standing" circuit split concerning antitrust standing, as only Third, Fifth, and Eighth Circuits have limited private antitrust standing to

This Casebrief discusses both the development and inner-workings of the Third Circuit's consumer-or-competitor standing test and serves as a guide to practitioners hoping to bring private party antitrust claims in the Third Circuit.[12] Part II discusses the development of differing antitrust standing tests in the federal circuits and specifically focuses on the development of the Third Circuit's consumer-or-competitor test.[13] Part III discusses the recent decision in *Ethypharm* and highlights how this decision has made it more difficult to qualify as a competitor under the consumer-or-competitor test.[14] Part IV then addresses the potential impact of this decision within the pharmaceutical industry.[15] Part V gives guidance to practitioners who wish to either bring private antitrust claims in the Third Circuit or structure distributor relationships while still maintaining their client's Section 4 private right to action.[16]

Ultimately, this Casebrief emphasizes how the Third Circuit has abandoned its traditional definition of a "competitor" under the consumer-or-competitor test in favor of a much more restrictive definition, thereby limiting the number of potential private antitrust plaintiffs.[17] Although the Third Circuit asserted that its decision in *Ethypharm* was based on its traditional "competitor" analysis, this Casebrief argues the Third Circuit has moved towards a stricter formulation of what constitutes a competitor and aims to aid practitioners in light of this development.[18]

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consumers or competitors); *see also* Marie L. Fiala et al., *Third Circuit Applies "Consumer-or-Competitor" Rule to Deny Antitrust Standing to Foreign Manufacturer of Drug Marketed in U.S. by Licensee*, ANTITRUST UPDATE (Sidley Austin LLP, Chicago, Ill.), Feb. 13, 2013, at 1, *available at* http://www.sidley.com/~/media/files/news/2013/02/third-circuit-applies-consumerorcompetitor-rule-__/files/view-update-in-pdf-format/fileattachment/antitrust-update-21313-as-of-2pm-final.pdf [http://perma.cc/V7AC-JZPG] (asserting that decision in *Ethypharm* has "reinforced" Third Circuit's consumer-or-competitor stance on antitrust standing).

12. *See infra* notes 19–118 and accompanying text.

13. *See infra* notes 19–41 and accompanying text (discussing development of antitrust standing pursuant to Section 4 of Clayton Act in federal circuits generally); *see also infra* notes 42–63 and accompanying text (discussing development of Section 4 standing and consumer-or-competitor test in Third Circuit).

14. *See infra* notes 64–93 and accompanying text (discussing Third Circuit's decision in *Ethypharm*).

15. For a discussion of how *Ethypharm* has essentially redefined who constitutes a competitor under the consumer-or-competitor test, see *infra* notes 94–131. For a discussion of the United States pharmaceutical industry's unique distribution chain and how the Third Circuit's decision will disproportionately affect standing in the pharmaceutical industry, see *infra* notes 132–45 and accompanying text.

16. *See infra* notes 132–45 and accompanying text (advising practitioners that represent pharmaceutical manufacturers to structure their distribution chains as "agency relationships" to maintain Section 4 standing).

17. *See infra* notes 94–131 and accompanying text (discussing impact of Third Circuit's altered definition of competitor on future antitrust litigation).

18. *See infra* notes 132–40 and accompanying text (discussing how practitioners can adapt their strategies in response to Third Circuit's decision in *Ethypharm*).

II. BACKGROUND: THE ADVANCEMENT OF ANTITRUST STANDING IN FEDERAL COURTS

The substantial number of private antitrust claims brought each year demonstrates the significance of standing under Section 4 of the Clayton Act.[19] Consequently, this Section offers a succinct overview of how the Supreme Court has construed Section 4 thus far and how the federal circuits have subsequently interpreted these decisions.[20] This Section also specifically details the evolution of antitrust standing in the Third Circuit.[21]

A. *The Supreme Court's Stance on Standing*

The Supreme Court addressed the issue of private standing under the Clayton Act in *Blue Shield v. McCready*[22] and *Associated General Contractors, Inc. v. California State Council of Carpenters*[23] in 1982 and 1983, respectively.[24] Prior to these decisions, the federal circuits had employed a number of different tests to determine whether a party had proper standing pursuant to Section 4.[25] In *McCready*, the Supreme Court held that a "group health plan" subscriber had standing under the Clayton Act to bring suit against a health insurer and a Virginia psychiatrist organiza-

19. *See* 2 SPENCER WEBER WALLER & ANDRE FIEBIG, ANTITRUST AND AMERICAN BUSINESS ABROAD § 13:19 (3d ed. 2014) (describing "major role" that private actions play in antitrust prosecution); Mayhan, *supra* note 5, at 464 (noting comparatively large number of private antitrust actions).

20. For a discussion of the Supreme Court's cases interpreting Section 4 of the Clayton Act, see *infra* notes 22–31 and accompanying text. For a discussion of the federal circuits' differing understandings of the Supreme Court's cases concerning standing, see *infra* notes 32–41 and accompanying text.

21. *See infra* notes 42–64 and accompanying text.

22. 457 U.S. 465 (1982).

23. 459 U.S. 519 (1983).

24. *See Associated General*, 459 U.S. at 521, 537–45 (setting out multifactor balancing test for determining standing under Section 4); *McCready*, 457 U.S. at 478 (setting out two-factor test for determining antitrust standing under Section 4).

25. *See* Mayhan, *supra* note 5, at 467–76 (explaining incongruous standing tests that federal circuits had deployed prior to *McCready* and *Associated General*). The prior tests included the "'direct injury' test, the 'target area' test, [ ] the 'zone of interests' test[ ] [and the] 'balancing'" test. *See id.* at 468 (footnotes omitted); *see also* Daniel Berger & Roger Bernstein, *An Analytical Framework for Antitrust Standing*, 86 YALE L.J. 809, 813–45 (1977) (discussing application of varying standing tests in federal circuits); David L. Swider, Note, *Standing to Sue in Private Antitrust Litigation: Circuits in Conflict*, 10 IND. L. REV. 532, 535–52 (1977) (tracing distinct development of standing tests in every circuit). *See generally* Malamud v. Sinclair Oil Corp., 521 F.2d 1142, 1151–52 (6th Cir. 1975) (applying zone of interests test, which granted standing to plaintiffs who were in "zone of interests protected" by antitrust acts); Calderone Enters. Corp. v. United Artists Theatre Circuit, Inc., 454 F.2d 1292, 1296 (2d Cir. 1971) (applying target area test, which granted standing to plaintiffs who were in target area or were "target of any antitrust violation"); Loeb v. Eastman Kodak Co., 183 F. 704, 709 (3d Cir. 1910) (applying direct injury test, which granted standing to plaintiffs who could show that they were directly injured by alleged antitrust violations).

tion.[26] In reaching this decision, the Supreme Court reasoned that Section 4 granted a non-restrictive approach to standing and explained, "[t]he statute does not confine its protection to consumers, or to purchasers, or to competitors, or to sellers. . . . Consistent with the congressional purpose, we have refused to engraft artificial limitations on the § 4 remedy."[27]

However, only one year later, the Supreme Court retreated from this broad interpretation of Section 4 standing in *Associated General*.[28] In denying standing to a labor union that sought damages from a contractor's association, the Supreme Court was quick to state that, despite the broad language of Section 4, Congress intended the courts to "delineate" the proper bounds of it.[29] To determine if a party had standing, the Court endorsed a multifactor-balancing test.[30] Because the labor union was not a consumer or competitor in the relevant marketplace, the Court noted this weighed against the union's standing claim.[31]

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26. *McCready*, 457 U.S. at 477–78, 485, 489 (determining standing using two-factor test that focused on (1) "nexus between the alleged violation and the harm" suffered and (2) whether Congress intended for defendant's conduct to be covered under Section 4). The case concerned an employee of a Virginia county who, pursuant to her employment contract, was provided with health coverage under Blue Shield of Virginia. *See id.* at 467–68. Under the plan, psychiatric treatment for mental disorders was reimbursed, but psychological treatment was not. *See id.* at 468. Subsequently, the plaintiff brought a class action suit against Blue Shield, claiming it had violated the Sherman Act by conspiring to "boycott clinical psychologists from receiving compensation under the Blue Shield plans." *See id.* at 468–70 (internal quotation marks omitted).

27. *Id.* at 472 (alterations in original) (quoting Mandeville Island Farms, Inc. v. Am. Crystal Sugar Co., 334 U.S. 219, 236 (1948)) (internal quotation marks omitted). The Supreme Court also relied on principles of statutory interpretation, which call for statutes to be read in light of their "plain language" in the absence of any contrary policy consideration. *See id.* at 473.

