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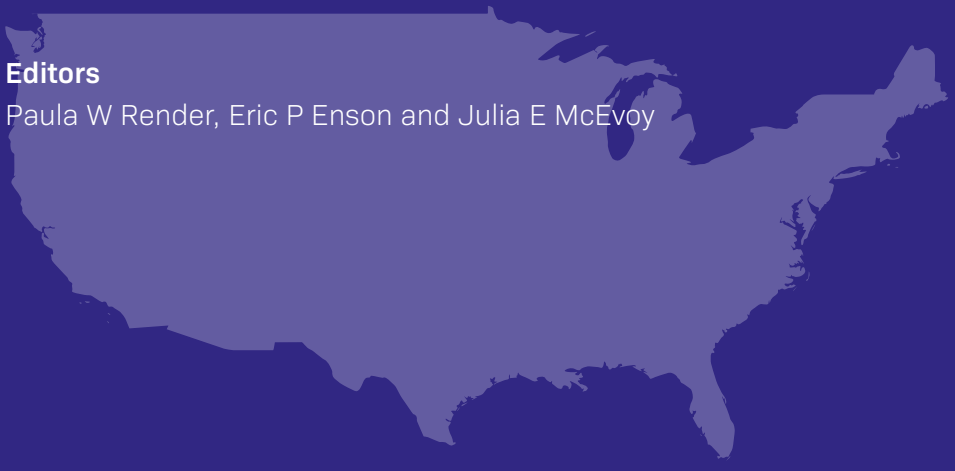
US COURTS
ANNUAL REVIEW



Editors
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Preface

Global Competition Review is a leading source of news and insight on competition law, economics, policy and practice, allowing subscribers to stay apprised of the most important developments around the world.

Alongside the daily content sourced by our global team of reporters, GCR also offers deep analysis of longer-term trends provided by leading practitioners from around the world. Within that broad stable, we are delighted to launch this new publication, *US Courts Annual Review*, which is our first to take a very deep dive into the trends, decisions and implications of antitrust litigation in the world's most significant jurisdiction for such cases.

The content is divided by court or circuit around the US, allowing our valued contributors to analyse both important local decisions and draw together national trends that point to a direction of travel in antitrust litigation. Both oft-discussed developments and infrequently noted decisions are thus surfaced, allowing readers to comprehensively understand how judges from around the country are interpreting antitrust law, and its evolution.

In producing this analysis, GCR has been able to work with some of the most prominent antitrust litigators in the US, whose knowledge and experience has been essential in drawing together these developments. That team has been led and indeed compiled by Paula W Render, Eric P Enson and Julia E McEvoy of Jones Day, whose insight, commitment and know-how have been fundamental to fostering the analysis produced here. We thank all the contributors, and the editors in particular, for their time and effort in compiling this report.

Although every effort has been made to ensure that all the matters of concern to readers are covered, competition law is a complex and fast-changing field of practice, and therefore specific legal advice should always be sought. Subscribers to Global Competition Review will receive regular updates on any changes to relevant laws during the coming year.

If you have a suggestion for a topic to cover or would like to find out how to contribute, please contact insight@globalcompetitionreview.com.

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Third Circuit: Pharmaceutical cases

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The Third Circuit is a prominent venue for antitrust litigation involving pharmaceuticals. The proximity of the industry and the large body of law ensure several noteworthy developments.

Plaintiffs are finding creative antitrust claims to assert, which raise novel questions of substantive and procedural law. Among others, this chapter describes a rare Federal Trade Commission (FTC) injunction request under section 13(b) of the FTC Act, indirect purchaser and competitor standing to sue under federal antitrust laws, class certification, and refusal to deal, pay for delay and exclusivity allegations.

FTC v Shire ViroPharma, Inc

The Third Circuit's 2019 decision in *FTC v Shire ViroPharma, Inc*[1] involves a rare FTC effort to use section 13(b) of the FTC Act to enjoin the recurrence of past conduct alleged to have been anticompetitive. In *Shire ViroPharma*, the Third Circuit held that the FTC cannot initiate litigation in federal court under section 13(b) for prior conduct without specifically alleging in its complaint how the defendant 'is violating or is about to violate' the law. The appellate court's denial dealt a significant blow to the FTC's ability to litigate cases in federal court where the challenged conduct has already ended.

