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United States: pharmaceutical antitrust

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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 looks at, among other things: antitrust claims under the rule of reason test announced by the US Supreme Court in *FTC v Actavis* for innovator and generic settlements of pharmaceutical patent litigation involving alleged reverse payments or 'pay-for-delay'; product-hopping antitrust claims against innovator pharmaceutical companies that introduce new versions of brand-name drugs facing generic competition; and pharmaceutical pricing developments involving legislation, regulations and legal challenges in court.

Discussion points

- Recent motion-to-dismiss decisions and a trial verdict concerning reverse payment claims
- Legislation and legal challenges to pharmaceutical manufacturers' pricing practices

Referenced in this article

- *FTC v Actavis*
- *In re Humira (Adalimumab) Antitrust Litigation*
- *In re Bystolic Antitrust Litigation*
- *In re Opana Antitrust Litigation*
- US Supreme Court
- Sherman Act

Reverse payment case law under Actavis

The US Supreme Court's June 2013 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 the first appellate decisions. As discussed below, the only certainty thus far is that the reverse payment waters are far from settled.

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 no authorised generic (no-AG), co-promotion, licensing and distribution agreements.[3] Courts,

1 *FTC v Actavis, Inc*, 570 US 136, 159 (2013).
2 id. at 156.
3 See, eg, I*n re Loestrin 24 FE Antitrust Litig*, 814 F.3d 538, 550 (3d Cir 2016) *(Loestrin)* ('[T]his no-AG agreement falls under *Actavis's* rule'); *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 Antitrust Litig,* No. 14-MD-2503, 2015 US Dist Lexis 125999, at *33–43 (D Mass 14 August 2015) (holding that a 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').

however, have grappled with how precisely a plaintiff must allege monetary estimates of value transferred to generic challengers,[4] with several courts requiring that 'plaintiffs plead information sufficient to estimate the value' of the non-cash transfer of value.[5]

For example, in January 2022, the court in *Bystolic* dismissed reverse payment claims as to each settlement between the brand company and the six generic defendants 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 nothing more than '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] The plaintiffs have since amended their complaints, and motions to dismiss those amended complaints are currently pending before the court.

Additionally, in March 2022, the court in *Sensipar* held that the plaintiffs' amended complaints failed to allege 'facts that might support a plausible theory of a conspiracy between Amgen and Teva to exclude *other* generic cinacalcet manufacturers from the market'.[10] The court reasoned that 'the earlier settlers had no contractual expectation or right requiring Amgen to settle its other pending infringement claims in a way that allowed those earlier settlers' acceleration clauses to take effect'.[11] The court explained that 'even further assuming that Amgen and Teva could have theoretically violated antitrust law by avoiding triggering the acceleration clauses in the settlement agreements of other generic cinacalcet manufacturers, the Amgen-Teva Agreement did not, in fact, have that effect' because litigation with one of those other generic manufacturers 'would have further opened the door to everyone else'.[12]

4 See, eg, *In re Lipitor Antitrust Litig*, 868 F.3d 231, 255 n.11 (3d Cir 2017); *United Food & Commercial 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,* 2015 US Dist Lexis 127748, at *61–62 (SDNY 22 Sept 2015)); see also *Opana*, 2016 US Dist Lexis 23319, at *29 (ND Ill 25 February 2016).

6 *In re Bystolic Antitrust Litig*, No. 20-cv-5735, 2022 US Dist Lexis 19334, at *55 (SDNY 2 February 2022).

7 id. at *59–60.

8 ibid.

9 ibid.

10 *In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.*, No. MDL No. 2895, 2022 US Dist Lexis 43561, at *27–33 (D Del 11 March 2022) (emphasis added).

11 ibid.

12 ibid.

As to whether Amgen's settlement with Teva delayed generic competition from Teva, the court previously permitted that reverse payment claim to go forward. The court reasoned that by allegedly 'giving up its claim to all but US$40 million (and not even the full US$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', which 'constitutes a "transfer of value" to Teva that may be proven' to be 'large and unjustified'.[13] The court further explained that the acceleration provision may constitute an 'additional transfer of value' when factored into the overall settlement and rule of reason analysis.[14]

Also, in July 2022, the court in *Seroquel* rejected a causation argument related to a settlement between AstraZeneca and Handa, concluding that discovery is needed to assess the argument that 'Handa's product lacked FDA approval until May 2017 – long after the period when Plaintiffs claim they should have been able to buy it – and so the launch was blocked by the FDA, and not Defendants'.[15] But the court dismissed reverse payment claims as to the settlement between AstraZeneca and Accord, finding the plaintiffs' causation theory to be conclusory and implausible because Accord had 'conceded in its [abbreviated new drug application] litigation with AstraZeneca that it infringed the #437 patent'.[16] 'Thus, at the time they struck their settlement agreement, both Accord and AstraZeneca knew that without such an agreement, Accord could not lawfully enter the market before May 28, 2017 unless it won at trial on its invalidity defenses.'[17] '[F]our generics that proceeded to trial after the Accord/AstraZeneca settlement was reached lost their invalidity challenges both at trial and then on appeal before the Federal Circuit.'[18]

The court also rejected the plaintiffs' argument that:

> *it would have been economically rational for AstraZeneca to enter into an alternative settlement agreement with Accord – ie, where Accord conceded that it infringed the #437 patent and in the absence of any allegation that the #437 patent was invalid or weak such that Accord could have prevailed or believed that it could have prevailed at trial on its invalidity defense.*[19]

13 *In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig*, MDL No 2895, 2020 US Dist Lexis 223786, at *18 (D Del 30 November 2020). The district court judge reversed an earlier decision by a magistrate judge holding that plaintiffs did not sufficiently allege an unlawful reverse payment between Amgen and Teva.
14 id. at *20.
15 *In re Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litig*, 2022 US Dist Lexis 117525, at *35–42 (D Del 5 July 2022).
16 id. at *42.
17 ibid.
18 id. at *42–43.
19 id. at *45.

And the court found that 'the allegation that the reverse payment was worth $107 million is by itself insufficient to support a plausible inference that AstraZeneca made a large and unjustified payment because it had serious doubts about the patent's validity',[20] particularly when 'AstraZeneca's *annual* sales of brand Seroquel XR® in the United States exceeded $1 billion'[21] and '[t]hose kinds of revenue figures breed patent litigation, and multi-billion dollar jury awards'.[22]

Further, in August 2022, the US Court of Appeals for the Seventh Circuit affirmed the dismissal of reverse payment claims concerning biological drug Humira. The plaintiffs had alleged that 'AbbVie paid biosimilar manufacturers in the form of European agreements that allowed the biosimilars to enter the European market' while agreeing to 'AbbVie-friendly' generic entry dates in the US.[23] The 'package deals' allegedly bought AbbVie 'more lucrative monopoly time in the US (worth billions of dollars in revenue for AbbVie)'.[24] But the district court rejected this theory because the settlements increased competition 'by bringing competitors into the market when patents otherwise prohibited competition'.[25]

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 AbbVie is said to have left on the table in Europe' by allowing biosimilars to launch earlier.[26] As the Seventh Circuit explained, '[o]n each continent AbbVie surrendered its monopoly before all of its patents expired, and the rivals were not paid for delay'.[27] '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.'[28] Thus, 'the US settlement and the EU settlement are traditional resolutions of patent litigation' that do not violate antitrust laws.

