GCR Global Competition Review

Americas Antitrust Review

2025

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

Americas Antitrust Review

2025

Since 2009, Global Competition Review's Americas Antitrust Review has been providing focused expertise and research designed to help readers – in-house counsel, government agencies and private practitioners – successfully navigate increasingly complex competition regimes across the Americas. For the last 14 years GCR has worked exclusively with leading competition practitioners, and it is their wealth of experience and knowledge – enabling them not only to explain law and policy, but also put it into context – that makes this review invaluable to anyone doing business in the Americas today.

From 2024, the review also includes the US Courts Annual Review, which delves into the regional differences in antitrust litigation in the United States, as well as the national trends that bring them together.

Generated: August 14, 2024

GCR Global Competition Review

Explore on GCR

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

Adam Acosta, Eric Grannon, Kristen O'Shaughnessy, Gina Chiappetta-, Daniel Grossbaum, Cansu Gunel and Eugene Hutchinson

White & Case

Summary

IN SUMMARY

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

DISCUSSION POINTS

- Recent motion-to-dismiss and summary judgment decisions for both plaintiffs and defendants in reverse-payment cases, including the Second Circuit's decision in Bystolic
- Recent jury verdicts in reverse-payment cases, all for defendants
- A recent summary judgment decision for a defendant, dismissing product-hopping claims
- Legal challenges to improper Orange Book patent listings that may allegedly delay generic competition
- Legal challenges relating to pharmaceutical manufacturers' pricing practices, including the passage of the federal Inflation Reduction Act and the role of pharmacy benefit managers in the drug-pricing chain

REFERENCED IN THIS ARTICLE

- *FTC v Actavis*
- *In re Bystolic Antitrust Litigation*
- *FTC v Endo Pharms Inc*
- *Sanofi Aventis US LLC v US Dep't of Health and Human Services*
- *Novartis Pharmaceuticals Corp v Johnson*
- The Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book)
- The Inflation Reduction Act
- Pharmacy Benefit Managers
- Government drug-pricing programmes and co-pay accumulators

REVERSE-PAYMENT CASE LAW UNDER ACTAVIS

The US Supreme Court's decision in FTC v Actavis opened a floodgate for more than 30 separate antitrust cases that have been filed or revived under that decision. Reverse-payment

claims generally allege that an innovator pharmaceutical company provided financial inducement to a potential generic competitor to settle patent litigation concerning the innovator's drug product, or to obtain a later settlement entry date than the generic company otherwise would have accepted, absent the innovator's financial inducement.

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

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

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

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

PLEADING STANDARDS UNDER ACTAVIS

Following the Supreme Court's Actavis decision, some courts have concluded that a reverse payment may include certain non-cash transfers of value from a brand company to a generic company at or near the time of their patent settlement. These non-cash transfers of value may sometimes include, for example, no-authorised generic (no-AG), co-promotion, licensing, distribution and other agreements.[3] At first, some courts grappled with how precisely a plaintiff must allege monetary estimates of value transferred to generic challengers,[4] but several courts have since explained that plaintiffs must 'plead information sufficient to estimate the value' of the non-cash transfer.[5]

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

In February 2023, after the plaintiffs amended their complaints in Bystolic, the court again dismissed the plaintiffs' claims, this time with prejudice.[10] The court held that the plaintiffs' amended complaints failed to include 'facts as to any of the factors that would suggest conduct inconsistent with a pro-competitive justification', concluding that the plaintiffs had

'not cured the deficiencies identified' in the previously dismissed complaints.[11] In doing so, the district court analysed the terms of each of the challenged 'side agreements' in detail, holding that the plaintiffs' allegations failed to plausibly show a large and unjustified payment for delay.

On appeal, the Second Circuit affirmed the district court's dismissal in Bystolic on 13 May 2024, agreeing that the plaintiffs did not allege a payment that represented 'anything other than "fair value" for goods and services'.[12] For instance, the court declined to find that a challenged supply agreement was a pretext for an unlawful reverse payment simply because the patent holder allegedly did not need an alternative supplier. The patent holder's public securities filings indicated the risk of future supply shortages or delays, and thus, the court found it was 'not plausible' that the supply agreement was 'nefarious, especially in light of an "obvious alternative explanation"'.[13] And other provisions in the challenged agreements likewise contradicted the plaintiffs' allegations, such as a 'meet or release' provision that allowed the patent holder to 'seek out alternative nebivolol API suppliers at lower prices'.[14] Given the plaintiffs' failure to 'sufficiently contextualise or compare' the challenged transactions, the Second Circuit could not plausibly infer that the payments were anything but legitimate agreements reflecting bona fide business considerations.[15] Notably, in affirming dismissal of all the reverse-payment claims, the Second Circuit declined to adopt the FTC's views as amici curiae, suggesting that such 'side deals' were inherently suspect and that the plaintiffs had sufficiently stated a claim.[16]

In another recent decision, the US Court of Appeals for the Seventh Circuit affirmed the dismissal of reverse-payment claims in August 2022. The plaintiffs alleged that the brand manufacturer of Humira 'paid biosimilar manufacturers in the form of European agreements that allowed the biosimilars to enter the European market' while agreeing to '[brand]-friendly' generic entry dates in the United States.[17] The 'package deals' allegedly bought the brand 'more lucrative monopoly time in the United States (worth billions of dollars in revenue for [the brand manufacturer])'.[18] The district court rejected this theory because the settlements increased competition 'by bringing competitors into the market when patents otherwise prohibited competition'.[19]

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, characterising the reverse-payment problem as "something quite different" from an opportunity cost', such as the 'money that [the brand] is said to have left on the table in Europe' by allowing biosimilars to launch earlier.[20] As the court explained:

On each continent [the brand] surrendered its monopoly before all of its patents expired, and the rivals were not paid for delay. 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.[21]

Thus, 'the US settlement and the EU settlement are traditional resolutions of patent litigation' that do not violate antitrust laws.[22]

By contrast, in March 2024, a district court declined to apply the Seventh Circuit's reasoning in Humira to the reverse-payment claims at issue.[23] The plaintiffs alleged that a pharmaceutical manufacturer agreed to stay out of the EpiPen market in exchange for EpiPen's brand manufacturer agreeing to stay out of the Nuvigil market, allowing each defendant to maintain a monopoly for their respective brand medications and avoid generic

competition.[24] The district court did not find Humira instructive where the plaintiffs made distinct allegations that the defendants were allegedly 'trading an extended monopoly on one drug for an extended monopoly on another drug', 'a far simpler and more plausible reverse settlement than the [Humira] plaintiffs alleged'.[25] The court also rejected the defendants' argument that the alleged reverse payment was simply an 'opportunity cost' and thus not a reverse payment under Actavis.[26] While the plaintiffs in Humira argued that the defendants were merely 'leaving money on the table in Europe', the plaintiffs here asserted that the alleged reverse payment was the amount each party gained through continued monopoly profits in its own brand drug, and not the opportunity cost of delayed entry into a generic market.[27] As a result, the court denied the defendants' motion to dismiss.[28]

In another motion-to-dismiss decision on 7 May 2024, another district court considered whether a reverse payment could be appropriately inferred at the motion-to-dismiss phase based on certain circumstantial allegations. There, the settlement was not part of the public record.[29] But the plaintiffs pleaded circumstantial facts, including a generic manufacturer's 'announcement of a generic . . . and subsequent, unexplained failure to launch the drug' to support the inference that a reverse payment was made.[30] The court held that these circumstantial facts were sufficient, including because the brand manufacturer did not sue the generic after receiving notice of the generic company's abbreviated new drug application (ANDA), and the generic company decided not to launch the drug following its ANDA approval. Given the significant financial incentive that ANDA first filers have to bring a generic to the market as quickly as possible, and the fact that first-filer exclusivity can be potentially worth millions, the court found that any inferred agreement to disincentivise the generic's launch would likely be substantial and denied the defendants' motion to dismiss based on those allegations.[31]

Finally, on 6 June 2024, the US District Court for the District of New Jersey dismissed reverse-payment allegations that the patent holder provided the generic manufacturer an unlawful, royalty-free licence to sell a limited volume of generic lenalidomide before the relevant patent expired in 2027.[32] After the plaintiffs conceded at oral argument that the patent holder was not required to charge a royalty, and that the royalty-free licence alone did not constitute an unlawful reverse payment, the court rejected the plaintiffs' reverse-payment theory, stressing that the volume-limiting aspect of the challenged licence did not constitute a 'payment' under Actavis.[33] The court also rejected the plaintiffs' argument that an acceleration clause, which allowed the generic manufacturer to launch its product upon any finding that patents are invalid, constituted an illegal reverse payment.[34] The court held that the acceleration clause did not confer any value to the generic manufacturer that it was not already entitled to as a first ANDA filer under the Hatch-Waxman Act, finding that the acceleration clause did not discourage later ANDA filers from challenging the patents.[35] In dismissing the plaintiffs' claims, the court emphasised that while the effect of exclusionary practices should be considered together, 'if none of the alleged conduct is exclusionary or anticompetitive, it cannot collectively violate' the law.[36]

SUMMARY JUDGMENT UNDER ACTAVIS

Courts have also grappled with how to apply Actavis at summary judgment when evaluating evidence. Many summary judgment decisions have focused on whether business agreements executed contemporaneously with patent settlements are 'large and unjustified'. In these decisions, district courts have analysed various arguments concerning whether there was sufficient evidence that the compensation for services was significantly above fair

market value; whether the services were unnecessary or unwanted; whether the agreements for services included 'unusual' terms; whether the brand company failed to follow certain industry or internal practices; and the extent to which these business agreements may be 'linked' to the patent settlements.[37]