Background

The FTC Act sets out the parameters of the FTC's enforcement authority.[2] While in-house administrative proceedings under section 5(b) are an often-used enforcement tool for antitrust litigation, the FTC can also seek a temporary restraining order or injunction in federal court under section 13(b) where there is 'reason to believe' that a party 'is violating, or is about to violate' any of

1 917 F.3d 147 (3d Cir. 2019).

2 See 15 U.S.C. § 41.

the laws enforced by the FTC.[3] In other words, section 13(b) gives the FTC the authority to 'speedily address ongoing or impending illegal conduct [in federal court], rather than wait for an administrative proceeding to conclude.'[4]

In 2017, the FTC sued Shire ViroPharma Inc (Shire) in federal court in Delaware, pursuant to section 13(b), alleging Shire violated the FTC Act by filing a number of allegedly meritless or 'sham' citizen petitions in an effort to delay or block the launch of generic versions of Shire's branded drug Vancocin, an antibiotic used to treat gastrointestinal infections. The FTC sought injunctive relief, in the form of permanently enjoining Shire from engaging in this type of conduct in the future, as well as for restitution and disgorgement.[5] Shire moved to dismiss the complaint, arguing that the alleged anticompetitive conduct occurred back in 2010–2012, and therefore Shire was not 'violating or about to violate' the FTC Act under section 13(b).[6] The FTC argued in response that dismissal would be improper because the FTC had pleaded a 'reasonable likelihood that past violations will recur,' which should have satisfied the 'about to violate' requirement.[7] The District Court, however, rejected the FTC's argument and granted Shire's motion to dismiss in 2018.[8]

Third Circuit decision

The Third Circuit affirmed the dismissal in February 2019, concluding that section 13(b) is 'unambiguous' in that 'it prohibits existing or impending conduct' and 'does not permit the FTC to bring a claim based on long-past conduct without some evidence that the defendant "is" committing or "is about to" commit another violation.'[9] The Court explained that the FTC's only allegations that Shire was 'about to violate' the law – that Shire had the ability and incentive to repeat the same type of behavior with other products – were 'woefully inadequate' to meet the 'about to violate' standard from section 13(b).[10] '[A]bout to violate,' the Court explained, 'means something more than a past violation and a likelihood of recurrence.'[11] The Third Circuit also rejected the FTC's argument that foreclosing the FTC from bringing section 13(b) in federal court for prior conduct could lead to a 'parade of horribles' in that wrongdoers could avoid the FTC in federal court by

3 See *id.* § 53(b).

4 *FTC v Shire ViroPharma, Inc.*, 917 F.3d 147, 155 (3d Cir. 2019).

5 *FTC v Shire ViroPharma, Inc.*, Civil Action No. 17-131-RGA, 2018 U.S. Dist. Lexis 45727, at *2 (D. Del. Mar. 20, 2018) ('The FTC seeks a permanent injunction and other equitable relief.').

6 See *id.* at *6–9.

7 *Id.* at *12.

8 See *id.* at *12–16.

9 *Shire ViroPharma*, 917 F.3d at 156.

10 *Id.* at 160 ('The few factual allegations in the FTC's forty-five page complaint that suggest Shire "is about to violate" the law are woefully inadequate to state a claim under Section 13(b).').

11 See *id.* at 158.

stopping the challenged conduct once it learned of the FTC's investigation.[12] The Court concluded that such circumstances could be addressed by traditional in-house administrative proceedings for prior violations under section 5(b) rather than in federal court.[13]

The Third Circuit's decision is a significant setback for the FTC, which until now has had success using section 13(b) cases to pursue large disgorgement awards for prior conduct. Moving forward, it is expected that the Third Circuit's interpretation of section 13(b) will put significant pressure on the FTC to accelerate investigations where there is a risk that the challenged conduct could stop before the FTC can file its complaint.

Walgreen Co v Johnson & Johnson

Federal standing considerations under the Supreme Court's *Illinois Brick* rule[14] generally ensure that most antitrust claims under section 1 of the Sherman Act are brought by direct purchasers with a contract or purchase agreement with the defendant. Increasingly, however, direct purchasers are assigning their contract rights to indirect purchasers, thus creating a threshold issue: whether an assignment of federal antitrust claims is barred by an anti-assignment provision proscribing the assignment of any 'rights or obligations under' that contract. The US Court of Appeals for the Third Circuit recently answered this question in *Walgreen Co v Johnson & Johnson*.[15]

Background

This section 1 case derived from the sale of Remicade, a biologic drug used to treat various autoimmune diseases. Remicade was marketed and manufactured by defendants Johnson & Johnson and Janssen Biotech, Inc (collectively, Janssen). In the supply chain, Janssen sold Remicade to various wholesale distributors, which then resold Remicade to retail pharmacies, such as the plaintiffs, Walgreen Co and the Kroger Co (collectively, Walgreen).

