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Contents

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 include this publication, *US Courts Annual Review*, which takes 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. New for our second edition of the publication are some high-level analysis chapters, looking at key trends across the country such as class certification, no poach and reverse payment cases.

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 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. Thanks also go to Paula W Render, formerly of Jones Day, as co-editor of the inaugural edition.

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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Part 2

Court Decisions

Third Circuit: Pharmaceutical cases

Noah A Brumfield, J Mark Gidley, Alyson Cox Yates, Kevin C Adam, Daniel Grossbaum and Gina Chiappetta
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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 that there will be noteworthy developments each year. And plaintiffs continue to find creative antitrust claims to assert that raise novel questions of substantive and procedural law. This chapter describes, among other things, a novel and potentially problematic interpretation of the sham litigation exception to *Noerr-Pennington* immunity, causation challenges concerning hypothetical patent litigations in competitor lawsuits, and the use of averages in assessing class-wide injury.

FTC v AbbVie, Inc

The Third Circuit's highly publicized decision in *FTC v AbbVie*[1] involves several topics of significance to antitrust litigants, including (1) interpretation of the seminal reverse-payment decision, *Actavis*,[2] (2) application of the sham litigation exception to *Noerr-Pennington* immunity, which is currently before the Supreme Court on the drug manufacturers' petition for a writ of certiorari, and (3) the availability of disgorgement under section 13(b) of the Federal Trade Commission Act (the FTC Act).

1 976 F.3d 327 (3d Cir. 2020).

2 *FTC v. Actavis, Inc.*, 570 U.S. 136, 143–44 (2013).

Background

The FTC litigation concerns a 2011 Abbott Laboratories settlement of patent infringement suits it brought against Perrigo and Teva relating to the testosterone-replacement therapy, AndroGel.[3] The FTC alleged that, on the same day as its settlement with Teva, Abbott also entered into a supply agreement with Teva for the cholesterol drug, TriCor.[4] The FTC claimed that the defendants filed sham patent-infringement suits against Teva and Perrigo, and entered into an anticompetitive reverse-payment agreement with Teva.[5] The FTC filed suit against Abbott, AbbVie, Unimed, Besins (collectively, the defendants), and Teva in the Eastern District of Pennsylvania pursuant to section 13(b) of the FTC Act.[6]

The district court granted the defendants' motion to dismiss the FTC's claims based on its reverse-payment theory.[7] The district court later granted summary judgment to the FTC on the objective-baselessness prong of *Professional Real Estate Investors*' (*PRE*) sham litigation exception to the *Noerr-Pennington* doctrine,[8] and after holding a bench trial, the district court found for the FTC on the subjective-motivation prong of the sham litigation exception and on monopoly power.[9] The court awarded $448 million in disgorgement but declined to order injunctive relief.[10]

Both the FTC and the defendants appealed to the Third Circuit. The FTC argued that the district court erred in dismissing its reverse-payment claims, in calculating the amount of disgorgement, and in denying injunctive relief.[11] The defendants argued that the district court erred in finding that the sham litigation exception applied and that the defendants possessed monopoly power.[12] The defendants further argued that the district court erred in ordering disgorgement and, alternatively, in calculating the amount of disgorgement.[13]

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3 *AbbVie*, 976 F.3d at 344.
4 *Id.*
5 *Id.* at 338.
6 *FTC v. AbbVie Inc.*, No. 2:14-cv-05151-HB (E.D. Pa.).
7 *AbbVie*, 976 F.3d at 346.
8 *Prof'l Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993).
9 *AbbVie*, 976 F.3d at 346.
10 *Id.*
11 *Id.*
12 *Id.*
13 *Id.*

Third Circuit decision

The Third Circuit held that the district court erred both in granting the defendants' motion to dismiss the FTC's reverse-payment claims, and in its summary judgment decision for the FTC that the defendants' patent-infringement suit against Teva was a sham.[14] The court affirmed the district court's findings that the suit against Perrigo was a sham, and also that the defendants possessed monopoly power.[15] Finally, the Third Circuit panel vacated the district court's disgorgement order, holding that the FTC lacks authority to seek disgorgement under section 13(b) of the FTC Act.[16]