Recently, there have been two summary judgment decisions, both allowing the reverse-payment claims to proceed to trial. In Zetia, the court found that disputed issues of fact remained as to whether the challenged settlement prevented the brand manufacturer of Zetia from launching an authorised generic product, as well as the value and justifications for such a provision.[38] The defendants argued that the plaintiffs lacked evidence showing that the alleged no-AG provision was a payment in exchange for delayed competition. But the magistrate judge found that the plaintiffs 'produce[d] sufficient evidence for a reasonable juror to find' that the brand company had agreed to refrain from launching an authorised generic version of Zetia in exchange for delayed entry.[39] The district court judge overruled the defendants' objections to the magistrate's report and recommendation and denied the defendants' motion for summary judgment.[40]

In the HIV Antitrust Litigation, the summary judgment motion focused on whether the settlement's non-royalty bearing most-favoured-nations clauses (MFNs) were negotiated in exchange for a later generic-entry date and effectively restored the first filer's forfeited exclusivity period.[41] The defendants argued that the MFNs were negotiated after an entry date had already been set, meaning the MFNs could not have impacted the settlement's generic-entry date. But the court found that a disputed question of material fact remained as to when the various contract terms were agreed.[42] As discussed below, this case proceeded to trial in June 2023 and a jury returned a verdict for the defendants.

In addition to these summary judgment decisions addressing whether an unlawful reverse payment was made, other district courts have focused on causation. Some courts have denied summary judgment where factual and expert evidence adequately supported plaintiffs' causation theories, finding that in the but-for world that disputed issues of material fact remained as to whether the generic challengers would have launched at risk, prevailed in the patent case or entered into an alternative, 'no-payment' settlement agreement.[43] At the same time, other decisions, such as AndroGel, have rejected patent-based causation theories as 'simply too procedurally burdensome and speculative' when there were no concrete developments in the underlying patent case.[44]

One of the most notable causation decisions is Wellbutrin, where the Third Circuit affirmed a grant of summary judgment for the defendants. The court held that the plaintiffs 'did not take into account Andrx's blocking patent' and that it is not enough 'to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal'.-[45] 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'.[46] Notably, the size of the reverse payment alone was an insufficient 'surrogate' for the weakness of the patent.[47] The Third Circuit also rejected the plaintiffs' but-for theory that Andrx had 'an independent economic interest' in providing a licence to Anchen and that licence negotiations were nearly complete days before the alleged reverse payment was made.[48] 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'.[49]

In June 2024, the court in Lipitor similarly held that the plaintiffs had failed to prove causation, relying heavily on Wellbutrin. In Lipitor, the plaintiffs argued that the Food and Drug Administration (FDA) would have approved the generic manufacturer's Lipitor ANDA earlier than it did if an alternative settlement agreement was entered.[50] In particular, the plaintiffs contended that the FDA would have 'targeted' any earlier agreed entry date that was allowed for by an alternative settlement and approval would thus have been granted earlier. But the court found that Ranbaxy faced significant and unique regulatory hurdles in the real world, including because it was subject to the FDA's rarely invoked Application Integrity Policy, and it was pure speculation to assume the FDA would have approved the ANDA sooner in light of those significant hurdles.[51] The court stressed, relying on Wellbutrin, that the plaintiffs' burden is to show that an earlier generic launch would have occurred. Because the plaintiffs only relied on speculation that the FDA would have 'targeted' earlier ANDA approval, they did not show a genuine issue of material fact as to whether the FDA would have approved Ranbaxy's ANDA even 'one day' sooner, and thus failed to show that an earlier launch would have been legal.[52] The court granted the defendants' motion for summary judgment.

TRIALS UNDER ACTAVIS

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

In Nexium, the private plaintiffs had calculated a reverse payment of US$22 million, argued that the contemporaneously executed business agreements 'provided a steady flow of revenue to Ranbaxy' during the same period it agreed not to launch its generic Nexium product and offered evidence that 'even if Ranbaxy had won its litigation instead of settling, it would not have secured such favourable arrangements'.[53] But in the first reverse-payment trial since Actavis, the jury reached a verdict for the defendants despite finding that there had been a reverse payment. The jury found that, although AstraZeneca had market power and there had been a 'large and unjustified' payment, the reverse payment did not cause delayed generic entry because AstraZeneca would not have agreed to an earlier settlement entry date absent a reverse payment.[54] The US Court of Appeals for the First Circuit affirmed the jury's verdict for the defendants.[55]

The next reverse-payment trials both concerned the same product, Opana. The first Opana trial involved an administrative action filed by the FTC, and the second involved a federal action filed by private plaintiffs. In the FTC action, the FTC's chief administrative law judge (ALJ) held an administrative bench trial and concluded that the alleged reverse payment was not anticompetitive. The brand and generic companies at issue had settled the underlying patent litigation and entered into a settlement and licence agreement (SLA) and a development and co-promotion agreement (DCA).[56] The SLA included a no-AG provision and a potential cash credit to the generic company if Opana sales fell below a certain threshold.[57] The DCA was executed contemporaneously with the SLA and provided an up-front payment of US$10 million for the development of a treatment for Parkinson's disease, with potential payments up to US$30 million at certain milestones.[58]

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'.[59] Despite finding that the SLA was 'large and unjustified', the ALJ concluded that any anticompetitive harm was outweighed by pro-competitive benefits because the brand company's 'acquisition of additional patents, and successful assertion of those additional patents in litigation, led to all generic manufacturers, other than Impax, being 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'.[60]

The FTC 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'.[61] In an April 2021 decision, the US Court of Appeals for the Fifth Circuit denied a petition for review and found that substantial evidence supported the Commission's factual findings.[62] The Fifth Circuit observed that the settlement saved the brand company 'only US$3 million in litigation expenses' and that only US$10 million in payments were associated with services, such that over US$100 million of the brand company's payment remains unjustified'.[63] The 'principal attack on the finding of anticompetitive effect [was] that the Commission needed to evaluate "the patent's strength, which is the expected likelihood of the brand manufacturer winning the litigation[.]"' but the Fifth Circuit rejected that argument, holding that the FTC need not assess the 'likely outcome of the patent case'.[64] The court also discounted the impact of the patents acquired after the settlement because 'the impact of an agreement on competition is assessed as of "the time it was adopted[.]"'.[65]

But in the parallel private-plaintiff litigation concerning Opana, a jury found in favour of the defendants in July 2022. After Impax settled mid-trial, the jury went on to find that while the brand company 'had market power for the brand name drug and made a reverse payment to delay [the] generic from entering the market, the deal between the companies was not unreasonably anti-competitive'.[66] The brand company argued that purchasers of Opana were relying on 'guesswork' and 'speculation' to argue that generic Opana could have been sold earlier but for the alleged reverse payment.[67] Similar to the FTC's case, the brand company argued that the 'underlying patent deal was procompetitive because it is the only reason a generic version of Opana has been consistently available on the market for nine years, with seven to go, since it included a broad licence covering current and future Opana-related patents'.[68] The brand company emphasised that it 'would have never given Impax both an earlier entry date and a broad licence to its Opana-related patents'.[69]

Finally, in June 2023, a jury returned a verdict for defendants in the HIV Antitrust Litigation. As described above, the alleged reverse payment involved the use of certain MFN clauses, which supposedly restored the first-filer's forfeited exclusivity in exchange for delayed generic entry. At the first step of the rule of reason analysis, the jury found that the plaintiffs failed to prove that the brand company 'had market power within the relevant market that included Truvada and/or Atripla'.[70] While that finding was dispositive, the jury went on to find that the plaintiffs also failed to prove that the patent settlement included a reverse payment that would delay generic 'entry into the market, and [the brand company] could thereby avoid the risk of generic competition'.[71]

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

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 have alleged that brand pharmaceutical manufacturers violate the antitrust laws by introducing new versions and discontinuing or improperly disparaging older versions of

brand drugs, or otherwise attempting to coerce purchases in an alleged attempt to thwart generic competition and generic substitution laws.[72]

Early Cases: TriCor, Prilosec And Suboxone

In some of the first cases to assert a 'product-hopping' theory, courts allowed some claims to move past the motion-to-dismiss stage while others did not. For example, in TriCor, the court 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.[73] Similarly, in Suboxone, the court held that the plaintiffs had sufficiently pleaded 'other wrongful conduct' insofar as removing the tablets from the market in conjunction with allegedly fabricating safety concerns could potentially coerce patients to switch from the tablet to the film, such that discovery was needed to further evaluate these allegations.[74] But, in Prilosec, the court granted the defendants' motion to dismiss, finding that where the 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.[75]

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 relating 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.[76] The court held that the plaintiff had met its burden of demonstrating a substantial risk that the plan to transition patients would harm competition because generics would not be able to take advantage of automatic state substitution laws to the extent generics had hoped.[77]

The defendants appealed the decision to the US Court of Appeals for the Second Circuit, raising an issue of first impression in the circuit courts regarding the circumstances under which alleged product hopping may violate the Sherman Act.[78] 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[79] 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.[80] 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.[81] In its decision, however, the Second Circuit distinguished between efforts to 'persuade patients and their doctors to switch' from one product to another on the merits and coercive conduct, stressing that 'the market can determine whether one product is superior to another only "so long as the free choice of consumers is preserved"'.[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.