12 See *id.* at 159.

13 See *id.* ('But there is no reason to believe that our decision today unnecessarily restricts the FTC's ability to address wrongdoing. Section 5 authorizes administrative proceedings based on past violations. And, of course, if the FTC believes that a wrongdoer is "about to violate" the law during the pendency of an administrative proceeding, it could then come to court and obtain an injunction under Section 13(b).').

14 Under *Illinois Brick Co. v Illinois*, 431 U.S. 720 (1977), the Supreme Court 'impos[ed] the "direct purchaser" rule on antitrust claims and provid[ed] that only entities that purchase goods directly from alleged antitrust violators have statutory standing to bring a lawsuit for damages.' *Wallach v Eaton Corp.*, 837 F.3d 356, 365 (3d Cir. 2016). 'The [Supreme] Court observed that such indirect purchaser suits would force courts to ascertain how much of the supracompetitive prices charged by the violator were passed from the direct purchaser to indirect purchasers down the market chain, and concluded that 'the antitrust laws will be more effectively enforced by concentrating the full recovery for the overcharge in the direct purchasers rather than by allowing every plaintiff potentially affected by the overcharge to sue only for the amount it could show was absorbed by it.' *Id.* (quoting *Illinois Brick*, 431 U.S. at 735).

15 Although this Opinion was designated as precedential, its freshness precludes citations herein to its published version, which will eventually be 950 F.3d 195 (3d. Cir. 2020). For purposes of this discussion, we cite to its unpublished version, No. 19-1730, 2020 U.S. App. Lexis 5336 (Feb. 21, 2020).

Janssen had entered into distribution agreements with the wholesalers, but not with Walgreen, which was an indirect purchaser. These distribution agreements contained an anti-assignment provision: 'neither party may assign, directly or indirectly, *this agreement or any of its rights or obligations under this agreement* . . . without the prior written consent of the other party . . . . Any purported assignment in violation of this section will be void.'[16] Despite this provision, some wholesalers assigned to Walgreen 'all of its rights, title and interest in and to' its claims against Janssen 'under the antitrust laws of the United States or of any State arising out of or relating to [the wholesaler]'s purchase of Remicade.'[17]

Shortly thereafter, Walgreen asserted federal antitrust claims against Janssen related to Remicade, challenging Janssen's exclusive contracts and anticompetitive bundling agreements with health insurers that allegedly suppressed generic competition and led to Janssen selling Remicade at supracompetitive prices.[18] Janssen moved to dismiss Walgreen's complaint, arguing that Janssen's anti-assignment provision with the wholesalers precluded their assignment to Walgreen. If true, Janssen argued, Walgreen would be considered an indirect purchaser that lacked antitrust standing under *Illinois Brick*. The District Court ultimately granted Janssen's motion for summary judgment and concluded that, under New Jersey law, the anti-assignment provision at issue precluded the wholesalers from assigning their federal antitrust claims against Janssen to Walgreen. Walgreen, therefore, lacked antitrust standing.[19]

Third Circuit decision

The Third Circuit ultimately reversed the dismissal on standing. In doing so, the appellate court relied heavily on an intra-Circuit decision, *Hartig Drug Co v Senju Pharmaceutical Co*.[20]

Factually similar to the instant case, the plaintiff in *Hartig* was an indirect purchaser that had been assigned antitrust claims from a direct-purchaser distributor of medicated eye drops.[21] The Third Circuit explained in dicta that '[b]ecause [the plaintiff's] antitrust causes of action arise by statute, there is a serious argument that they do not fall within the [agreement's] plain language limiting assignment of "rights and obligations hereunder" – that is, they arise by operation of an extrinsic legal regime rather than by contract.'[22]

16 *Id.* at *3 (*emphasis in original*). In its Opinion, the Third Circuit discussed the distribution agreements as if they were a single agreement as 'those agreements [were] identical in all material respects.' See *id.* at *3 n.1. We will do the same herein.

17 *Id.*

18 *Id.* at *3–4.

19 *Walgreen Co.*, 2020 U.S. App. Lexis 5336, at *4–5.

20 836 F.3d 261 (3d Cir. 2016).

21 *Id.* at 264.