28. *See* Floyd, *supra* note 8, at 26–28 (discussing narrowing of private antitrust standing under *Associated General*); Mayhan, *supra* note 5, at 476 ("It is clear that *Associated General Contractors* has adopted a more restrictive test for granting antitrust standing than *McCready*."); *see also* Robert P. Taylor, *Antitrust Standing: Its Growing—or More Accurately Its Shrinking—Dimensions*, 55 ANTITRUST L.J. 515, 519–22 (1986) (discussing *Associated General*'s significant restriction of Section 4 antitrust standing).

29. *See Associated General*, 459 U.S. at 531 ("One problem presented by the language of § 1 of the Sherman Act is that it cannot mean what it says." (quoting Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 687 (1978)) (internal quotation mark omitted)); *see also* Nat Stern & Kevin B. Getzendanner, *Gauging the Impact of* Associated General Contractors *on Antitrust Standing Under Section 4 of the Clayton Act*, 20 U.C. DAVIS L. REV. 159, 176 (1986) (noting *Associated General*'s "restrictive" effect on private antitrust standing).

30. *See Associated General*, 459 U.S. at 536–46 (discussing relevant factors in denying standing); Mayhan, *supra* note 5, at 473 (listing different factors Court weighed).

31. *See Associated General*, 459 U.S. at 539 (explaining relevance that labor union was "neither a consumer nor a competitor"). The case involved a labor union comprised of carpenters and a general contractor association. *See id.* at 521–23. The labor union brought suit against the contractor association, alleging

B. *The Federal Circuits Stand Up: Interpreting* McCready *and* Associated General

Given the divergent standards set out in *McCready* and *Associated General*, the federal circuits have been unable to institute a uniform approach to determine standing under Section 4.[32] The Second Circuit initially interpreted the balancing test in *Associated General* to be a mere complement to the two-pronged *McCready* test and thus analyzed standing cases with a primary focus on *McCready*.[33] Notably, the Second Circuit declared that a plaintiff may have Section 4 standing despite being neither a consumer nor a competitor, because holding otherwise would be contrary to *Associated General* and *McCready*.[34] The Tenth Circuit also explicitly endorsed the view that pursuant to *McCready*, plaintiffs could have Section 4 standing even if they were not consumers or competitors in the relevant marketplace.[35]

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that the contractor association had violated antitrust laws by conspiring to deny the labor union the ability to "enter into collective bargaining agreements" with other contractors. *See id.* at 522 n.2 (internal quotation marks omitted). However, the Court determined that the labor union "was neither a consumer nor a competitor in the market in which trade was restrained" and therefore was "not a person injured by reason of a violation of the antitrust laws within the meaning of § 4 of the Clayton Act." *See id.* at 539, 546.

32. *See* Mayhan, *supra* note 5, at 478–82 (explaining how Supreme Court's decisions have engendered incongruent results in federal circuits). One hypothesis for the inconsistent results in the circuits is that although the two cases utilize extremely different balancing tests, the Court in *Associated General* did not explicitly overrule *McCready*. *See id.* at 474. Nor did the Supreme Court explicitly state that the *Associated General*'s test should be used in place of the federal circuits' prior standing tests, which led to some federal circuits creating fusion tests. *See id.* at 491. The circuits have also chosen to "emphasize different factors" in the Supreme Court's balancing test, which has further promoted contrasting results. *See id.* at 479; *see also* Ronald W. Davis, *Standing on Shaky Ground: The Strangely Elusive Doctrine of Antitrust Injury*, 70 ANTITRUST L.J. 697, 699 (2003) (reviewing Supreme Court and federal circuits' antitrust standing tests and describing then-current state of private antitrust actions); Kevin D. Gordon, *Private Antitrust Standing: A Survey and Analysis of the Law After* Associated General, 61 WASH. U.L.Q. 1069, 1072 (1984) (describing tests that circuits have employed post *McCready* and *Associated General*).

33. *See* Crimpers Promotions Inc. v. Home Box Office, Inc., 724 F.2d 290, 293, 293–97 (2d Cir. 1983) (explaining that "*Associated General* indicates no departure from *McCready* in any fashion pertinent to this case" and applying *McCready* test first before addressing factors in *Associated General*); *see also* SigmaPharm Cert. Petition, *supra* note 11, at 15 (quoting *Crimpers* to illustrate problems associated with circuit split on consumer-or-competitor test). *But see* Meijer, Inc. v. Ferring B.V. (*In re* DDAVP Direct Purchaser Antitrust Litig.), 585 F.3d 677, 687–88 (2d Cir. 2009) (utilizing two-part standing test that favors many of factors from *Associated General*).

34. *See Crimpers*, 724 F.2d at 297 (explaining lack of consumer-or-competitor status should not bar Section 4 standing).

35. *See* Reazin v. Blue Cross & Blue Shield, Inc., 899 F.2d 951, 963 (10th Cir. 1990) (explaining Supreme Court held consumer-or-competitor status unnecessary for standing).

Furthermore, in *Novell, Inc. v. Microsoft Corp.*,[36] the Fourth Circuit specifically denounced the practice of using the consumer-or-competitor test as an absolute bar to antitrust standing.[37] In *Novell*, a software company brought suit against Microsoft for alleged antitrust violations, which included an allegation that Microsoft had harmed competition in the operating systems market.[38] In holding that the plaintiff had standing, the Fourth Circuit stated that in *Associated General*, the Supreme Court had disavowed a bright-line determinative approach.[39] The Fourth Circuit summarily concluded that a plaintiff's status as a non-consumer and non-competitor was a relevant but non-dispositive factor in addressing standing.[40] However, other circuits, including the Third, Fifth, and Eighth Circuits, have interpreted *Associated General* as standing for the proposition that an antitrust plaintiff *must* be a consumer or a competitor in the relevant marketplace to have standing.[41]

C. *Embracing the Consumer-or-Competitor Test: The Evolution of Standing in the Third Circuit Post-*McCready *and* Associated General

In 1997, the Third Circuit adopted the consumer-or-competitor test in *Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co.*[42] The

36. 505 F.3d 302 (4th Cir. 2007).

37. *See id.* at 311 (rejecting defendant's position that plaintiff must be consumer-or-competitor to have standing and explaining that this "bright-line" rule does not adhere to prior precedent); *see also* Neal R. Stoll & Shepard Goldfein, *Standing: Rejecting a 'Consumer-or-Competitor' Rule*, 239 N.Y. L.J., Apr. 15, 2008, *available at* http://www.skadden.com/sites/default/files/publications/Publications1388_0.pdf [http://perma.cc/4NFH-WKK6] (explaining that Fourth Circuit in *Novell* had declined to accept consumer-or-competitor rule as governing principle in standing cases).

38. *See Novell*, 505 F.3d at 306–07 (describing facts of case); *see also* Stoll & Goldfein, *supra* note 37 (describing fundamentals of case and claims brought against defendant Microsoft).

39. *See Novell*, 505 F.3d at 310–13 (dismissing defendant's argument that plaintiff lacks standing simply because it is neither consumer nor competitor in PC operating system market and predicating dismissal on *Associated General* decision).

40. *See id.* at 312–13 (holding that being consumer or competitor was not "necessary prerequisite" to finding proper standing under Section 4).

41. *See, e.g.*, Norris v. Hearst Trust, 500 F.3d 454, 467 (5th Cir. 2007) (holding plaintiff lacked standing pursuant to *McCready* because it was neither consumer nor competitor); S.D. Collectibles, Inc. v. Plough, Inc., 952 F.2d 211, 213 (8th Cir. 1991) (same). The Eighth Circuit has similarly interpreted *Associated General* to mean standing is limited to "actual market participants, that is, competitors or consumers." *See id.* at 213.