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.[83] The court also rejected the plaintiffs' contention that insufficiently innovative product reformulations could be anticompetitive, doubting that any intelligible test for innovation 'sufficiency' could ever be fashioned by courts.[84] The court also held that generics could compete without automatic substitution through advertising and cost competition, concluding that brand manufacturers have no duty to facilitate generic manufacturers' business plans by keeping older versions of a drug on the market.[85] The Third Circuit affirmed the lower court's grant of summary judgment in the defendants' favour.[86]

Since the Namenda and Doryx decisions, additional courts have addressed product-hopping claims at the motion-to-dismiss and summary judgment stages.

For example, in Solodyn, the court dismissed the plaintiffs' product-hopping claim, holding that because the defendants kept the older strengths of Solodyn on the market until two years after the older strengths faced generic competition, the introduction of newer strengths did not limit customer choice and was therefore not anticompetitive.[87] And other courts have allowed certain product-hopping claims to move forward, such as in Asacol,[88] Suboxone,[89] Loestrin[90] and Namenda,[91] based on various material issues of disputed fact specific to those cases.

Recent Developments: HIV, QVAR And Copaxone

More recently, in the In re HIV Antitrust Litigation, the district court relied on the Second Circuit's distinction in Namenda between coercive and persuasive conduct and granted the defendants' motion for summary judgment on the plaintiffs' product-hop claim.[92] The plaintiffs argued that the defendants' pricing decisions and promotion of safety benefits forced patients to switch from older HIV treatments to newer treatments.[93] But the court found that the plaintiffs had failed to demonstrate that any of the defendants' pricing and promotional decisions rose to the level of coercion – a necessary element of the plaintiffs' product-hop claim – such that 'HIV patients', doctors', and/or payors' choices regarding products were constrained'.[94]

In QVAR, the district court denied a motion to dismiss where the plaintiffs alleged that the defendants engaged in an overarching scheme to delay generic competition for its asthma medication, which included an alleged set of product hops.[95] The plaintiffs alleged, among other things, that the defendants' decision to add a dose counter to their existing QVAR inhaler product in 2014 before discontinuing the version without the dose counter amounted to a hard switch.[96] The complaint further alleged that defendants engaged in a second hard switch when it discontinued all QVAR sales and began marketing the QVAR Redihaler, which dispenses the drug when a user inhales.[97]

Though the district court in QVAR noted that 'the First Circuit had yet to rule on the antitrust ramifications of "soft switch" and "hard switch" product hops',[98] the court concluded that 'a so-called "soft switch" is not anti-competitive because it preserves consumer choice whereas a "hard switch" is anti-competitive because it forces adoption of the new iteration of the drug before generics have the chance to compete'.[99] The defendants, in part, contended

that the transition to the Redihaler was a permissible 'soft switch' that preserved consumer choice because the FDA allowed the older version of QVAR to remain listed on the Orange Book Discontinued Drug Products List and because generic competitors to QVAR could, in theory, 'automatically be substituted for prescriptions written just for QVAR, instead of QVAR Redihaler'.[100] The district court found that argument unavailing at the motion-to-dismiss stage because the complaint alleged that no generic QVAR existed at the time the defendants discontinued QVAR in favour of QVAR Redihaler, so asthma patients 'necessarily had to be transitioned onto QVAR Redihaler'.[101] Ultimately, the court found the issue to be 'academic' because there was no stand-alone product-hop claim alleged.[102] Three additional cases have been filed, each asserting similar product-hopping allegations.[103]

Finally, in Copaxone, plaintiffs alleged that the defendants engaged in a multi-pronged campaign to 'coerce' and 'induce' doctors, pharmacies and patients to switch to a higher-dose version of Copaxone before lower-dose generics became available for purchase.[104] Defendants argued that the complaint fails to allege a 'hard switch' because the lower-dose product remained available. The defendants also argued that the complaint failed to allege any coercion, absent such a hard switch.[105]

The district court in Copaxone did not agree with the plaintiffs' assertion that conduct to entice patients to switch products may constitute a hard switch, which requires the withdrawal of an older product.[106] Indeed, the court concluded 'that a "product hop" by definition involves the withdrawal of an "old" or "legacy" product'.[107] Still, the court found that a hard switch or product hop was not essential to the plaintiffs' Sherman Act claims because the plaintiffs alleged an anticompetitive scheme, not a stand-alone product-hop claim.[108] Ultimately, the plaintiffs' allegations that the defendants (1) manipulated the price of its Copaxone products, (2) pressured pharmacy benefit managers (PBMs) by withholding rebates on the lower-dose product unless the PBMs made the higher-dose product available on their formularies, (3) colluded with PBMs on a Copaxone conversion initiative, (4) explored a plan to discontinue co-pay assistance for the lower dose product and (5) launched an intense outreach campaign towards prescribing physicians, were sufficient in the court's view to state a claim that the defendants engaged in coercive conduct to further an anticompetitive scheme.[109]

FTC'S FOCUS ON 'IMPROPER' ORANGE BOOK LISTINGS

On 14 September 2023, the FTC issued a policy statement, warning pharmaceutical companies that they could face legal action if they improperly list patents in the FDA's Orange Book.[110] The FTC explained that '[b]rand manufacturers' listing in the Orange Book patents that do not meet the statutory listing criteria undermines the competitive process and may constitute an unfair method of competition in violation of Section 5 of the FTC [Federal Trade Commission] Act' by triggering a 30-month stay.[111] The FTC further explained that 'improper Orange Book Listings may disincentivise investments in developing a competing product and increase the risk of delayed generic and follow-on product entry, reducing patient access to more affordable prescription drugs and increasing costs to the healthcare system'.[112]

Less than two months after the policy statement was issued, on 7 November 2023, the FTC sent warning letters to 10 pharmaceutical companies requesting that they delist over 100 patents from the Orange Book.[113] The FTC issued additional warning letters to 10 pharmaceutical companies on 30 April 2024, targeting 300 more patents.[114] While the FTC has not specified the type of patents they would contest, other than those that constitute allegedly 'improper' Orange Book listings, so far, the warning letters have targeted

manufacturers of Drug Device Combination products such as inhalers and self-injectors, and their 'drug product' patents, which claim the product's 'device' component rather than its active ingredient.

Regulatory Dispute Mechanism Used In FTC's 'warning Letters'

The FTC has explained that the warning letters were sent to notify the recipient patent holders that the FTC has availed itself of a 'regulatory process' overseen by the FDA. While the FTC did not detail this process in the warning letters, it relied on section 314.53(f)(1) of Code of Federal Regulations Title 21, which provides that anyone may dispute an Orange Book listing by submitting a written 'patent listing dispute' to the FDA.[115] The FTC thus filed 'statements of dispute' with the FDA, describing the specific grounds for disagreement regarding the accuracy or relevance of a drug substance or drug product claim, which the FDA automatically, and without review, forwarded to the patent holders.[116]

The receipt of a statement of dispute by a patent holder triggers a 30-day deadline to either confirm the correctness of the patent information or provide the FDA with amended patent information along with a signed verification.[117] However, the FDA does not have the authority to remove the contested patents or otherwise change the patent information in the Orange Book unless the patent holder withdraws or amends the information itself.[118] Some recipients of the first round of warning letters delisted the contested patents while others did not after the 30-day deadline lapsed, and the recipients of the second round of letters declined to make any changes to the contested patent listings.[119]

Potential Implications For Allegedly 'improper' Patent Listings

In its 2023 policy statement, the FTC warns that it would use its 'full legal authority' to take action against brand manufacturers with improperly listed Orange Book patents under section 5 of the FTC Act and would scrutinise any 'history of improperly listing patents during merger review'.[120] But so far, the FTC has not taken any legal action relating to allegedly 'improper' patent listings. However, in July 2024, the FTC reportedly sent a Civil Investigative Demand to at least one of the recipients of the warning letters after the patent holder allegedly refused to remove the contested patents from the Orange Book, suggesting that the FTC has now opened an investigation and may potentially pursue an enforcement action.[121]

Lawmakers have also joined the conversation about 'improper' Orange Book listings as several members of the Congress issued public statements that they would scrutinise pharmaceutical companies with improper patent listings.[122] Subsequently, on 1 May 2024, the Congressional Research Service published a short report, suggesting that Congress consider 'whether to impose more responsibilities on FDA, FTC, or the courts, or whether to expand current procedures for challenging Orange Book patents before FDA or in court'.[123] The same report also pointed out that 'additional clarity is needed on the types of patents that may be listed in the Orange Book.'[124]

Private plaintiffs have also challenged Orange Book patent listings in courts. For example, in June 2024, the US District Court for the District of New Jersey agreed with a generic-manufacturer plaintiff that the alleged improper listing of patents in the Orange Book could violate the antitrust laws by preventing generic alternatives from entering the market and allowed the claims to proceed against the brand manufacturer.[125] Previous private-plaintiff lawsuits challenging Orange Book patent listings have also been allowed to proceed, such as in the First Circuit's Lantus decision and the Second Circuit's Actos decision,

although both decisions focused on the specific patents at issue and did not categorically find that certain types of patents are per se improper to list.[126] The increased scrutiny of Orange listings by the FTC and lawmakers suggest that greater scrutiny lies ahead.

PHARMACEUTICAL MANUFACTURER PRICING PRACTICES

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

Most notably, in 2022, Congress passed the federal Inflation Reduction Act (IRA), which includes drug-pricing components that have been pushed by Democratic lawmakers for several years, such as direct-government negotiation of drug prices under Medicare. The impact of that legislation remains to be seen as the government begins to implement the new law while numerous industry participants have brought legal challenges.