22 *Id.* at 275 n.17. The anti-assignment provision at issue in *Hartig* provided that '[t]his Agreement may not be assigned' without prior written consent, but that 'either party may assign its rights and obligations hereunder' without written consent if the assignment is to a 'subsidiary or affiliate.' *Id.*

In an attempt to distinguish *Hartig*, Janssen advanced two primary arguments on appeal, both of which ultimately failed.[23] First, Janssen argued that New Jersey law, which governed the distribution agreements, recognizes that statutory causes of action fall within the scope of anti-assignment clauses prohibiting the assignment of 'rights under' that agreement. But the Third Circuit noted that the only statutory claims that were precluded by such an anti-assignment clause were those that 'flowed from an underlying breach of one or more provisions of the contract,' and that antitrust claims are 'separate from any contractual right.'[24]

Next, Janssen contended that the wholesalers' antitrust claims fell within the scope of the anti-assignment clause prohibiting the assignment of 'rights under' that distribution agreement because the wholesalers 'could not have purchased Remicade and accrued standing to assert antitrust claims but for [their distribution agreements].'[25] However, the Third Circuit recognized that Walgreen's antitrust claims were not attempting to invoke any contractual 'substantive right' derived from the actual distribution agreement.[26]

Janssen's efforts to distinguish *Hartig* failed, and the Third Circuit reversed the District Court's judgment in favor of Janssen.[27] The Third Circuit found that statutory antitrust claims are not 'rights under' a contract such that they fall within the scope of a boilerplate anti-assignment provision. Because most antitrust claims brought under section 1 are premised on some sort of contract or purchase agreement, and because many sellers have sought to use anti-assignment provisions in their contracts to protect against indirect purchaser claims, the Third Circuit's opinion in *Walgreen* may have the effect of a substantial increase in the number of indirect-purchaser litigants. These are claimants who otherwise would not be able to find relief in federal court pursuant to *Illinois Brick*.

23 Janssen advanced a third argument, which is discussed below.

24 *Walgreen Co.*, 2020 U.S. App. Lexis 5336, at *8–10.

25 *Id.* at *10.

26 The Third Circuit noted that the contract language from Janssen's case law – cases addressing whether certain claims 'arise out of' or 'arise under' an agreement to arbitrate – was 'more encompassing, and ultimately distinct from, the concept of "rights under" an agreement' and therefore inapposite. *Id.* at *11. The Third Circuit also addressed that the fact that the distribution agreements set the price for Remicade was not dispositive and did not necessarily mean that Walgreen's antitrust claims, complaining of supracompetitive prices, fell within the scope of the anti-assignment provision. *Id.* at *11–12.

27 Janssen also argued that 'the rationale of *Hartig* has been "eclipsed" by [the Third Circuit's] subsequent decisions in *Wallach v Eaton Corp.*, 837 F.3d 356 (3d Cir. 2016), and *American Orthopedic & Sports Medicine v Independence Blue Cross Blue Shield*, 890 F.3d 445 (3d Cir. 2018).' *Id.* at *8. First, the Third Circuit explained that in *Wallach* it had addressed 'whether the assignment of antitrust claims must be supported by consideration' and had not suggested, despite Janssen's argument to the contrary, that statutory claims were 'rights' under a contract. *Id.* at *12–13. Next, the Third Circuit found *American Orthopedic* to be inapposite because it involved the validity of an anti-assignment clause in an ERISA (Employee Retirement Income Security Act of 1974) benefit plan, not its scope. *Id.* at *13. In contrast to Walgreen's antitrust claims at issue here, the ERISA claims 'foreclosed by the anti-assignment clause flowed directly from an underlying breach of a contractual right.' *Id.*

Spring Pharmaceuticals LLC v Retrophin, Inc

Spring Pharmaceuticals LLC v Retrophin, Inc,[28] also involves a question of standing. This decision concerned a generic pharmaceutical company's competitor standing to sue a branded company. The litigation involves a creative antitrust claim by Spring Pharmaceuticals LLC (Spring) that a branded pharmaceutical company's refusal to sell samples of its drug – under the guise of risk evaluation and mitigation strategy prohibitions or otherwise – is an unlawful refusal to deal.[29] The US District Court for the Eastern District of Pennsylvania dismissed the antitrust claims alleged against the defendant, Retrophin, Inc (Retrophin).[30]

Background

The antitrust action concerned the market for a prescription drug with the active ingredient tiopronin. Retrophin marketed tiopronin under the brand name Thiola to treat the rare genetic disease cystinuria, which causes recurring kidney stones.[31] Although Thiola was off-patent at the time, it was the only Food and Drug Administration (FDA) approved tiopronin product of its kind.[32]

Spring formed for the purpose of developing a generic version of Thiola. It alleged that Retrophin violated antitrust laws by refusing to sell Thiola samples to Spring. The samples would have enabled Spring to develop a generic version of Thiola because, in order to do so, it must first demonstrate to the FDA that its generic product is the bioequivalent of the brand-name drug.