Finally, later in August 2022, the district court in the *EpiPen* litigation permitted some reverse payment claims to move forward against Mylan. The court found that the plaintiffs plausibly alleged a reverse payment claim where 'Teva agreed to delay its launch of an EpiPen generic' and did so allegedly 'in exchange for Mylan's agreement to delay its launch of a Nuvigil generic and settle patent litigation with Teva over Mylan's Nuvil generic'.[29] The complaint also included

20 id. at *46.
21 ibid.
22 ibid.
23 *In re Humira (Adalimumab) Antitrust Litig*, No. 19-CV-1873, 2020 US Dist Lexis 99782, at *57 (ND Ill 8 June 2020).
24 id. at *57–58.
25 id. at *58–61.
26 *Mayor of Baltimore v AbbVie Inc*, No. 20-2402, 2022 US App Lexis 21165, at *16–17 (7th Cir 1 August 2022).
27 id. at *17.
28 ibid.
29 *KPH Healthcare Servs v Mylan NV*, No. 20-2065, 2022 US Dist Lexis 140848, at *105 (D Kan 8 August 2022).

'additional facts about the alleged merits of the Teva and Nuvigil litigation, the status of each litigation when the parties settled, and the parties' motivations for entering an unlawful reverse payment settlement'.[30] The court also found that another settlement with Intellijject was plausibly alleged to constitute a reverse payment 'because it involved an agreement to delay entry of a competing product into the EAI market', and 'the relatively short duration of delay before entry of the competing Intellijject product, likely indicates that strength of Intellijject's defenses to the patent litigation'.[31] The court, however, dismissed the reverse payment allegations against Sandoz as conclusory, observing that the plaintiffs 'fail to assert any facts' in support of that settlement potentially constituting a reverse payment.[32]

Summary judgment under Actavis

Courts have likewise 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 generally denied summary judgment based on various disputed factual issues unique to each case. For example, those decisions analysed: whether there was sufficient evidence to support allegations 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 such business agreements may be 'linked' to the patent settlement.[33]

For instance, in June 2021, the court in *Namenda* found that there were disputed factual issues as to the value associated with a distribution and supply agreement negotiated at the time of the parties' patent settlement. In reaching this conclusion, the court rejected the plaintiff's 'generic inducement test' where the 'trier of fact can consider only the generic's perspective' and 'it does not matter if [the brand company] expected to save money in the long run' under the distribution and supply agreement.[34] Instead, the court held that a 'factfinder

30 id. at *109.
31 id. at *111–12.
32 id. at *114.
33 *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); *In re AndroGel Antitrust Litig* (No. II), 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*, No. 13-md-2472, 2019 US Dist Lexis 220262, at *53–54, *62–70 (D RI 17 December 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).
34 *In re Namenda Indirect Purchaser Antitrust Litig*, No. 1:15-cv-6549, 2021 US Dist Lexis 110081, at *75 (SDNY 11 June 2021).

must also be allowed to consider the net benefits to the branded manufacturer, which could include, among other things, reduced Medicaid liabilities and saved manufacturing costs – all in addition to the saved litigation costs from settling'.[35] *Actavis* made clear that 'litigation expenses saved through the settlement' and 'compensation for other services' are not exhaustive and that the factfinder may address other considerations.[36] 'The only consideration that cannot factor into whether the reverse settlement was made are the expected profits from delayed competition.'[37]

Other district courts have also denied summary judgment where factual and expert evidence adequately supported plaintiffs' causation theories of earlier generic entry that in the but-for world the generic challenger would have launched at risk, prevailed in the patent case, or entered into an alternative, 'no-payment' settlement agreement.[38] At the same time, other district courts, such as in *AndroGel*, have rejected patent-based causation theories as unsupported and 'simply too procedurally burdensome and speculative' when there were no concrete developments in the underlying patent case in which to base such a causation theory.[39]

One of the most notable causation decisions is *Wellbutrin*, where the Third Circuit affirmed a grant of summary judgment for the defendants. The Third Circuit 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'.[40] 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'.[41] Notably, the size of the reverse payment alone was an insufficient 'surrogate' for the weakness of the patent.[42] Additionally, the court rejected the plaintiffs' but-for theory that Andrx had 'an independent economic interest' in providing

35 id. at *76.
36 id. at *77.
37 id. at *78.
38 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 & Commercial Workers Local 1776 v Teikoku Pharma USA*, 296 F Supp 3d 1142, 1156–58, 1160–64 (ND Cal 2017).
39 *In re AndroGel Antitrust Litig (No. II)*, No. 1:09-md-2084, 2018 US Dist Lexis 99716, at *49–50 (ND Ga 14 June 2018). 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.')
40 *In re Wellbutrin XL Antitrust Litig*, 868 F.3d 132, 165 (3d Cir 2017). But see *In re Opana ER Antitrust Litig,* MDL No. 2580, 2021 US Dist Lexis 105342, at *89 (ND Ill 4 June 2021) ('Because Endo did not acquire its additional patents until years after the agreement was signed, the additional patents do not break the causal chain.').
41 *In re Wellbutrin XL Antitrust Litig*, 868 F.3d 132, 169 (3d Cir 2017).
42 id. at 168–69.

a licence to Anchen and that licence negotiations were nearly complete days before the alleged reverse payment was made.[43] 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'.[44]

Trials under Actavis

Several cases, such as *Modafinil* and *Solodyn*, have proceeded to trial since *Actavis* but were resolved by settlements mid-trial. Three reverse payment cases, however, have proceeded through trial 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'.[45] But at trial, 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.[46] The US Court of Appeals for the First Circuit affirmed the jury's verdict for the defendants.[47]

More recently, following an administrative bench trial in the FTC's *Opana* suit, the FTC's chief administrative law judge (ALJ) concluded that an alleged reverse payment between Endo and Impax was not anticompetitive. Endo and Impax had settled the underlying patent litigation and entered into a settlement and licence agreement (SLA) and a development and co-promotion agreement (DCA).[48] The SLA included a no-AG provision and a potential cash credit to Impax if Opana sales fell below a certain threshold.[49] 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.[50]

43 id. at 166–67.
44 id. at 167.
45 *In re Nexium (Esomeprazole) Antitrust Litig*, 42 F Supp 3d 231, 264 (D Mass 2014).
46 Jury Verdict, *In re Nexium (Esomeprazole) Antitrust Litig*, No. 1:12-md-02409 (D Mass 5 December 2014), ECF No. 1383.
47 *In re Nexium (Esomeprazole) Antitrust Litig*, 842 F.3d 34 (1st Cir 2016).
48 Initial Decision at 85, *In the Matter of Impax Labs, Inc,* FTC Dkt No. 9373 (11 May 2018).
49 id. at 114.
50 id. at 120.

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'.[51] Despite finding that the SLA was 'large and unjustified', the ALJ concluded that any anticompetitive harm was outweighed by pro-competitive benefits because 'Endo's acquisition of additional patents, and successful assertion of those additional patents in litigation, has led to all generic manufacturers, other than Impax, being 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'.[52]

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'.[53] In an April 2021 decision, the US Court of Appeals for the Fifth Circuit denied a petition for review and found that the Commission did not commit any legal errors and that substantial evidence supported the Commission's factual findings.[54] The Fifth Circuit observed that the settlement 'saved Endo 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 Endo's payment remains unjustified'.[55] Impax's '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'.[56] The Fifth Circuit 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"'.[57] Ultimately, the Fifth Circuit concluded that substantial evidence supports the Commission's conclusion that the parties could have entered a less restrictive alternative settlement that did not include the payments.[58]

But in the parallel private-plaintiff litigation concerning Opana, a jury subsequently found in favour of the defendants in July 2022. After Impax settled mid trial, the jury went on to find 'that while Endo had market power for the brand name drug and made a reverse payment to delay Impax's generic from entering the market, the deal between the companies was not unreasonably anti-competitive'.[59] Endo argued that purchasers of Opana were relying on

51 id. at 132.
52 id. at 145.
53 Opinion of the Commission at 42, *In the Matter of Impax Labs, Inc*, FTC Dkt No. 9373 (28 March 2019).
54 *Impax Labs, Inc v FTC*, 994 F.3d 484, 488 (5th Cir 2021).
55 id. at 494–95.
56 id. at 495.
57 id. at 496.
58 id. at 498–500.
59 Lauraann Wood, 'Jury Hands Endo Win In Opana Pay-For-Delay Case', Law360, https://www.law360.com/articles/1508192/jury-hands-endo-win-in-opana-pay-for-delay-case.