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

LEGISLATION AND REGULATION RELATING TO PHARMACEUTICAL PRICING

Federal Inflation Reduction Act

The Biden administration continued to focus on competition issues in the pharmaceutical industry as outlined in its 2021 'Executive Order on Promoting Competition in the American Economy'.[127] The most significant event to happen to drug pricing under the Biden administration in recent years has been the passage of the IRA in August 2022. The law has curtailed versions of long sought-after drug-pricing components by congressional Democrats, such as: empowering the Department of Health and Human Services (HHS) to 'negotiate' drug prices (with civil monetary penalties and the threat of an excise tax of up to 95 per cent for non-compliance) on a narrowed set of 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.[128] The law directly impacts drug pricing under the government Medicare Part D plan, but the Biden administration indicated it may push to expand some of these components to the private sector.[129] However, such an expansion will certainly come with opposition, and would be an uphill battle in Congress.[130]

The IRA's direct-negotiation provisions have garnered the most attention, as the HHS begins implementing the law.[131] The first round of drugs subject to the provision have been selected[132] and the negotiated prices are scheduled to be published on 1 September 2024.-[133] Once announced, the negotiated prices are to take effect on 1 January 2025.[134]

Manufacturers and other industry stakeholders have raised concerns that the law will curb innovation and have negative impacts on patients,[135] including because the IRA disadvantages small-molecule drugs by allowing Medicare to negotiate prices on small-molecule drugs four years sooner than biologics.[136] Industry experts also predict broader changes to product-development and patent-assertion strategy as a result of the law, suggesting, for example, that the IRA could create an imbalance of incentives to foster generic and biosimilar competition that is exempt from price negotiation.[137] Manufacturers have also raised concerns with the HHS's drug-selection process, highlighting a lack of transparency.[138]

The fate of the law, however, remains uncertain as courts grapple with its legality. The US Chamber of Commerce, industry group PhRMA and manufacturers have brought lawsuits challenging the law.[139] These challenges attack its constitutionality and the procedure under which it was enacted.[140] The challenges primarily argue that the negotiation is not meaningful but rather a price-control mandate, as the manufacturers do not have an economically feasible way to back down from the negotiation because doing so would require the manufacturer to remove all products (not just those subject to negotiation) from both the Medicaid and Medicare markets or face excessive penalties.[141] These suits also assert that Congress exceeded its powers in giving the HHS the ability to implement prices without the requisite knowledge or opportunity for industry stakeholders to comment.[142]

The trial courts that have reached decisions on the merits of the challenges have thus far ruled in favour of the government — granting a summary judgment motion and denying allegations that the Medicare Drug Price Negotiation programme constitutes a physical taking or violates free speech under the Constitution.[143] Courts have also found that the Medicare programme is voluntary, and therefore the imposed penalties are not unconstitutional.[144] However, many of these decisions have been appealed to various US Courts of Appeal.[145] On an oral argument held in May 2024 in the US Court of Appeals for the Fifth Circuit for one such appeal, a judge on the panel questioned the legality of the provision requiring exclusion of all a manufacturer's products to avoid negotiation on the one selected by the government, by likening this to anticompetitive practices that would be illegal in other contexts and describing it as 'intentionally coercive'.[146]

The IRA's direct negotiation provision has been scrutinised by lawmakers as well.[147] Republican and Democratic lawmakers have proposed legislation to scale back the IRA, including bills to extend drugmakers' immunity from negotiation for small-molecule drugs to reflect the immunity afforded to biologics under the law.[148] These proposed changes aim to ensure that small-molecule and biosimilar drugs have the same immunity period in order to address concerns that the IRA might disadvantage small-molecule development in favour of biologics.[149] It remains to be seen whether such proposals will gain any traction in Congress, despite support from industry stakeholders.[150]

Several other significant drug-pricing bills aimed at addressing antitrust and patent enforcement issues were introduced to Congress in 2023 but they have yet to gain traction.[151] These bills included measures to presume certain reverse-payment settlements, product-hopping and sham petitioning as anticompetitive, and to cap patents in infringement actions from the 'patent dance' exchange. They also proposed creating an inter-agency task force for information sharing between the US Patent and Trademark Office and the FDA.[152] Despite advancing through the Senate Judiciary Committee, these bills ultimately failed to

pass. Because similar bills have been introduced before,[153] there is a strong possibility that updated versions of these bills will be introduced in later congressional sessions.

Pharmacy Benefit Managers

Lawmakers on both sides of the aisle continue to focus on PBM practices. In March 2023, the House Committee on Oversight and Accountability launched an investigation into PBMs, seeking transparency into PBMs' practices involving formulary designs and rebating[154] and issuing document requests to the largest PBMs.[155] In April 2023, the Senate Committee on Finance announced a bipartisan framework for PBM-related legislation aimed to increase transparency and correct what it described as PBMs' 'misaligned incentives' that result from PBMs receiving greater payouts from rebates where list prices are higher.[156] Under that framework, a bipartisan group of senators proposed the Patients Before Middleman Act, a bill that would prohibit PBM compensation based on the price of drugs under Medicare Part D contracts and require PBMs to forfeit to the HHS any amount paid to the PBM that is in excess of 'bona fide service fees'.[157] That bill was read twice and referred to a congressional committee for further commentary last June, but no further actions have been taken since.-[158]

The FTC has also continued to focus 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.[159] In addition to issuing orders to the largest PBMs to produce information, the FTC also issued orders to group purchasing organisations (GPOs) affiliated with the PBMs.[160] The study examines vertically integrated PBMs — pharmacy benefit managers that have merged with insurance companies and pharmacy services — thereby controlling multiple stages of the drug supply chain from insurance and payment processing to drug distribution and retail sales and their impact on access to and affordability of prescription drugs, including the effect of manufacturer rebates on formulary design and drugs costs. The use of clawbacks, steering patients to PBM-affiliated pharmacies and administrative restrictions on coverage (eg, prior authorisations) and other practices also fall within the scope of the study.[161] This section 6(b) inquiry follows the FTC's failed February 2022 effort to gain consensus on such a study (the Commission deadlocked 2–2) and subsequent request for public comment on the impact of PBM practices.[162]

Shortly after announcing its section 6(b) inquiry, the FTC also issued an enforcement policy statement on 16 June 2022, concerning manufacturer-PBM formulary rebate practices, which the FTC described as a top priority.[163] The policy statement focuses on rebates and fees paid by manufacturers to PBMs in 'exchange for excluding lower-cost drug products'.-[164] According to the FTC, formulary agreements that 'foreclose competition from less expensive alternatives' may be unlawful restraints of trade, unlawful monopolisation or exclusive dealing.[165] The policy statement further asserts that formulary agreements that exclude less expensive alternatives 'in a manner that shifts costs to payer and patients' may be unlawful as an unfair method of competition or unfair act or practice under section 5 of the FTC Act, as well as a violation of the Robinson-Patman Act's commercial-bribery provision under section 2(c).[166]

Actions under the Robinson-Patman Act, a federal price-discrimination statute, have been exceedingly rare in recent decades, but both the FTC and lawmakers have recently reiterated that the law is a tool that can be used to challenge alleged anticompetitive conduct in the pharmaceutical industry, such as certain formulary and rebate practices.[167] It remains to be seen whether and how actions under the Robinson-Patman Act will be brought in the

pharmaceutical context, but the FTC has initiated price-discrimination investigations in other industries, signalling an intent to carry through on such actions.[168]

Building on these developments, in July 2023, the FTC issued a statement 'cautioning against reliance on prior advocacy statements and studies related to pharmacy benefit managers that no longer reflect current market realities'.[169] The statement was in 'response to PBMs' continued reliance on older FTC advocacy materials that opposed mandatory PBM transparency and disclosure requirements, and it warns against reliance on the FTC's prior conclusions, particularly given the FTC's ongoing study of the PBM industry to update its understanding of the industry and its practices'.[170]

Finally, in July 2024, the FTC published an interim report on the PBM industry based on information it received from its June 2022 inquiry into PBMs and GPOs. The report highlights that PBMs have become highly concentrated and vertically integrated, controlling nearly 80 per cent of all prescriptions filled in the United States.[171] The FTC concluded that the concentration gives PBMs 'significant power over the pharmaceutical chain', such that they can 'significantly influence what drugs are available and at what price'.[172] For instance, the FTC found that PBMs may limit lower-cost alternatives by 'negotiat[ing] prescription drug rebates' with manufacturers that 'limit[] access to potentially lower-cost generic and biosimilar competitors'.[173] The report further highlights that the concentration 'gives PBMs leverage to enter contractual relationships that disadvantage smaller, unaffiliated pharmacies' that contain opaque contractual terms, which has resulted in numerous small retail pharmacies having to shut down in rural parts of the United States.[174] The FTC voted 4-1 to issue the report, with one commissioner voting against the report because it lacks the quality expected of reports issued under the FTC's section 6(b) authority and included process irregularities and concerns about the substance.[175] This inquiry remains ongoing.