District Court decision

In assessing Spring's antitrust standing, the District Court discussed only one aspect of the analysis: whether Spring sufficiently pleaded its 'intent and preparedness' to enter the generic market for the prescription drug Thiola.[33] The District Court concluded that Spring failed to satisfy its pleading burden regarding 'intent and preparedness' for two distinct reasons.

28 No. 18-4553, 2019 U.S. Dist. Lexis 213901 (E.D. Pa. Dec. 11, 2019).

29 See, eg, Darren S Tucker et al., 'REMS: The Next Pharmaceutical Enforcement Priority?', *Antitrust Magazine* 28(2) (Summer 2014), at 74 (condemning brand-name pharmaceutical manufacturers for 'inappropriately limit[ing] access to product samples' that generic manufacturers 'need for bioequivalence testing, a predicate for FDA approval of generic drugs').

30 Specifically, the District Court dismissed claims for monopolization and/or attempted monopolization under section 2 of the Sherman Act, conspiracy to monopolize under section 2 of the Sherman Act, and contract in restraint of trade under section 1 of the Sherman Act. Though not discussed herein, the District Court also addressed standing and jurisdictional arguments asserted by the other defendants, Martin Shkreli, Mission Pharmacal Company and Alamo Pharma Services, Inc.

31 *Id.* at *2.

32 *Id.*

33 The District Court outlined other aspects required for antitrust standing: (1) the plaintiff suffered an injury of the type the antitrust laws were intended to prevent, (2) the defendant's allegedly anticompetitive conduct, and (3) material causal connection between the defendant's allegedly unlawful conduct and the plaintiff's harm – but declined to discuss those aspects. See *id.* at *32–34.

First, Spring 'failed to allege explicitly that the FDA [was] likely to approve its product or, alternatively, that [Spring] believe[d] that the FDA [was] likely to approve its product.'[34] In its complaint, Spring merely described the general process of securing FDA approval for a generic Thiola – namely, that (1) it must first receive FDA approval that its proposed generic product is indeed the bioequivalent of brand-name Thiola and receive an 'AB' rating, and then (2) the generic product becomes subject to 'automatic substitution' laws in effect in most states.[35] The District Court compared Spring's pleadings to those that failed in another intra-district case and concluded that Spring's allegations that the FDA's approval is required, coupled with a mere description of the FDA approval process, are insufficient to establish 'intent and preparedness.'[36]

Separately, Spring failed to 'adequately plead that it ha[d] taken sufficient affirmative steps to enter the market.'[37] Spring pleaded that it (1) attempted to obtain Thiola samples, (2) 'had discussions' with manufacturers regarding the development of generic Thiola, (3) negotiated with multiple contract development and manufacturing organizations (CDMOs) and 'reached an agreement with one CDMO to perform the necessary development work once Spring is able to acquire the Thiola samples,' and (4) had 'discussions with' regulatory expert consultants to obtain approval.[38] The District Court distinguished two intra-district cases and ultimately concluded that it was unclear from the complaint whether Spring had established sufficient networks to manufacture and distribute generic Thiola or whether any other relevant contracts would be needed to achieve FDA approval.[39]

Despite Spring's novel theory of anticompetitive conduct, or perhaps in light of it, this Opinion demonstrates a court's willingness to dispose of an antitrust case without reaching the merits and determining whether the refusal to sell samples – still a somewhat novel theory of harm – constitutes anticompetitive conduct for purposes of a motion to dismiss. The District Court avoided

34 See *id.* at *38–39.

35 See *id.*

36 Cf. *Brotech Corp. v White Eagle Int'l Techs. Grp., Inc.*, No. 03-232, 2004 U.S. Dist. Lexis 11552, at *17–22 (E.D. Pa. June 21, 2004) (holding that the plaintiff failed to plead antitrust standing where its complaint contained no allegations regarding 'the degree of FDA review which must be completed before those products may be marketed' or 'how far [plaintiff] has gone in the process of obtaining FDA approval of products incorporating its polymeric resin, when such approval may be anticipated, or whether it will be prepared to enter the product market as soon as such approval has been received').