'guesswork' and 'speculation' to argue that generic Opana could have been sold earlier but for the alleged reverse payment.[60] Like in the FTC case, Endo 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 license covering current and future Opana-related patents'.[61] Endo emphasised that it 'would have never given Impax both an earlier entry date and a broad license to its Opana-related patents'.[62]

With this July 2022 trial verdict, private plaintiffs have now lost both of the jury trials – *Nexium* and *Opana* – that have proceeded to verdict since *Actavis* was decided in 2013.

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.[63] Initially, the law was unsuccessfully challenged at the district court level,[64] and that challenge was rejected for lack of standing by the US Court of Appeals for the Ninth Circuit in July 2020.[65]

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'.[66] 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'.[67] 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

60 ibid.
61 ibid.
62 ibid.
63 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.
64 *Ass'n for Accessible Meds v Becerra,* No. 2:19-cv-2281, 2019 US Dist Lexis 223342 (ED Cal 31 December 2019).
65 *Ass'n for Accessible Meds v Becerra*, No. 20-15014 (9th Cir 24 July 2020), ECF No. 55-1.
66 *Ass'n for Accessible Meds v Bonta*, No. 2:20-cv-01708, 2022 US Dist Lexis 27533, at *24 (ED Cal 14 February 2022).
67 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'.[68]

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 older versions of brand drugs in an alleged attempt to thwart generic competition and generic substitution laws.[69]

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.[70] 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.[71]

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.[72] 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.[73]

68 id. at *11 (internal quotation marks and alterations omitted).
69 See Michael Gallagher, Eric Grannon et al., 'United States: Pharmaceutical Antitrust', *Americas Antitrust Review 2020*, Global Competition Review, 2019, at 116, www.whitecase.com/sites/default/files/2019-09/gcr-united-states-pharmaceutical-antitrust-2020.pdf (addressing the regulatory background related to product-hopping claims).
70 *Abbott Labs v Teva Pharms USA, Inc,* 432 F Supp 2d 408, 422 (D Del 2006).
71 id. at 423–24.
72 *Walgreen Co v AstraZeneca Pharma LP*, 534 F Supp 2d 146, 151 (DDC 2008).
73 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*, direct and indirect purchasers 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 the product-hopping claims, holding that 'what is clear from the case law is that simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct [that stymies competition]'.[74] The court determined that the defendants' conduct fell somewhere in between the conduct at issue in *TriCor* and *Prilosec*. The court found that the conduct was more problematic than in *Prilosec* because the defendants removed the Suboxone tablets from the market, but less problematic than in *TriCor* because the defendants did not buy back existing Suboxone tablets or label the tablets obsolete.[75] The court nonetheless found that the plaintiffs had sufficiently pleaded 'other wrongful conduct' insofar as removing the tablets from the market in conjunction with fabricating safety concerns could coerce patients to switch from the tablet to the film.[76]

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.[77] Unlike in *TriCor* and *Suboxone*, in which the defendants fully removed the older formulation from the market, the *Namenda* defendants planned to continue making the older formulation available to any patient who had a medical need for it. Nonetheless, the *Namenda* 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 hoped.[78]

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

74 *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig*, 64 F Supp 3d 665, 682 (ED Pa 2014).
75 id. at 681–82.
76 id. at 682–85.
77 *New York v Actavis, PLC*, No. 14-cv-7572, 2014 US Dist Lexis 172918, at *118–23 (SDNY 11 December 2014).
78 id. at *107–08.

Act.[79] 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*[80] 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.[81] 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 withdrawing' the old version was sufficiently coercive that it violated the Sherman Act.[82]

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.[83] 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.[84]

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.[85] 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.[86] As to the role of state-substitution laws in the analysis of

79 *New York v Actavis, PLC*, 787 F.3d 638, 643 (2d Cir 2015).
80 *Berkey Photo, Inc v Eastman Kodak Co*, 603 F.2d 263 (2d Cir 1979).
81 787 F.3d at 653–54.
82 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 *New York v 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)).
83 *Mylan Pharms, Inc v Warner Chilcott Pub*, No. 12-3824, 2013 US Dist Lexis 152467 (ED Pa 11 June 2013).
84 id. at *11.
85 *Mylan Pharms, Inc v Warner Chilcott Pub*, No. 12-3824, 2015 US Dist Lexis 50026 (ED Pa 16 April 2015); see also id. at *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); see also id. at *34.
86 id. at *42.

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 can compete without automatic substitution through advertising and cost competition, and concluded that brand manufacturers have no duty to facilitate generic manufacturers' business plans by keeping older versions of a drug on the market.[87] The US Court of Appeals for the Third Circuit affirmed the lower court's grant of summary judgment in the defendants' favour.[88]

Post-Namenda and Doryx: Solodyn, Asacol and Suboxone revisited

Since the *Namenda* and *Doryx* decisions, additional courts have addressed product-hopping claims at the motion-to-dismiss stage. The *Solodyn* 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.[89]

In *Asacol*, the direct and indirect purchasers 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.[90] 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.[91] 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, but it did not revisit the legal framework for product-hopping claims.[92]

Subsequent to the 2014 motion-to-dismiss decision in *Suboxone* related to the purchaser plaintiffs' complaints, state plaintiffs filed complaints with similar claims, and the court revisited its product-hopping analysis in light of the *Namenda*, *Doryx* and *Asacol* decisions rendered since the earlier *Suboxone*

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

decision. The court reached the same result as it did in its previous decision in which it analysed the product-hopping claims in view of *TriCor* and *Prilosec*, determining that the conduct was more akin to the claims allowed to proceed in *Namenda* than to claims dismissed in *Doryx* and *Asacol* because the old Suboxone product was withdrawn prior to generic entry.[93] The private plaintiffs' and the state attorneys general's cases were coordinated for pretrial discovery, and the court recently denied summary judgment.[94]

Further, the court in *Loestrin* relied heavily on *Namenda* when denying the defendants' motion to dismiss the product-hopping claims.[95] 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.[96] 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.[97] 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.[98]

Finally, 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'.[99] 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'.[100] 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"'.[101]

93 *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig*, No. 13-md-2445, 2017 US Dist Lexis 627 (ED Pa 8 September 2017).
94 See *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig*, No. 13-md-2445 (ED Pa). Following a Federal Trade Commission (FTC) investigation related to Suboxone, the FTC filed an antitrust action against Reckitt Benckiser in July 2019 concerning allegations of product hopping and sham petitioning, which Reckitt settled the next day.
95 *In re Loestrin 24 FE Antitrust Litig*, 261 F Supp 3d 293, 307 (DRI 2017).
96 ibid.
97 *In re Loestrin 24 Fe Antitrust Litig*, No. 13-md-2472, 2019 US Dist Lexis 220262, at *89–91 (DRI 17 December 2019).
98 id. at *92.
99 *In re Namenda Indirect Purchaser Antitrust Litig,* No. 1:15-cv-6549, 2021 US Dist Lexis 110081, at *126 (SDNY 11 June 2021).
100 ibid. (emphasis in original).
101 *In re Namenda Indirect Purchaser Antitrust Litig*, No. 1:15-cv-6549 (SDNY 26 July 2021), ECF No. 694.