Other Drug-pricing Regulation

The concept of 'march-in rights' under the Bayh-Dole Act has also received increased attention, particularly in the context of rising drug prices and access to medications. March-in rights allow federal agencies to require patent holders of federally funded inventions to grant licences to others.[176] Despite never having been exercised, these measures are meant to serve as a safeguards against non-use.[177] In December 2023, the National Institute of Standards and Technology issued new guidance to clarify the procedures for federal agencies to exercise these rights.[178] This guidance outlines flexible criteria under which agencies can compel a patent holder to grant licences for federally funded inventions. One such situation is where the patent holder has not taken adequate steps to achieve practical application of the invention, which the guidance suggests may include instances where the price offered for a product is deemed to be unreasonable.[179] The FTC expressed support of this view in a comment on the guidance, explaining that it wishes to prevent high drug prices that limit access to medications that were developed with taxpayer funds.[180]

Additionally, the FTC and HHS have recently initiated a separate inquiry focused on the role of GPOs in the generic drug market. On 14 February 2024, the FTC and HHS jointly issued a Request for Information to understand how the practices of GPOs and drug wholesalers and market concentration might be contributing to generic-drug shortages.[181] Not only is this part of a broader effort to examine whether these organisations are discouraging competition among generic drug suppliers,[182] but the FTC's scrutiny aims to assess how their compensation models, including rebates and administrative fees, may impact the pricing and availability of generic drugs.[183]

The FTC also intends to broaden the scope of its enforcement under section 5 of the FTC Act. In November 2022, the FTC departed from prior bipartisan policy statements and adopted a new 'Policy Statement Regarding the Scope of Unfair Methods of Competition under Section 5 of the Federal Trade Commission Act'.[184] Historically, section 5 has been enforced in harmony with the antitrust laws, requiring proof of actual harm and market power to bring a claim. In the Statement, however, the FTC takes the new position that it is not necessary to show such harm and market power, defining unfair methods of competition as conduct 'that goes beyond competition on the merits' and may include conduct that is 'coercive, exploitative, collusive, abusive, deceptive, predatory, or involve[s] the use of economic power of a similar nature' and 'tend[s] to negatively affect competition'.[185] The FTC further identifies what it views as 'historical examples of unfair competition', including contractual arrangements involving 'incipient violation of the antitrust laws' such as 'loyalty rebates, tying, bundling, and exclusive dealing arrangements that have the tendency to ripen into violations of the antitrust laws by virtue of industry conditions and the respondent's position within the industry'.[186] But the FTC has yet to take enforcement action in the pharmaceutical sector based purely on an 'unfair competition' theory, and more generally significant questions about the FTC's authority to take such enforcement activity remain.[187]

Finally, state authorities have also continued their efforts to regulate drug pricing with various legislative measures in 2024.[188] For example, Oklahoma revised its requirements for pharmacy audits, including refund processes and fraud notifications.[189] Kentucky clarified pharmacy minimum drug reimbursement requirements and set temporary exemptions for retail chain pharmacies.[190] Other states have also passed laws requiring pricing transparency, mandating disclosures from PBMs and insurers, capping consumer cost-sharing on certain drugs and creating frameworks for drug importation programmes.-[191] New York, for example, recently passed a law that requires manufacturers to report price increases that are greater than 16 per cent over the wholesale acquisition cost for a course of therapy over a 24-month period, which came into effect in June 2024.[192] Manufacturers must report an expected increase to the New York State Department of Financial Services 60 days before the price comes into effect. Other states have passed similar laws, but those laws have faced legal challenges in courts.[193] Legislative activity is expected to continue in the states.

LITIGATION RELATING TO PHARMACEUTICAL PRICING

Challenges To Formulary Deals And Other Potentially Exclusionary Conduct

Litigation regarding pharmaceutical pricing remains active as well, with cases addressing a range of issues. Several recent lawsuits, for example, contend that manufacturers used rebate arrangements and other practices to unlawfully exclude competing drugs from payer coverage. But, in July 2022, the US Court of Appeals for the Tenth Circuit upheld a summary judgment dismissal of antitrust claims alleging that a manufacturer executed an exclusionary formulary contracting scheme to maintain a monopoly.[194] In that case, a manufacturer argued that a competing manufacturer used conditional rebate contracts for EpiPen, an epinephrine auto-injector for anaphylaxis, to block the plaintiff's Auvi-Q product from formulary coverage.[195]

The Tenth Circuit found no evidence that the defendant's rebate agreements for preferred and exclusive formulary positions substantially foreclosed Auvi-Q from the market.[196] As the Court explained, the defendant's conduct did not impair the plaintiff's ability to compete

because the defendant's 'rebate agreements were short and easily terminable';[197] rebates in exchange for exclusivity were 'a normal competitive tool' in the epinephrine auto-inject market that 'stimulate price competition';[198] and 'when [the plaintiff] beat [the defendant]'s price it succeeded' in gaining coverage and in some instances its own exclusivity.[199] The Court also found no evidence of coercion because PBMs only risked losing discounts for rejecting the defendant's exclusive contracts. As a result, the plaintiff only needed to offer 'a better product or a better deal' to avoid exclusion.[200]

In separate litigation involving EpiPen, the plaintiffs have also advanced novel theories under the federal Racketeer Influenced and Corrupt Organizations Act (RICO) statute to challenge formulary agreements. In a case filed in the Northern District of Minnesota, the court initially permitted direct purchasers of EpiPen to bring RICO claims based on allegations that the defendants' rebates to PBMs for favourable formulary status were kickbacks in violation of the Anti-Kickback Statute.[201] To overcome the fact 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. However, in ruling on the defendants' renewed motion to dismiss, which was filed after the plaintiffs amended their complaint to add an antitrust claim and additional defendants, the court reversed course and granted the defendants' motion in part.[202] The court held that bribery under the anti-kickback statute is broader than bribery under the Travel Act and therefore cannot form a predicate act for plaintiffs' RICO claims.[203] The same issue has been briefed in other cases on motions to dismiss, which remain pending at the time of writing.[204]

Similarly, in a June 2021 lawsuit, a manufacturer alleged that a competitor sought to protect its Copaxone product by contracting to exclude generic competitors from formularies and to preference Copaxone over generics at specialty pharmacies.[205] The competitor also allegedly engaged in regulatory abuses, improperly prevented generic substitution and violated anti-kickback rules in providing donations to charities that were used as co-pay assistance to Medicare patients.[206] Direct and indirect purchasers filed separate lawsuits based on the same conduct, and motions to dismiss remain pending in all actions.[207]

In addition to these cases, certain other contracting practices in the pharmaceutical industry have also come under antitrust scrutiny. In April 2023, for example, a class of consumers brought a challenge to a manufacturer's list pricing and rebating practices. The plaintiffs allege that the manufacturer 'artificially inflates' the list price of a lead-selling product in order to pay out higher rebates to PBMs in exchange for preferred positions on the PBMs' formularies.[208] The plaintiffs contend that the defendant's list-pricing practices violate state consumer-protection law because they are unfair and unconscionable.[209] The parties are currently awaiting a decision on a motion to dismiss.[210]

Plaintiffs have also turned their attention to PBMs rather than manufacturers. The Attorney General for the state of Ohio sued some of the largest PBMs in the United States, alleging that the PBM groups colluded to fix drug prices and engaged in a 'pay to play' rebate scheme that 'pushes manufacturers to increase drug prices in order to be placed on, or receive, preferred placement on PBM formularies'.[211] The complaint further alleges that, through industry consolidation, the largest PBMs have been able to 'extract both monopoly profits from individual and monopsony profits from the market'.[212] The suit also alleges PBMs are able to use their market power to engage in spread pricing to the financial detriment of pharmacies.[213]

In April 2024, a health and welfare fund plaintiff filed a civil RICO lawsuit against manufacturers and several PBMs, alleging that these entities conspired to artificially inflate insulin prices to maximise profits.[214] The plaintiffs claim that the defendants coordinated to raise list prices and then provided significant rebates to PBMs to secure favourable formulary placement, which has dramatically increased costs for life-saving medications such as insulin.[215] Demonstrating a broader trend of PBMs leveraging market power to manipulate drug prices, rather than fulfilling their role of negotiating lower prices on behalf of consumers and health plans, this lawsuit has the potential to prompt significant regulatory scrutiny and reshape market dynamics if successful.[216] The case has since been transferred to the District of New Jersey, where further pretrial proceedings are expected.[217]

Exclusive patent licensing practices have also come under scrutiny by plaintiffs. In 2021, the FTC filed suit against a pair of manufacturers who had entered into a licence agreement for the patents covering the product Opana XR.[218] The patent-holder manufacturer of Opana XR entered into an agreement with another manufacturer under which the patent holder granted a licence to all Opana XR's patents in exchange for a monetary payment and royalties from the licence holder's sales of Opana XR, while also agreeing that the royalty obligation would terminate if the patent-holder manufacturer marketed an equivalent product.[219] That licence agreement was reached as a settlement between the manufacturers in a suit alleging that a previous licence agreement (which itself was part of a settlement of an infringement suit between the parties after the licence-holder manufacturer attempted to market generic versions of Opana XR) was breached.[220] The FTC argued the former licence agreement was 'an impermissibly anticompetitive licensing arrangement' because it removed a market competitor.[221] The manufacturers won a motion to dismiss in the trial court, which was affirmed by the US Court of Appeals for the District of Columbia Circuit.

