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FTC v Actavis and pricing practices spearhead rise in US pharmaceutical antitrust cases

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In summary

The past year has continued to see an increase in US case law and other developments in the area of pharmaceutical antitrust. This article examines antitrust claims under the US Supreme Court's decision in *FTC v Actavis* for settlements of patent litigation involving alleged reverse payments or 'pay for delay'; antitrust claims against innovator pharmaceutical companies that allegedly engage in product hopping by introducing new versions of brand-name drugs facing generic competition; and pharmaceutical pricing developments involving legislation, regulation and legal challenges.

Discussion points

- Recent motion-to-dismiss decisions for both plaintiffs and defendants in reverse-payment cases
- Recent jury verdicts in reverse-payment cases, all for defendants
- A recent summary judgment decision for a defendant, dismissing product-hopping claims
- Legislation and legal challenges related to pharmaceutical manufacturers' pricing practices, including the passage of the federal Inflation Reduction Act and the role of pharmacy benefit managers in the drug-pricing chain

Referenced in this article

- *FTC v Actavis*
- *In re Bystolic Antitrust Litigation*
- *In re Humira (Adalimumab) Antitrust Litigation*
- *In re HIV Antitrust Litigation*
- The Sherman Act
- The Inflation Reduction Act
- Pharmacy benefit managers

Reverse-payment case law under Actavis

The US Supreme Court's decision in *FTC v Actavis* opened a floodgate for more than 30 separate antitrust cases that have been filed or revived under that decision. Reverse-payment claims generally allege that an innovator pharmaceutical company provided financial inducement to a potential generic competitor to settle patent litigation concerning the innovator's drug product, or to obtain a later settlement entry date than the generic company otherwise would have accepted, absent the innovator's financial inducement.

The majority opinion in *Actavis* rejected the deferential 'scope of the patent' test, but the majority opinion likewise rejected the Federal Trade Commission's (FTC) proposed 'quick look' rule of presumptive unlawfulness. Instead, the Supreme Court charted a middle course, holding that 'the FTC must prove its case as in other rule-of-reason cases'.[1]

In doing so, the Supreme Court expressly reserved an option for innovators to provide financial settlement consideration to generic companies beyond the value of early entry alone:

> *Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.*[2]

The Supreme Court expressly delegated to the lower courts the task of figuring out how to apply the rule of reason to alleged reverse-payment settlements. In the years since, we have seen conflicting district court decisions, the first jury verdicts and several appellate decisions.

Pleading standards under Actavis

Following the Supreme Court's *Actavis* decision, some courts have concluded that a reverse payment may include certain non-cash transfers of value from a brand company to a generic company at or near the time of their patent settlement. These non-cash transfers of value may sometimes include, for example, no-authorised generic (no-AG), co-promotion, licensing, distribution and other agreements.[3] At first, some courts grappled with how precisely

1 *FTC v Actavis, Inc*, 570 US 136, 159 (2013).
2 id., at 156.
3 See, eg, *King Drug Co of Florence v Smithkline Beecham Corp*, 791 F.3d 388, 394 (3d Cir 2015) (*Lamictal*) ('[T]his no-AG agreement falls under *Actavis*'s rule'); *In re Loestrin 24 FE Antitrust Litig*, 814 F.3d 538, 550 (1st Cir 2016) (*Loestrin*) ('[T]he district court erred in determining that non-monetary reverse payments do not fall under *Actavis*'s scope'); *Picone v Shire PLC*, No. 16-cv-12396, 2017 US Dist Lexis 178150, at *10 (D Mass 20 October 2017) (holding that a no authorised generic agreement and a 'sharply discounted royalty rate' may constitute a payment); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503, 2015 US Dist Lexis 125999, at *33–43 (D Mass 14 August 2015) (holding that a

a plaintiff must allege monetary estimates of value transferred to generic challengers,[4] but several courts have since explained that plaintiffs must 'plead information sufficient to estimate the value' of the non-cash transfer of value.[5]

For example, in January 2022, the district court in *Bystolic* dismissed reverse-payment claims as to separate settlements between a brand company and several generic challengers that shared 'first filer' status. The court held that the plaintiffs did not sufficiently allege facts to 'support the plausible inference of a large and unexplained reverse payment under *Actavis*'.[6] The brand company, for instance, entered into a supply agreement with one of the generic defendants, which plaintiffs alleged 'exceeded the fair value of any products delivered or services' and 'was a pretextual conduit of cash in exchange for an agreement not to compete'.[7] The court rejected those allegations as mere 'labels and conclusions' that 'could be asserted in every case in which there is a side agreement with a generic manufacturer who agrees to honor a patent'.[8] The court explained that '[i]f those naked allegations were enough to require an answer and to shift the burden to the defendant to prove fair value and the absence of pretext, there would be nothing left of the Supreme Court's rejection of the per se rule in *Actavis*'.[9]

In February 2023, after the plaintiffs amended their complaints in *Bystolic*, the court again dismissed plaintiffs' claims, this time with prejudice.[10] The court held that plaintiffs' amended complaints failed to include 'facts as to any factors that would suggest conduct inconsistent with a pro-competitive justification', concluding that plaintiffs had 'not cured the deficiencies identified in the' previously dismissed complaints.[11] In doing so, the district court analysed the terms of each of the challenged 'side agreements' in detail, holding that plaintiffs' allegations failed to plausibly show a large and unjustified payment for delay. Following the dismissal, plaintiffs filed an appeal in the US Court of Appeals for the Second Circuit, which remains pending as at the time of writing and has garnered the attention of various organisations as amicus curiae, including the FTC.

settlement and licence agreement with upfront and milestone payments may constitute a payment); *In re Aggrenox Antitrust Litig*, 94 F Supp 3d 224, 242 (D Conn 2015) (holding that a '"payment" is not limited to cash transfers').

4 See, eg, *In re Lipitor Antitrust Litig*, 868 F3d 231, 255 n.11 (3d Cir 2017); *United Food & Commer Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v Teikoku Pharma USA, Inc*, 74 F Supp 3d 1052, 1070 (ND Cal 2014) (*Lidoderm*); *In re Opana ER Antitrust Litig*, 162 F Supp 3d 704, 718 (ND Ill 2016).

5 *Loestrin*, 814 F.3d at 552 (quoting *In re Actos End Payor Antitrust Litig*, No. 13-CV-9244, 2015 US Dist Lexis 127748, at *61–62 (SDNY 22 September 2015)); see also *In re Opana ER Antitrust Litig*, 2016 US Dist Lexis 23319, at *29 (ND Ill 25 February 2016).

6 *In re Bystolic Antitrust Litig*, 583 F Supp 3d 455, 482 (SDNY 2 February 2022).

7 id., at 484.

8 ibid.

9 ibid.

10 *In re Bystolic Antitrust Litig*, No. 20-cv-5735, 2023 US Dist Lexis 52269, at *92 (SDNY 21 February 2023).

11 id., at *41.

In another recent decision, the US Court of Appeals for the Seventh Circuit affirmed the dismissal of reverse-payment claims in August 2022. The plaintiffs alleged that the brand manufacturer of Humira 'paid biosimilar manufacturers in the form of European agreements that allowed the biosimilars to enter the European market' while agreeing to '[brand]-friendly' generic entry dates in the US.[12] The 'package deals' allegedly bought the brand 'more lucrative monopoly time in the US (worth billions of dollars in revenue for [the brand manufacturer])'.[13] The district court rejected this theory because the settlements increased competition 'by bringing competitors into the market when patents otherwise prohibited competition'.[14]

On appeal, the Seventh Circuit agreed with the district court, emphasising that *Actavis* 'rejected the possibility of treating an "implicit net payment" as equivalent to an actual payment, characterizing the reverse-payment problem as "something quite different" from an opportunity cost', such as the 'money that [the brand] is said to have left on the table in Europe' by allowing biosimilars to launch earlier.[15] As the court explained, '[o]n each continent [the brand] surrendered its monopoly before all of its patents expired, and the rivals were not paid for delay'.[16] 'It would be much too speculative to treat the different entry dates as some kind of "reverse payment" rather than a normal response to a different distribution of legal rights under different patent systems.'[17] Thus, 'the US settlement and the EU settlement are traditional resolutions of patent litigation' that do not violate antitrust laws.

By contrast, in December 2022, the court in *Amitiza* denied in part a motion to dismiss where plaintiffs alleged that the generic manufacturer agreed to delay launching a generic version of Amitiza.[18] In exchange, the brand manufacturer allegedly accepted below-market royalties on the generic manufacturer's generic sales and structured the settlement agreement's royalty provisions to discourage an authorised generic.[19] The brand manufacturer argued that the settlement provides only for payment from the generic manufacturer, an alleged infringer, to the patentee and thus is not a reverse payment under *Actavis*.[20] The court, however, found that plaintiffs plausibly alleged that the generic manufacturer received 'unjustified profits' from its alleged monopoly in the generic Amitiza market based on the alleged settlement structure discouraging an authorised generic and the allegedly discounted royalties.[21] The court was

12 *In re Humira (Adalimumab) Antitrust Litig*, 465 F Supp 3d 811, 840 (ND Ill 2020).
13 id., at 840–41.
14 id., at 840–42.
15 *Mayor of Baltimore v AbbVie Inc*, 42 F 4th 709, 716 (7th Cir 2022).
16 ibid.
17 ibid.
18 *In re Amitiza Antitrust Litig*, No. 21-11057, 2022 US Dist Lexis 231668, at *6 (D Mass 27 December 2022).
19 ibid.
20 id., at *10–11.
21 ibid.