Reverse payment

Relying on its prior decisions in *King Drug*[17] and *Lipitor*,[18] the Third Circuit reinstated the FTC's claims based on the reverse-payment theory.[19] The court held that the FTC had plausibly pleaded that the supply agreement under which the generic allegedly paid the patent owner may be construed as a 'large' and 'unexplained' payment under *Actavis*.[20] The court provided that 'a reverse payment's legality depends mainly on its economic substance, not its form,' and that 'economic realities rather than a formalistic approach must govern.'[21] It also rejected the district court's approach of viewing the settlement and supply agreements separately, noting that such a rule 'elevates form over substance because companies could avoid liability for anticompetitive reverse payments simply by structuring them as two separate agreements.'[22]

Sham litigation

Next, the Third Circuit held that the district court erred in concluding that the defendants' patent-infringement suit against Teva was a sham but did not err in finding that the suit against Perrigo was a sham.[23] The court concluded that the district court improperly found that the defendants' patent-infringement suit against Teva was objectively baseless because 'the FTC ha[d] not shown that no reasonable

14 *Id.* at 351, 359.
15 *Id.* at 359, 371.
16 *Id.* at 374.
17 *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).
18 *In re Lipitor Antitrust Litig.*, 855 F.3d 126, 145 (3d Cir. 2017).
19 *AbbVie*, 976 F.3d at 351–56.
20 *Id.* at 356.
21 *Id.*
22 *Id.* at 358.
23 *Id.* at 359.

litigant in [the defendants'] position would believe it had a chance of winning.' The Third Circuit reviewed the legal arguments in the underlying patent case and determined that 'the [applicable] law is not as well-settled as the FTC suggests' and so the patent claims were not objectively baseless.[24] By contrast, the Third Circuit affirmed the district court's conclusion that the defendants' suit against Perrigo was objectively baseless, because '[n]o reasonable litigant in [the defendants'] position would believe it had a chance of winning.'[25]

The Third Circuit also affirmed the district court's conclusion that the defendants' suit against Perrigo satisfied the subjective-motivation prong of *PRE*.[26] It rejected the defendants' argument that the district court had 'improperly merged sham litigation's objective baselessness and subjective motivation prongs,' finding instead that the two prongs 'are interrelated.'[27] The court then confirmed the district court's conclusion that 'because [the defendants'] decisionmakers were all very experienced patent attorneys who had reviewed Perrigo's paragraph IV notices and consulted outside counsel, they knew the lawsuits were baseless,' and thus, 'the decisionmakers . . . must have been motivated by something other than success on the merits.'[28] The court concluded: 'Especially given the collateral injury the Hatch-Waxman Act's 30-month stay invariably inflicts, the [district court] was permitted to conclude from this evidence that in filing an objectively baseless lawsuit against Perrigo, the decisionmakers were motivated not to assert a patent in good faith, but to impose expense and delay on Perrigo to delay its entry.'[29]

Disgorgement

With regard to the remedy awarded, the Third Circuit vacated the disgorgement order, holding that 'district courts lack the power to order disgorgement under Section 13(b) of the FTC Act.'[30] The court explained: 'Section 13(b) authorizes a court to "enjoin" antitrust violations. It says nothing about disgorgement, which is a form of restitution, not injunctive relief.'[31]

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24 *Id.* at 364–65.
25 *Id.* at 366.
26 *Id.* at 368.
27 *Id.* at 370.
28 *Id.*
29 *Id.* at 371.
30 *Id.* at 374.
31 *Id.* at 375.

The Third Circuit found that remand on the FTC's reverse-payment theory would not be futile. Even though disgorgement is not available for the reverse-payment claim, the court could not determine, 'based on the pleadings alone, that the [district court] would abuse its discretion by granting the FTC injunctive relief.'[32]

Pending certiorari petition

The defendants have filed a petition for a writ of certiorari, asking the Supreme Court to address '[w]hether the subjective element of the "sham litigation" exception to *Noerr–Pennington* immunity may be met by an inference from a finding that a challenged lawsuit was objectively baseless, even without evidence that the antitrust defendant actually believed the suit lacked merit or was indifferent to the outcome.'[33] Three amicus briefs have been filed in support of the petitioners.[34]

Fresenius Kabi USA LLC v Par Sterile Products LLC

The dispute between Fresenius and Par concerns exclusive supply allegations relating to the active pharmaceutical ingredient (API) for vasopressin, a drug used to increase blood pressure in adults. The specific issue on appeal was whether valid patents independently prevented entry and, thus, broke the chain of causation.