The District of Columbia Circuit found that while the FTC plausibly alleged the licence agreement was exclusive and furthered a patent monopoly, its claims were correctly dismissed because the FTC failed to plausibly allege that the exclusive licence agreement imposed a further restraint on competition beyond what is permitted by the Patent Act.[222] The court explained 'a patent holder's grant of an exclusive licence to a potential competitor in exchange for a payment of a royalty generally raises no issues under antitrust laws'.[223] Thus, to maintain a claim that an exclusive licence agreement is unlawful, a plaintiff must allege there was something unusual about the exclusive licence such that it resulted in 'unjustifiable competitive harms' that 'exceed what the Patent Act and settled precedent permit'.[224] The court found the FTC failed to do so in its complaint and affirmed the dismissal.[225]

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. The 340B Program requires pharmaceutical manufacturers to provide outpatient drugs at significant discounts to covered entities serving a high proportion of needy patients.[226] As the programme grew rapidly, manufacturers raised concerns about the increasing use of contract pharmacies to manage drug purchases for covered entities, which could lead to potential issues like fraud and duplicate discounts.[227] In response, some drug makers limited 340B discounts for drugs dispensed via contract pharmacies. The HHS sent 'violation letters' to manufacturers contending such limitations violated section 340B of the Public Health Service Act. Upon receiving such letters, manufacturers commenced a series of challenges,[228] which have resulted in a split among lower federal courts on whether manufacturers can impose conditions on contract pharmacies under the 340B Program.[229]

The US Court of Appeals for the Third Circuit ruled in favour of the manufacturers and found that the 340B statute did not require manufacturers to deliver their drugs to an unlimited number of contract pharmacies, and thus the HHS could not enforce its interpretation of the statute.[230] The DC Circuit further reinforced this reading of the statute by also holding that section 340B does not prohibit drug manufacturers from imposing delivery conditions on their discounted drug sales to covered entities.[231]

In a separate dispute concerning the 340B Program, the US Supreme Court addressed the authority of HHS to manage reimbursement rates paid to 340B-covered entities. Hospitals and hospital associations challenged the HHS's power under the outpatient prospective payment system to cut the statutory reimbursement rates that the federal government pays to 340B-covered entities. The Supreme Court, in a unanimous decision, held that the government did not have the authority to adjust the reimbursement rates to covered entities, unless the government conducts a survey of the covered entities' acquisition costs (which the government had not performed in the first instance).[232]

Co-pay accumulator programmes also have been the subject of litigation regarding the flow of benefits provided by manufacturer co-pay assistance programmes. In an important win for manufacturers, a May 2022 federal district court decision rejected a Centers for Medicare and 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.[233] The CMS rule, scheduled to be effective as of 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.[234] The court also acknowledged the difficulty in tracking payments made by the manufacturers to patients and incorporating those payments into the best price calculation.[235]

Separately, in what appears to be the first manufacturer challenge to the operation of a co-pay accumulator programme, a drug manufacturer filed a May 2022 lawsuit against SaveOn Specialty Assistances, partner to PBM Express Scripts, for tortious interference with the plaintiff's co-pay assistance agreements with patients and related deceptive practices. The manufacturer alleges that SaveOn artificially inflated patients' co-pays to coerce patients to enrol in a SaveOn programme that would enrol those patients in their co-pay assistance programme. The scheme allegedly resulted in the manufacturer overpaying for co-pay assistance by at least US$100 million and SaveOn profiting on those overpayments through fees received from its health plan customers.[236] These claims survived a motion to dismiss.[237]

In short, between proposed legislation, policy changes and litigation, the pharmaceutical sector continues to face significant scrutiny. These proposals and legal challenges are rapidly evolving and should be carefully monitored at both the federal and state levels.[238]

Endnotes

[1] FTC v Actavis, Inc, 570 US 136, 159 (2013).

[2] id., at 156.

[3] See, eg, King Drug Co of Florence, Inc v Smithkline Beecham Corp, 791 F3d 388, 394 (3d Cir 2015) (Lamictal) ('[T]his no-AG agreement falls under Actavis's rule'); In re Loestrin 24 FE Antitrust Litig, 814 F3d 538, 549 (1st Cir 2016) (Loestrin) ('[T]he district court erred in determining that non-monetary reverse payments do not fall under Actavis's scope'); Picone v Shire PLC, No. 16-cv-12396, 2017 US Dist Lexis 178150, at *10 (D Mass 20 October 2017) (holding that a no-authorised generic agreement and a 'sharply discounted royalty rate' may constitute a payment); In re Solodyn (Minocycline Hydrochloride) Antitrust Litig, No. 14-md-2503, 2015 US Dist Lexis 125999, at *33–43 (D Mass 14 August 2015) (holding that a settlement and licence agreement with up-front and milestone payments may constitute a payment); In re Aggrenox Antitrust Litig, 94 F Supp 3d 224, 242–43 (D Conn 2015) (holding that a '"payment" is not limited to cash transfers').

[4] See, eg, In re Lipitor Antitrust Litig, 868 F3d 231, 255 n.11 (3d Cir 2017); United Food & Com 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 F3d at 552 (internal quotation marks omitted) (quoting In re Actos End Payor Antitrust Litig, No. 13-CV-9244, 2015 US Dist Lexis 127748, at *43 (SDNY 22 September 2015)); see also In re Opana ER Antitrust Litig, 2016 US Dist Lexis 23319, at *29 (ND Ill 25 February 2016).

[6] In re Bystolic Antitrust Litig, 583 F Supp 3d 455, 482 (SDNY 2022).

[7] id., at 484.

[8] ibid.

[9] ibid.

[10] In re Bystolic Antitrust Litig, 657 F Supp 3d 337, 371–72 (SDNY 2023).

[11] id., at 353.

[12] In re Bystolic Antitrust Litig, 101 F4th 223, 240 (2d Cir 2024).

[13] id., at 242 (citation omitted).

[14] ibid.

[15] id., at 241–42 (cleaned up).

[16] id., at 239–40.

[17] In re Humira (Adalimumab) Antitrust Litig, 465 F Supp 3d 811, 840 (ND Ill 2020).

[18] id., at 840.

[19] id., at 841.

[20] Mayor of Baltimore v AbbVie Inc (Humira), 42 F4th 709, 716 (7th Cir 2022).

[21] ibid.

[22] ibid.

[23] Edgar v Teva Pharm Indus, No. 22-2501, 2024 US Dist LEXIS 53742, at *60–61 (D Kan 26 March 2024).
[24] id., at *3–4.
[25] id., at *71–72.
[26] id., at *71–73.
[27] id., at *69–73 (noting the plaintiffs argued Mylan's gain was the profits it earned by maintaining its monopoly in brand name EpiPen, not the opportunity cost of foregone profits from delayed entry into the generic Nuvigil market).
[28] id., at *78.
[29] Iron Workers Dist Council of New Eng Health & Welfare Fund v Teva Pharm Indus Ltd, No. 23-11131, 2024 US Dist LEXIS 82887, at *16–17 (D Mass 7 May 2024).
[30] id., at *16.
[31] id., at *18.
[32] In re Revlimid & Thalomid Purchaser Antitrust Litig, No. 19-7532, 2024 US Dist LEXIS 100743, at *24–26 (DNJ 6 June 2024).
[33] id., at *257.
[34] id., at *28–32.
[35] id., at *253–56.
[36] id., at *143–44 (citation omitted).
[37] In re EpiPen (Epinephrine Injection, USP) Mktg, Sales Pracs & Antitrust Litig, 545 F Supp 3d 922, 981 (D Kan 2021); In re Intuniv Antitrust Litig, 496 F Supp 3d 639, 661 (D Mass 2020); In re Loestrin 24 FE Antitrust Litig, 433 F Supp 3d 274, 316–17, 319–23 (DRI 2019); In re Namenda Direct Purchaser Litig, 331 F Supp 3d 152, 198–99 (SDNY 2018); FTC v Actavis, Inc (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); King Drug Co of Florence, Inc v Cephalon, Inc, 88 F Supp 3d 402, 407–10, 419–21 (ED Pa 2015); In re Nexium (Esomeprazole) Antitrust Litig, 42 F Supp 3d 231, 263–64 (D Mass 2014).
[38] In re Zetia Ezetimibe Antitrust Litig, No. 2:18-md-2836, 2022 US Dist Lexis 171241, at *63 (ED Va 2 September 2022).
[39] id., at *62–63.
[40] In re Zetia Ezetimibe Antitrust Litig, 655 F Supp 3d 406, 413–14 (ED Va 2023).
[41] In re HIV Antitrust Litig, 656 F Supp 3d 963, 1010–11 (ND Cal 2023).
[42] ibid.
[43] 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 & Com Workers Loc

1776 & Participating Emp'rs Health & Welfare Fund v Teikoku Pharma USA, 296 F Supp 3d 1142, 1156–58, 1160.

[44] In re AndroGel Antitrust Litig (No. II), 2018 US Dist Lexis 99716, at *49–50. But see Fresenius Kabi USA, LLC v Par Sterile Prods, LLC, 841 F App'x 399, 404 (3d Cir 2021) ('The analysis of such a hypothetical infringement suit or patent challenge may in some cases be predicted based on binding legal precedents, including statutory and case law. Whether the record permits the District Court to engage in such an analysis of course will be for it to decide.').

[45] In re Wellbutrin XL Antitrust Litig, 868 F3d 132, 165 (3d Cir 2017).

[46] id., at 169.

[47] id., at 168–69.

[48] id., at 166–67.

[49] id., at 167.

[50] In re Lipitor Antitrust Litig, No. 3:12-CV-2389, 2024 US Dist LEXIS 101262, at *72 (DNJ June 2024).

[51] id., at *79.

[52] id., at *13.

[53] In re Nexium (Esomeprazole) Antitrust Litig, 42 F Supp 3d 231, 264 (D Mass 2014).