42. 113 F.3d 405 (3d Cir. 1997). In adopting this bright-line rule, the Third Circuit did not justify its reasoning under *Associated General* or *McCready*. *See id.* (neglecting to reference *McCready* or *Associated General* in its opinion). Instead, the Third Circuit simply followed the Ninth Circuit's adoption of the consumer-or-competitor standard. *See id.* at 415 (adopting standard announced in Vinci v. Waste Mgmt., Inc., 80 F.3d 1372 (9th Cir. 1996)). If a plaintiff is considered to be a competitor or a consumer, the Third Circuit will weigh the other *Associated General* factors to determine if the plaintiff has standing. City of Pittsburgh v. W. Penn Power Co., 147 F.3d 256, 265 (3d Cir. 1998). Thus, under the

definitions of competitor and the relevant marketplace were further refined in *Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*[43] and *Carpet Group International v. Oriental Rug Importers Ass'n.*[44]

In *Barton & Pittinos*, the Third Circuit addressed the definition of a competitor within the consumer-or-competitor test by focusing on the cross-elasticity of a company's products.[45] The plaintiff, a pharmaceutical marketing company, entered into an agreement with the defendant, a pharmaceutical company.[46] Under the agreement, the plaintiff would market and obtain orders of the defendant's hepatitis B vaccine, and then have a licensed medical supply house fill the orders.[47] However, the defendant-pharmaceutical company halted the agreement after pharmacists, who had previously solicited *and* filled orders for the vaccine, complained.[48] The plaintiff brought suit against the defendant for alleged antitrust violations, predicating standing on the fact that even though it was a marketing company, it nonetheless functioned as the pharmacists' competitor in the pharmaceutical industry.[49]

The Third Circuit stated that to qualify as competitors in the relevant marketplace, there must be cross-elasticity of demand, meaning the products in the market must be "reasonably interchangeable" goods.[50] In other words, companies were considered competitors if an increase in product *A*'s prices caused consumers to buy product *B*.[51] The court ulti-

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Third Circuit's view, consumer or competitor status is a prerequisite for Section 4 standing. *See id.*

43. 118 F.3d 178 (3d Cir. 1997) (defining competitor).

44. 227 F.3d 62 (3d Cir. 2000) (expanding on *Barton & Pittinos* court's definition of competitor), *overruled on other grounds by* Animal Sci. Prods., Inc. v. China Minmetals Corp., 654 F.3d 462 (3d Cir.), *as amended* (Oct. 7, 2011).

45. *See Barton & Pittinos*, 118 F.3d at 182 (comparing plaintiff's product with pharmacist's product to determine if they were "reasonably interchangeable").

46. *See id.* at 178–80 (stating facts of case).

47. *Id.* (same).

48. *See id.* (noting actions leading up to lawsuit).

49. *See id.* at 180–81 (discussing procedural posture of case).

50. *See id.* at 182–83 (defining relevant marketplace of defendant-pharmacist's product in terms of cross-elasticity of demand and discussing cross-elasticity of products); *see also* M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 633, 657 (2003) (describing cases in pharmaceutical industry that define relevant industry in terms of "reasonab[ly] interchangeability" of products (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962)) (internal quotation marks omitted)).

51. *See* 1 JOHN J. MILES, HEALTH CARE AND ANTITRUST LAW § 2:4 (2014) (referencing all cases that have defined relevant product market and cross-elasticity in terms of "substitutability" and using generic "product *A*" and "product *B*" to illustrate these points); *see also Barton & Pittinos*, 118 F.3d at 182–83 (analyzing whether consumers would turn to plaintiff's product if defendant's offering increased in price).

Delineating the relevant marketplace by cross-elasticity has been endorsed by the Supreme Court and widely followed by the federal circuits. *See, e.g.*, United States v. E. I. du Pont de Nemours & Co., 351 U.S. 377, 392–95 (1956) (stating other wrapping producers were competitors with cellophane producers if consummately found there was no cross-elasticity of the plaintiff's and the pharmacists' products.[52] First, as a marketing company, the plaintiff did not offer the same products or services as the pharmacists; the plaintiff's product was its marketing program for the defendant's hepatitis vaccine, while the pharmacy's product was the drug itself.[53] Second, the court also found "no matter how much" the defendant's vaccine prices rose, consumers of the vaccine would not turn to the plaintiff's marketing as a substitute product.[54] Thus, the court held that there was no cross-elasticity of demand, and consequently the plaintiff was not a competitor within the meaning of Section 4 of the Clayton Act.[55]

In *Carpet Group*, the Third Circuit employed the definition of competitor it had first established in *Barton & Pittinos*.[56] The plaintiff was a corporation formed with the intention of connecting United States rug retailers with foreign rug manufacturers, thus cutting out the wholesaler-middleman.[57] In response to this, a carpet wholesaler trade association initiated group boycotts against manufacturers who did business with the plaintiff.[58] The plaintiff subsequently brought suit against the trade association for antitrust violations.[59]

The court decided the plaintiff was the defendant's competitor because its product's avenue of distribution was a reasonably interchangea-

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ers would switch from cellophane to wrapping products in response to cellophane prices increase); Geneva Pharms. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 496 (2d Cir. 2004) (holding Coumadin and generic warfarin did not compete with one another because consumers would not switch to generic warfarin if Coumadin's prices rose); United Farmers Agents Ass'n v. Farmers Ins. Exch., 89 F.3d 233, 236 n.3 (5th Cir. 1996) (defining relevant market place by cross-elasticity of demand, which measures consumers' willingness to switch to product *B* if product *A*'s prices rise (citing WILLIAM J. BAUMOL & ALAN S. BLINDER, ECONOMICS: PRINCIPLES AND POLICY 343 (6th ed. 1979))).

52. *See Barton & Pittinos*, 118 F.3d at 182–83 (holding no cross-elasticity of demand between plaintiff's and defendant's services).

53. *See id.* (describing services plaintiff and defendant offered).

54. *See id.* (explaining cross-elasticity occurs if, after competitor raises prices for its good, consumer turns to substitute source to receive good).

55. *See id.* at 184 (bolstering holding by providing examples of circuit courts that have held "advertisers and brokers of a good or service are not competitors of companies that actually supply the good or service" (citing Bodie-Rickett & Assocs. v. Mars, Inc., 957 F.2d 287, 290–91 (6th Cir. 1992) and S.D. Collectibles, Inc. v. Plough, Inc., 952 F.2d 211, 213 (8th Cir. 1992))).

56. *See* Carpet Grp. Int'l v. Oriental Rug Imps. Ass'n, 227 F.3d 62, 76–78 (3d Cir. 2000) (comparing case's facts to *Barton & Pittinos*'s facts and analyzing whether plaintiff was competitor pursuant to test laid out in *Barton & Pittinos*), *overruled on other grounds by* Animal Sci. Prods., Inc. v. China Minmetals Corp., 654 F. 3d 462 (3d Cir.), *as amended* (Oct. 7, 2011).

57. *See id.* at 64–66 (describing traditional carpet distribution system and plaintiff's disruptive business model).

58. *See id.* at 64–65 (describing anticompetitive conduct that trade association allegedly took to force plaintiff out of market).

59. *See id.*

ble alternative to the defendants'.[60] If wholesalers raised the price of their product, consumers could turn to Carpet Group's product as a substitute.[61] Thus, their products were cross-elastic, and they were consequently competitors for purposes of Section 4 standing.[62] Notably, although *Carpet Group's* "competitor" analysis remains intact, the portion of the case relating to the jurisdictional limits of the Foreign Trade Antitrust Improvements Act was subsequently overruled.[63]

III. STEPPING UP THE REQUIREMENTS ON STANDING UNDER THE CONSUMER-OR-COMPETITOR TEST: THE THIRD CIRCUIT'S DECISION IN *ETHYPHARM*

In *Ethypharm*, the Third Circuit once again addressed the delineation of competitor when determining antitrust standing under the consumer-or-competitor test.[64] The court considered whether a manufacturer of a cholesterol drug had standing to bring suit for anticompetitive conduct against a dual manufacturer and distributor of a similar drug.[65] Although the court used the consumer-or-competitor test, it abandoned the earlier definition of competitor articulated in *Barton & Pittinos* and *Carpet Group* and instead adopted a much more restrictive definition that focuses on a company's distribution chain.[66] In doing so, the Third Cir-

60. *See id.* at 77 (holding plaintiff "'endeavored to forge a link in a chain of the sale' of oriental rugs between foreign rug manufacturers and domestic rug retailers. That link competed directly with the traditional middlemen—the rug importer/wholesalers." (quoting Crimpers Promotions Inc. v. Home Box Office, 724 F.2d 290 (2d Cir.1983))).

61. *See id.* at 77–78 (stating defendant's rigorous attempts to abolish plaintiff's business was evidence consumers found their products to be substitutable).

62. *See id.* at 75–80 (holding plaintiff was competitor in relevant marketplace and subsequently weighing other *Associated General* factors for standing).

63. *Animal Sci. Prods., Inc.*, 654 F.3d 464, 467–68 (3d Cir.), *as amended* (Oct 7. 2011) ("We will now overturn this aspect of our. . . *Carpet Group* decision[ ] and hold that the FTAIA constitutes a substantive merits limitation rather than a jurisdictional limitation.").