37 See *Spring Pharms.*, 2019 U.S. Dist. Lexis 213901, at *39–41.

38 *Id.* at *40.

39 Cf. *Roxane Labs., Inc. v Smithkline Beecham Corp.*, No. 09-CV-1638, 2010 U.S. Dist. Lexis 5963, at *11–12 (E.D. Pa. Jan. 26, 2010) (finding antitrust standing where the plaintiff (1) 'had the background, experience and financial ability to market and sell generic Flonase'; (2) 'had manufacturing and distribution networks in place at the relevant time, and possessed a familiarity with the FDA approval process'; (3) 'took affirmative actions to enter the market for Flonase' such as 'submit[ing] an ANDA' and 'manufactur[ing] approximately four million units of generic Flonase in anticipation of market approval'; and (4) 'alleged that it reasonably believed that FDA approval was probable'); *Brotech Corp.*, 2004 U.S. Dist. Lexis 11552, at *18 (noting that, among other factors, 'the taking of actual and substantial affirmative steps toward entry, "such as the consummation of relevant contracts and procurement of necessary facilities and equipment"' are considered sufficient indicia of preparedness to enter the market (quoting *Hecht v Pro-Football, Inc.*, 570 F.2d 982, 994 (D.C. Cir. 1977))).

dusting off the doctrines of anticompetitive harm such as the 'no economic sense' or 'essential facility' doctrines to analyze the alleged conduct. We can expect in the future that district courts will continue to scrutinize such allegations of anticompetitive conduct with an eye on the plaintiff's standing allegations of its preparedness to enter in competition with the existing branded formulation. Generic companies may find it difficult to surmount antitrust standing as an obstacle to bring such claims.

In re Niaspan Antitrust Litigation

Background

In *Niaspan*, two putative classes of plaintiffs brought section 1 and 2 claims against AbbVie and Teva, challenging an alleged 'pay-for-delay' or 'reverse payment' settlement concerning the drug Niaspan.[40] The plaintiffs claimed that patent settlement agreements between the brand manufacturer and the generic manufacturer harmed competition and caused Niaspan purchasers to overpay.[41]

The US District Court for the Eastern District of Pennsylvania certified a class of direct-purchaser plaintiffs (DPPs) under Rule 23(b)(3) in this decision, rejecting the defendants' numerosity, adequacy and predominance arguments.[42] The Court's thorough analysis of antitrust class certification case law should prove useful to future litigants in the Third Circuit.

District Court decision

Numerosity

DPPs contended that the putative class contained 48 members.[43] The defendants, however, argued that the putative class only contained 42 members because DPPs' calculation improperly included 'six entities that have been acquired by other members of the proposed class.'[44] The Court rejected the pharmaceutical companies' argument, citing several district court decisions from the First, Second and Fourth Circuits in support.[45] Moreover, the Court noted that, even if the defendants' argument held water, a class size of 42 would still raise the presumption that joinder was impracticable.[46]

40 *In re Niaspan Antitrust Litig.*, 397 F. Supp. 3d 668, 673 (E.D. Pa. 2019).

41 *Id.* at 674.

42 The Court additionally found that commonality was 'easily met' (*Id.* at 679), the defendants had not challenged typicality (*Id.* at 680), the defendants had only challenged superiority based on its numerosity arguments, which the court rejected (*Id.* at 690), and DPPs had 'easily satisfied' the ascertainability requirement (*Id.* at 691).

43 *Id.* at 677.

44 *Id.*

45 *Id.*

46 *Id.*

Adequacy

With regard to adequacy of the named DPPs' representation, the defendants argued that 'there is a conflict between the named plaintiffs, all of which purchased brand Niaspan, and the class members which purchased only the generic' because 'class members which purchased brand Niaspan would prefer an overcharges theory of injury, whereas the generic-only purchasers could theoretically pursue much larger lost-profits damages.'[47] The Court also rejected this argument, finding that the named DPPs would 'fairly and adequately protect the interests of the class.'[48] It specifically noted that 'the possibility that a few plaintiffs in this case may prefer pursuing a lost profits damages theory rather than the standard overcharge theory does not create the type of fundamental conflict required' to defeat class certification.[49]

Predominance

Finally, the defendants made several predominance challenges to the DPPs' proposed class. The defendants first argued that the DPPs' expert witness had failed to demonstrate classwide proof of antitrust injury.[50] In rejecting this argument, the District Court noted that '[c]ourts have consistently ruled that this type of common evidence of brand-generic overcharges is sufficient to establish antitrust injury on a classwide basis.'[51] And even if some amount of individualized evidence would be required in this case, it would not overwhelm common questions.[52]