Background

Vasopressin was marketed and sold as an unapproved drug in the United States for decades, until the Food and Drug Administration (FDA) published a policy guide in 2011 indicating that the FDA would remove unapproved products from the market.[35] Following the issuance of that policy guide, Par sought FDA approval to market and sell its brand vasopressin product, Vasostrict, and received approval to do so in April 2014. Fresenius alleged that, following that approval, Par sought to force Fresenius's product

32 *Id.* at 381.

33 Petition for Writ of Certiorari, *AbbVie Inc. v. FTC*, No. 20-1293 (filed Mar. 18, 2021).

34 Brief of the Chamber of Commerce of the United States of America as Amicus Curiae in Support of Petitioners, *AbbVie Inc. v. FTC*, No. 20-1293 (filed Apr. 19, 2021); Brief of Amici Curiae Law Professors in Support of Petition for a Writ of Certiorari, *AbbVie Inc. v. FTC*, No. 20-1293 (filed Apr. 19, 2021); Brief for the Pharmaceutical Research and Manufacturers of America et al. as Amici Curiae in Support of Petition for a Writ of Certiorari, *AbbVie Inc. v. FTC*, No. 20-1293 (filed Apr. 19, 2021).

35 *Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, No. 16-4544 (SDW) (LDW), 2017 U.S. Dist. LEXIS 19084, at *2 (D.N.J. Feb. 10, 2017) ('*Fresenius* Motion to Dismiss Ruling').

out of the market by, among other things, purportedly contacting the FDA about Fresenius's sale of unapproved vasopressin.[36] In 2014, the FDA instructed Fresenius to cease manufacture and distribution of its vasopressin product by mid-2015.[37]

After withdrawing its product, Fresenius claimed it sought to submit an abbreviated new drug application[38] (ANDA) to launch a generic version of vasopressin. Yet, in trying to prepare its ANDA, Fresenius claimed that suppliers of the API had become subject to exclusive dealing arrangements with Par.[39] These agreements, Fresenius alleged, were part of Par's efforts to 'lock up difficult-to-source API' to prevent competitors from entering the market.[40] Fresenius sued Par, alleging that Par delayed the launch of generic vasopressin manufacturers' entry by entering into exclusive agreements with the only three API suppliers who could supply vasopressin, asserting claims under sections 1 and 2 of the Sherman Act and the New Jersey Antitrust Act.

On 25 February 2020, US District Court Judge Susan D Wigenton granted Par's motion for summary judgment, concluding that the existence of Par's patents on Vasostrict broke the chain of causation because they prevented Fresenius from entering the market.[41] Although Fresenius had alleged that but for Par's alleged anti-competitive conduct Fresenius would have successfully challenged those patents, Judge Wigenton emphasized that Fresenius had never even filed an ANDA, concluding that Fresenius's argument that it would have challenged the patents in a but-for world and prevailed was unduly speculative:

> *Evaluating this argument would require a jury, amidst an antitrust trial, to predict what the resolution of these hypothetical patent challenges would have been. This task, however, would be unduly speculative and procedurally burdensome. First, there was never an actual patent challenge and, thus, no concrete basis to determine what a hypothetical adjudicator would have found at each stage of such action. Second, Fresenius never submitted the*

36 *Id.*

37 *Id.*

38 See 21 U.S.C. § 355(j); 21 C.F.R. § 314.92.

39 *Fresenius* Motion to Dismiss Ruling at *3–4.

40 *Id.*

41 *Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, No. 16-4544 (SDW) (LDW), 2020 U.S. Dist. LEXIS 32034, at *8–9, *15 (D.N.J. Feb. 25, 2020).

> *ANDA outlining the Vasopressin product it would have created ('Hypothetical Product'), therefore, evaluating a hypothetical infringement action based on that product is even more speculative.*[42]

In reaching her conclusion and dismissing Fresenius's claims, Judge Wigenton distinguished the *Wellbutrin*[43] case, which Fresenius argued required an assessment of a hypothetical patent litigation, concluding that unlike in *Wellbutrin*, there 'was never an underlying patent challenge or an underlying ANDA from which a jury could make a reasoned decision on how such hypothetical patent action on invalidity or infringement would have been resolved.'[44]