64. *See* Ethypharm S.A. Fr. v. Abbott Labs. (*Ethypharm III*), 707 F.3d 223, 232–37 (3d Cir. 2013) (applying consumer-or-competitor test to specific facts of case).

65. *See id.* at 225–26.

66. *See id.* at 236 (noting distributor-manufacturer relationship and regulated pharmaceutical industry and explaining its effects on plaintiff's standing); *see also* Editorial Board, *3rd Circuit: Foreign Drug Maker Lacks Antitrust Standing to Challenge Actions Allegedly Taken Against Its U.S. Distributor*, ORRICK, HERRINGTON & SUTCLIFFE (Feb. 4, 2013), http://blogs.orrick.com/antitrust/2013/02/04/3rd-circuit-rules-that-foreign-drug-manufacturer-lacks-antitrust-standing-to-challenge-actions-allegedly-taken-against-its-u-s-distributor/ [http://perma.cc/2ALN-CJPN] (describing general holding in *Ethypharm*); Barbara T. Sicalides & Deirdre E. McInerney, *A Cure for Antitrust Standing?*, COMPETITION NEWS (Pepper Hamilton, Philadelphia, Pa.), Mar. 7, 2013, at 7, 8, *available at* http://www.pepperlaw.com/resource/463/23D3 [http://perma.cc/WK67-HX32] (discussing how Third Circuit's decision will impact "different levels of the distribution chain"); Molly Storey, *Third Circuit: A Drugmaker That Cannot Legally Compete in the US Lacks Antitrust Standing*, WEIL GOTSHAL (Apr. 1, 2013), http://antitrust.weil.com/articles/third-circuit-a-drug

cuit has further limited the number of companies who have standing under Section 4 and thus stands in stark contrast to the federal circuits that promote a broad approach to private antitrust standing.[67]

A. *Setting the Scene on Standing: Facts and Background of* Ethypharm

In *Ethypharm*, a French pharmaceutical company brought suit against an American pharmaceutical company for allegedly violating federal antitrust laws.[68] Ethypharm S.A. France (Ethypharm), the French corporation, was responsible for developing and manufacturing a fenofibrate cholesterol drug called Antara.[69] Instead of directly selling Antara to consumers in the United States, Ethypharm sold the exclusive right to distribute Antara in the United States to Reliant Pharmaceuticals, Inc. (Reliant).[70] Thus, Ethypharm was responsible for providing the finished drug to Reliant, and Reliant was tasked with marketing and selling the drug in the United States as well as procuring FDA (Food and Drug Administration) approval.[71]

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maker-that-cannot-legally-compete-in-the-us-lacks-antitrust-standing/ [http://perma.cc/FMR7-MBWQ] (explaining that certain manufacturers who use distributors will not have Section 4 standing after Third Circuit's decision).

67. For a discussion of how the Third Circuit's decision in *Ethypharm* has narrowed the meaning of a competitor in the consumer-or-competitor test, see *infra* notes 83–91 and accompanying text. For a discussion of federal circuits that have adopted broader tests for antitrust standing, see *supra* notes 32–41 and accompanying text.

68. *See Ethypharm III*, 707 F.3d at 225.

69. *Id.* at 225–26 (explaining nature of Ethypharm corporation and development of Antara).

70. *See id.* at 226–27 (explaining Ethypharm's development of distribution chain). Due to the intensely regulated nature of the pharmaceutical industry, product licensing is a highly common practice. *See* Patricia M. Danzon, *Economics of the Pharmaceutical Industry*, NBER. REP., Fall 2006, *available at* http://www.nber.org/reporter/fall06/fall06.pdf [http://perma.cc/4A6C-Q2TK] (discussing common practice of licensing in pharmaceutical industry). As smaller research companies often do not have the resources necessary to capitalize on their products, they will often license out their products' rights to well-connected large pharmaceutical companies. *See id.* at 14 ("Increasingly, new drugs originate in small firms, which often out-license their products to more experienced firms for later-stage drug development, regulatory review, and commercialization.").

71. *See Ethypharm III*, 707 F.3d at 226–27 (discussing license and distribution agreement between Ethypharm and Reliant). Ethypharm tasked Reliant with obtaining FDA approval because of the "substantial time and resources" it would take to get the approval. *See id.* at 226 (internal quotation marks omitted). The economics of the pharmaceutical industry is unique in a variety of aspects, which enhances the need for strict regulation. *See* Danzon, *supra* note 70, at 14 (examining price regulation in pharmaceutical industry). For example, the pharmaceutical industry is regulated because of the "uncertainty about drug safety and efficacy." *Id.* Furthermore, prices are regulated due to the presence of partial inelasticity of demand. *See id.* at 15 (explaining that it is insurance companies, not consumers, who absorb burden of higher drug prices, and thus consumers are "insensitive" to drug price increases).

"Reliant sought FDA approval of Antara pursuant to [Section] 505(b)(2) of the Food, Drug, and Cosmetics Act [(FDCA)]," which is a process intended for companies that have a "drug that is not entirely new but is not simply a generic version of a branded drug."[72] By taking this approval path, Reliant was able to cut costs by relying "on the data [and results] of another, already approved, fenofibrate [cholesterol] drug," TriCor.[73] After obtaining FDA approval, Reliant began to sell Antara, and in 2005 alone, Antara sales had generated $23.5 million in profits for the company.[74] Then, "[i]n a prophylactic maneuver, Reliant filed a declaratory judgment action" requesting an avowal that Antara was not infringing on TriCor's patents.[75] Abbott Laboratories (Abbott), a company holding both the right to manufacture and distribute TriCor, "counterclaimed for infringement" of two TriCor patents.[76]

Reliant and Abbott eventually settled the case, and their settlement terms restricted Reliant from licensing Antara to certain "large pharmaceutical companies."[77] Reliant ultimately sold its license to a small phar-

72. *See Ethypharm III*, 707 F.3d at 226, 227 (explaining how Reliant obtained FDA approval).

Usually, obtaining FDA approval for a pharmaceutical product requires the manufacturer to submit "detailed safety and efficacy data for the drug to the FDA . . . ." *Id.* at 226. However, under Section 505(b)(2), a manufacturer can circumvent this costly submission if its drug is roughly similar to a branded drug that has had its safety and efficacy data already submitted to the FDA. *See id.* But if a manufacturer takes this route, it must also allege whether its product infringes on any other manufacturers drug patents. *See id.* at 227–28. Reliant chose this option, but it failed to certify that Antara did not infringe any patents; thus, it "exposed Reliant to a possible infringement suit." *Id.* at 228.

73. *See id.* at 227 (explaining how Reliant received FDA approval for Antara). TriCor, a fenofibrate cholesterol drug, was originally developed and manufactured by the French corporation Laboratories Fournier; however, Laboratories Fournier sold the right to manufacture and distribute TriCor to an American company, Abbott Industries. *See id.* Thus, although Ethypharm could not distribute its fenofibrate drug in the United States, both Ethypharm and Abbott manufactured fenofibrate cholesterol drugs. *See id.* at 227 & n.5 (explaining that Ethypharm manufactured Antara and Abbott was "granted [ ] an exclusive license to manufacture and sell TriCor").

74. *See id.* at 228 (explaining Antara was able to successfully compete in the market notwithstanding its legal troubles).

75. *Id.*

76. *See id.* (discussing Abbott's patent infringement claims).

77. *See id.* at 228–29 (explaining terms of 2006 settlement). Pursuant to the settlement, Reliant received a license to the TriCor patents while Abbott received royalty payments. *See id.* at 227–28. The "Restricted Entity" provision of the settlement agreement prohibited Reliant from selling "its rights in Antara . . . . [to] about 20 large pharmaceutical companies [and] 10 generic companies." *See id.* at 229 (internal quotation marks omitted).

maceutical company, Oscient.[78] However, sales of Antara plummeted, and Oscient filed for bankruptcy shortly thereafter.[79]

In 2009, troubled by Reliant's failure to sell its product Antara in the United States, the manufacturer, Ethypharm, brought suit against Abbott under Section 4 of the Clayton Act, claiming that Abbott and Reliant's settlement terms were anticompetitive and violated Sections 1 and 2 of the Sherman Antitrust Act.[80] The district court found that Ethypharm had proper standing under Section 4 and held that a foreign manufacturer who used a distributor to sell its product in the United States could use "the antitrust laws . . . [to] challeng[e] the conduct of a manufacturer of a competing brand name drug."[81] Relying on *Barton & Pittinos* and *Carpet Group*'s definition of competitor, the district court surmised that if TriCor's prices rose, consumers would switch to Antara.[82] Therefore, there was cross-elasticity of demand, which made Ethypharm a competitor and satisfied the consumer-or-competitor test.[83] Nonetheless, the district court granted summary judgment to Abbott on other grounds, and Ethypharm subsequently appealed.[84]

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78. *See id.* at 229–30 (explaining Oscient "did not appear on the Restricted Entity list").