[54] Jury Verdict, In re Nexium (Esomeprazole) Antitrust Litig, No. 1:12-md-02409 (D Mass 5 December 2014), ECF No. 1383.

[55] Am Sales Co, LLC v AstraZeneca LP (In re Nexium (Esomeprazole) Antitrust Litig), 842 F3d 34, 39–40 (1st Cir 2016).

[56] Initial Decision at 85, Impax Laboratories, Inc, FTC Docket No. 9373 (18 May 2018), https://www.ftc.gov/system/files/documents/cases/d09373initialdecisionpublic.pdf.

[57] id., at 114.

[58] id., at 120.

[59] id., at 132.

[60] id., at 145.

[61] Opinion of the Commission at 42,Impax Laboratories, Inc, FTC Docket No. 9373 (28 March 2019), https://www.ftc.gov/system/files/documents/cases/d09373_impax_laboratories_opinion_of_the_commission_-_public_redacted_version_redacted_0.pdf.

[62] Impax Laboratories, Inc v FTC, 994 F3d 484, 488 (5th Cir 2021).

[63] id., at 494–95.

[64] id., at 495.

[65] id., at 496.

[66] Lauraann Wood, 'Jury Hands Endo Win In Opana Pay-For-Delay Case', Law360 (1 July 2022), https://www.law360.com/articles/1508192/jury-hands-endo-win-in-opana-pay-for-delay-case.

[67] ibid.

[68] ibid.

[69] ibid.

[70] Transcript of Proceedings at 3408, In re HIV Antitrust Litig, No. 19-cv-2573 (ND Cal 3 July 2023), ECF No. 2048.

[71] id., at 3409.

[72] See Eric Grannon, et al, 'United States: Pharmaceutical Antitrust', Americas Antitrust Review 2020, Global Competition Review, at 107, 116 (2019), https://www.whitecase.com/sites/default/files/2019-09/gcr-united-states-pharmaceutical-antitrust-2020.pdf (addressing the regulatory background related to product-hopping claims).

[73] Abbott Laboratories v Teva Pharms USA, Inc, 432 F Supp 2d 408, 423–24 (D Del 2006).

[74] In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig, 64 F Supp 3d 665, 682–85 (ED Pa 2014).

[75] Walgreen Co v AstraZeneca Pharms LP, 534 F Supp 2d 146, 151 (DDC 2008).

[76] New York v Actavis, PLC, No. 14-cv-7473, 2014 US Dist Lexis 172918, at *118–23 (SDNY 11 December 2014).

[77] id., at *107–08.

[78] New York v Actavis, PLC, 787 F3d 638, 643 (2d Cir 2015).

[79] Berkey Photo, Inc v Eastman Kodak Co, 603 F2d 263 (2d Cir 1979).

[80] Actavis, 787 F3d at 653–54.

[81] 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 into switching to the newer drug. Notwithstanding that the court in Actavis had prevented the defendants from withdrawing the older drug from the market, the court subsequently allowed the private plaintiffs' product-hopping claims to survive the defendants' motion to dismiss (-Sergeants Benevolent Ass'n Health & Welfare Fund v Actavis, PLC, No. 15-cv-6549, 2016 US Dist Lexis 128349 (SDNY 13 September 2016)), and held that the defendants were precluded from arguing certain issues related to the product-hopping allegations that were already determined in the earlier litigation (In re Namenda Direct Purchaser Antitrust Litig, No. 15-cv-7488, 2017 US Dist Lexis 83446, at *50–51 (SDNY 23 May 2017)). In the indirect purchaser plaintiffs' action, the court ultimately denied the motion to certify a class under the 'hard-switch' product-hopping theory, finding that determining whether a member of a putative indirect purchaser subclass was harmed by a hard switch was an individualised inquiry, and plaintiffs had not shown that only a de minimis number of putative class members would be uninjured (In re Namenda Indirect Purchasers Antitrust Litigation, 338 FRD 527 (SDNY 2021)).

[82] Sergeants Benevolent, 787 F3d at 654–55.

[83] Mylan Pharms, Inc v Warner Chilcott Pub, No. 12-3824, 2015 US Dist Lexis 50026, at *33-34 (ED Pa 16 April 2015); see also id., at *34, *42 (noting that it had denied the motion to dismiss to consider the legality of the novel product-hopping theory with the benefit of a fully developed record, and that the record on summary judgment now underscored that the defendants did not violate the Sherman Act).

[84] id., at *42.

[85] id., at *40.

[86] Mylan Pharms, Inc v Warner Chilcott Pub, 838 F3d 354, 421 (3d Cir 2016).

[87] In re Solodyn (Mincocycline Hydrochloride) Antitrust Litig, No. 14-md-2503, 2015 US Dist Lexis 125999, at *52 (D Mass 14 August 2015).

[88] In re Asacol Antitrust Litig, 323 FRD 451 (D Mass 2017).

[89] In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig, No. 13-md-2445, 2017 US Dist Lexis 627 (ED Pa 8 September 2017).

[90] In re Loestrin 24 FE Antitrust Litig, 261 F Supp 3d 307 (DRI 2017).

[91] In re Namenda Indirect Purchaser Antitrust Litig, No. 1:15-cv-6549, 2021 US Dist Lexis 110081 (SDNY 11 June 2021).

[92] In re HIV Antitrust Litig, 656 F Supp 3d 963, 974–80 (ND Cal 2023).

[93] id., at 977–78.

[94] id., at 976–80.

[95] Iron Workers Dist Council of New England Health & Welfare Fund v Teva Pharm Indus Ltd, No. 1:23-cv-11131, 2024 US Dist Lexis 82887 (D Mass 7 May 2024).

[96] id., at *7.

[97] id., at *8.

[98] id., at *13 (cleaned up).

[99] id., at *14 (citing Actavis, 787 F3d at 654–55; In re Asacol Antitrust Litig, 233 F Supp 3d at 269).

[100] id., at *14.

[101] id., at *14–15.

[102] id., at *15.

[103] Utah-Idaho Teamsters Security Fund v Teva Pharm Indus Ltd, No. 1:23-cv-11198 (D Mass 26 May 2023); Value Drug Company v Teva Pharm Indus Ltd, No. 1:24-cv-11312 (D Mass 16 May 2024); DC Liquidating Trust v Teva Pharm Indus Ltd, No. 1:24-cv-11320 (D Mass 17 May 2024).

[104] Blue Cross & Blue Shield of Vermont v Teva Pharm Indus Ltd, 2024 US Dist Lexis 17447 (D Vt 22 January 2024).

[105] id., at *64.
[106] id., at *65.
[107] id., at *69.
[108] id., at *70.
[109] id., at *71–78.
[110] See Federal Trade Commission (FTC), 'Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book' (14 Sept. 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.
[111] id. at 3 (emphasis added).
[112] id. at 4.
[113] ibid.
[114] FTC, Press Release, 'FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs' (30 Apr 2024), https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.
[115] 21 CFR § 314.53 (f)(1).
[116] ibid.
[117] 21 CFR § 314.53(f)(1)(i)(2).
[118] ibid.
[119] US Food and Drug Administration, 'Patent Listing Disputes' (10 May 2024), https://www.fda.gov/media/105080/download.
[120] See FTC, 'Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book', at 4 (14 September 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.
[121] See Dan Diamond, 'FTC opens investigation into Teva, escalating patent fight with pharma industry', The Washington Post (1 July 2024), https://www.washingtonpost.com/health/2024/07/01/teva-patent-pharma-generic-inhaler/.
[122] See News Release, 'Senator Amy Klobuchar, Klobuchar Calls on Pharmaceutical Companies To Remove Improperly Listed Patents from FDA Orange Book To Allow for More Competition' (18 January 2024), https://www.klobuchar.senate.gov/public/index.cfm/2024/1/klobuchar-calls-on-pharmaceutical-companies-to-remove-improperly-listed-patents-from-fda-orange-book-to-allow-for-more-competition.

[123] Kevin J Hickey, Congressional Research Service, IF12644, 'Patent Listing in FDA's Orange Book', at 2 (1 May 2024), https://crsreports.congress.gov/product/pdf/IF/IF12644.

[124] ibid.

[125] Teva Branded Pharm Prods R&D, Inc v Amneal Pharms of NY, LLC, No. 2:23-cv-20964, at *1 (DNJ 10 June 2024), ECF No. 88; see also FTC's Brief as Amicus Curiae, Teva Branded Pharm Prods R&D, Inc v Amneal Pharms of NY,LLC, No. 2:23-cv-20964, (DNJ filed 22 March 2024), ECF No. 61-1.

[126] In re Lantus Direct Purchaser Antitrust Litig, 950 F3d 1 (1st Cir 2020); In re Actos End-Payor Antitrust Litig, 848 F3d 89 (2d Cir 2017).

[127] Executive Order on Promoting Competition in the American Economy, Executive Order No. 14036, 86 Fed Reg 36987 (9 July 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/; 'Fact Sheet: Executive Order on Promoting Competition in the American Economy', The White House (9 July 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/.

[128] 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.

[129] Rachel Cohrs, 'Biden to propose expanding Medicare drug price negotiation in State of the Union', STAT (6 March 2024), https://www.statnews.com/2024/03/06/medicare-drug-price-negotiation-state-of-the-union.

[130] Policy Brief, 'Biden's Life Threatening Drug Price Controls', House Republican Policy Committee, https://republicanpolicy.house.gov/sites/evo-subsites/republicanpolicy.house.gov/files/evo-media-document/RPC%20Brief%20-%20Bidens%20life%20threatening%20drug%20price%20controls.pdf.