Third Circuit decision

On 11 January 2021, the Third Circuit rejected the trial court's causation analysis and vacated the district court's summary judgment ruling, remanding the case.[45] The Third Circuit explained that, under *Wellbutrin*, 'the district court "must consider the substance of" [the patent claims at issue] because where a valid patent independently blocks the plaintiff's entry into the relevant market, the defendant's allegedly anticompetitive conduct cannot be the cause of the plaintiff's injury.'[46] The district court's failure to analyze whether a reasonable jury could have found that Par's patents would have blocked Fresenius's entry – even though Fresenius had not filed an ANDA – was inconsistent with *Wellbutrin*, the Third Circuit concluded.[47] 'Because *Wellbutrin* required the District Court to examine the record to determine whether a reasonable jury could find that Par's patents would have blocked Fresenius Kabi's market entry, we will remand.'[48]

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42 *Id.* at *8–9.

43 *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017).

44 *Fresenius*, 2020 U.S. Dist. LEXIS 32034, at *14–15 ('Unlike here, in *Wellbutrin*, (1) underlying patent actions actually existed and were litigated past the early stages; and (2) an ANDA underlying the patent challenge had been filed. . . . *Wellbutrin*'s alternative world was much more concrete than the alternative world Fresenius proposes considering here, allowing experts a less speculative basis for their opinions.').

45 *Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, No. 20-1618, 2021 U.S. App. LEXIS 614, at *8 (3d Cir. Jan. 11, 2021).

46 *Id.* at *6–7 (quoting *Wellbutrin*, 868 F.3d at 166–67 (internal citations omitted)).

47 *Id.*

48 *Id.* at *8.

Although the decision is non-precedential, the Third Circuit's conclusion that 'an argument that a patent would have blocked an antitrust plaintiff's market entry, and a response that the patent is either invalid, or unenforceable, or the product at issue does not infringe it' necessarily 'triggers a patent analysis under *Wellbutrin*,' provides a cautionary example of the potential scope of *Wellbutrin*. Indeed, district courts must already assess what would have happened in a hypothetical patent litigation in which the patents at issue were actually challenged, and now they must do so, even when a generic company has failed to even file an ANDA (that is, without knowing which patents, if any, would have been subject to challenge or why). The Third Circuit's parting words do not provide much in the way of guidance for district courts trying to determine how far this speculative exercise must go: 'Whether the record permits the District Court to engage in such an analysis of course will be for it to decide.'[49]

In re Lamictal Direct Purchaser Antitrust Litigation

The *In re Lamictal* appeal concerns proof of class-wide injury – specifically the use of averages – in considering class certification.

Background

The defendants in *In re Lamictal* appealed the decision of the US District Court for the District of New Jersey certifying a class of direct-purchaser plaintiffs (DPPs) that alleged that a patent litigation settlement involving anti-epilepsy drug Lamictal constituted an anticompetitive reverse payment under *FTC v Actavis*.[50] In support of their motion for class certification, the DPPs argued that common evidence, such as economic literature, pricing forecasts, and transactional data (which suggested that, on average, the price of generic drugs declines as more generic competitors enter the market) demonstrated class-wide injury.[51] The DPPs further proffered an economic model prepared by their expert, which relied on hypothetical average prices to show that each class member would have paid less for generic Lamictal absent the defendants' alleged conduct.[52] The district court found that the DPPs' proffered evidence satisfied

49 *Id.*

50 *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184 (3d Cir. 2020).

51 *Id.* at 193.

52 *Id.*

Rule 23's predominance requirement.[53] On interlocutory appeal, the Third Circuit vacated the district court's certification order and stressed that lower courts must engage in a 'rigorous analysis' of competing evidence at the class certification stage.[54]

Third Circuit decision

In reversing the district court's certification order, the Third Circuit found that the district court failed to resolve several factual disputes that bear on whether the DPPs' reliance on averages was appropriate to prove class-wide injury.[55] For instance, one defendant presented evidence that it engaged in a unique contracting strategy to promote the sale of its brand product over an available generic, and that in response, a generic company preemptively lowered the price of its product to effectively compete with its brand counterpart.[56] According to the defendants' expert, by relying on averages and not accounting for the generic firm's preemptive price-lowering and individualized negotiations in the actual world, the DPPs masked that up to one-third of the proposed class likely paid less for their purchases than they would have paid absent the challenged settlement agreement.[57]