79. *See id.* (discussing fate of Oscient). Despite early competitive sales, Antara quickly lost traction due to the appearance of "generic fenofibrate manufacturers." *See id.*

80. *See id.* at 230 (claiming agreement was anticompetitive because Abbott intended settlement agreement to prevent Antara from competing with TriCor by "mak[ing] sure that Antara would be put in the hands of a company with limited resources" (internal quotation marks omitted)).

81. Ethypharm S.A. Fr. v. Abbott Labs. (*Ethypharm I*), 598 F. Supp. 2d 611, 616 (D. Del. 2009), *disapproved in later appeal*, 707 F.3d 223 (3d Cir. 2013).

In its standing analysis, the district court focused on the fact that Ethypharm and Abbott were manufacturers of a drug that competed directly with each other. *See id.* at 616. By honing in on the similarity of Antara and TriCor, the court forewent a structural analysis of Ethypharm's distribution process. *See id.* ("Ethypharm does not forfeit the protection of the antitrust laws merely because it sought to enter the U.S. fenofibrate market by utilizing the route of an exclusive distributor rather than, for example . . . organizing its own U.S. marketing force." (internal quotation marks omitted)). Lastly, the court explained that Ethypharm had proper standing because it had only licensed Antara to Reliant, and thus there was no threat of "duplicative recovery." *See id.* at 618.

82. *See id.* at 616–22 (comparing facts of case to those in *Barton & Pittinos* and *Carpet Group*).

83. *See id.* at 617–24 (stating Antara and TriCor were reasonably interchangeable drugs and holding that Ethypharm had standing because its injury was "inextricably intertwined" with injury to market (internal quotation marks omitted)).

84. Ethypharm S.A. Fr. v. Abbott Labs. (*Ethypharm II*), 805 F. Supp. 2d 59, 67 (D. Del. 2011) (granting summary judgment for Abbott Industries because plaintiff failed to show nexus "between the [alleged] antitrust violation and actual damage suffered [by Ethypharm]" (first alteration in original) (internal quotation marks omitted)), *rev'd in part*, 707 F.3d 223 (3d Cir. 2013); *see also Ethypharm III*, 707 F.3d 223, 225 (3d Cir. 2013) (providing background on Ethypharm's appeal to Third Circuit).

B. *No Standing to Sue: The Third Circuit's Analysis in* Ethypharm

The Third Circuit vacated the district court's decision in part, holding that Ethypharm was not a consumer or competitor in the pharmaceutical market, and that the company consequently lacked standing to bring a private antitrust claim against Abbott.[85] In its analysis, the Third Circuit analogized Ethypharm to the plaintiff in *Barton & Pittinos* and distinguished the facts from those in *Carpet Group* based on Ethypharm's inability to supply its product *directly* to consumers.[86] The court pronounced that a plaintiff was a competitor in the relevant marketplace if consumers turned *directly to the plaintiff* for its product in response to a rise in the price of the defendant's product.[87] According to the court, Ethypharm, much like the plaintiffs in *Barton & Pittinos*, could not legally provide its cholesterol drug to consumers in the United States: Ethypharm had to use a third party—Reliant—to act as its distributor.[88] Thus, the court held that there was no cross-elasticity (and hence no direct competition) between Ethypharm's and Abbott's products because even if Abbott raised TriCor's prices, consumers could only procure Antara *indirectly* from Reliant.[89] In so holding, the Third Circuit was adamant that its formulation of a competitor was no different than it had been in *Barton & Pittinos* and *Carpet Group*.[90]

Interestingly, the Third Circuit went on to state that it was not the manufacturer-distributor relationship between Ethypharm and Reliant that precluded standing, but rather Ethypharm's legal inability to "sell Antara in the United States."[91] The court noted the strict FDA regulations

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85. *See Ethypharm III*, 707 F.3d at 237 ("[W]e conclude that Ethypharm did not suffer antitrust injury because it does not and indeed cannot compete in the United States fenofibrate market . . . . As a result, Ethypharm lacks antitrust standing to sue Abbott.").

86. *See id.* at 233–35 (distinguishing facts of case from *Carpet Group*). This approach, which focused on a company's distribution system, is markedly different from the product-level approach that the district court took. *Compare id.*, *with Ethypharm I*, 598 F. Supp. 2d at 614–15 (focusing on whether Antara and TriCor competed with one another in market).

87. *See Ethypharm III*, 707 F.3d at 236 (stating Ethypharm was not a competitor with Abbott because it could not "directly supply" fenofibrate products to American consumers).

88. *See id.* at 234–36 (stating that facts of *Ethypharm* most closely resembled those in *Barton & Pittinos*).

89. *See id.* This focus on a consumer turning *directly* to a company differs from the test laid out in *Carpet Group* and *Barton & Pittinos*, both of which focused on whether a consumer would turn to a certain *product*, not a company. For an in-depth discussion of this change and the effect that it has had on standing in the Third Circuit, see *infra* notes 94–131 and accompanying text.

90. For a discussion of how the decision in *Ethypharm III* has essentially narrowed the traditional definition of competitor, see *infra* notes 94–131 and accompanying text.

91. *See Ethypharm III*, 707 F.3d at 234–36 (describing how Ethypharm forewent obtaining FDA approval to sell Antara in United States and instead passed burden onto Reliant).

that precluded Ethypharm from directly entering the United States market "differentiate[d] th[e] case from others in which a manufacturer ha[d] a legal right to sell a good in the United States but cho[se] to utilize an exclusive distributor" because, unlike those manufacturers, Ethypharm was "literally not a lawful competitor."[92] Ultimately, the Third Circuit concluded that a pharmaceutical manufacturer that fails to obtain FDA approval for its product cannot then benefit from United States antitrust laws enacted to protect legal competitors; the antitrust acts do not allow a company to "pass on . . . the expense and risk of qualifying to compete in the United States" while also taking advantage of the United States' plaintiff-friendly competition laws.[93]

IV. ANALYZING ANTITRUST STANDING IN THE THIRD CIRCUIT: *ETHYPHARM*'S IMPACT ON THE CONSUMER-OR-COMPETITOR TEST

In narrowing the meaning of competitor under the consumer-or-competitor test in *Ethypharm*, the Third Circuit has effectively widened the circuit split that currently exists concerning antitrust standing.[94] Because the court's definition of competitor focused on a manufacturer's distribution process, the decision will further limit the number of plaintiffs, especially those in the pharmaceutical industry, who will have Section 4 antitrust standing.[95] The court's stance stands in stark contrast to other circuits that have interpreted Section 4 to provide consumers, competitors, and many others a private right of action to obtain redress.[96]

A. *Who Is a Competitor? Not Whom You Think, According to the Third Circuit*

Under the Third Circuit's traditional definition, two companies were competitors for antitrust purposes if their products were "reasonably interchangeable" with one another.[97] In *Ethypharm*, the Third Circuit dis-

92. *Id.* at 236.

93. *See id.* at 236 (discussing impact of Ethypharm's choice to forego obtaining FDA approval to sell its own product).

94. *See generally* SigmaPharm Cert. Petition, *supra* note 11, at 14 (describing nature of circuit split that currently exists over antitrust standing and consumer-or-competitor test); Fiala et al., *supra* note 11, at 1–2 (same). For a discussion of how the decision has specifically widened the circuit split, see *infra* notes 130–31 and accompanying text.

95. *See generally* Floyd, *supra* note 8, at 6–7 (stating how consumer-or-competitor test is restrictive and has resulted in "underdeterrence").

96. *See supra* notes 32–41 and accompanying text (discussing how various circuits treat standing under the Clayton Act).