The defendants also challenged the DPPs' class certification expert's use of average prices.[53] While noting that the 'use of averages in a common impact analysis is controversial' and 'somewhat suspect,' the Court found that it was acceptable in this case because (1) the level of differentiation did not make the use of averages misleading, and (2) the averages did not hide the 'true story' of the averaged data.[54]

Furthermore, the defendants contended that the DPPs' three theories of overcharge injury would necessitate individualized inquiry.[55] They argued that it would be improper under *Comcast v Behrend*,[56] for DPPs to prove only one theory on a classwide basis 'then use that injury as a hook

47 *Id.* at 680 (*quotation marks omitted*).

48 *Id.* at 681.

49 *Id.*

50 *Id.* at 683.

51 *Id.* at 685 (citing *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 220 (3d Cir. 2012); *In re Wellbutrin Sr Direct Purchaser Antitrust Litig.*, No. 04-5525, 2008 U.S. Dist. Lexis 36719, 2008 WL 1946848, at *8 (E.D. Pa. May 2, 2008); and *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-02503, 2017 U.S. Dist. Lexis 170676, 2017 WL 4621777, at *7 (D. Mass. Oct. 16, 2017)).

52 *Id.* at 686.

53 *Id.* at 687.

54 *Id.* (quoting *In re Blood Reagents Antitrust Litig.*, No. 09-2081 , 2015 U.S. Dist. Lexis 141909, 2015 WL 6123211, at *18 (E.D. Pa. Oct. 19, 2015)).

55 *Id.* at 688.

56 569 U.S. 27, 38 (2013).

for recovering damages on unrelated theories of harm.'[57] The District Court concluded that, unlike in *Comcast*, the DPPs had presented only one theory of liability, which 'resulted in three types of overcharges.'[58]

Shire US, Inc v Allergan, Inc

In *Shire US, Inc v Allergan, Inc*,[59] Shire alleged that the defendants, multiple Allergan entities (Allergan), violated sections 1 and 2 of the Sherman Act by engaging in an 'ongoing, overarching, and interconnected scheme' to block Shire from competing with Allergan in the Medicare Part D prescription drug market for dry eye treatment.[60] The District Court for New Jersey granted Allergan's motion to dismiss.

Background

Shire and Allergan produced the only two FDA-approved prescription drugs for the treatment of dry eye disease.[61] Shire claimed that although its product, Xiidra, was superior, that Allergan unlawfully blocked it from competing with Allergan's product, Restasis.[62] Shire alleged that Allergan perpetuated an anticompetitive scheme by entering into bundled rebate deals and exclusive dealing agreements with Medicare Part D plan providers.[63]

District Court decision

The US District Court for the District of New Jersey granted Allergan's motion to dismiss Shire's complaint for failure to state a claim. The court found that Shire had failed to plead (1) a plausible product market, and (2) anticompetitive conduct.

First, the Court held that Shire failed to plausibly plead a relevant product market for Medicare Part D dry eye disease allegedly affected by the challenged agreements.[64] In supporting this market definition, Shire argued that the '[p]laintiff alleges that commercial prescription drug plans are not substitutes for Part D because individuals covered by Part D (individuals aged 65 and older or with permanent disabilities) receive lower premiums for a comprehensive list of prescription drugs,' and 'industry participants recognize Part D as its own independent market.'[65] Allergan contended that, because Shire alleged 'supplier exclusion, the relevant product market must be defined from the supplier's perspective' and that a market definition limited to Part D reimbursements was 'implausibly narrow.'[66]

57 *Id.*

58 *Id.* at 689.

59 375 F. Supp. 3d 538 (D.N.J. 2019).

60 *Id.* at 540.

61 *Id.* at 541.

62 *Id.* at 540.

63 *Id.*

64 *Id.* at 541.

65 *Id.* at 542.

66 *Id.* at 546.