Pharmaceutical manufacturer pricing practices

The pharmaceutical industry continues to see substantial activity on a number of fronts directed at the pricing of prescription drugs. Federal legislators persist in pursuing a variety of proposed changes, some of which have passed in Congress while others remain stalled. Most notably, Congress passed the 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 FTC appears poised for action on manufacturer rebate agreements with pharmacy benefit manager (PBM) middlemen for formulary access, after launching an inquiry into the PBM industry and issuing an enforcement policy statement to put the industry 'on notice' as to when these agreements may be unlawful. Congress, likewise, has increased its focus on PBMs, expressing concerns that certain PBM practices lead to higher drug prices for consumers and calling for regulation of those practices and increased transparency. State lawmakers continue to pass new laws targeting key issues in the ongoing drug pricing debate, adding to existing complexity and compliance obligations. Litigation remains active as well, with developments in a range of cases regarding marketplace practices and pricing in government programmes.

Legislation and regulation relating to pharmaceutical pricing

Federal legislation and regulation

Legislative proposals on drug pricing remained active in 2022, with some long-sought proposals becoming law. However, the prospects for additional meaningful federal legislation on drug pricing continue to be uncertain, despite activity on both sides of the aisle and public support for action. 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-time wish list drug pricing components for Congressional Democrats, including:

- 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 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.[102]

Manufacturers have already signalled their intention to challenge the Act's Medicare price negotiation provisions.[103] The IRA also further delayed implementation of the Trump-era rule that would eliminate the anti-kickback law safe harbour for drug manufacturer rebates paid to Medicare Part D plan sponsors (or their contracted PBMs) and replace it with new safe-harbour protections, such as one for discounts that pass through directly to patients at the point of sale.[104] 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.[105] These continued delays raise doubts that the rule will ever be allowed to take effect.

Other significant drug pricing proposals remained stalled. A package of four bills introduced in 2021 to revise aspects of antitrust and patent enforcement likewise has made little recent progress.[106] 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. Three of the bills advanced through the House Judiciary

102 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.

103 See Adam Lidgett and Jeff Overley, 'Big Pharma Expected to Put Up Fight over Drug Price Negotiations', Law360 (12 August 2022), https://www.law360.com/articles/1520819/big-pharma-expected-to-put-up-fight-over-drug-negotiations.

104 See Inflation Reduction Act of 2022, HR 5376, 117th Cong (2022), Subtitle B, Part 4 – Continued Implementation of Prescription Drug Rebate Rule, § 11301 (delaying implementation of rule until 2032); Michael Gallagher and Kevin C Adam, 'Trump Administration's Eleventh-Hour Drug Pricing Regulations Face an Uncertain Path', White & Case LLP, 3 December 2020, https://www.whitecase.com/publications/alert/trump-administrations-eleventh-hour-drug-pricing-regulations-face-uncertain-path; see also Infrastructure Investment and Jobs Act, Pub L No. 117-58, 135 Stat 429 (2021), § 90,006 (delaying implementation of the Trump-era rule for three years).

105 Bipartisan Safer Communities Act, Pub L 117-159, 117th (2022), § 13101, https://www.congress.gov/117/plaws/publ159/PLAW-117publ159.pdf.

106 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/publications/alert/federal-lawmakers-turn-their-sights-drug-pricing-introducing-package-bills.

Committee to the congressional floor in the last quarter of 2021, but have yet to get to a vote.[107]

Duelling majority and minority reports from the House Oversight and Reform Committee reflect why it has been – and may continue to be – difficult to advance further federal legislation on the subject of drug pricing, with lawmakers unable to agree on which industry players should be targeted, let alone how to go about doing so.[108] The December 2021 reports present findings from eight interim staff reports and five public hearings as part of the Committee's drug-pricing investigation that kicked off in January 2019. The Democrats' Majority Staff Report focuses on 'reverse payment' patent settlements, 'product hopping', patent 'thicketing' and other drug manufacturer conduct that the Majority Report concludes suppresses competition from less-expensive generic and biosimilar drugs, leading to higher prices.[109] By contrast, the Republicans' Minority Staff Report takes aim at the role of PBMs and concludes that PBMs drive up drug prices by leveraging the influence these intermediaries have to force manufacturer price concessions for popular drugs.[110] The Minority Report explains that pharmaceutical manufacturers must raise prices to pay these growing rebates and discounts, which PBMs then largely pocket rather than pass along to consumers.

Notably, following those reports, there has been further attention from both parties on PBM practices. The proposed Pharmacy Benefit Manager Transparency Act of 2022, introduced in May 2022 with a Republican and a Democrat sponsor, seeks to ban certain PBM practices, such as spread pricing[111] and unfair clawbacks of reimbursement payments from pharmacies, as unfair and deceptive acts and practices under the Federal Trade Commission Act of 1914 (the FTC Act), unless certain exceptions apply.[112] Also, in an effort to improve transparency, the bill would require PBMs to disclose annually to the FTC certain aggregate financial information, such as the spread retained by the PBM and any clawbacks.[113] In a

107 See Affordable Prescriptions for Patients through Promoting Competition Act of 2021, HR 2873, 117th Cong (2021), https://www.congress.gov/bill/117th-congress/house-bill/2873; Stop Stalling Access to Affordable Medications, HR 2883, 117th Cong (2021), https://www.congress.gov/bill/117th-congress/house-bill/2883; Preserve Access to Affordable Generics and Biosimilar Act, HR 2891 (2021), https://www.congress.gov/bill/117th-congress/house-bill/2891.

108 See David Baumann, 'High drug prices: Congress can't agree on a solution or even who's to blame', BenefitsPRO, 15 December 2021, https://www.benefitspro.com/2021/12/15/high-drug-prices-congress-cant-agree-on-a-solution-or-even-whos-to-blame/?slreturn=20220028130526.

109 US House of Representatives Committee on Oversight and Reform, Drug Pricing Investigation, Majority Staff Report, 10 December 2021, https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf.

110 US House of Representatives Commission on Oversight and Reform, Minority Staff, 'A View From Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets', 10 December 2021, https://republicans-oversight.house.gov/wp-content/uploads/2021/12/PBM-Report-12102021.pdf.

111 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.

112 Pharmacy Benefit Manager Transparency Act of 2022, S 4293, 117th Cong (2022), https://www.congress.gov/bill/117th-congress/senate-bill/4293.

113 ibid.

17 June 2022 letter to the US Government Accountability Office (GAO), a group of House Republicans raised concerns about the 'central role' PBMs play in 'the market price of prescriptions', given their position in the pharmaceutical supply chain.[114] The letter asks the GAO to study how PBMs are reimbursed for services provided to commercial health plans, the effect of PBM formularies and related manufacturer contracts on commercial health plan drug spending, and the role of Employee Retirement Income Security Act (ERISA) fiduciary requirements on the services PBMs provide.

For its part, the FTC appears to be following the direction from the Biden administration to be more aggressive on drug pricing, although action by the FTC may have been hampered by the absence of a working Democratic majority from October 2021, when Commissioner Rohit Chopra stepped down, to May 2022 when the Senate confirmed Alvaro Bedoya as his replacement. In a 9 July 2021 Executive Order and remarks at the end of 2021, President Biden called on the FTC to take action concerning the costs of drugs and healthcare, flagging, in particular, the need to facilitate competition from generic and biosimilar alternatives and prevent allegedly anticompetitive agreements.[115] The FTC's Statement of Regulatory Priorities for 2022 reflects these administration's priorities, pledging to define rules to address 'unfair methods of competition' linked to 'pay for delay agreements' as well as other 'unfair or deceptive acts or practices'.[116] More generally, that FTC Statement asserted that case-by-case antitrust enforcement 'has proven insufficient, leaving behind a hyper-concentrated economy whose harms to American workers, consumers, and small businesses demand new approaches'.[117] FTC rule-making for pharmaceuticals, if pursued, could trigger legal challenges as well as substantial changes, increased uncertainty and significant compliance challenges for the industry.