97. *See Barton & Pittinos*, 118 F.3d at 182 ("In order to hold that [the plaintiff] was in competition with the pharmacists, we would have to conclude that what [the plaintiff] offered was reasonably interchangeable with what the pharmacists offered."). The Third Circuit has used this formulation in a multitude of cases besides *Barton & Pittinos* and *Carpet Group*. *See, e.g.*, Brokerage Concepts, Inc. v. U.S. Healthcare, Inc., 140 F.3d 494 (3d Cir. 1998) (using traditional definition of competitor); Tunis Bros. Co. v. Ford Motor Co., 952 F.2d 715 (3d Cir. 1991) (same);

carded its traditional formulation of what constitutes a competitor in favor of a significantly more restrictive definition.[98] As compared to the court's previously more liberal requirements under the consumer-or-competitor test, the new test articulated in *Ethypharm* will reduce private antitrust litigation within the Third Circuit's jurisdiction.[99]

Under this well-established meaning, Ethypharm and Abbott were unquestionably competitors in the relevant marketplace.[100] Ethypharm's product, Antara, was a fenofibrate cholesterol drug, which was reasonably interchangeable with Abbott's fenofibrate cholesterol drug, TriCor.[101] Because consumers would likely switch from Abbott's TriCor to Ethypharm's Antara if TriCor's price rose, Abbott and Ethypharm were competitors and Ethypharm had standing to sue under the Third Circuit's traditional analysis.[102]

The traditional definition of competitor does not take into account a company's distribution strategy.[103] It is irrelevant that consumers did not obtain Antara directly from Ethypharm under the established competitor formulation; it only matters that consumers would ultimately buy Antara if TriCor's price rose.[104] This understanding is analogous to a retail store distribution strategy; the fact that a manufacturer's goods are sold via retailers such as CVS, for example, does not mean that the goods are no

Pa. Dental Ass'n v. Med. Serv. Ass'n of Pa., 745 F.2d 248 (3d Cir. 1984) (same); *see also* 1 MILES, *supra* note 51 (referencing all cases that have defined relevant product market and cross-elasticity in terms of substitutability). The Supreme Court has also defined the terms *competitor* and *relevant marketplace* by comparing cross-elasticity of products. *See* United States v. E. I. du Pont de Nemours & Co., 351 U.S. 377, 394 (1956).

98. For a discussion of how the definition of competitor has been narrowed, see *infra* notes 109–18 and accompanying text.

99. For a discussion of how the decision will affect the healthcare industry, see *infra* notes 132–45 and accompanying text.

100. *See supra* notes 42–63 and accompanying text (discussing Third Circuit's adoption of consumer-or-competitor test and its subsequent case law defining competitor).

101. *See Ethypharm I*, 598 F. Supp. 2d 611, 616 (D. Del. 2009) (noting that Antara and TriCor were reasonably interchangeable), *disapproved in later appeal*, 707 F.3d 223 (3d Cir. 2013). Antara and TriCor's interchangeability was further evidenced by the fact that Reliant was able to bypass mandated drug-efficacy investigations by relying on TriCor's earlier investigations. *See Ethypharm III*, 707 F.3d 223, 227 (3d Cir. 2013). Furthermore, suspicions that Antara was infringing TriCor's patents highlighted the similarity of the drugs. *See id.*

102. *See Ethypharm I*, 598 F. Supp. 2d at 617 (finding cross-elasticity of Antara and TriCor sufficient to satisfy standing claim).

103. *See id.* at 618 (noting manufacturer does not "forfeit" antitrust standing just by using distribution system instead of supplying its product directly to consumers (internal quotation marks omitted)). *See generally* 54 AM. JUR. 2D § 410 (2009) (noting manufacturers and wholesalers "generally have standing" under Section 4).

104. *See Ethypharm I*, 598 F. Supp. 2d at 616–17 (noting consumers would switch to Antara if TriCor's price rose).

longer the manufacturer's product.[105] Here, Abbott and Ethypharm both manufactured fenofibrate cholesterol drugs, and although the two employed different distribution systems for their drugs, Antara was still Ethypharm's product, and thus it was interchangeable with Abbott's product TriCor.[106] The Third Circuit's traditional definition of competitor, which the district court initially used, recognized that distribution methods are extraneous to determine whether two companies are competing.[107] Thus, under the traditional test, Ethypharm would have had Section 4 standing (provided the other *McCready* factors were met).[108]

In *Ethypharm*, however, the Third Circuit jettisoned its traditional formulation and adopted a much more limited approach.[109] Specifically, the court narrowly defined the concept of cross-elasticity.[110] Under the Third Circuit's new formulation of cross-elasticity, it is not enough that consumers "turn to" product *B* if product *A*'s price increases.[111] Instead, if prod-

105. *See generally Distributing Your Product*, ONTARIO MINISTRY AGRIC., FOOD & RURAL AFFS., http://www.omafra.gov.on.ca/english/food/industry/food_proc_guide_html/chapter_10.htm [http://perma.cc/7K8F-CZ57] (last modified Nov. 13, 2013) (discussing how companies can use wholesaler or distributor to sell their products); Austin Grandt, *Distributor vs. Reseller: What's Right for Me?*, EXPORTABROAD BLOG (Oct. 2, 2014), http://blog.exportabroad.com/distributor-vs-reseller-whats-right-for-me/ [http://perma.cc/2ZV2-A35J] (explaining that when manufacturers use distributors, distributor is involved with selling manufacturer's product); Entrepreneur Staff, *Distribution Models*, ENTREPRENEUR, http://www.entrepreneur.com/encyclopedia/distribution-models [http://perma.cc/6YWV-78EX] (last visited Oct. 29, 2015) (describing varying types of distribution models).

106. *See Ethypharm I*, 598 F. Supp. 2d at 615–17 (noting Antara was ultimately Ethypharm's product).

107. *See id.* at 617–20 (using traditional definition of competitor and ultimately holding that Ethypharm had standing).

108. *See supra* notes 79–82 and accompanying text (discussing district court's decision).

109. *See supra* note 99.

110. *See Ethypharm III*, 707 F.3d 223, 236 (3d Cir. 2013) (finding Ethypharm and Abbott did not compete against one another because Ethypharm did not distribute its own drug in United States); Sicalides & McInerney, *supra* note 66 (noting *Ethypharm* narrows consumer-or-competitor test by focusing on distribution chain); Storey, *supra* note 66 (noting impact of decision on manufacturers). *Compare Ethypharm III*, 707 F.3d at 236 (holding competitor in relevant marketplace is one where, if product *A*'s price rises, consumers will turn to *company* for product *B*), *with* Barton & Pittinos, Inc. v. SmithKline Beecham Corp., 118 F.3d 178, 182–83 (3d Cir. 1997) (holding competitor in marketplace is one where, if product *A*'s price rises, consumers will turn to product *B*). The Third Circuit has refused to acknowledge the marked difference between these two tests. *See Ethypharm III*, 707 F.3d at 233–36 (noting its analysis is consistent with analysis used in *Barton & Pittinos*).

111. *See Ethypharm III*, 707 F.3d at 236; *see also* GETTING THE DEAL THROUGH—PHARMACEUTICAL ANTITRUST 189 (Marleen Van Kerckhove ed., 7th ed. 2014), *available at* http://www.hoganlovells.com/files/Publication/7d9b61a1-1ab1-47d4-84a4-7711db4e2188/Presentation/PublicationAttachment/29500be6-1fc5-4177-be7d-8659f2e8535a/PH2014-United-States_05_09_14.pdf [http://perma.cc/9RW4-D7X4] (describing traditional antitrust test and the emphasis placed on company's prod-

uct *A*'s prices increase, product *A*'s consumers must *directly* turn to the *company* producing product *B*.[112] Put differently, in order to meet the Third Circuit's newly formulated competitor test, a company must now not only manufacture its product, but also sell it directly to consumers.[113] By inserting a "method-of-distribution" analysis into the cross-elasticity standard, Ethypharm was no longer a competitor because it utilized a third party to distribute its product to consumers.[114]

The Third Circuit attempted to distinguish Ethypharm from the plaintiffs in prior cases based on its lack of a legal right to sell its drug in the United States; this distinction, however, is incongruous with the new, narrower consumer-or-competitor test the court set out.[115] In dicta, the court noted that it was not the manufacturer-distributor relationship that barred standing; instead, it was "the fact that Ethypharm [could] not [legally] sell Antara in the United States . . . ."[116] But the court's holding also maintained that a company is a competitor only if the consumer directly "turn[s] to" the company itself to obtain a substitute product.[117] Thus, a manufacturer, even if it had the legal right to sell its product in the United States, would still fail the aforementioned test if it used a distributor to sell its product.[118] Because the Third Circuit failed to pronounce a test that properly distinguished between the types of manufacturer-distributor relationships, the court has left many antitrust-competition questions unanswered.[119]

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ucts and the alternative products "customers could turn to in the face of an attempted price increase").

112. *See Ethypharm III*, 707 F.3d at 236 (discussing how consumers could not "turn to Ethypharm for Antara" if TriCor's price rose).

113. *See id.* at 235 (stating "there is no cross-elasticity of demand between Ethypharm's offerings and Abbott's offerings [because] . . . . customers in the United States cannot purchase the drug at issue from Ethypharm").