The District Court agreed with Allergan's analysis and granted the motion to dismiss on market definition. The Court concluded that, 'under the circumstances alleged (that is, a supplier allegedly excluded from a market), the relevant product market consists of those to whom the supplier can sell unless special circumstances exist.'[67] Shire's alleged Medicare Part D product market was not plausibly pleaded because it did not account for other customers, 'such as non-government payers,' to whom Shire could possibly sell its dry eye product.[68] The Court found that Shire's market definition was indeed 'too narrow.'[69]

In deciding that Shire had failed to allege a plausible product market, the Court noted that the Third Circuit had not yet ruled on the appropriate relevant market where a supplier alleges that it has been improperly excluded.[70] Thus, the District Court looked to – and ultimately followed – First and Eighth Circuit precedent, concluding that 'when a supplier who is allegedly shut out of a market (or a substantial portion of the market), the relevant product market consists of all persons or entities to whom that supplier can reasonably sell unless special circumstances exist.'[71] In the Court's view, 'perspective is critical.'[72]

The District Court's product market reasoning is expected to carry significant weight within the Third Circuit, where the appellate court has not ruled on this issue.

The District Court held that Shire also failed to plead anticompetitive conduct or agreements violating sections 1 and 2 of the Sherman Act. The District Court explained that the challenged acts – bundled rebates and exclusive dealing contracts – are not inherently anticompetitive.[73] It observed, rather, that there are circumstances in which they can be pro-competitive, requiring analysis of the effects. Shire did not adequately allege that Allergan had monopoly power over the glaucoma drugs, which it was purported to have bundled with its dry eye treatment. The Court observed that bundling could be anticompetitive when a bundle links a competitive product with a product that is monopolized.[74] Furthermore, the contracts at issue were short-term and thus presented 'little threat to competition.'[75] For these reasons, the Court granted Allergan's motion to dismiss Shire's antitrust claims.

67 *Id.* at 547.

68 *Id.*

69 *Id.*

70 *Id.*

71 *Id.* at 551. The Court found that Shire had not 'plausibly alleged special circumstances.' *Id.* Special circumstances were found in other case law examined by the Court where suppliers were shut out of specific sub-markets that were critical to the suppliers' sustainability. See *id.* at 551 (analyzing *Methodist Health Servs. Corp. v OSF Healthcare Sys.*, No. 13-01054, 2015 U.S. Dist. Lexis 37887, 2015 WL 1399229 (C.D. Ill. Mar. 25, 2015)).

72 *Id.* at 552.

73 *Id.* at 557.

74 *Id.*

75 *Id.* at 558.

In re Generic Pharmaceuticals Pricing Antitrust Litigation

In re Generic Pharmaceuticals Pricing Antitrust Litigation,[76] the sprawling multidistrict litigation in the Eastern District of Pennsylvania involving allegations of price-fixing in the generic pharmaceutical industry, has given rise to a series of notable decisions regarding the appropriate scope of discovery in large antitrust price-fixing cases. In October 2019, the District Court issued an unprecedented discovery order requiring the defendants to produce all documents responsive to the plaintiffs' proposed search terms and forbidding defendants from withholding any of those documents on relevance or responsiveness grounds prior to production.[77] Following the order, the defendants filed a petition for writ of mandamus to the Third Circuit. The Third Circuit, however, denied the defendants' mandamus petition in December 2019, concluding that the District Court 'has wide latitude in controlling discovery' and 'the Federal Rules of Civil Procedure permit a district court to compel the production of documents within broad parameters.'[78] The defendants then turned to the Supreme Court, requesting that the Court stay the discovery order pending their pending resolution of their petition for certiorari. On 28 February 2020, Justice Samuel A Alito Jr granted a temporary stay of the discovery order.[79] Less than two weeks later, however, Justice Alito's stay was vacated.[80]

The defendants' petition for certiorari is currently pending. In the meantime, a number of major companies have filed amicus briefs urging the Court to take the case. These amici and many others argue that the order turns Rule 26 on its head and, more importantly, is an egregious example of district courts' growing willingness to force defendants to take on the burden and costs of producing massive amounts of discovery with little regard for relevance or responsiveness of that information.

76 No. 2:16-md-2724-CMR (E.D. Pa. Oct. 24, 2019).

77 *Id.* Dkt. No. 1135, at ¶ 3(b).

78 *In re Actavis Holdco U.S., Inc.*, No. 19-3549, 2019 U.S. App. Lexis 39254, at *7 (3d Cir. Dec. 6, 2019).

79 *Actavis Holdco U.S., Inc. v Connecticut*, 206 L.Ed.2d 250 (U.S. 2020).

80 *Actavis Holdco U.S., Inc. v Connecticut*, 206 L. Ed. 2d 270 (U.S. 2020) ('The application for stay presented to Justice Alito and by him referred to the Court is denied. The order heretofore entered by Justice Alito is vacated.').

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