'not prepared to say, at this early stage in the litigation, that these alleged profits do not qualify as a reverse payment'.[22]

Summary judgment under Actavis

Courts have also grappled with how to apply *Actavis* at summary judgment when evaluating evidence. Many summary judgment decisions have focused on whether business agreements executed contemporaneously with patent settlements are 'large and unjustified'. In these decisions, district courts have analysed various arguments concerning whether there was sufficient evidence that the compensation for services was significantly above fair market value; whether the services were unnecessary or unwanted; whether the agreements for services included 'unusual' terms; whether the brand company failed to follow certain industry or internal practices; and the extent to which these business agreements may be 'linked' to the patent settlements.[23]

In the past year, there have been two summary judgment decisions, both allowing the reverse-payment claims to proceed to trial. In *Zetia*, the court found that disputed issues of fact remained as to whether the challenged settlement prevented the brand manufacturer of Zetia from launching an authorised generic product, as well as the value and justifications for such a provision.[24] Defendants argued that plaintiffs lacked evidence showing that the alleged no-AG provision was a payment made in exchange for delayed competition. But the court found that the plaintiffs 'produce[d] sufficient evidence for a reasonable juror to find' that the brand company had agreed to refrain from launching an authorised generic version of Zetia in exchange for delayed entry.[25]

In the *HIV Antitrust Litigation*, the summary judgment motion focused on whether the settlement's non-royalty bearing most-favoured-nations clauses (MFNs) were negotiated in exchange for a later generic-entry date and effectively restored the first filer's forfeited exclusivity period.[26] The defendants argued that the MFNs were negotiated after an entry date had already been set, meaning the MFNs could not have impacted the settlement's generic-entry date. But the court found that a disputed question of material fact remained as to when

22 ibid.

23 *In re EpiPen (Epinephrine Injection, USP) Mktg, Sales Practices & Antitrust Litig*, 545 F Supp 3d 922 (D Kan 2021); *In re Intuniv Antitrust Litig*, 496 F Supp 3d 639, 661 (D Mass 2020); *FTC v Actavis Inc (In re AndroGel Antitrust Litig (No. III)*, No. 1:09-md-2084, 2018 US Dist Lexis 99716, at *42–43 (ND Ga 14 June 2018); *In re K-Dur Antitrust Litig*, No. 01-cv-1652, 2016 US Dist Lexis 22982, at *54–62 (DNJ 25 February 2016); *In re Loestrin 24 FE Antitrust Litig*, 433 F Supp 274, 316–17, 319–23 (D RI 2019); *In re Namenda Direct Purchaser Litig*, 331 F Supp 3d 152, 198–99 (SDNY 2018); *In re Nexium (Esomeprazole) Antitrust Litig*, 42 F Supp 3d 231, 263–64 (D Mass 2014); *King Drug Co of Florence v Cephalon, Inc*, 88 F Supp 3d 402, 407–10, 419–21 (ED Pa 2015).

24 *In re Zetia Ezetimibe Antitrust Litig*, MDL No. 2:18-md-2836, 2022 US Dist Lexis 171241, at *63 (ED Va 2 September 2022).

25 id., at *62–63.

26 *In re HIV Antitrust Litig*, No. 19-cv-02573, 2023 US Dist Lexis 73635, at *127–30 (ND Cal 5 January 2023).

the various contract terms were agreed upon.[27] As discussed below, this case proceeded to trial in June 2023 and a jury returned a verdict for the defendants.

In addition to these summary judgment decisions addressing whether an unlawful reverse payment was made, other district courts have focused on causation. Some courts have denied summary judgment where factual and expert evidence adequately supported plaintiffs' causation theories, finding that in the but-for world that disputed issues of material fact remained as to whether the generic challengers would have launched at risk, prevailed in the patent case, or entered into an alternative, 'no-payment' settlement agreement.[28] At the same time, other decisions, such as *AndroGel*, have rejected patent-based causation theories as 'simply too procedurally burdensome and speculative' when there were no concrete developments in the underlying patent case.[29]

One of the most notable causation decisions is *Wellbutrin*, where the Third Circuit affirmed a grant of summary judgment for the defendants. The court held that the plaintiffs 'did not take into account Andrx's blocking patent' and that it is not enough 'to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal'.[30] The plaintiffs' but-for theory that Anchen would have prevailed in the patent litigation failed because the 'unrebutted analysis was that Andrx would have an 80 per cent chance of proving infringement' and the parties did not 'identify any other evidence in the record that speaks to the possible outcomes of the *Anchen/Andrx* litigation'.[31] Notably, the size of the reverse payment alone was an insufficient 'surrogate' for the weakness of the patent.[32] The Third Circuit also rejected the plaintiffs' but-for theory that Andrx had 'an independent economic interest' in providing a licence to Anchen and that licence negotiations were nearly complete days before the alleged reverse payment was made.[33] The plaintiffs failed to point to evidence showing 'it is more likely than not that Anchen would have obtained a licence', and it is possible that 'negotiations would have stalled and failed'.[34]

27 ibid.
28 See, eg, *In re Glumetza Antitrust Litig*, No. 19-05822, 2021 US Dist Lexis 87085, at *44–55 (ND Cal 6 May 2021); *In re Intuniv Antitrust Litig*, 496 F Supp 3d 639, 672–77 (D Mass 2020); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503, 2018 US Dist Lexis 11921, at *20–21 (D Mass 25 January 2018); *United Food & Commer Workers Local 1776 v Teikoku Pharma USA*, 296 F Supp 3d 1142, 1156–58, 1160.
29 *In re AndroGel Antitrust Litig (No. II)*, 2018 US Dist Lexis 99716, at *49–50. But see *Fresenius Kabi USA, LLC v Par Sterile Prods*, LLC, 841 F App'x 399, 404 (3d Cir 2021) ('The analysis of such a hypothetical infringement suit or patent challenge may in some cases be predicted based on binding legal precedents, including statutory and case law. Whether the record permits the District Court to engage in such an analysis of course will be for it to decide.').
30 *In re Wellbutrin XL Antitrust Litig*, 868 F3d 132, 165 (3d Cir 2017).
31 id., at 169.
32 id., at 168–69.
33 id., at 166–67.
34 id., at 167.

Trials under Actavis

Since *Actavis* was decided in 2013, four reverse-payment cases have proceeded through full trials to judgment.

In *Nexium*, the private plaintiffs had calculated a reverse payment of US$22 million, argued that the contemporaneously executed business agreements 'provided a steady flow of revenue to Ranbaxy' during the same period it agreed not to launch its generic Nexium product and offered evidence that 'even if Ranbaxy had won its litigation instead of settling, Ranbaxy would not have secured such favourable arrangements'.[35] But in the first reverse-payment trial since *Actavis*, the jury reached a verdict for the defendants despite finding that there had been a reverse payment. The jury found that, although AstraZeneca had market power and there had been a 'large and unjustified' payment, the reverse payment did not cause delayed generic entry because AstraZeneca would not have agreed to an earlier settlement entry date absent a reverse payment.[36] The US Court of Appeals for the First Circuit affirmed the jury's verdict for the defendants.[37]

The next reverse-payment trials both concerned the same product, Opana. The first Opana trial involved an administrative action filed by the FTC, and the second Opana trial involved a federal action filed by private plaintiffs. In the FTC action, the FTC's chief administrative law judge (ALJ) held an administrative bench trial and concluded that the alleged reverse payment was not anticompetitive. The brand and generic companies at issue had settled the underlying patent litigation and entered into a settlement and licence agreement (SLA) and a development and co-promotion agreement (DCA).[38] The SLA included a no-AG provision and a potential cash credit to the generic company if Opana sales fell below a certain threshold.[39] The DCA was executed contemporaneously with the SLA and provided an up-front payment of US$10 million for the development of a Parkinson's disease treatment, with potential payments up to US$30 million at certain milestones.[40]

The ALJ concluded that the DCA 'was a bona fide product development collaboration, and that the US$10 million payment was justified by the profit-sharing rights given to Endo under the DCA'.[41] Despite finding that the SLA was 'large and unjustified', the ALJ concluded that any anticompetitive harm was outweighed by pro-competitive benefits because the brand company's 'acquisition of additional patents, and successful assertion of those additional patents in litigation, led to all generic manufacturers, other than Impax, being

35 *In re Nexium (Esomeprazole) Antitrust Litig*, 42 F Supp 3d 231, 264 (D Mass 2014).
36 Jury Verdict, *In re Nexium (Esomeprazole) Antitrust Litig*, No. 1:12-md-02409 (D Mass 5 December 2014), ECF No. 1383.
37 *Am Sales Co, LLC v AstraZeneca LP (In re Nexium (Esomeprazole) Antitrust Litig)*, 842 F3d 34 (1st Cir 2016).
38 Initial Decision at 85, *Impax Labs, Inc*, FTC Docket No. 9373 (11 May 2018).
39 id., at 114.
40 id., at 120.
41 id., at 132.

enjoined from selling a generic version of Opana ER', and 'absent the SLA, such after-acquired patents also would have been successfully asserted to enjoin Impax from selling generic Opana ER'.[42]

The FTC Commission unanimously rejected the ALJ's decision, concluding that 'Impax failed to show that the challenged restraint furthered any cognisable procompetitive justifications', and 'even if Impax had satisfied this burden, Complaint Counsel identified a viable less restrictive alternative'.[43] In an April 2021 decision, the US Court of Appeals for the Fifth Circuit denied a petition for review and found that substantial evidence supported the Commission's factual findings.[44] The Fifth Circuit observed that the settlement saved the brand company 'only US$3 million in litigation expenses' and that only US$10 million in payments were associated with services, such that over US$100 million of the brand company's payment remains unjustified'.[45] The 'principal attack on the finding of anticompetitive effect [was] that the Commission needed to evaluate 'the patent's strength, which is the expected likelihood of the brand manufacturer winning the litigation', but the Fifth Circuit rejected that argument, holding that the FTC need not assess the 'likely outcome of the patent case'.[46] The court also discounted the impact of the patents acquired after the settlement because 'the impact of an agreement on competition is assessed as of "the time it was adopted"'.[47]

But in the parallel private-plaintiff litigation concerning Opana, a jury found in favour of the defendants in July 2022. After Impax settled mid-trial, the jury went on to find that while the brand company 'had market power for the brand name drug and made a reverse payment to delay [the] generic from entering the market, the deal between the companies was not unreasonably anti-competitive'.[48] The brand company argued that purchasers of Opana were relying on 'guesswork' and 'speculation' to argue that generic Opana could have been sold earlier but for the alleged reverse payment.[49] Similar to the FTC's case, the brand company argued that the 'underlying patent deal was procompetitive because it is the only reason a generic version of Opana has been consistently available on the market for nine years, with seven to go, since it included a broad licence covering current and future Opana-related patents'.[50] The brand company emphasised that it 'would have never given Impax both an earlier entry date and a broad licence to its Opana-related patents'.[51]

42 id., at 145.
43 Opinion and Order of the Commission at 42, *Impax Labs, Inc*, FTC Docket No. 9373 (28 March 2019).
44 *Impax Labs, Inc v FTC*, 994 F3d 484, 488 (5th Cir 2021).
45 id., at 494–95.
46 id., at 495.
47 id., at 496.
48 Lauraann Wood, 'Jury Hands Endo Win In Opana Pay-For-Delay Case', Law360 (1 July 2022), https://www.law360.com/articles/1508192/jury-hands-endo-win-in-opana-pay-for-delay-case; see also ibid.
49 ibid.
50 ibid.
51 ibid.