The FTC, like some in Congress, has also focused its attention on the role of PBMs and their effect on drug pricing. On 7 June 2022, the FTC announced a Section 6(b) inquiry into the PBM industry.[118] 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

114 See Letter from Rep Virginia Foxx et al. to Hon Gene L Dodaro, US Government Accountability Office, 17 June 2022.

115 See Executive Order on Promoting Competition in the American Economy, WhiteHouse.gov, 9 July 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/; Michael Gallagher et al., 'What Does President Biden's 9 July 2013 Executive Order on Competition Mean for the Pharma Industry?', White & Case LLP, 13 July 2021, https://www.whitecase.com/publications/alert/what-does-president-bidens-july-9-2021-executive-order-competition-mean-pharma.

116 Statement of Regulatory Priorities, FTC (10 December 2021).

117 ibid.

118 FTC Matter No. P221200, 6 June 2022; 'FTC Launches Inquiry Into Prescription Drug Middlemen Industry', FTC.gov, 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.

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.[119] This 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.[120]

Shortly after announcing its 6(b) inquiry, the FTC issued a 16 June 2022 enforcement policy statement concerning manufacturer-PBM formulary rebate practices that the FTC described as a 'top priority'.[121] The policy statement focuses on rebates and fees paid by manufacturers to PBMs in 'exchange for excluding lower-cost drug products'.[122] According to the FTC, formulary agreements that 'foreclose competition from less expensive alternatives' may be unlawful restraints of trade (Sherman Act Section 1), unlawful monopolisation (Sherman Act Section 2) or exclusive dealing (Clayton Act Section 3).[123] Also, the policy statement 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 (FTC Act Section 5), as well a violation of the Robinson-Patman Act's commercial bribery provision (Section 2(c)).[124] This policy statement follows the FTC's 5 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 rule-making and the FTC's 28 May 2021 report on 'rebate wall' practices, which some have argued foreclose competition from less expensive drugs.[125] FTC chair Lina Khan stated that the 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'.[126]

119 FTC Matter No. P221200, 6 June 2022, footnote 118.
120 ibid.
121 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/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf.
122 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.
123 id. at 5.
124 ibid.
125 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.
126 'FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs', FTC.gov, 16 June 2022, https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes.

State legislation

Following the same pattern as recent years, states continue to be active on drug pricing, passing legislation on a range of issues. In 2021, states debated more than 650 bills that purported to reduce or control drug prices and enacted more than 30 of them.[127] In the first half of 2022, more than 280 state drug laws had been introduced, several of which would go beyond mere reporting requirements and institute various degrees of price control.[128] Among other changes, states have passed 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.[129] A growing number of states have 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 and are not co-opted by commercial health plans through the use of these programmes, which 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-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.[130] States may also pursue additional legislation touching more directly on drug pricing following the Supreme Court's 2020 decision in *Rutledge v Pharmaceutical Care Management Association*, which outlined a pathway for

127 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/publications/alert/states-remain-drivers-new-drug-pricing-legislation-washington-weighs.

128 National Academy for State Health Policy, '2022 State Legislative Action to Lower Pharmaceutical Costs', https://www.nashp.org/rx-legislative-tracker.

129 See id.; 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/publications/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', footnote 127.

130 See Arizona: HB 2166, 54th Leg, 1st Reg Sess (Az 2019), https://legiscan.com/AZ/text/HB2166/2019; Arkansas: HB 1569, 93rd Gen Assemb, Reg Sess (Ark 2021), https://legiscan.com/AR/text/HB1569/id/2386322; Connecticut: SB 1003, Gen Assemb, 2021 Sess (Conn 2021), https://www.cga.ct.gov/2021/ACT/PA/PDF/2021PA-00014-R00SB-01003-PA.PDF; Georgia: HB 946, Gen Assemb, 2019-20 Sess (Ga 2020), http://www.legis.ga.gov/Legislation/20192020/195227.pdf; Illinois: HB 465, 101st Gen Assemb (Ill 2019), https://ilga.gov/legislation/fulltext.asp?DocName=&SessionId=108&GA=101&DocTypeId=HB&DocNum=465&GAID=15&LegID=114693&SpecSess=&Session=; Kentucky: SB 45, Gen Assemb, Reg Sess (Ky 2021), https://legiscan.com/KY/text/SB45/2021; Louisiana: SB 94, 2021 Leg, Reg Sess (La 2021), http://www.legis.la.gov/legis/ViewDocument.aspx?d=1235886; Oklahoma: HB 2678, 2021 Leg, Reg Sess (Ok 2021), https://legiscan.com/OK/text/HB2678/2021; Tennessee: HB 619, Gen Assemb, Reg Sess (Tenn 2021), https://wapp.capitol.tn.gov/apps/Billinfo/default.aspx?BillNumber=HB0619&ga=112; Virginia: HB 2515, Gen Assemb, 2019 Sess (Va 2019), https://lis.virginia.gov/cgi-bin/legp604.exe?191+sum+HB2515; West Virginia: HB 2770, 2019 85th Leg, 1st Sess (W Va 2019), https://www.wvlegislature.gov/Bill_Status/bills_text.cfm?billdoc=hb2770%20intr.htm&yr=2019&sesstype=RS&i=2770.

states to implement PBM-focused 'cost regulation' that would not be pre-empted by federal ERISA law.[131]

Litigation relating to pharmaceutical pricing

Litigation regarding pharmaceutical pricing remains active, with cases addressing a range of issues, including the limits on enforcers' ability to seek disgorgement in antitrust cases in federal court, sham patent litigation, allegedly exclusionary formulary agreements and other exclusionary conduct, novel theories of liability under the federal Racketeer Influenced and Corrupt Organizations (RICO) statute, 'patent thickets', regulatory changes affecting pricing under federal government programmes and other topics.

Disgorgement claims by federal and state enforcers

The FTC and state enforcers have seen the ripple effects of the Supreme Court's April 2021 decision in *AMG,* which held that the 'permanent injunction' remedy available to the FTC in federal court under Section 13(b) of the FTC Act does not also permit the court to award equitable monetary relief, such as disgorgement.[132] In *In re: Generic Pharmaceuticals Pricing Antitrust Litigation*, the court relied on *AMG* to dismiss price-fixing claims seeking disgorgement under Section 16 of the Clayton Act brought by state attorneys general, reasoning that the injunctive relief provision in Section 16 of the Clayton Act invoked by the states is similar to Section 13(b) of the FTC Act and required a similar result.[133]

In a joint action by the FTC and state attorneys general against Martin Shkreli and Vyera Pharmaceuticals for allegedly using exclusive ingredient supply agreements and other restrictive contracts to block generic competition to Vyera's Daraprim product, the FTC dropped its claims for monetary relief following *AMG*, and the state attorney generals agreed not to seek civil penalties or forfeitures in exchange for the defendants' agreement to withdraw their jury demands.[134] The court permitted the state attorney generals, however, to pursue equitable claims for disgorgement under state antitrust and unfair competition

131 *Rutledge v Pharm Care Mgmt Ass'n*, 141 S Ct 474, 483 (2020); see also Michael Gallagher et al., '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?s=Supreme%20Court%20Green%20Lights%20Arkansas%20Law%20Regulating%20PBM%20Pricing%20Practices.