The Third Circuit concluded that the district court inappropriately assumed that the DPPs' antitrust injury occurred the moment that the challenged patent settlement agreement was executed.[58] Instead, the court should have analyzed arguments about whether generic prices were ever inflated and scrutinized the evidence relied upon by competing experts to determine which analysis was more credible. Ultimately, the court found that, although reliance on averages may be acceptable when the averages 'do not mask individualized injury,' the district court's failure to resolve the various factual disputes that bear on the analysis made it impossible for the Third Circuit to determine whether such reliance was appropriate in this case.[59]

In rendering its decision, the Third Circuit stressed that courts must perform an exacting review to determine whether class representatives can prove class-wide injury through common evidence. For instance, the court reaffirmed that plaintiffs must show by a preponderance of evidence that their claims are 'capable of common

53 *Id.* at 190.
54 *Id.* at 191, 193–94, 196.
55 *Id.* at 194–95.
56 *Id.* at 189.
57 *Id.* at 192.
58 *Id.* at 194.
59 *Id.*

proof.' The court rejected the DPPs' argument that courts must accept any proposed common evidence of class injury 'unless no reasonable juror could believe the common proof at trial.'[60] The court noted, further, that the Third Circuit applies a 'more lenient predominance standard for damages than for injury,' and the district court's application of the 'more permissive damages' standard to its analysis of the DPPs' common evidence of injury required remand.[61]

In re Sensipar Cinacalcet Hydrochloride Tablets Antitrust Litigation

In re Sensipar[62] involves a familiar reverse-payment theory, but is based on infrequently alleged facts. The antitrust claim concerned a settlement reached after an at-risk launch, and on the basis of a cash payment by the generic defendant to the branded plaintiff to settle the litigation.

Background

Sensipar is the trademarked name for Amgen's cinacalcet product, which is used to treat certain conditions in patients with chronic kidney disease. Like many products, Sensipar was patent protected and also the subject of Paragraph IV challenges by generic manufacturers. But unlike in many other reverse-payment cases, generic manufacturer Teva obtained a judgment from the district court that its product did not infringe Amgen's patents over Sensipar. After obtaining that judgment, Teva launched 'at-risk' – having not yet obtained a final, non-appealable judgment – and sold approximately $393 million of its product in just seven days. Shortly after Teva's launch, Amgen and Teva entered into a settlement agreement.

Private plaintiffs challenged the Amgen–Teva settlement claiming that it constituted an unlawful reverse payment. The crux of the plaintiffs' claim was that Teva and Amgen reached a sweetheart deal in which Teva agreed to pay Amgen only $40 million in damages, agreed to refrain from entering until June 2021 (five years before the expiry of Amgen's patent), and obtained an acceleration provision that allowed Teva to enter the market earlier under certain circumstances. The defendants filed their motions to dismiss, and the district court granted the motions in part and denied in part.

60 *Id.* at 191–92.

61 *Id.* at 194–95.

62 2020 U.S. Dist. LEXIS 223786 (D. Del. Nov. 30, 2020).

District court decision

The plaintiffs first attempted to challenge the settlement agreement outside the '*Actavis* framework,' arguing that the Amgen–Teva settlement was 'a "rank allocation agreement between Teva and Amgen" which is *per se* unlawful.'[63] The district court rejected the plaintiffs' argument, holding that *Actavis* and the rule-of-reason apply.[64]

The court then evaluated each of the plaintiffs' arguments under the *Actavis* rule-of-reason framework. In evaluating the plaintiffs' specific challenges, the court found that the plaintiffs' claim – that by 'dropping that appeal, and thereby giving up its claim to all but $40 million (and not even the full $393 million of revenues Teva had earned from its at-risk launch), Amgen was permitting Teva to retain at least some of the profits Teva had earned at Amgen's expense'[65] – was a plausible reverse-payment theory. Specifically, the court found the '"forward" payment' of $40 million from Teva to Amgen could not 'be divorced from what Teva did *not* pay Amgen' (i.e., the remaining $250 million in sales Teva had made from its at-risk launch and Amgen's lost profits). The court also refused to dismiss the plaintiffs' challenge to the acceleration provision under which Teva was entitled to enter the market earlier should another generic competitor enter with its own ANDA product. The court held that provision contained value to Teva and, therefore, constituted an 'additional transfer of value [that] must also be factored into the rule of reason analysis.'[66]