Finally, in June 2023, a jury returned a verdict for defendants in the *HIV Antitrust Litigation*. As described above, the alleged reverse payment involved the use of certain MFN clauses, which supposedly restored the first-filer's forfeited exclusivity in exchange for delayed generic entry. At the first step of the rule of reason analysis, the jury found that plaintiffs failed to prove that the brand company 'had market power within the relevant market that included Truvada and/or Atripla'.[52] While that finding was dispositive, the jury went on to find that plaintiffs also failed to prove that the patent settlement included a reverse payment that would delay generic 'entry into the market, and [the brand company] could thereby avoid the risk of generic competition'.[53]

With this June 2023 trial verdict, private plaintiffs have now lost all three reverse-payment jury trials – *Nexium*, *Opana*, *HIV* – that have proceeded to verdict since *Actavis* was decided.

California deviates from Actavis

At the state level, California enacted a new reverse-payment law (AB 824), effective from January 2020, which deviates from the rule of reason standard announced in *Actavis* and codifies that certain alleged reverse-payment settlements are to be treated as presumptively anticompetitive.[54] Initially, the law was unsuccessfully challenged at the district court level,[55] and that challenge was rejected for lack of standing by the US Court of Appeals for the Ninth Circuit in July 2020.[56]

But, in February 2022, a federal district court in California held that AB 824 may only be enforced 'with respect to settlement agreements negotiated, completed, or entered into within California's borders'.[57] The district court denied the California Attorney General's request to 'allow California to continue to enforce AB 824 whenever a settlement agreement is made in connection with in-state pharmaceutical sales if that agreement artificially distorts the pharmaceutical market in California'.[58] The court rejected the Attorney General's expansive interpretation that would have created risks for a much broader set of settlements because the 'dormant Commerce Clause precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State, and the

52 Transcript of Proceedings, *In re HIV Antitrust Litig* (2023) (No. 19-cv-2573), 2023 WL 3088218 at *3409.
53 id., at *3410.
54 See Kristen O'Shaughnessy et al., 'California's New Reverse Payment Law Departs from Supreme Court Standard in FTC v. Actavis', White & Case LLP (17 October 2019), www.whitecase.com/publications/alert/californias-new-reverse-payment-law-departs-supreme-court-standard-ftc-v-actavis.
55 *Ass'n for Accessible Meds v Becerra*, No. 2:19-cv-2281, 2019 US Dist Lexis 223342 (ED Cal 31 December 2019).
56 *Ass'n for Accessible Meds v Becerra*, No. 20-15014, US Cir Lexis 223342 (9th Cir 24 July 2020).
57 *Ass'n for Accessible Meds v Bonta*, No. 2:20-cv-01708, 2022 US Dist Lexis 27533, at *24 (ED Cal 14 February 2022).
58 id., at *4, 11 (internal quotation marks omitted).

critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State'.[59]

Product-hopping antitrust cases

Plaintiffs have also attempted to use antitrust laws to challenge brand manufacturers' introduction of new versions of existing drugs. In these product-hopping cases, plaintiffs allege that brand pharmaceutical manufacturers violate the antitrust laws by introducing new versions and discontinuing or improperly disparaging older versions of brand drugs in an alleged attempt to thwart generic competition and generic substitution laws.[60]

Pre-2015 decisions: TriCor, Prilosec and Suboxone

In one of the first 'product-hopping' decisions, the court in *TriCor* rejected the defendants' argument that any product change that is an improvement is per se legal under the antitrust laws.[61] Instead, the court concluded that the introduction of a new product should be assessed under the rule of reason approach, requiring the plaintiffs to demonstrate that the anticompetitive harm from the formulation change outweighed any benefits of introducing a new version of the product. The court in *TriCor* denied the defendants' motion to dismiss, finding the plaintiffs' specific allegations – that the defendants bought back supplies of the old formulation and changed product codes for the old products to 'obsolete' to prevent pharmacies from filling TriCor prescriptions with generic versions of the old formulation – sufficient to support the plaintiffs' antitrust claims.[62]

In *Prilosec*, the district court concluded that antitrust laws do not require new products to be superior to existing ones and that consumer choice plays into the analysis of a product-hopping claim.[63] In granting the defendants' motion to dismiss, the court found that where defendants left the old product on the market but heavily (and successfully) promoted their new product, the plaintiffs could not allege that the defendants interfered with competition because consumer choice was not eliminated.[64]

59 id., at *11 (internal quotation marks and alterations omitted).
60 See Michael Gallagher et al., 'United States: Pharmaceutical Antitrust', *Americas Antitrust Review 2020*, 107, 116 (Global Competition Review, 2019), https://www.whitecase.com/sites/default/files/2019-09/gcr-united-states-pharmaceutical-antitrust-2020.pdf (addressing the regulatory background related to product-hopping claims).
61 *Abbott Lab'ys v Teva Pharms USA, Inc*, 432 F Supp 2d 408, 422 (D Del 2006).
62 id., at 423–24.
63 *Walgreen Co v AstraZeneca Pharma LP*, 534 F Supp 2d 146, 151 (DDC 2008).
64 See id., at 152 (further holding that 'the fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action').

In *Suboxone*, plaintiffs alleged that the defendants unlawfully shifted patients from Suboxone tablets to Suboxone film by falsely disparaging and fabricating safety concerns about the tablet, and by removing Suboxone tablets from the market just as generic versions of the tablets were set to enter the market. The court denied the defendants' motion to dismiss, explaining 'that simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct'; rather 'the key question is whether the defendant combined the introduction of a new product with some other wrongful conduct [that stymies competition]'.[65] The court held that the plaintiffs had sufficiently pleaded 'other wrongful conduct' insofar as removing the tablets from the market in conjunction with allegedly fabricating safety concerns could potentially coerce patients to switch from the tablet to the film, such that discovery was needed to further evaluate these allegations.[66]

Two appellate decisions: Namenda and Doryx

Namenda and *Doryx* were the first cases to address pharmaceutical product-hopping claims beyond the motion-to-dismiss stage. In *Namenda*, the court granted a motion for a preliminary injunction on a limited record related to product-hopping claims as to the defendants' plan to transition Alzheimer's patients from an older, twice-daily drug to a newer, once-daily formulation.[67] The court held that the plaintiff had met its burden of demonstrating a substantial risk that the plan to transition patients would harm competition because generics would not be able to take advantage of automatic state substitution laws to the extent generics had hoped.[68]

The defendants appealed the decision to the US Court of Appeals for the Second Circuit, raising an issue of first impression in the circuit courts regarding the circumstances under which alleged product hopping may violate the Sherman Act.[69] Despite the continued availability to any patient with a need for the older formulation, the Second Circuit affirmed the district court's decision and cited *Berkey Photo*[70] in its holding that although neither product withdrawal nor product improvement alone is anticompetitive, the combination of product withdrawal with other conduct that coerces, rather than persuades, consumers to switch products can be anticompetitive under the Sherman Act.[71] The Second Circuit substantially relied upon the district court's findings in its conclusion that the combination of introducing a new version of the drug and 'effectively

65 *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig*, 64 F Supp 3d 665, 682 (ED Pa 2014).
66 id., at 682–85.
67 *New York v Actavis, PLC*, No. 14-cv-7572, 2014 US Dist Lexis 172918, at *118–23 (SDNY 11 December 2014).
68 id., at *107–08.
69 *New York v Actavis, PLC*, 787 F3d 638, 643 (2d Cir 2015).
70 *Berkey Photo, Inc v Eastman Kodak Co*, 603 F2d 263 (2d Cir 1979).
71 *Actavis*, 787 F.3d at 653–54.

withdrawing' the old version was sufficiently coercive that it violated the Sherman Act.[72] In its decision, however, the Second Circuit distinguished between efforts to 'persuade patients and their doctors to switch' from one product to another on the merits and coercive conduct, stressing that 'the market can determine whether one product is superior to another only 'so long as the free choice of consumers is preserved'.[73]

The US Court of Appeals for the Third Circuit in *Doryx*, however, became the first court to evaluate product-hopping claims, with the benefit of full discovery, at the summary judgment stage. In *Doryx*, the plaintiffs alleged that numerous product reformulations (including changes from capsules to tablets, changes to dosage strength and introduction of score lines to the tablets), coupled with the subsequent discontinuation of older versions, constituted anticompetitive product hopping. The court denied the defendants' motion to dismiss on the ground that the court would be required to consider facts beyond the pleadings to decide the product-hopping issue.[74] However, the court noted that the plaintiffs' product-hopping theory was 'novel at best' and conveyed scepticism that product hopping even constitutes anticompetitive conduct under the Sherman Act.[75]