132 See *AMG Capital Mgmt, LLC v FTC*, 141 S Ct 1341 (2021).

133 *In re: Generic Pharmaceuticals Pricing Antitrust Litig*, No. 16-MD-2724, 2022 US Dist Lexis 101212 (ED Pa 7 June 2022). The court allowed the state attorneys general to pursue its additional claim for injunctive relief as *parens patriae*, but not damages.

134 See Joint Stipulation and Order to Amend the Relief Requested in the Pleadings, *Federal Trade Commission et al. v Vyera Pharmaceuticals et al.*, No. 1:20-cv-00706 (SDNY 30 March 2021), ECF No. 408.

laws.[135] Following a bench trial win for the enforcers, the court ordered Mr Shkreli to pay US$64 million in disgorgement and issued an unprecedented lifelong ban for Mr Shkreli, barring him from 'participating in the pharmaceutical industry in any capacity'.[136]

Sham patent litigation

In October 2021, the court in *Zytiga* dismissed claims that the defendants used sham patent litigation to delay generic competition. In granting the defendants' motion to dismiss, the court held that the defendants' 'infringement action, though unsuccessful, was not objectively baseless'.[137] The court explained that the patent action 'was a triable one, in my view, and was hard fought by both parties'.[138] The court emphasised that the patent action required a 30-page *Markman* ruling, and only after an eight-day bench trial requiring another 70-page opinion was the court able to find that the patent was invalid.[139] The obviousness issue 'required close analysis of multiple factors', including the argument that the patent was not obvious from the prior art and whether the commercial success of Zytiga, which 'yielded billions of dollars in sales', was attributed to a 'blocking patent'.[140] Considering these multiple factors, the court held that the defendants 'presented a plausible case, if not a winning one'.[141]

Challenges to formulary deals, 'patent thickets' and other potentially exclusionary conduct

Private plaintiffs continue to challenge certain manufacturer rebating and patenting practices as unlawfully exclusionary, focusing on formulary agreements that allegedly exclude less expensive alternatives and 'patent thickets'. These cases come at the same time as federal enforcers and lawmakers are taking a closer look at the same conduct.

Several recent lawsuits contend that manufacturers used rebate arrangements (and other practices) to unlawfully exclude competing drugs from payer coverage.

135 *FTC v Vyera Pharms, LLC*, No. 1:20-cv-00706, 2021 US Dist Lexis 183303, at *13 (SDNY 24 September 2021). While the states also sought relief under Section 16 of the Clayton Act, the court only decided the scope of relief available to the states under state laws, but noted that 'the reasoning in AMG appears to preclude all of the plaintiffs from seeking disgorgement pursuant to § 16 [of the Clayton Act]'. id. at *7 n.6.

136 See Opinion and Order at 121, 135, *FTC v Vyera Pharms, LLC*, No. 20-cv-00706 (SDNY 14 January 2022), ECF No. 865.

137 *La Health Serv & Indem Co v Janssen Biotech, Inc*, No. 19-cv-14146, 2021 US Dist Lexis 207239, at *25 (DNJ 27 October 2021).

138 id. at *25.

139 ibid.

140 id. at *25–26.

141 id. at *26.

Most recently, 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.[142] In that case, Sanofi argued that Mylan used conditional rebate contracts for EpiPen, the leading epinephrine auto-injector product for anaphylaxis, to block Sanofi's Auvi-Q product from formulary coverage, thereby unlawfully maintaining an alleged monopoly for EpiPen.[143] Applying primarily an exclusive dealing lens, the Tenth Circuit found no evidence that Mylan's rebate agreements for preferred and exclusive formulary positions substantially foreclosed Auvi-Q from the market.[144] As the Court explained, Mylan's conduct did not impair Sanofi's ability to compete because the Mylan '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 Sanofi beat Mylan's price it succeeded' in gaining coverage and in some instances its own exclusivity.[145] The Court also found no evidence of coercion; PBMs only risked losing discounts for rejecting Mylan's exclusive contracts, therefore Sanofi only needed to offer 'a better product or a better deal' to avoid exclusion.[146]

Lower federal courts also continue to address similar claims. Beginning in 2017, purchaser and competitor plaintiffs sued Johnson & Johnson (J&J) and Janssen for allegedly using exclusionary contracts with health insurers and healthcare providers (eg, hospitals and clinics) to thwart biosimilar competition.[147] While the antitrust theories supporting these actions survived motions to dismiss, the last of these cases settled in early 2022 without further substantive decisions from the courts.[148] Similarly, in a June 2021 lawsuit, Mylan Pharmaceuticals alleged that Teva sought to protect its Copaxone product by contracting to exclude generic competitors from formularies and to prefer Copaxone over generics at specialty pharmacies.[149] Teva also allegedly engaged in regulatory abuses, improperly prevented generic substitution and violated kickback rules in providing donations to charities that were used as co-pay assistance to Medicare patients.[150] Direct and indirect purchasers filed separate lawsuits based on the same conduct, and motions to dismiss remain pending in all actions.[151] More

142 *In re EpiPen Epinephrine Injection, Mkt Sales Pracs & Antitrust Litig*, No. 21-3005, 2022 US App Lexis 20998 (10th Cir 29 July 2022).
143 See Complaint, *Sanofi-Aventis US LLC v Mylan Inc, et al.*, No. 3:17-cv-02763 (DNJ 24 April 2017), ECF No. 1.
144 See *In re EpiPen*, 2022 US App Lexis 20998, at *57–70, 102–03.
145 See id. at 61–70.
146 id. at 65–66, 83–91.
147 See Consolidated Amended Compl, *Nat'l Employees Health Plan v Johnson & Johnson*, No. 17-cv-04326 (ED Pa 21 February 2018), ECF No. 53.
148 See *In re Remicade Antitrust Litig*, 345 F Supp 3d 566 (ED Pa 2018); see also *Pfizer Inc v Johnson & Johnson*, 333 F Supp 3d 494, 502 (ED Pa 2018).
149 See Complaint, *Mylan Pharmaceuticals Inc v Teva Pharmaceuticals Industries Ltd et al.*, No. 2:21-cv13087 (DNJ 29 June 2021), ECF No. 1.
150 See id. at paragraphs 6–7.
151 See Class Action Complaint and Demand for Jury Trial, *FWK Holdings, LLC v Teva Pharms Idustrs, Ltd*, No. 22-cv-01232 (DNJ 7 Mar 2022), ECF No. 1; Brief in Supp of Defs' Motion to Dismiss,

recently, Regeneron filed an antitrust suit against Amgen in May 2022, alleging that Amgen leveraged its product portfolio in a bundled rebate scheme to coerce insurers and PBMs to favour Amgen's Repatha over Regeneron's Praluent.[152]

Plaintiffs' use of novel theories of liability under the federal RICO statute to challenge formulary agreements have encountered additional setbacks. Defendants in a litigation in the Northern District of Minnesota regarding Mylan's drug EpiPen successfully tossed RICO claims based on alleged violations of the Anti-Kickback Statute, despite the court allowing the claims to proceed just last year. The court in that case initially permitted direct purchasers of EpiPen to bring RICO claims based on allegations that Mylan's rebates to PBMs for favourable formulary status were kickbacks in violation of the Anti-Kickback Statute.[153] To get past the issue that private 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. In ruling on the defendants' renewed motion to dismiss, filed after the plaintiffs amended their complaint to add an antitrust claim and additional defendants, the court reversed course and granted the defendants' motion.[154] The court held that bribery under the Anti-Kickback Statute is broader than bribery under the Travel Act, and therefore cannot from a predicate act for plaintiffs' RICO claims.[155] The same issue is currently being briefed in the District of New Jersey, where the court allowed similar claims to proceed based on the initial motion-to-dismiss ruling from the Northern District of Minnesota case in the *EpiPen* litigation[156] and in direct purchasers' suit against Teva regarding Copaxone.[157]

In re Capoxone Antitrust Litig DPP Class Action, No. 22-cv-01232 (DNJ 15 June 2022); Consolidated Class Action Compl and Demand for Jury Trial, *In re Capoxone Antitrust Litig TPP Class Action*, No. 22-cv-01232 (DNJ 29 April 2022); Brief in Supp of Defs' Mot to Dismiss, *In re Capoxone Antitrust Litig TPP Class Action*, No. 22-cv-01232 (DNJ 15 June 2022).