The court did, however, dismiss the plaintiffs' theory that the Amgen–Teva agreement deterred other generic competitors from filing their own ANDAs and seeking to market their products. The court held that 'if [the Amgen–Teva] agreement was lawful when they executed it, that same agreement could not later become unlawful solely due to the actions of other parties, e.g., other generic competitors of Teva.'[67] Moreover, the court found that 'ANDA filers understand the nature of competition in the pharmaceutical market' and therefore would not be deterred 'from launching their generic product just because Amgen agreed to allow Teva also to re-launch upon any third-party launch.'[68]

63 *Id.* at *10–11.
64 *Id.* at *11, *14–15.
65 *Id.* at *18.
66 *Id.* at *19–20.
67 *Id.* at *25.
68 *Id.* at *26.

In re Niaspan Antitrust Litigation

This district court denial of class certification turned on findings for defendants on three separate issues: ascertainability, predominance, and superiority.

Background

In 2019, the US District Court for the Eastern District of Pennsylvania certified a class of direct-purchaser plaintiffs challenging an alleged 'pay-for-delay' or 'reverse-payment' settlement concerning the drug Niaspan.[69] In this case, the court considered whether a second class of indirect-purchaser plaintiffs (IPPs) – including both third-party payers and consumers – alleging similar claims should also be certified.[70] The court ultimately found that class certification was not appropriate because the IPPs failed to satisfy the Third Circuit's ascertainability requirement, and the predominance and superiority requirements of Rule 23(b)(3).

District court decision

Ascertainability

As an initial matter, the court rejected the IPPs' argument that under Third Circuit precedent, 'plaintiffs can satisfy ascertainability with "almost zero evidence,"' and noted that the court would rigorously analyze whether proposed class members could be identified.[71]

In analyzing the first prong of the ascertainability analysis, the court rejected the defendants' arguments that 'given the complex flow of payments and reimbursements in the pharmaceutical distribution chain, it is far from clear exactly who is in the class and who is not,' finding that the class definition was defined with reference to objective criteria.[72] Moreover, the court agreed that the IPPs submitted sufficient evidence to show that pharmacy benefit managers maintain the pharmaceutical transaction data necessary to identify class members in a standardized industry format and that the IPPs could obtain such data.[73] However, the court found that the IPPs did not propose an administratively feasible method for applying class exclusions.[74] In rendering its decision, the court noted that the IPPs' expert's six-step methodology

69 *In re Niaspan Antitrust Litig.*, 397 F. Supp. 3d 668 (E.D. Pa. 2019).
70 *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678 (E.D. Pa. 2020).
71 *Id.* at 700–01.
72 *Id.* at 701.
73 *Id.* at 704.
74 *Id.* at 704–07.

was not 'specific to [the] case,' and the IPPs did not provide the defendants with necessary information that would allow them to meaningfully test the reliability of the IPPs' proposed method of identifying class members.[75] Moreover, the court found that even if the IPPs could use their expert's methodology to identify class members and apply class exclusions, the proposed methodology would be prohibitively expensive and, thus, was not feasible.[76]

Predominance

The court also held that the IPPs failed to show that questions of law or fact common to the proposed class members predominated over questions affecting only individual members. The IPPs argued that the analysis of its expert demonstrated that virtually all proposed class members were injured on at least one transaction by the alleged delay in generic Niaspan competition.[77] However, the defendants argued that the expert's analysis impermissibly masked the presence of uninjured class members and that the identification of uninjured class members would require individualized inquiry.[78]

The court agreed that the IPPs' expert's use of averages hid 'several groups of uninjured class members who cannot be easily identified,' and noted the critical admission by the IPPs' expert that her model did not purport to show that all class members were injured.[79] Moreover, the court was not satisfied that the IPPs had a 'non-individualized means of identifying' the 'substantial numbers of uninjured consumer brand loyalists, coupon users, and flat co-payers' in the class.[80] As a result, the court held that the IPPs lacked common evidence of antitrust injury and did not satisfy the predominance requirement.[81]

Superiority

Finally, the court found that the IPPs did not establish that a class action was superior to alternative methods of adjudication. The defendants argued that the court would need to analyze the IPPs' claims under 53 state laws and decide 'critical and

75 *Id.*
76 *Id.* at 707.
77 *Id.* at 715.
78 *Id.*
79 *Id.* at 714–21.
80 *Id.* at 720–21.
81 *Id.* at 721.