After full discovery, the *Doryx* court granted summary judgment for the defendants and dismissed all claims, holding that the introduction of a reformulated drug and withdrawal of the older version was not exclusionary conduct where the generic was not foreclosed from competing.[76] The court also rejected the plaintiffs' contention that the product reformulations were anticompetitive because they were insufficiently innovative, noting that no intelligible test for innovation 'sufficiency' had been offered and doubting that courts could ever fashion one.[77] As to the role of state-substitution laws in the analysis of product-hopping claims, the court rejected the notion that the brand excluded competition by denying the generic the opportunity to take advantage of the 'regulatory bonus' afforded by state substitution laws. Rather, the court held that generics could compete without automatic substitution through advertising and cost competition, concluding that brand manufacturers have

72 See id., at 653–59. In a subsequent, separate action, direct purchasers in *Namenda* alleged that the defendants' mere announcement of their intention to remove the older drug from the market constituted a product hop because it coerced customers to switch to the newer drug. Notwithstanding that the court in *Actavis* had prevented the defendants from withdrawing the older drug from the market, the court subsequently allowed the private plaintiffs' product-hopping claims to survive the defendants' motion to dismiss (*Sergeants Benevolent Ass'n Health & Welfare Fund v Actavis, PLC*, No. 15-cv-6549, 2016 US Dist Lexis 128349 (SDNY 13 September 2016)), and held that the defendants were precluded from arguing certain issues related to the product-hopping allegations that were already determined in the earlier litigation (*In re Namenda Direct Purchaser Antitrust Litig*, No. 15-cv-7488, 2017 US Dist Lexis 83446, at *50–51 (SDNY 23 May 2017)).

73 id., at 654–55.

74 *Mylan Pharms, Inc v Warner Chilcott Pub*, No. 12-3824, 2013 US Dist Lexis 152467 (ED Pa 11 June 2013).

75 id., at *11.

76 *Mylan Pharms, Inc v Warner Chilcott Pub*, No. 12-3824, 2015 US Dist Lexis 50026 (ED Pa 16 April 2015); see also id., at *34, *42 (noting that it had denied the motion to dismiss to consider the legality of the novel product-hopping theory with the benefit of a fully developed record, and that the record on summary judgment now underscored that the defendants did not violate the Sherman Act).

77 id., at *42.

no duty to facilitate generic manufacturers' business plans by keeping older versions of a drug on the market.[78] The Third Circuit affirmed the lower court's grant of summary judgment in the defendants' favour.[79]

Developments post-Namenda and Doryx

Since the *Namenda* and *Doryx* decisions, additional courts have addressed product-hopping claims at the motion-to-dismiss and summary judgment stages. In *Solodyn*, the court dismissed the plaintiffs' product-hopping claim, holding that because the defendants kept the older strengths of Solodyn on the market until two years after the older strengths faced generic competition, the introduction of newer strengths did not limit customer choice and was therefore not anticompetitive.[80]

In *Asacol*, plaintiffs alleged that the defendants engaged in a product hop that thwarted generic competition for branded drug Asacol by first introducing and promoting Asacol HD (a high-dose version of Asacol), years later introducing the drug Delzicol with the same active ingredient and dose as Asacol, and shortly thereafter removing Asacol from the market prior to the entry of generic Asacol products. Relying on *Namenda*, the *Asacol* court dismissed the plaintiffs' claims of a product hop between Asacol and Asacol HD because Asacol continued to be sold side-by-side with Asacol HD for several years after Asacol HD was introduced.[81] However, the court allowed the plaintiffs' claims of a product hop from Asacol to Delzicol to survive the defendants' motion to dismiss, where the defendants allegedly withdrew Asacol from the market shortly after introducing the close substitute Delzicol.[82] Following a settlement with direct purchasers, the court denied summary judgment as to the remaining indirect-purchasers' claims based on disputed factual issues concerning coercion, causation and product market.[83]

In *Suboxone*, state plaintiffs filed complaints with product-hopping claims similar to those addressed in the court's earlier motion-to-dismiss decision involving Suboxone purchasers. The court revisited its product-hopping analysis in light of the *Namenda*, *Doryx* and *Asacol* decisions rendered since the earlier *Suboxone* decision. The court reached the same result as it did in its previous decision,

78 id., at *40.
79 *Mylan Pharms, Inc v Warner Chilcott Pub*, 838 F.3d 354, 421 (3d Cir 2016).
80 *In re Solodyn (Mincocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503, 2015 US Dist Lexis 125999 (D Mass 14 August 2015).
81 *In re Asacol Antitrust Litig*, No. 15-cv-12730 (D Mass 10 February 2017), ECF No. 279.
82 *In re Asacol Antitrust Litig*, No. 15-cv-12730, 2016 US Dist Lexis 94605 (D Mass 20 July 2016).
83 *In re Asacol Antitrust Litig*, 323 FRD 451 (D Mass 2017).

allowing the claims to proceed to discovery.[84] The court recently denied summary judgment, finding that certain disputed facts necessitated a resolution at trial.[85]

In *Loestrin*, the court relied heavily on *Namenda* when denying the defendants' motion to dismiss the product-hopping claims.[86] The court found that the removal of the earlier version of the drug prior to generic entry was distinguishable from the conduct in Doryx and Solodyn (product removed after generic competition) and Prilosec (no product removal), and in line with allegations in *Suboxone*, *TriCor* and *Asacol*, which survived motions to dismiss.[87] At summary judgment, however, the *Loestrin* court rejected the plaintiffs' argument 'that no showing of anticompetitive conduct is required beyond the hard switch itself'; the court instead required the plaintiffs to come forward with evidence of 'anticompetitive conduct to coerce consumers to switch' products to prove their product-hopping claim.[88] The court found that there was competing evidence on the issue of coercion, which was 'all fodder for the jury' under the circumstances, and therefore allowed the product-hopping claim to proceed to trial.[89]

In the indirect-purchaser action in *Namenda*, the court granted summary judgment for the defendant on the plaintiff's hard-switch theory of liability because the plaintiff failed to 'demonstrate that it was personally harmed by the hard switch'.[90] Instead, the plaintiff simply relied on class-wide evidence and did not 'prove its *own* case, with evidence relating to its *own* customers, and its *own* reimbursements'.[91] Despite being afforded an opportunity to provide additional evidence, the court subsequently granted summary judgment for the defendant in July 2021 because the plaintiff again failed to 'identify which of [its] reimbursements were attributable to the "hard switch"'.[92]

Finally, in the *HIV Antitrust Litigation*, the district court relied on the Second Circuit's distinction in *Namenda* between coercive and persuasive conduct and granted the defendants' motion for summary judgment on plaintiffs' product-hop claim.[93] The plaintiffs argued that the defendants' pricing decisions and promotion of safety benefits forced patients to switch from older HIV treatments to newer treatments.[94] But the court found that the plaintiffs had failed to demonstrate that any of the defendants' pricing and promotional decisions

84 *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig*, No. 13-md-2445, 2017 US Dist Lexis 627 (ED Pa 8 September 2017).
85 See ibid. Following an FTC investigation related to Suboxone, the FTC filed an antitrust action against Reckitt Benckiser.
86 *In re Loestrin 24 FE Antitrust Litig*, 261 F Supp 3d 293, 307 (DRI 2017).
87 ibid.
88 *In re Loestrin 24 Fe Antitrust Litig*, No. 13-md-2472, 2019 US Dist Lexis 220262, at *89–91 (DRI 17 December 2019).
89 id., at *92.
90 *In re Namenda Indirect Purchaser Antitrust Litig*, No. 1:15-cv-6549, 2021 US Dist Lexis 110081, at *126 (SDNY 11 June 2021).
91 ibid. (emphasis in original).
92 *In re Namenda Indirect Purchaser Antitrust Litig*, No. 1:15-cv-6549 (SDNY 26 July 2021), ECF No. 694.
93 *In re HIV Antitrust Litig*, No. 19-cv-02573, 2023 US Dist Lexis 73635, at *36-52 (ND Cal 5 January 2023).
94 id., at *45–47.

rose to the level of coercion – a necessary element of the plaintiffs' product-hop claim – such that 'HIV patients', doctors', and/or payors' choices regarding products were constrained'.[95]

Pharmaceutical manufacturer pricing practices

The pharmaceutical industry also continues to see substantial action relating to drug pricing. Federal and state legislators persist in pursuing a variety of proposed changes, some of which have passed while others remain stalled.

Most notably, Congress passed the federal Inflation Reduction Act (IRA), which includes drug-pricing components that have been pushed by Democratic lawmakers for several years, such as direct-government negotiation of drug prices under Medicare. The impact of that legislation remains to be seen as the government begins to implement the new law and numerous industry participants have brought legal challenges.

Additionally, as addressed below, legislators and regulators continue to focus their attention on the role of pharmacy benefit managers (PBMs) in the drug-pricing chain, including as to formulary management and rebating practices. Multiple laws have been proposed to increase transparency and regulate PBM practices. The FTC also appears poised for action on manufacturer rebate agreements, after launching an inquiry into the PBM industry, issuing an enforcement policy statement putting the industry 'on notice' as to when these agreements may be unlawful and withdrawing prior guidance from the FTC in support of certain PBM practices. States have also continued their pursuit of regulating PBM practices, focusing on pricing transparency, in addition to other laws pertaining to drug pricing.