152 See Compl, *Regeneron Pharms, Inc v Amgen Inc*, No. 1:22-cv-00697 (D Del 27 May 2022), ECF No. 1.

153 *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).

154 See *In re EpiPen Direct Purchaser Litig*, No. 20-cv-0827, 2022 US Dist Lexis 63272 (D Minn 5 April 2022).

155 See id. at *10–15.

156 See PBM Defs' Rule 12(c) Motion for Partial Judg on the Pleadings, *In re: Direct Purchaser Insulin Litig*, No. 20-cv-3426 (DNJ 21 June 2022), ECF No. 234; Class Action Complaint and Demand for Jury Trial, *FWK Holdings, LLC v Teva Pharms Idustrs, Ltd*, No. 22-cv-01232 (DNJ 7 March 2022), ECF No. 1.

157 See Class Action Complaint and Demand for Jury Trial, *FWK Holdings, LLC v Teva Pharms Idustrs, Ltd*, No. 22-cv-01232 (DNJ 7 March 2022), ECF No. 1; Brief in Supp of Defs' Motion to Dismiss, *In re Capoxone Antitrust Litigation DPP Class Action*, No. 22-cv-01232 (DNJ 15 June 2022), ECF No. 41. The plaintiffs also alleged that the defendants committed wire and mail fraud as predicate RICO acts. id.

Certain other contracting practices in the pharmaceutical industry have also come under antitrust scrutiny. For instance, in early 2021, the US Court of Appeals for the Third Circuit addressed allegations concerning an exclusive supply agreement for the active pharmaceutical ingredient (API) in vasopressin, a blood pressure treatment.[158] Plaintiff Fresenius alleged that while seeking to submit an abbreviated new drug application (ANDA) for vasopressin, it realised that the only suppliers of the API were subject to exclusive-dealing arrangements with Par Pharmaceutical.[159] These arrangements allegedly are part of Par's efforts to '"lock up difficult-to-source API" to prevent competitors from entering the [intravenous vasopressin injection] market'.[160] The district court granted Par's motion for summary judgment, concluding that the existence of Par's patents on its brand vasopressin product broke the chain of causation and that Fresenius' theory that it would have successfully challenged those patents was 'unduly speculative' because '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'.[161] But the Third Circuit reversed, holding that the district court should have analysed whether a reasonable jury could have found that Par's patents would have blocked Fresenius's entry.[162] The Third Circuit noted, however, that '[o]n remand, the District Court may choose to consider whether the exclusivity agreement even constitutes anticompetitive conduct because if it does not, then no patent analysis is needed'.[163] Following remand, the parties have filed supplemental summary judgment briefs with the district court, and, in a non-public order from October 2021, the court appears to have granted the defendants' motion for summary judgment.[164]

In December 2021, the court in *Colcrys* granted the defendants' motions to dismiss for failure to adequately allege that three settlement agreements are part of a larger antitrust conspiracy to order market entry and restrict output – deviating from reverse payment allegations that are typically alleged in connection with patent settlements.[165] The court first evaluated whether the separate patent settlements that Takeda made with Par, Amneal and Watson, respectively, could constitute direct evidence of a restraint of trade. The court found that the mere fact that the agreements occurred at a similar time using similar terms and structures does not transform the agreements into direct evidence of a conspiracy.[166] At most, the court stated, the similarity and timing

158 *Fresenius Kabi USA, LLC v Par Sterile Prods, LLC*, 841 F App'x 399 (3d Cir 2021).
159 *Fresenius Kabi USA, LLC v Par Sterile Prods, LLC*, No. 16-4544, 2017 US Dist Lexis 19084, at *3–4 (DNJ 10 February 2017).
160 id. at *4.
161 *Fresenius Kabi USA, LLC v Par Sterile Prods, LLC*, No. 16-4544, 2020 US Dist Lexis 32034, at *8–9, *14–15 (DNJ 25 February 2020).
162 841 F App'x at 403–04.
163 id. at 404 n.12.
164 See *Fresenius Kabi USA, LLC v Par Sterile Prods, LLC*, No. 16-4544, ECF Nos. 264, 265.
165 *Value Drug Co v Takeda Pharm, USA, Inc*, No. 21-3500, 2021 US Dist Lexis 246364, at *4–5 (ED Pa 28 December 2021).
166 id. at *34.

could constitute circumstantial evidence.[167] But the court was ultimately not satisfied with Value Drug's alleged circumstantial evidence, which hinged on one point: the purpose of the conspiracy, as evinced by the settlement agreements, is to prevent Colcrys's price from collapsing by keeping out all entrants but the two allowed by the settlements.[168] The court rejected this argument based on the inclusion of the 'escape clauses' in the settlement agreements that allowed the generic manufacturers to sell their version of generic Colcrys under certain conditions, including if another generic manufacturer entered the market.[169] The proposed theory, the court stated, 'makes no economic sense' and 'it forecloses an inference of concerted action among the four competitors' because the presence of the 'escape clauses' did not forestall a price collapse, it guaranteed it.[170]

The plaintiffs, however, were permitted to amend their complaints and subsequently survived another motion to dismiss, at least in part. In a March 2022 decision, the court permitted the amended conspiracy claim to go forward, explaining that by entering into the alleged conspiracy, 'Par would face no other generic competition when it took over selling Takeda's authorized generic', 'Par also extended its market exclusivity period as the only generic from 180 days to 837 days' and 'Watson and Amneal obtained 135 days of limited competition with only Par in the market for generics, allowing the generic price to be maintained at least twenty percent higher than when more than three generics sell on the market with the brand'.[171] But the court rejected the plaintiffs' allegations of separate bilateral conspiracies because '[o]rdering the market as alleged here required all four conspirators' active and knowing participation to derive the benefit to the conspirators'.[172] The court found that '[t]his reality alone necessitates a finding all three Generics participated in *one* conspiracy with Takeda, rather than three separate bilateral conspiracies'.[173]

Finally, challenges to 'patent thickets' as exclusionary conduct also continue. In 2019, class-action plaintiffs filed antitrust complaints concerning AbbVie's best-selling biological drug Humira. The plaintiffs alleged that AbbVie developed an anticompetitive patent thicket to protect Humira, arguing that AbbVie 'secured over 100 patents designed solely to insulate Humira from any biosimilar competition' and then entered into unlawful patent settlement agreements.[174] In June 2020, the district court granted a motion to dismiss, recognising that the patent thicket claim is a 'new kind of antitrust claim' that 'brings together a

167 id. at *32.
168 id. at 42.
169 id. at 14.
170 ibid.
171 *Value Drug Co v Takeda Pharm, USA, Inc*, No. 21-3500, 2022 US Dist Lexis 58574, at *17 (ED Pa 30 March 2022).
172 ibid.
173 ibid. (emphasis in original).
174 See, eg, Class Action Compl, paragraph 6, *UFCW Local 1500 Welfare Fund v AbbVie*, No. 1:19-cv1873 (ND Ill 18 March 2019), ECF No. 1.