unsettled legal issues regarding how those laws would apply' to the IPPs' allegations.[82] The defendants also stressed that the IPPs did not provide an analysis of the state laws at issue or explain how they planned to manage variations among the state laws at trial.[83] In response, the IPPs argued that the variations in applicable state laws are 'minor and manageable' and that variations among the various relevant statutes could be addressed on a special verdict form.[84]

The court was 'not persuaded by [the IPPs'] *ipse dixit* that there are no significant variations between the various state laws' and held that the IPPs did not provide the court with 'a record sufficient for the Court to conclude that variations in applicable state laws are manageable in a single trial.'[85]

82 *Id.* at 724.
83 *Id.*
84 *Id.*
85 *Id.* at 724–25.

NOAH A BRUMFIELD
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Noah Brumfield is a partner in White & Case's global competition practice group, which is ranked among the 'Global Elite' for antitrust.

Antitrust plaintiffs and enforcers are invoking the antitrust laws in increasingly novel ways in private litigation and government investigations. Noah provides creative and nimble strategies that are specific to his clients' business objectives, whether they are in high-stakes litigation or planning a transformative deal. He is singularly focused on understanding each client to provide practical, business-oriented solutions.

Noah draws on his 20 years of experience with complex antitrust issues under US federal and state competition law, with a focus on how the antitrust laws intersect with intellectual property. He has successfully defended and asserted antitrust claims in merger and non-merger investigations before the enforcement agencies, and in federal district court.

Noah is an adjunct professor for antitrust at UC Berkeley, Boalt Hall School of Law, teaching Antitrust and Innovation (Spring 2020). He is a prolific author and speaker on a range of competition topics, and contributes to American Bar Association (ABA) publications and commentary.

J MARK GIDLEY
White & Case LLP

J Mark Gidley chairs the White & Case global antitrust and competition practice, which is the only such practice to have been named Competition Group of the Year for seven years by *Law360*. In 2019, he was named Competition MVP by *Law360* for the second time.

Mr Gidley is one of the most experienced lawyers in the United States in trying criminal and civil antitrust cases, whether involving claims of price-fixing, monopolization, or arising from a merger. In US trials, he has victories over the US Department of Justice (DOJ) in foreign exchange case (criminal) *US v Usher*, *Stolt I* and *Stolt II* (criminal cartel/amnesty agreement), *Ian Norris* (criminal cartel/obstruction), *Sungard* (merger) and *AgriMark* (merger); over the Federal Trade Commission (FTC) in *FTC v Schering-Plough* (the first reverse payment trial in the United States); and over class actions and opt-out litigants (Toshiba LCD $2.7 billion direct purchaser class action; Toshiba LCD $2.4 billion *Best Buy* trial, *Heveafil*). His cases have shaped modern antitrust law in mergers, cartels, monopolization, and pharma antitrust.

Mr Gidley served as the Acting Assistant Attorney General for the DOJ Antitrust Division in 1992–1993 with responsibility for all civil, criminal and merger matters of the Division. Prior to that, he served as Deputy Assistant Attorney General for Regulated Industries in the Antitrust Division from 1991 to 1992, responsible for civil, criminal and merger matters in the telecommunications, energy, computers, intellectual property, and banking and finance industries. From 1990 to 1991, Mr Gidley served as Associate Deputy Attorney General under the then Deputy Attorney William P Barr, specializing in antitrust and violent crime issues.

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Alyson Cox Yates is an associate in White & Case's Washington, DC, office and a member of the firm's global antitrust/competition practice. Her practice concentrates on complex federal litigation in the areas of antitrust and class actions, at both the trial and appellate levels. Alyson has regularly represented global pharmaceutical companies, such as Allergan, in class action litigation matters involving reverse-payment settlements of patent disputes and life cycle management strategies. Alyson also devotes substantial time to pro bono matters, with a focus on solitary confinement litigation.

Prior to joining White & Case, Alyson served as a judicial law clerk to the Honorable Eugene Siler, Jr of the US Court of Appeals for the Sixth Circuit and the Honorable Thomas Varlan, of the US District Court for the Eastern District of Tennessee. During law school, Alyson was the Managing Online Editor of the *Washington & Lee Law Review* and the Senior Articles Editor of the *German Law Journal*. She also served as a judicial intern to the Honorable Royce Lamberth of the US District Court for the District of Columbia.

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