Legislation and regulation relating to pharmaceutical pricing

The Federal Inflation Reduction Act

The most significant legislative activity was passage of the IRA in August 2022, a bill that was pushed by the Biden administration and includes curtailed versions of long sought-after drug-pricing components by congressional Democrats, such as:

- empowering the Department of Health and Human Services (HHS) to 'negotiate' drug prices (with civil monetary penalties and the threat of an excise tax of up to 95 per cent for non-compliance) on a narrowed set of

95 id., at *42–52.

certain older, innovator drugs for Medicare Part B and D and to make those prices available to commercial plans;
- imposing mandatory rebates on certain Medicare Part B and D drugs with price increases greater than the rate of inflation, similar to inflation-based rebates in Medicaid;
- capping annual out-of-pocket costs for prescription drugs under Medicare Part D; and
- limiting co-payments for insulin to US$35 per month under Medicare Part D.[96]

The IRA's direct-negotiation provisions have garnered the most attention, as HHS begins implementing the law.[97] The first round of drugs subject to the provision are to be selected in September 2023 and the negotiated prices are to be published a year later.[98]

Manufacturers and other stakeholders have raised concerns that the law will curb innovation,[99] including because the IRA disadvantages small-molecule drugs by allowing Medicare to negotiate prices four years sooner than biologicals.[100] Industry experts also predict broader changes to product-development and patent-assertion strategy as a result of the law, suggesting, for example, that the IRA could create an imbalance of incentives to foster generic and biosimilar competition that is exempt from price negotiation.[101]

96 See Inflation Reduction Act of 2022, HR 5376, 117th Cong (2022), Subtitle B, Part 1 – Lowering Prices Through Drug Price Negotiation; id., at Part 2 – Prescription Drugs Inflation Rebates; id., at Part 3 – Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries; id., at Part 5 – Miscellaneous, § 11406, Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D.

97 The Centers for Medicare & Medicaid Services (CMS) issued initial guidance on implementation in March 2023, and issued a revised guidance in June 2023. See CMS, 'Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments' (15 March 2023), https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf; CMS, 'Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026' (30 June 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

98 See CMS, 'Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments' (footnote 97).

99 See, eg, Cathy Kelly, 'IRA Effect: Alnylam Acting "Rationally" In Halting Second Orphan Indication for Amvuttra – Analysts', Pink Sheet (7 November 2022), https://pink.pharmaintelligence.informa.com/PS147255/IRA-Effect-Alnylam-Acting-Rationally-In-Halting-Second-Orphan-Indication-For-Amvuttra--Analysts; Joe Grogan, 'The Inflation Reduction Act Is Already Killing Potential Cures', *Wall Street Journal* (3 November 2022), https://www.wsj.com/articles/the-inflation-reduction-act-killing-potential-cures-pharmaceutical-companies-treatment-patients-drugs-prescriptions-ira-manufacturers-11667508291.

100 See John Stanford, 'Congress must fix the IRA's small molecule penalty', *STAT* (6 March 2023), https://www.statnews.com/2023/03/06/congress-must-fix-ira-small-molecule-penalty/.

101 See Arti K Rai et al., 'Cryptic Patent Reform Through the Inflation Reduction Act', *Harvard J L & Tech, Forthcoming* (27 March 2023); Cathy Kelly, 'Game On: Medicare Will Parry Manufacturer Efforts to Sidestep Price Negotiation, Guidance Says', Pink Sheet (28 March 2023), https://pink.pharmaintelligence.informa.com/PS147960/Game-On-Medicare-Will-Parry-Manufacturer-Efforts-To-Sidestep-Price-Negotiation-Guidance-Says; Cathy Kelly, 'Medicare Negotiation Workarounds: Lilly's Ricks on Big Pharma Pricing Strategies for Small Molecule Drugs', Pink Sheet (15 June 2023), https://pink.pharmaintelligence.informa.com/PS148389/Medicare-Negotiation-Workarounds-Lillys-Ricks-On-Big-Pharma-Strategies-For-Small-Molecule-Drugs.

Multiple manufacturers, the US Chamber of Commerce and industry group PhRMA have brought lawsuits challenging the law, and other industry participants have signalled an intent to do so too. The current challenges attack the Constitutionality of the law and procedure under which it was enacted.[102] The challenges primarily argue that the negotiation is not meaningful but rather a price-control mandate, as the manufacturers do not have an economically feasible way to back down from the negotiation as doing so would require the manufacturer to remove all products from the Medicare programme or face excessive penalties.[103] The suits also assert that Congress exceeded its powers in essentially giving HHS the ability to implement prices without the requisite knowledge or opportunity for industry stakeholders to comment.[104]

Finally, the IRA further delayed implementation of the Trump-era rule that would eliminate the anti-kickback safe harbour for drug-manufacturer rebates paid to Medicare Part D plan sponsors (or their contracted PBMs). The IRA would replace that rule with new safe-harbour protections, such as one for discounts that pass through directly to patients at the point of sale. The latest delay in the IRA, which pushes back implementation until 2032, followed an earlier delay that was used to generate savings to pay for bipartisan gun-control legislation passed in June 2022. These continued delays raise doubts that this rule will ever take effect.

Pharmacy benefit managers

Lawmakers on both sides of the aisle continue to focus on PBM practices. In March 2023, the House Committee on Oversight and Accountability launched an investigation into PBMs, seeking transparency into PBMs' practices involving formulary designs and rebating[105] and issuing document requests to the largest PBMs.[106] In April 2023, the Senate Finance Committee announced a bipartisan framework for PBM-related legislation aimed to increase transparency and correct what it described as PBMs' 'misaligned incentives' that result from

102 See Compl, *Merck & Co Inc v Becerra*, No. 1:23-cv-01615 (DDC 6 June 2023), ECF No. 1; Complaint, *US Chamber of Commerce v Becerra*, No. 3:23-cv-00156 (SD Ohio 9 June 2023), ECF No. 1; Compl, *Bristol Myers Squibb Co v Becerra*, No. 3:23-cv-03335 (DNJ 16 June 2023); Compl, *Pharm Research and Manufacturers of America v Becerra*, No. 1:23-cv-00707 (WD Texas 21 June 2023).

103 See, eg, Complaint ¶¶ 2–9, *Bristol Myers Squibb Co v Becerra*, No. 3:23-cv-03335 (DNJ 16 June 2023); Compl ¶ 86, *Merck & Co Inc v Becerra*, No. 1:23-cv-01615 (DDC 6 June 2023).

104 See, eg, Complaint ¶¶ 1–24, *US Chamber of Commerce v Becerra*, No. 3:23-cv-00156 (SD Ohio 9 June 2023); Compl ¶¶ 12–17, *Pharm Research and Manufacturers of America v Becerra*, No. 1:23-cv-00707 (21 June 2023).

105 'Comer Launches Investigation into Pharmacy Benefit Managers' Role in Rising Health Care Costs', Committee on Oversight and Accountability (1 March 2023), https://oversight.house.gov/release/comer-launches-investigation-into-pharmacy-benefit-managers-role-in-rising-health-care-costs%EF%BF%BC/.

106 See, eg, Letter from Representative James Comer to David Joyner, President, CVS Caremark (1 March 2023), https://oversight.house.gov/wp-content/uploads/2023/03/Letter-to-CVS-Caremark.pdf.

PBMs receiving greater payouts from rebates where list prices are higher.[107] Under that framework, a bipartisan group of senators proposed the Patients Before Middleman Act, a bill that would prohibit PBM compensation based on the price of drugs under Medicare Part D contracts and require PBMs to forfeit to HHS any amount paid to the PBM that is in excess of 'bona fide service fees'.[108]

Numerous other bills involving PBMs have been introduced as well, with examples given below.

- The Pharmacy Benefit Manager Transparency Act of 2023 seeks to ban certain PBM practices, such as spread pricing[109] and certain clawbacks of reimbursement payments from pharmacies. Under the proposed law, such practices would be considered unfair and deceptive acts and practices under the Federal Trade Commission Act (the FTC Act), unless certain exceptions apply.[110] The bill would also require PBMs to disclose annually to the FTC certain aggregate financial information, such as the spread retained by the PBM and any clawbacks.[111]
- The Prescription Pricing for the People Act of 2023 would direct the FTC to issue a report on what the bill contends are anticompetitive behaviours by PBMs, including spread pricing, steering patients to pharmacies in which the PBM has an ownership stake, and using formulary designs to advantage higher priced drugs that earn higher rebates over lower priced alternatives.[112]
- The Pharmacy Benefit Manager Reform Act of 2023 would require PBMs to remit all rebates, fees, alternative discounts and other remuneration received from drug manufacturers to health-plan sponsors, such as employers and others.[113]

Each of these three bills passed through Senate committees. While the bills have garnered bipartisan support, it is unclear whether they will reach a vote and ultimately be enacted.[114]

The FTC has also continued to focus its attention on the role of PBMs and their effect on drug pricing. On 7 June 2022, the FTC announced a Section 6(b)

107 A Bipartisan Framework for Reducing Prescription Drug Costs by Modernizing the Supply Chain and Ensuring Meaningful Relief at the Pharmacy Counter, https://www.finance.senate.gov/imo/media/doc/042023%20SFC%20Framework%20for%20Rx%20Supply%20Chain%20Modernization.pdf.

108 Patients Before Middleman Act.

109 Spread pricing generally refers to the pharmacy benefit manager (PBM) practice of charging insurance plans and payers more for prescription drugs than what the PBM pays to pharmacies and retaining any difference.

110 Pharmacy Benefit Manager Transparency Act of 2023, S 127, 117th Cong (2023), https://www.congress.gov/bill/118th-congress/senate-bill/127#:~:text=Introduced%20in%20Senate%20(01%2F26%2F2023)&text=This%20bill%20generally%20prohibits%20pharmacy,the%20PBM%20reimburses%20the%20pharmacy.

111 ibid.