disparate set of aggressive but mostly protected actions'.[175] The court held that the 'allegations – even when considered broadly and together for their potential to restrain trade – fall short of alleging the kind of competitive harm remedied by antitrust law'.[176] On appeal, the Seventh Circuit affirmed, holding that the 'patent laws do not set a cap on the number of patents any one person can hold – in general, or pertaining to a single subject'.[177] The court emphasised that plaintiffs 'have abjured any reliance on the Walker Process doctrine [for alleged procurement of patents by fraud], which makes it hard to see how AbbVie can be penalized for its successful petitions to the Patent Office'.[178]

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 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 – such as Walgreens, CVS Health and Express Scripts – 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'.[179] 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 followed up with violation letters to certain manufacturers. Drug makers challenged the advisory opinion and HHS violation letters through lawsuits in federal courts. HHS voluntarily withdrew the advisory opinion after unsuccessfully moving to dismiss the challenges brought against

175 *In re Humira (Adalimumab) Antitrust Litig*, 465 F Supp 3d 811, 827 (ND Ill 8 June 2020).
176 ibid.
177 *Mayor of Baltimore v AbbVie Inc*, No. 20-2402, 2022 US App LEXIS 21165, at *7 (7th Cir 1 August 2022).
178 id. at 8–9.
179 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.

it, but maintained enforcement of the violation letters.[180] 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.[181] Appeals from these rulings remain pending.[182]

In a separate controversy surrounding the 340B programme, the 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 reimbursements rates to covered entities, unless the government conducts a survey of the covered entities' acquisitions costs (which the government had not performed in the first instance).[183]

Co-pay accumulator programmes 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 17 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.[184] The CMS rule, scheduled to be effective from 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. 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.[185] The court also acknowledged the difficulty in tracking payments made by the manufacturers to patients and incorporating those payments into the best

180 See HHS, Notice of Withdrawal of AO, 18 June 2021, at 1, available at https://www.hhs.gov/guidance/document/notice-withdrawal-ao-contract-pharmacies-under-340b; *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)).

181 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 et al. v Becerra et al..*, 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).

182 See *Sanofi-Aventis US LLC v US Dep't of Health and Hum Servs*, No. 21-3168 (3d Cir 26 November 2021); *Novartis Pharms Corp v Espinosa*, No. 21-5299 (DC Cir 30 December 2021); *Eli Lilly and Co et al.. v Becerra et al..*, No. 21-03128 (7th Cir 15 November 2021).

183 *American Hospital Ass'n v Becerra*, Slip Op, No. 20-2114 (15 June 2022).

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

185 ibid.

price calculation.[186] Separately, in what appears to be the first manufacturer challenge to the operation of a co-pay accumulator programme, J&J filed a May 2022 lawsuit against SaveOn Specialty Assistances, partner to PBM Express Scripts, for tortious interference with J&J's co-pay assistance agreements with patients and related deceptive practices. J&J alleges that SaveOn artificially inflated patients' co-pays to coerce patients to enrol in a SaveOn programme that would, in turn, enrol those patients in J&J's co-pay assistance programme. The scheme allegedly resulted in J&J 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.[187]

Overall, between proposed legislation, policy changes and litigation, the pharmaceutical sector continues to face significant scrutiny and legal challenges.[188]

Adam M Acosta

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Adam Acosta is a partner in the Washington, DC, office of White & Case LLP. 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). He 'continues to establish himself as a key player in complex cartel litigation' and is 'very thorough' (*The Legal 500: US*, 2022).

Mr Acosta served as counsel for two pharmaceutical companies in the seminal *FTC v Actavis* reverse payment litigation. He has also litigated many of the major pharmaceutical antitrust matters over the past decade, including *AndroGel*, *Asacol*, *Bystolic*, *Doryx*, *Effexor*, *Lipitor*, *Loestrin*, *Zytiga* and the ongoing antitrust litigation involving HIV treatments.

186 id. at *15.

187 See Compl, *Johnson & Johnson Healthcare Sys Inc v Save on SP, LLC*, No. 22-cv-02632 (DNJ 4 May 2022).

188 White & Case LLP was counsel of record for two pharmaceutical company defendants in the US Supreme Court in *FTC v Actavis*. In addition, White & Case LLP represents several of the parties in the following cases discussed in this article: *AndroGel*, *Aggrenox*, *Asacol*, *Bystolic*, *Doryx*, *EpiPen*, *Humira*, *K-Dur*, *Lidoderm*, *Lipitor*, *Loestrin*, *Namenda*, *Remicade*, *Zytiga* and *In re Generic Pharmaceuticals Pricing 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.

Mr Acosta also routinely provides competition-related counselling to pharma clients involving competitor collaborations, settlements of patent litigation, drug pricing and distribution, trade associations, information exchanges and competitive intelligence.

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Mr Gallagher has successfully defended a wide range of innovator and generic manufacturer business practices, including: reverse payment (pay-for-delay) patent litigation settlements; pricing and contracting strategies throughout the distribution and payment chain; average-wholesale-price and wholesale-acquisition-cost policies; co-pay assistance programmes; and product innovation strategies (product hopping). He has also successfully challenged anticompetitive supply agreements and filed, on behalf of a biosimilar manufacturer, the first antitrust challenge to exclusionary contracting by the innovator biological manufacturer.

For close to three decades, Mr Gallagher has litigated jury and non-jury cases before federal and state trial and appellate courts throughout the United States.

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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.

Mr Grannon served as lead trial counsel defending two pharmaceutical companies in *FTC v Actavis*, as well as counsel of record for those companies before the US Supreme Court. In *In re Bystolic Antitrust Litigation*, he served as lead counsel, successfully arguing a motion to dismiss reverse payment, pay-for-delay complaints by all plaintiffs (direct-purchaser, end-payer and opt-out) against all defendants (innovator and generic) concerning seven settlements of pharmaceutical patent litigation (No. 20-5735, 2022 WL 323945, __ F. Supp. 3d __ (SDNY 2 February 2022)). 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.

In 2022, *Chambers USA* said: 'Eric Grannon is noted for his trial skills, representing pharmaceutical sector clients in complex antitrust litigation. He has particular experience defending pay-for-delay allegations. "He provides excellent legal advice."'

Heather K McDevitt

White & Case LLP

Heather K McDevitt is a commercial litigator based in White & Case LLP's New York office. She is a member of the firm's four-member global executive committee. She has served the firm in numerous leadership roles in the past, including most recently as the head of its global pharmaceuticals and healthcare group, which pools the talents of more than 100 senior lawyers with regulatory, litigation, antitrust, M&A, corporate and tax experience.

Ms McDevitt has extensive experience in the preparation and trial of complex commercial litigation in federal and state courts, and has litigated cases in trial and appellate courts throughout the United States. Her clients come from a wide range of industries, including pharmaceuticals, energy, banking (US and international), insurance, agriculture and crop protection and manufacturing.

Ms McDevitt recently represented a major generic pharmaceutical manufacturer facing a number of cases brought by state attorneys general based on contentions that drug manufacturers reported inaccurate pricing information, which allegedly caused state Medicaid agencies to overpay for prescription drugs.

Kristen O'Shaughnessy

White & Case LLP

Kristen O'Shaughnessy is a partner in the New York office of White & Case LLP. She is a member of the firm's global competition practice group and global pharmaceuticals and healthcare group. She regularly counsels and represents clients in the pharmaceutical industry, and has significant experience with complex antitrust litigations involving allegations of product hopping, reverse payment settlements and generic delay.

Eugene Hutchinson

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Eugene Hutchinson is an associate in the New York office of White & Case LLP and a member of the firm's global competition group. His practice involves complex antitrust litigation and counselling, with a specific focus on class action litigation at the cutting edge of pharmaceutical antitrust and intellectual property, including reverse payment and product-hopping matters.

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