114. *See id.* at 236–37 (holding that because consumers could get TriCor directly from Abbott but could not get Antara directly from Ethypharm, Ethypharm and Abbott were not competitors in marketplace).

115. *See supra* notes 83–113 (discussing consumer-or-competitor test outlined by Third Circuit). The test, which on its face mandates that a consumer turn to a manufacturer for a product, does not distinguish between manufacturers that have the ability to sell to consumers in the United States and those who do not. *See id.*

116. *See Ethypharm III*, 707 F.3d at 236 (emphasizing fact that Ethypharm cannot legally sell Antara in United States).

117. *See id.* at 236–37.

118. For example, if Ethypharm had FDA approval to sell Antara in the United States but chose to license Antara's distribution rights to Reliant, consumers would still be "turn[ing] to" Reliant, not Ethypharm, for Antara. Under the Third Circuit's newly formulated test, Ethypharm would still not qualify as competitor in marketplace, and therefore, would not have standing. *See id.* at 235–36.

119. This uncertainty will continue to exist until the Third Circuit again addresses the issue, and manufacturers who have the legal right to sell their product in the United States but choose to use a distributor will not know if they have standing under the Clayton Act. *See generally* IIA PHILLIP E. AREEDA ET AL., ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION (3d ed. 2007) (discussing varying interpretations of Section 4 that have resulted in poten-

B. *The Third Circuit Tells Pharmaceutical Plaintiffs to Sit Down*

The Third Circuit's new, more restrictive version of the consumer-or-competitor test will significantly limit the number of plaintiffs who can bring suit under Section 4 of the Clayton Act.[120] Now, it seems that manufacturers who use a traditional distribution model are not competitors with manufacturers that sell their products directly to consumers.[121] This will have the largest impact in the pharmaceutical industry, where licensing and distribution agreements are especially prevalent.[122] It is exceedingly common for small pharmaceutical companies and research facilities to develop and patent a new drug, yet lack the capital and resources to properly distribute it.[123] To work around this issue, many of these small entities enter into distribution agreements with larger pharmaceutical companies to market and sell their products.[124] In light of the Third Circuit's new and limited application of the consumer-or-competitor test, these small entities can no longer use Section 4 as a sword and may find themselves as "[v]ictims [w]ithout [ ] [r]emed[y]."[125]

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tial plaintiff's lacking clarity concerning standing); Michael Puleo, Casebrief, *Antitrust—Being a Player Against a Monopoly—How Plaintiffs Can Pass Go and Collect $200: The Third Circuit's Requirements for Consumer Standing Under Sections 4 and 16 of the Clayton Act*, 46 VILL. L. REV. 881, 890 (2001) (positing that there is no "black-letter rule" to antitrust standing and examining history of antitrust standing and uncertainty that it has engendered).

120. *See* Fiala et al., *supra* note 11 (noting that post-*Ethypharm*, manufacturers of products who do not have right to sell in United States and do not sell their product directly to consumers will lack antitrust standing in Third Circuit).

121. *See id.* (identifying new limitation of antitrust standing based on *Ethypharm*).

122. *See generally* HEALTH STRATEGIES CONSULTANCY LLC, FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 4 (2005), *available at* http://www.avalerehealth.net/research/docs/Follow_the_Pill.pdf [http://perma.cc/N9GT-7AYF] (describing role of manufacturer in pharmaceutical industry and stating that "[v]ery few drugs are distributed directly to consumers"); INST. OF MED., COUNTERING THE PROBLEM OF FALSIFIED AND SUBSTANDARD DRUGS 9 (Gillian J. Buckley & Lawrence O. Gostin eds., 2013), *available at* http://www.ncbi.nlm.nih.gov/books/NBK202530/pdf/Bookshelf_NBK202530.pdf [http://perma.cc/769W-N32D] (describing "complex" drug distribution chain that exists in United States).

123. *See* Jacob Serebrin, *Big Pharma Turns to Smaller Firms for Innovation*, GLOBE & MAIL (June 24, 2013, 9:43 A.M.), http://www.theglobeandmail.com/report-on-business/small-business/sb-money/business-funding/big-pharma-turns-to-smaller-firms-for-innovation/article12751137/ [http://perma.cc/9S7D-QMN5] (discussing small pharmaceutical companies that have been at forefront of developing new drugs).

124. *See* John LaMattina, *Does Pharma's Emphasis on External Sourcing of Drugs Represent a Strategic Shift Away from Internal Research?*, FORBES (Mar. 11, 2014) http://www.forbes.com/sites/johnlamattina/2014/03/11/does-pharmas-emphasis-on-external-sourcing-of-drugs-represent-a-strategic-shift-away-from-internal-research/ [http://perma.cc/A28D-D6PG] (describing trend of big pharmaceutical companies entering into agreements with small pharmaceutical companies and academic research institutions to obtain licenses of drug patents).

125. *See* Floyd, *supra* note 8, at 6–30, 66–70. Competitors are often the ideal candidates to bring antitrust violators to task because of the collective action prob-

Because competitors are often the ideal candidates to enforce antitrust laws, it is probable that the Third Circuit's constricted view of what constitutes a competitor will result in "underdeterrence" of anticompetitive actions.[126]

The Third Circuit's constriction of competitor is significant when placed in the context of the recent increase in antitrust litigation.[127] Unlike most other industries, antitrust cases in the pharmaceutical industry are rapidly on the rise.[128] Additionally, because a vast number of pharmaceutical companies are located in New Jersey and Delaware, the Third Circuit has dealt with a large influx of these cases.[129] Thus, it is notable that the decision in *Ethypharm*, which will likely limit the number of potential pharmaceutical antitrust plaintiffs, coincides with the dramatic increase of healthcare antitrust cases in the Third Circuit.[130] It seems probable that the Third Circuit's decision in *Ethypharm* was motivated by a desire to significantly reduce the amount of pharmaceutical antitrust litigation.[131]

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lem that consumers face. *See id.* at 6, 7–30, 60–70; *id.* at 6 ("Courts that restrict the universe of potential plaintiffs to those who have felt the ultimate price and output effects of the defendant's anticompetitive scheme often screen out those plaintiffs who were most directly and visibly harmed, who are most aware of their injuries, and who have the greatest ability and incentive to sue."). In this case, Ethypharm, as the entity who most acutely felt the ramifications of Abbott's actions, was the ideal candidate to challenge the legality of Abbott's actions under the Sherman and Clayton Acts. *See Ethypharm I*, 598 F. Supp. 2d 611, 618 (D. Del. 2009) (finding Reliant had no reason to challenge anticompetitive nature of agreement because it had received benefit of immunity as condition of infringement suit settlement, and thus there was no risk of duplicative recovery), *disapproved in later appeal*, 707 F.3d 223 (3d Cir. 2013).

126. *See* Floyd, *supra* note 8, at 5–6. By holding that Ethypharm did not have standing to bring suit, the Third Circuit essentially immunized Abbott's conduct from review. Dan Packel, *Ethypharm Urges 3rd Circ. to Revive Abbott Antitrust Row*, LAW 360 (Sept. 25, 2012), http://www.law360.com/articles/380633/ethypharm-urges-3rd-circ-to-revive-abbott-antitrust-row [http://perma.cc/3A8L-7A89] (quoting Ethypharm's attorney, who stated, "If we don't give Ethypharm standing . . . . [t]he conclusion is that no other entity can bring an antitrust suit." (internal quotation marks omitted)).

127. *See Third Circuit Other Statutes Cases*, JUSTIA, https://dockets.justia.com/browse/circuit-3/noscat-13/nos-410 [http://perma.cc/7A93-Y967] (last visited Oct. 29, 2015) (providing extensive list of antitrust cases in Third Circuit).

128. Morse, *supra* note 50, at 633 ("The pharmaceutical industry has become a major target of antitrust investigations and litigation.").

129. *See Pharmaceuticals*, N.J. BUS. ACTION CTR., http://www.nj.gov/njbusiness/industry/pharmaceutical/ [http://perma.cc/JYQ2-SE48] (last visited Oct. 27, 2015) (noting New Jersey houses 14 of 22 biggest pharmaceutical companies).

130. *See, e.g.*, *In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012), *vacated sub nom.* Merck & Co. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013); Animal Sci. Prods., Inc. v. China Minmetals Corp., 654 F.3d 462 (3d Cir.), *as amended* (Oct. 7, 2011); W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85 (3d Cir. 2010).