112 Prescription Pricing for the People Act of 2023, S 113, 118th Cong (2023).

113 Pharmacy Benefit Manager Reform Act, S 1339, 118th Cong (2023).

114 See Stephanie Armour and Liz Essley White, 'Something Congress Might Agree On: Tackling Drug Costs', *Wall Street Journal* (8 May 2023), https://www.wsj.com/articles/something-congress-might-agree-on-tackling-drug-costs-39f6574d.

inquiry into the PBM industry.[115] In addition to ordering the largest PBMs to produce information about their practices, the FTC ordered group purchasing organisations (GPOs) affiliated with the PBMs to do so as well.[116] The study will analyse vertically integrated PBMs and their impact on access to and affordability of prescription drugs, including the effect of manufacturer rebates on formulary design and drugs costs. The use of clawbacks, steering patients to PBM-affiliated pharmacies and administrative restrictions on coverage (eg, prior authorisations), and other practices also fall within the scope of the study.[117] This Section 6(b) inquiry follows the FTC's failed February 2022 effort to gain consensus on such a study (the Commission deadlocked 2-2) and subsequent request for public comment on the impact of PBM practices.[118]

Shortly after announcing its Section 6(b) inquiry, the FTC issued an enforcement policy statement on 16 June 2022, concerning manufacturer-PBM formulary rebate practices, which the FTC described as a 'top priority'.[119] The policy statement focuses on rebates and fees paid by manufacturers to PBMs in 'exchange for excluding lower-cost drug products'.[120] According to the FTC, formulary agreements that 'foreclose competition from less expensive alternatives' may be unlawful restraints of trade, unlawful monopolisation or exclusive dealing.[121] The policy statement further asserts that formulary agreements that exclude less expensive alternatives 'in a manner that shifts costs to payer and patients', may be unlawful as an unfair method of competition or unfair act or practice under Section 5 of the FTC Act, as well as a violation of the Robinson-Patman Act's commercial-bribery provision under Section 2(c).[122]

This policy statement follows the FTC's August 2021 solicitation for public comment on contract terms that may harm competition, which identified exclusive-formulary positions by allegedly dominant drugs as an example of problematic conduct to be addressed through rulemaking and the FTC's May 2021 report on 'rebate wall' practices, which some have argued foreclose competition from less expensive drugs.[123] FTC chair Lina Khan stated that the

115 FTC Matter No. P221200, 6 June 2022; 'FTC Launches Inquiry Into Prescription Drug Middlemen Industry', 7 June 2022, https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry. Section 6(b) of the FTC Act authorises the FTC to seek documents and data without a specific law enforcement purpose.
116 'FTC Further Expands Inquiry Into Prescription Drug Middlemen Industry Practices', FTC (8 June 2023).
117 FTC Matter No. P221200 (footnote 115).
118 ibid.
119 'Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products', FTC (16 June 2022), https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.
120 id., at 1. According to the FTC, when formulary agreements 'favour high-cost drugs that generate large rebates and fees that are not always shared with patients', they create the potential for misaligned incentives, increased costs to consumers and reduced competition from generic and biosimilar drugs.
121 id., at 5.
122 ibid.
123 Solicitation for Public Comment, FTC (5 August 2021), https://www.regulations.gov/document/FTC-2021-0036-0022; Report on Rebate Walls, FTC, 28 May 2021, https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls_.pdf.

new enforcement policy statement was meant to put 'the entire prescription drug industry on notice' that the FTC will not hesitate to 'bring our full authorities to bear' if it sees 'illegal rebate practices that foreclose competition'.[124]

Finally, on 20 July 2023, the FTC issued a statement 'cautioning against reliance on prior advocacy statements and studies related to pharmacy benefit managers that no longer reflect current market realities'.[125] The statement was in 'response to PBMs' continued reliance on older FTC advocacy materials that opposed mandatory PBM transparency and disclosure requirements, and it warns against reliance on the Commission's prior conclusions, particularly given the FTC's ongoing study of the PBM industry to update its understanding of the industry and its practices'.[126]

Other federal legislation and regulation

As at the time of writing, other significant drug-pricing proposals have been introduced in Congress, but uncertainty remains as to whether they will be enacted. For example, a package of bills to revise aspects of antitrust and patent enforcement, similar to bills introduced in previous Congressional sessions, was introduced in the Senate in 2023. These bills were advanced through the Senate Judiciary Committee in early 2023 and moved to the Senate floor in preparation for a vote.[127]

The antitrust portions of these bills would create a presumption of anticompetitive conduct for certain reverse-payment patent settlements, instances of product-hopping and sham petitioning. The patent changes would cap the number of patents in an infringement action resulting from the 'patent dance' information exchange created by the Biosimilar Products Innovation Act. The bills also contain a new legislative proposal aimed to create an 'inter-agency task force' between the US Patent and Trademark Office and the Federal Drug Administration to encourage information-sharing between the agencies.[128] It remains to be seen, however, whether the bills will gain further traction, as a similar package of bills

124 'FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman that Block Cheaper Drugs', FTC (16 June 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes.

125 'FTC Votes to Issue Statement Withdrawing Prior Pharmacy Benefit Manager Advocacy', FTC (20 July 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-votes-issue-statement-withdrawing-prior-pharmacy-benefit-manager-advocacy.

126 ibid.

127 Preserve Access to Affordable Generics and Biosimilars Act, S. 142, 118th Cong (2023), https://www.congress.gov/bill/118th-congress/senate-bill/142/text; Affordable Prescriptions for Patients Act of 2023, S. 150, 118th Cong (2023), https://www.congress.gov/bill/118th-congress/senate-bill/150/text; Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics Act, S. 148, 118th Cong (2023), https://www.congress.gov/bill/118th-congress/senate-bill/148/text.

128 Interagency Patent Coordination and Improvement Act of 2023, S 79, 118th Cong (2023).

that made it through the House Judiciary Committee and to the House floor in 2022 has stalled.[129]

The FTC also intends to broaden the scope of its enforcement under Section 5 of the FTC Act. In November 2022, the FTC departed from prior bipartisan policy statements and adopted a new 'Policy Statement Regarding the Scope of Unfair Methods of Competition under Section 5 of the Federal Trade Commission Act' (the Policy Statement).[130] Historically, Section 5 has been enforced in harmony with the antitrust laws, requiring proof of actual harm and market power to bring a claim. In the statement, however, the FTC takes the new position that it is not necessary to show such harm and market power, defining unfair methods of competition as conduct 'that goes beyond competition on the merits' and may include conduct that is 'coercive, exploitative, collusive, abusive, deceptive, predatory, or involve[s] the use of economic power of a similar nature' and 'tend[s] to negatively affect competition'.[131]

The FTC's November 2022 policy statement further identifies what it views as 'historical examples of unfair competition', including contractual arrangements involving 'incipient violation of the antitrust laws' such as 'loyalty rebates, tying, bundling, and exclusive dealing arrangements that have the tendency to ripen into violations of the antitrust laws by virtue of industry conditions and the respondent's position within the industry'.[132] Legal challenges to the FTC's proposed use of Section 5 are expected as the FTC engages in rulemaking and enforcement actions.

State legislation

Following the same pattern as recent years, states continue to actively regulate drug pricing. In 2022, states debated more than 290 bills that purported to

129 Preserve Access to Affordable Generics and Biosimilars Act, S 64, 116th Cong (2019), https://www.congress.gov/bill/116th-congress/senate-bill/64/text; Affordable Prescriptions for Patients through Promoting Competition Act, HR 4398, 116th Cong (2019), https://www.congress.gov/bill/116th-congress/house-bill/4398/text; Stop Stalling Act, HR 2374, 116th Cong (2020), https://www.congress.gov/bill/116th-congress/house-bill/2374/text; Affordable Prescriptions for Patients through Improvements to Patent Litigation Act, HR 3991, 116th Cong (2019), https://www.congress.gov/bill/116th-congress/house-bill/3991/text; see also Michael Gallagher et al., 'Federal Lawmakers Turn Their Sights to Drug Pricing, Introducing a Package of Bills Seeking Changes to Antitrust and Patent Law', White & Case LLP (25 May 2021), https://www.whitecase.com/insight-alert/federal-lawmakers-turn-their-sights-drug-pricing-introducing-package-bills-seeking.

130 'Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act' (10 November 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyStatement.pdf; see also Kevin C Adam and Eugene Hutchinson, 'Five Drug Pricing Issues to Watch in 2023', White & Case LLP (20 December 2022), https://www.whitecase.com/insight-alert/five-drug-pricing-issues-watch-2023.

131 'Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act' (10 November 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyStatement.pdf.

132 ibid.

reduce or control drug prices and enacted more than 30 of them.[133] In the first half of 2023, more than 300 state drug laws had been introduced, several of which would go beyond mere reporting requirements and institute various degrees of price control.[134] For example, in May 2023, Minnesota passed a law banning excessive price increases on generic drugs and establishing a price cap on certain drugs.[135]

States have passed other laws that require pricing transparency from pharmaceutical manufacturers, mandate disclosures from PBMs and insurers, including rebates and fees received from manufacturers, cap consumer cost-sharing on certain drugs and create the framework for drug importation programmes.[136] A growing number of states have also taken issue with the growth of 'co-pay accumulator' programmes and have acted to ensure that the benefits of manufacturer co-pay assistance offers reach consumers. But one concern is that these benefits are not co-opted by commercial health plans through the use of these programmes, which may exclude manufacturer co-pay assistance from counting towards a consumer's deductible or out-of-pocket maximum.

At least 11 states require commercial health plans and self-funded non-Employee Retirement Income Security Act (ERISA) plans to count the value of any co-pay assistance – manufacturer coupons, non-profit assistance programmes or prescription discounters – towards patient deductibles or out-of-pocket maximums.[137] States may also pursue additional legislation touching more directly on drug pricing following the US Supreme Court's 2020 decision in *Rutledge v Pharmaceutical Care Management Association*, which outlined a pathway for states to implement PBM-focused cost regulation that would not be pre-empted by federal ERISA law.[138]

133 National Academy for State Health Policy (NASHP) 2022 Rx Tracker, https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2023/01/Rx-Tracker-2022-Archive.pdf.

134 NASHP, '2023 State Legislative Action to Lower Pharmaceutical Costs', https://nashp.org/2023-state-legislative-action-to-lower-pharmaceutical-costs/.

135 Commerce and Consumer Protection Omnibus Bill, Senate File 2744 (Minn).

136 See ibid.; Michael Gallagher and Kevin Adam, 'Growing Web of State Drug-Pricing Legislation Increases Challenges for Pharmaceutical Manufacturers and Other Industry Participants', White & Case LLP (19 May 2020), https://www.whitecase.com/insight-alert/growing-web-state-drug-pricing-legislation-increases-challenges-pharmaceutical; Michael Gallagher et al., 'States Remain the Drivers of New Drug Pricing Legislation As Washington Weighs In', White & Case LLP (23 August 2021), https://www.whitecase.com/insight-alert/states-remain-drivers-new-drug-pricing-legislation-washington-weighs.

137 See Arizona: HB 2166, 54th Leg, 1st Reg Sess (Ariz 2019); Arkansas: HB 1569, 93rd Gen Assemb, Reg Sess (Ark 2021); Connecticut: SB 1003, Gen Assemb, 2021 Sess (Conn 2021); Georgia: HB 946, Gen Assemb, 2019-20 Sess (Ga 2020); Illinois: HB 465, 101st Gen Assemb (Ill 2019); Kentucky: SB 45, Gen Assemb, Reg Sess (Ky 2021); Louisiana: SB 94, 2021 Leg, Reg Sess (La 2021); Oklahoma: HB 2678, 2021 Leg, Reg Sess (Okla 2021); Tennessee: HB 619, Gen Assemb, Reg Sess (Tenn 2021); Virginia: HB 2515, Gen Assemb, 2019 Sess (Va 2019); West Virginia: HB 2770, 2019 85th Leg, 1st Sess (W Va 2019).

138 *Rutledge v Pharm Care Mgmt Ass'n*, 141 S Ct 474, 483 (2020); see also Michael Gallagher and Eugene Hutchinson, 'Supreme Court Green Lights Arkansas Law Regulating PBM Pricing Practices', White & Case LLP (22 December 2020), https://www.whitecase.com/insight-alert/supreme-court-green-lights-arkansas-law-regulating-pbm-pricing-practices.

Litigation relating to pharmaceutical pricing

Challenges to formulary deals and other potentially exclusionary conduct

Litigation regarding pharmaceutical pricing remains active as well, with cases addressing a range of issues. Several recent lawsuits, for example, contend that manufacturers used rebate arrangements and other practices to unlawfully exclude competing drugs from payer coverage. But in July 2022, the US Court of Appeals for the Tenth Circuit upheld a summary judgment dismissal of antitrust claims alleging that a manufacturer executed an exclusionary formulary contracting scheme to maintain a monopoly.[139] In that case, a manufacturer argued that a competing manufacturer used conditional rebate contracts for EpiPen, an epinephrine auto-injector for anaphylaxis, to block plaintiff's Auvi-Q product from formulary coverage.[140]

The Tenth Circuit found no evidence that defendant's rebate agreements for preferred and exclusive formulary positions substantially foreclosed Auvi-Q from the market.[141] As the Court explained, the defendant's conduct did not impair plaintiff's ability to compete because the defendant's 'rebate agreements were short and easily terminable'; rebates in exchange for exclusivity were 'a normal competitive tool' in the epinephrine auto-inject market that 'stimulate price competition'; and 'when plaintiff beat defendant's price it succeeded' in gaining coverage and in some instances its own exclusivity.[142] The Court also found no evidence of coercion because PBMs only risked losing discounts for rejecting defendant's exclusive contracts. As a result, the plaintiff only needed to offer 'a better product or a better deal' to avoid exclusion.[143]

In separate litigation involving EpiPen, plaintiffs have also advanced novel theories under the federal RICO statute to challenge formulary agreements. In a case filed in the Northern District of Minnesota, the court initially permitted direct purchasers of EpiPen to bring RICO claims based on allegations that defendants' rebates to PBMs for favourable formulary status were kickbacks in violation of the anti-kickback statute.[144] To overcome the fact that private

139 *In re EpiPen Epinephrine Injection, Mkt Sales Pracs & Antitrust Litig*, No. 21-3005, 2022 US App Lexis 20998 (10th Cir 29 July 2022).
140 See *Compl, Sanofi-Aventis US LLC v Mylan Inc*, No. 3:17-cv-02763 (DNJ 24 April 2017), ECF No. 1.
141 See *In re EpiPen*, 2022 US App Lexis 20998, at *57–70, *102–03.
142 See id., at *61–70.
143 id., at *65–66, *83–91.
144 *In re EpiPen Direct Purchaser Litig*, No. 20-cv-02827, 2021 WL 147166 (D Minn 15 January 2021). Defendants in 2019 had also successfully tossed federal Racketeer Influenced and Corrupt Organizations Act (RICO) claims by a proposed class of diabetes patients who alleged that three insulin manufacturers artificially inflated benchmark prices for their drugs through a purported scheme between the manufacturers and PBMs. The class plaintiffs tried but failed to reframe their claims as injunctive claims in 2020, with the court finding no RICO private right of equitable relief. The class plaintiffs tried a third time by alleging state RICO claims in April 2021, and the court dismissed all state law RICO claims for a lack of standing except for the claims under Arizona RICO law. See *In re Insulin Pricing Litig*, No. 17-cv-00699, 2021 US Dist Lexis 241582, at *43 (DNJ 17 December 2021).

litigants cannot sue directly under the statute, the court accepted the plaintiffs' rationale that violations of the statute constitute bribery in violation of the Travel Act, a statute that qualifies as a predicate for RICO claims. However, in ruling on the defendants' renewed motion to dismiss, which was filed after the plaintiffs amended their complaint to add an antitrust claim and additional defendants, the court reversed course and granted the defendants' motion.[145] The court held that bribery under the anti-kickback statute is broader than bribery under the Travel Act, and therefore cannot form a predicate act for plaintiffs' RICO claims.[146] Throughout 2022 and 2023, the same issue has been briefed in other motions to dismiss, which remain pending as at the time of writing.[147]

Similarly, in a June 2021 lawsuit, a manufacturer alleged that a competitor sought to protect its Copaxone product by contracting to exclude generic competitors from formularies and to preference Copaxone over generics at specialty pharmacies.[148] The competitor also allegedly engaged in regulatory abuses, improperly prevented generic substitution and violated anti-kickback rules in providing donations to charities that were used as co-pay assistance to Medicare patients.[149] Direct and indirect purchasers filed separate lawsuits based on the same conduct, and motions to dismiss remain pending in all actions.[150]

In addition to these cases, certain other contracting practices in the pharmaceutical industry have also come under antitrust scrutiny. In April 2023, for example, a class of consumers brought a challenge to a manufacturer's list pricing and rebating practices. The plaintiffs allege that the manufacturer 'artificially inflates' the list price of a lead-selling product in order to pay out higher rebates to PBMs in exchange for preferred positions on the PBMs' formularies.[151] The plaintiffs contend that the defendant's list-pricing practices violate state consumer-protection law because they are unfair and unconscionable.[152] The parties are currently briefing a motion to dismiss.[153]

145 See *In re EpiPen Direct Purchaser Litig*, No. 20-cv-0827, 2022 US Dist Lexis 63272 (D Minn 5 April 2022).
146 See id., at *10–15.
147 See PBM Defs' Motion to Dismiss at § II.B, *In re Direct Purchaser Insulin Pricing Litig*, No. 3:20-cv-3426 (DNJ 17 April 2023), ECF No. 294; Brief in Supp of Defendants' Motion to Dismiss at § II.A.2, *In re Copaxone Antitrust Litig*, No. 2:22-cv-1232 (DNJ 15 June 2022), ECF No. 41.
148 See Compl, *Mylan Pharmaceuticals Inc v Teva Pharms Indus*, No. 2:21-cv13087 (DNJ 29 June 2021), ECF No. 1.
149 See id., at ¶¶ 6–7.
150 See Class Action Compl and Demand for Jury Trial, *FWK Holdings, LLC v Teva Pharms Industries, Ltd*, No. 22-cv-01232 (DNJ 7 Mar 2022), ECF No. 1; Brief in Supp of Defs' Motion to Dismiss, *In re Copaxone Antitrust Litig DPP Class Action*, No. 22-cv-01232 (DNJ 15 June 2022), ECF No. 41; Consolidated Class Action Compl and Demand for Jury Trial, *In re Copaxone Antitrust Litig TPP Class Action*, No. 22-cv-01232 (DNJ 29 April 2022), ECF No. 31; Brief in Supp of Defs' Motion to Dismiss, *In re Copaxone Antitrust Litig TPP Class Action*, No. 22-cv-01232 (DNJ 15 June 2022), ECF No. 40.
151 See Class Action Compl, *Camargo v Abbvie, Inc*, No. 23-cv-02589 (ND Ill 25 April 2023), ECF No. 1.
152 ibid.
153 See Mem In Supp Of Motion to Dismiss, *Camargo v Abbvie Inc*, No. 23-cv-02589 (ND Ill 23 June 2023), ECF No. 18.

Finally, the Attorney General for the state of Ohio turned his attention to PBMs' role – rather than that of the manufacturer, as has commonly been challenged – in formulary management and sued some of the largest PBMs in the US.[154] The suit alleges that the PBM groups colluded to fix drug prices and engaged in a 'pay to play' rebate scheme that 'pushes manufacturers to increase drug prices in order to be placed on, or receive, preferred placement on PBM formularies'.[155] The complaint further alleges that through industry consolidation the largest PBMs have been able to 'extract both monopoly profits from individual and monopsony profits from the market'.[156] The suit also alleges PBMs are able to use their market power to engage in 'spread pricing' to the financial detriment of pharmacies.[157]

Government drug pricing programmes and challenges to co-pay accumulators

Federal courts continue to address disputes concerning the federal government's 340B Drug Pricing Program, with the US Supreme Court weighing in on the federal government's authority to vary reimbursement rates paid to hospitals and ultimately cut those rates. The 340B programme requires pharmaceutical manufacturers to provide outpatients drugs at significant discounts to 'covered entities' serving a high proportion of needy patients, such as hospitals and clinics in low-income areas. As the 340B programme grew faster than expected in terms of spending, manufacturers raised concerns about the increasing use of contract pharmacies to manage drug purchases for covered entities, and the potential for fraud, duplicate discounts and drug diversions. Pharmacy chains and PBMs have allegedly dominated these 340B contract pharmacy relationships, where they may earn per-prescription fees that are 'much higher than a pharmacy's typical gross profit from a third-party payer'.[158] As a result, certain drug makers took steps to limit 340B discounts for prescription drugs dispensed via contract pharmacies.