131. The Third Circuit has been suspected of attempting to reduce pharmaceutical antitrust litigation by raising standing requirements in the past. *See generally* Joseph P. Bauer, *The Stealth Assault on Antitrust Enforcement: Raising the Barriers for Antitrust Injury and Standing*, 62 U. PITT. L. REV. 437, 445 (2001) ("I believe that

Ultimately, the Third Circuit's decision has widened the current Section 4 standing circuit split.[132] Compared to the other federal circuits, the Third Circuit now has the harshest, most defendant-friendly approach to private antitrust standing.[133]

V. GET UP AND RUN: HOW PHARMACEUTICAL MANUFACTURERS CAN MAINTAIN STANDING IN THE THIRD CIRCUIT

Because pharmaceutical actions compose a large amount of the antitrust litigation brought each year, it is necessary for pharmaceutical practitioners to be aware of whether their clients have standing to sustain a Section 4 claim.[134] With the recent developments in the Third Circuit concerning antitrust standing, counsel should take Section 4 standing into account when structuring their client's supply chain agreements.[135] Currently, if a manufacturer lacks the legal right to sell its product in the United States and instead uses a distributor to sell its product, the manufacturer will also lack Section 4 standing because it is not selling its product *directly* to consumers.[136] If a manufacturer wants to maintain its Section 4 standing in the Third Circuit, it should structure its distribution model as a sole-agency agreement.[137]

Under agency law, an agent is considered to "act on the principal's behalf" and is viewed as an extension of the principal.[138] Therefore, in an agency relationship, an act by the agent is viewed as an act by the principal.[139] Consequently, if a manufacturer uses an agency agreement instead of a typical retailer distribution agreement, the manufacturer will be con-

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the court's cramped approach to antitrust injury was at least in part a reflection of its desire to cut down on antitrust litigation.").

132. *Compare Ethypharm III*, 707 F.3d 223, 233, 236 (3d Cir. 2013) (explaining plaintiff must be consumer or competitor in market to have standing and further narrowing definition of competitor), *with* Novell, Inc. v. Microsoft Corp., 505 F.3d 302, 311 (4th Cir. 2007) (declining to follow consumer-or-competitor test).

133. *See* Mayhan, *supra* note 5, at 464–73 (explaining consumer-or-competitor test is unduly restricting). The Third Circuit has taken an already restrictive test and limited it further by narrowing the definition of a competitor. *See generally* Jay L. Himes, *When Caught with Your Hand in the Cookie Jar . . . Argue Standing*, 41 RUTGERS L.J. 187 (2009) (noting antitrust standing generally has been subject to defendant-friendly interpretation by federal circuits).

134. *See* Morse, *supra* note 50, at 633 (noting healthcare antitrust cases are increasing).

135. *See* Sicalides & McInerney, *supra* note 66 (identifying *Ethypharm* court's emphasis on party's location within distribution chain).

136. *See id.* (discussing how manufacturers who cannot legally sell their product in United States and use distributor will lack antitrust standing post-*Ethypharm*).

137. *See generally* Sales Agency Agreement, IMDA, http://www.imda.org/documents/sales_agency_agreement.pdf [http://perma.cc/Z76Q-GEFS] (last visited Oct. 29. 2015) (demonstrating agreement for sole agency distribution model).

138. *See* RESTATEMENT (THIRD) OF AGENCY § 1.01 (2006) (defining agency relationship).

139. *See id.* cmt. c (stating legal consequences of principal-agent relationship).

sidered to be *directly* selling its products to consumers via its agents.[140] Accordingly, if Reliant had been characterized as Ethypharm's agent instead of a third party distributor, Ethypharm would have met the Third Circuit's definition of competitor.[141] Characterizing the supply chain as an agency relationship is not a novel idea in antitrust law; on the contrary, it has been wielded before to circumvent liability in other antitrust matters.[142]

To successfully implement an agency relationship between pharmaceutical manufacturers and retailers, practitioners should structure the contract as a "sole agency model."[143] These contracts are increasingly used in Europe, and under these contracts, "the manufacturer [ ] sell[s] directly to their customers with an exclusive wholesaler acting as a . . . logistics service provider only."[144] To constitute this agency contract, a practitioner must warrant that its client bears the brunt of the risk and retains a high degree of control in effectuating the day-to-day business.[145] By structuring the relationship this way, practitioners should be aware that their manufacturer-clients will retain ownership of their product stock until their retailer-agents pass it on to consumers.[146] Ultimately, an agency relationship should be incorporated into the supply chain if a manufac-

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140. *See id.* (noting principals act through their agents).

141. *See Ethypharm III*, 707 F.3d 223, 236 (3d Cir. 2013) (noting Ethypharm did not sell its product directly to consumers and hence was not a competitor). If Reliant had been Ethypharm's agent, Ethypharm would have been viewed as selling products directly to consumers via its agent. *See* RESTATEMENT (THIRD) OF AGENCY § 1.01 cmt. c (defining principal-agent relationship).

142. *See, e.g.*, United States v. Gen. Elec. Co., 272 U.S. 476, 481–88 (1926) (holding manufacturer did not violate antitrust acts via "resale price" maintenance because its retailers were its agents and not third-party distributors). *But see* United States v. Apple, Inc., 952 F. Supp. 2d 638, 689–94 (S.D.N.Y. 2013) (discussing e-book publisher's attempt to structure its relationship with iBook as agency relationship did not save it from antitrust liability when relationship was facial conspiracy to fix prices). *See generally* Stephen Smith & Andrew Hobson, *Agency or Distribution? The Struggle for Mastery in E-book Pricing*, LEXOLOGY (May 9, 2011), http://www.lexology.com/library/detail.aspx?g=81389527-652e-4f27-8705-6028f88f2999 [http://perma.cc/4PD5-H9E6] (discussing antitrust consequences that stem from characterization of supply chain as agency or retail distribution model).

143. *See* Sales Agency Agreement, *supra* note 137 (demonstrating sample agreement to create agency relationship).

144. *See* PANOS KANAVOS ET AL., THE PHARMACEUTICAL DISTRIBUTION CHAIN IN THE EUROPEAN UNION: STRUCTURE AND IMPACT ON PHARMACEUTICAL PRICES 33 (2011), *available at* http://eprints.lse.ac.uk/51051/1/Kanavos_pharmaceutical_distribution_chain_2007.pdf [http://perma.cc/W73C-JLHR] (noting increasing prevalence of agency relationships in European pharmaceutical industry); *Supply Chain Arrangements*, ALLIANCE HEALTHCARE, http://www.alliance-healthcare.co.uk/useful-information/agency-wholesaler-agreements/ [http://perma.cc/7YVV-6Y5P] (last updated Oct. 29, 2015) (listing all pharmaceutical manufacturers that have agency arrangements with retailers).

145. *See* Smith & Hobson, *supra* note 142 (discussing how company can structure its relationship as "genuine agency").

146. *See* KANAVOS ET AL., *supra* note 144, at 33 (discussing consequences of sole agency model).

turer wishes to use a distributor while maintaining Section 4 standing under the Clayton Act.[147]

VI. Consumer-or-Competitor Test Stands Strong After *Ethypharm*

The *Ethypharm* opinion showcases the Third Circuit's reluctance to "open the gates" to private antitrust litigation.[148] Instead, the court has now inserted an additional restriction on standing that arbitrarily accounts for a plaintiff's position on the distribution chain.[149] This restriction further distances the Third Circuit from the Supreme Court's expansive approach to standing in *McCready*.[150] Ultimately, the Third Circuit's strict interpretation of Section 4 means that the circuit split will continue for the foreseeable future.[151] Until the Supreme Court again addresses standing, the narrow consumer-or-competitor test will reign supreme in the Third Circuit.[152]

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147. *See id.* (detailing structure of sole agency agreement in pharmaceutical industry).

148. *See* Fiala et al., *supra* note 11 (asserting decision in *Ethypharm* has "reinforced" Third Circuit's consumer-or-competitor stance on antitrust standing).

149. *See supra* notes 109–18 and accompanying text (discussing *Ethypharm's* impact on distribution chain).

150. *See supra* notes 22–27 and accompanying text (discussing *McCready*'s broad interpretation of standing under Section 4 of the Clayton Act).

151. *See, e.g.*, SigmaPharm Cert. Petition, *supra* note 11, at 14 (stating circuit split exists with regards to both antitrust standing and use of consumer-or-competitor test).

152. The last notable standing issue the Supreme Court addressed concerned who qualifies as a consumer in their relevant market. *See generally* Kansas v. UtiliCorp United, Inc., 497 U.S. 199 (1990) (denying standing to a plaintiff deemed to be "indirect purchaser").