In 2020, HHS issued an advisory opinion that any pharmacy contracting with 340B-covered entities must get the same drug discounts that the hospitals get under the current law and sent violation letters to certain manufacturers. Drug manufacturers challenged the advisory opinion and HHS's violation letters through lawsuits in federal courts. HHS voluntarily withdrew the advisory

154 See Compl for Disgorgement, Injunctive Relief, and Declaratory Judgment, *Ohio v Ascent Health Servs LLC*, No. 23 CV H 03 0179 (Ohio Ct Common Pleas 27 March 2023).
155 id., at ¶ 3.
156 id., at ¶ 5.
157 id., at ¶ 8.
158 Adam J Fein, 'Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs', *Drug Channels* (15 June 2021), https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html; Adam J Fein, 'How Hospitals and PBMs Profit—and Patients Lose—From 340B Contract Pharmacies', *Drug Channels* (30 July 2020), https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html.

opinion after unsuccessfully moving to dismiss those challenges but maintained enforcement of the violation letters.[159]

The challenges to the violation letters resulted in a split among lower federal courts on whether manufacturers can impose conditions on contract pharmacies under the 340B programme.[160] The US Court of Appeals for the Third Circuit ruled in favour of the manufacturers and found that the 340B statute did not require manufacturers to deliver their drugs to an unlimited number of contract pharmacies, and thus HHS could not enforce its interpretation of the statute.[161] Appeals in two other circuit courts remain pending as at the time of writing.[162]

In a separate dispute concerning the 340B programme, the US Supreme Court addressed the authority of HHS to manage reimbursement rates paid to 340B-covered entities. Hospitals and hospital associations challenged HHS's power under the outpatient prospective payment system to cut the statutory reimbursement rates that the federal government pays to 340B-covered entities. The Supreme Court, in a unanimous decision, held that the government did not have the authority to adjust the reimbursement rates to covered entities, unless the government conducts a survey of the covered entities' acquisition costs (which the government had not performed in the first instance).[163]

Co-pay accumulator programmes also have been the subject of litigation regarding the flow of benefits provided by manufacturer co-pay assistance programmes. In an important win for manufacturers, a May 2022 federal court decision rejected a Centers for Medicare & Medicaid Services (CMS) rule change that would have required drug manufacturers to include consumer co-pay assistance in Medicaid 'best price' calculations in certain circumstances.[164] The CMS rule, scheduled to be effective 1 January 2023, directed manufacturers to include co-pay assistance in best price calculations if the co-pay assistance ultimately benefited a health plan through an accumulator programme.

159 See HHS, Notice of Withdrawal of AO, 18 June 2021, at 1, https://www.hhs.gov/sites/default/files/notice-of-withdrawal-of-ao-20-06-6-18-21.pdf; *Sanofi-Aventis US, LLC*, 2021 US Dist Lexis 214462, at *19–21 (citing *AstraZeneca Pharms LP v Becerra*, 543 F Supp 3d 47 (D Del 2021)).

160 See *Sanofi-Aventis US LLC v US Dep't of Health and Hum Servs*, No. 21-00634, 2021 US Dist Lexis 214462 (DNJ 5 November 2021) (holding that manufacturers cannot unilaterally impose restrictions on offers to covered entities); *Novartis Pharms Corp v Espinosa*, No. 21-cv-1479, 2021 US Dist Lexis 214824 (DDC 5 November 2021) (vacating violation letters and finding that 340B does not prohibit manufacturers from imposing conditions on the use of contract pharmacies); *Eli Lilly and Co v Becerra*, No. 1:21-cv-0081 (SD Ind 29 October 2021), ECF No. 144 (setting aside violation letter as arbitrary and capricious, but finding that 340B statute does not permit manufacturers to impose conditions on covered entities' access to discounts).

161 *Sanofi Aventis US LLC v United States HHS*, 58 F.4th 696, 703–07 (3d Cir 2023).

162 *Novartis Pharms Corp v Espinosa*, No. 21-5299 (DC Cir 30 December 2021); *Eli Lilly and Co v Becerra*, No. 21-03128 (7th Cir 15 November 2021).

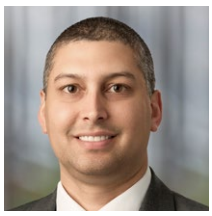
163 *American Hospital Ass'n v Becerra*, Slip Op, No. 20-1114 (15 June 2022).

164 *Pharm Research & Manufs of Am v Becerra*, No. 1:21-cv-1395, 2022 US Dist Lexis 88736, at *14 (DC Cir 17 May 2022).

The court held that any financial assistance a drug manufacturer pays to a patient 'does not qualify as a price made available from a manufacturer to a best-price-eligible purchaser', and therefore co-pay assistance to patients (even if absorbed by the payer through the accumulator programme) does not fall within the best price calculation under the terms of the applicable statute.[165] The court also acknowledged the difficulty in tracking payments made by the manufacturers to patients and incorporating those payments into the best price calculation.[166]

Separately, in what appears to be the first manufacturer challenge to the operation of a co-pay accumulator programme, a drug manufacturer filed a May 2022 lawsuit against SaveOn Specialty Assistances, partner to PBM Express Scripts, for tortious interference with plaintiff's co-pay assistance agreements with patients and related deceptive practices. The manufacturer alleges that SaveOn artificially inflated patients' co-pays to coerce patients to enrol in a SaveOn programme that would enrol those patients in their co-pay assistance programme. The scheme allegedly resulted in the manufacturer overpaying for co-pay assistance by at least US$100 million and SaveOn profiting on those overpayments through fees received from its health plan customer.[167] These claims survived a motion to dismiss, and the case remains pending.[168]

In short, between proposed legislation, policy changes and litigation, the pharmaceutical sector continues to face significant scrutiny. These proposals and legal challenges are rapidly evolving and should be carefully monitored at both the federal and state levels.[169]



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165 ibid.
166 id., at *15.
167 See Compl, *Johnson & Johnson Healthcare Sys Inc v Save on SP, LLC*, No. 22-cv-02632 (DNJ 4 May 2022), ECF No. 1.
168 See *Johnson & Johnson Health Care Sys v Save on SP, LLC*, No. 22-2632, 2023 US Dist Lexis 12619 (DNJ 25 January 2023).
169 White & Case LLP represents several of the parties in cases discussed in this article: *FTC v Actavis*, *AndroGel*, *Aggrenox*, *Asacol*, *Bystolic*, *Doryx*, *EpiPen*, *Humira*, *K-Dur*, *Lidoderm*, *Lipitor*, *Loestrin*, *Namenda*, *Remicade*, *Zytiga*, *In re Generic Pharmaceuticals Pricing Antitrust Litigation* and *In re HIV Antitrust Litigation*. No statement in this article may be imputed to any client in those actions or any other client of White & Case LLP. No client of White & Case LLP contributed to this article.

Recognised by *The Legal 500* in the antitrust cartel and antitrust class-action defence categories, Mr Acosta has 'a strong reputation for successfully handling government investigations and litigating cartel/conspiracy antitrust cases, including a recent string of client wins in the pharmaceutical sector' (*The Legal 500: US*, 2021). In 2022, he was named 'MVP' by Law360 in the life sciences category – the only attorney in the United States to receive that distinction for antitrust litigation.

Mr Acosta has litigated many of the major pharmaceutical antitrust matters over the past decade, including *FTC v Actavis*, *AndroGel*, *Asacol*, *Bystolic*, *Doryx*, *Effexor*, *Lipitor*, *Loestrin*, *Zytiga* and *In re HIV Antitrust Litigation*. He also routinely provides competition-related counselling to pharma clients involving competitor collaborations, patent-litigation settlements, drug-pricing and distribution practices, competitive intelligence, non-compete agreements and various other business initiatives in the pharmaceutical sector.

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Eric Grannon, who began at the firm as a summer associate in 1997 and has been a partner since 2007, is based in the Washington, DC, office of White & Case LLP, where he helps clients with antitrust matters, including civil and criminal defence, as well as counselling for mergers and acquisitions, settlements of pharmaceutical patent litigation and strategic planning. He returned to White & Case after serving as counsel to the assistant attorney general in charge of the Antitrust Division of the Department of Justice in 2003–2004, where he helped formulate US antitrust enforcement policy and manage the civil and criminal investigations and court cases brought by the Antitrust Division.

In private practice, Mr Grannon has argued in district courts across the country, including an antitrust jury trial, argued appeals in the Eleventh and DC Circuits, and worked on 12 matters before the US Supreme Court, 10 of which were antitrust cases.

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He has counselled more than 40 pharmaceutical patent settlements that have avoided challenge by the Federal Trade Commission and private plaintiffs. His other recent successes on behalf of clients include defeating class certification for direct purchasers, obtaining the dismissal of indirect-purchaser actions, winning summary judgment and successfully moving to bifurcate a trial into two phases, all in different pharmaceutical antitrust cases. He has also helped pharmaceutical clients obtain merger clearance in the United States.

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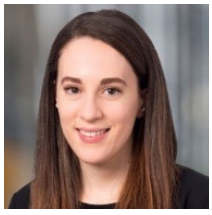

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