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

[132] Medicare Drug Price Negotiation, CMS, 'Selected Drugs for Negotiation', https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

[133] Drug Price Negotiation Timeline for 2026, CMS, https://www.cms.gov/files/document/drug-price-negotiation-timeline-2026.pdf.

[134] ibid.

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

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

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

[138] See, eg, Complaint ¶ 69, National Infusion Center Association v Becerra, 2024 WL 561860 (WD Tex 12 February 2024).

[139] See Arthur Allen, 'Patients See First Savings from Biden's Drug Price Push, as Pharma Lines Up Its Lawyers,' Fortune (16 February 2024), https://fortune.com/well/2024/02/16/patients-see-first-savings-from-bidens-drug-price-push/.

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

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

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

[143] See Bristol Myers Squibb Company v Becerra, 2024 WL 1855054 (DNJ 29 April 2024).

[144] See id. at *6; National Infusion Center Association v Becerra, 2024 WL 561860 (WD Tex 12 February 2024); Boehringer Ingelheim Pharms, Inc v United States Dep't of Health & Hum Servs, 2024 WL 3293657 (D Conn 3 July 2024).

[145] See, eg, Complaint ¶¶ 2–9, Bristol Myers Squibb Co v Becerra, No. 3:23-cv-03335 (DNJ 16 June 2023) (appeal filed 29 April 2024); Natl Infusion Center v Becerra, No. 24-50180 (5th Cir 14 June 2024) (appeal ordered 6 March 2024).

[146] Cathy Kelly, 'Pharma's IRA Complaints Find Sympathetic Ear In US Appeals Court But Near-Term Relief Unlikely', Pink Sheet (1 May 2024), https://pink.citeline.com/PS154648/Pharmas-IRA-Complaints-Find-Sympathetic-Ear-In-US-Appeals-Court-But-Near-Term-Relief-Unlikely.

[147] Rachel Cohrs, 'A lone Democrat willing to weaken Medicare's power to negotiate drug prices', STAT (5 Feb. 2024), https://www.statnews.com/2024/02/05/democrat-weaken-medicare-drug-price-negotiation/.

[148] ibid.

[149] See HR7174 – To amend title XI of the Social Security Act to equalise the negotiation period between small-molecule and biologic candidates under the Drug Price Negotiation Program.

[150] ibid.; see also 'Lawmakers introduce bill to fix the Inflation Reduction Act's 'small molecule policy', Chemical and Engineering News (6 February 2024), https://cen.acs.org/policy/legislation-/Lawmakers-introduce-bill-fix-Inflation/102/web/2024/02.

[151] Preserve Access to Affordable Generics and Biosimilars Act, S 142, 118th Cong (2023), https://www.congress.gov/bill/118th-congress/senate-bill/142?s=2&r=1-; Affordable Prescriptions for Patients Act of 2023, S 150, 118th Cong (2023), https://www.congress.gov/bill/118th-congress/senate-bill/150/all-info#:~:text=%2F01%2F2023; Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics Act, S. 148, 118th Cong (2023) https://www.congress.gov/bill/118th-congress/senate-bill/148?s=4&r=1.

[152] Interagency Patent Coordination and Improvement Act of 2023 – S 79, 118th Cong (2023), https://www.congress.gov/bill/118th-congress/house-bill/1717/text.

[153] See, eg, Medicare Prescription Drug Price Negotiation Act of 2017, S 41, 115th Cong (2017), https://www.congress.gov/bill/115th-congress/senate-bill/41-; Prescription Drug Pricing Reduction Act of 2019, S.2543, 116th Cong (2019), https://www.congress.gov/bill/116th-congress/senate-bill/2543-; Prescription Drug Pricing Reduction Act of 2020, S 4199, 116th Cong (2020), https://www.congress.gov/bill/116th-congress/senate-bill/4199/all-actions-; Elijah E Cummings Lower Drug Costs Now Act, HR3, 117th Cong (2021), https://www.congress.gov/bill/117th-congress/house-bill/3-; Drug Price Transparency in Medicaid Act of 2023, HR1613, 118th Cong (2023), https://www.congress.gov/bill/118th-congress/house-bill/1613/all-actions-; Pharmacy Benefit Manager Transparency Act of 2023, S 127, 117th Cong (2023), https://www.congress.gov/bill/118th-congress/senate-bill/127?s=7&r=1.

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

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

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

[157] PBM Act S.1967, 118th Cong (2023), https://www.congress.gov/bill/118th-congress/senate-bill/1967/text?s=2&r=1&q=%7B%22search%22%3A%5B%22patients+before+middlemen%22%5D%7D.

[158] ibid.

[159] FTC Matter No. P221200 (6 June 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PBMModelOrder.pdf; FTC, Press Release, 'FTC Launches Inquiry Into Prescription Drug Middlemen Industry', FTC (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 Federal Trade Commission Act authorises the FTC to seek documents and data without a specific law enforcement purpose.

[160] FTC, Press Release, 'FTC Further Expands Inquiry Into Prescription Drug Middlemen Industry Practices' (8 June 2023), https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-practices.

[161] FTC Matter No. P221200 (6 June 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PBMModelOrder.pdf.

[162] ibid.

[163] FTC, 'Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products' (16 June 2022), https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.

[164] 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.

[165] id., at 5.

[166] ibid.

[167] See Lina Khan, Chair, FTC, 'Letter to FTC Regarding Robinson-Patman Act', at 1–3 (28 March 2024); 'US FTC adding "muscle" to tackle anticompetitive discrimination with Robinson-Patman Act, Khan says', MLex, (4 March 2024), https://mlexmarketinsight.com/news/insight/us-ftc-adding-muscle-to-tackle-anticompetitive-discrimination-with-robinson-patman-act-khan-says.

[168] 'FTC Leans on Robinson-Patman Act to Curb Anticompetitive Conduct: The Commission's Explanation', Global Competition Review (9 May 2023), https://globalcompetitionreview.com/hub/class-actions-hub/2022/article/ftc-leans-robinson-patman-act-curb-anticompetitive-conduct-the-commissions-explanation.

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

[170] ibid.

[171] FTC, 'Office of Policy Planning, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies Interim Staff Report', at 2 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[172] FTC, Press Release, 'FTC Releases Interim Staff Report on Prescription Drug Middlemen' (9 July 2024), https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen?utm_source=govdelivery.

[173] ibid.

[174] ibid; FTC, 'Office of Policy Planning, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies Interim Staff Report', at 3 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[175] FTC, Press Release, 'FTC Releases Interim Staff Report on Prescription Drug Middlemen' (9 July 2024), https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen?utm_source=govdelivery.

[176] Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593, 85594 (Notice, 8 December 2023), https://www.govinfo.gov/content/pkg/FR-2023-1208/pdf/2023-26930.pdf.

[177] id., at 85596.

[178] ibid.

[179] id., at 85598.

[180] FTC, 'Comment on NIST's Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights', at 7 (6 February 2024),

https://www.ftc.gov/system/files/ftc_gov/pdf/2024.02.06March-InRightsComment.pdf.

[181] US Dep't of Health and Human Services (HHS), Press Release, 'FTC, HHS Seek Public Comment on Generic Drug Shortages and Competition Amongst Powerful Middlemen' (14 February 2024), https://www.hhs.gov/about/news/2024/02/14/ftc-hhs-seek-public-comment-generic-drug-shortages-competition-amongst-powerful-middlemen.html.

[182] Davy James, 'FTC, HHS Launch Investigation into Role of GPOs, Wholesalers in Ongoing Generic Drug Shortages Pharmaceutical Executive', Pharmaceutical Executive (15 February 2024), https://www.pharmexec.com/view/ftc-hhs-launch-investigation-into-role-of-gpos-wholesalers-in-ongoing-generic-drug-shortages.

[183] HHS, Press Release, supra note 181.

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

[185] FTC, 'Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act' (supra note 184), at 8–9.

[186] id. at 11–16.

[187] Adam M Acosta, Eric Grannon, et al., 'Uncertainty Remains More Than One Year After the FTC Announces New "Unfair Methods of Competition" Policy', White & Case LLP (31 January 2024).

[188] See, eg, Mississippi: HB 728, 2024 Leg, Reg Sess (Miss 2024); Tennessee: SB 2016, 2024 Gen Assembly, Reg Sess (Tenn 2024); Maine: LD 2282, 2024 Leg, Reg Sess (Me 2024); Kentucky: SB 188, 2024 Gen Assembly, Reg Sess (Ky 2024); Oregon: HB 4149, 82nd Leg Assembly, 2024 Reg Sess (Or 2024); Virginia: HB 1402, 2024 Gen Assembly, Reg Sess (Va 2024); Idaho: HB 596, 67th Leg, 2d Reg Sess (Idaho 2024); West Virginia: SB 325, 2024 Leg, Reg Sess (W Va 2024); Indiana: HB 1332, 123rd Gen Assembly, 2d Reg Sess (Ind 2024); South Dakota: HB 1147, 99th Leg Sess (SD 2024); New Mexico: HB 33, 2024 Leg, Reg Sess (NM 2024); New Mexico: HB 165, 2024 Leg, Reg Sess (NM 2024); New Jersey: SB 3604, 220th Leg, Reg Sess (NJ 2024); New York: AB 1707, 2024 Assembly, Reg Sess (NY 2024); New York: SB 608-C, 2024 Leg, Reg Sess (NY 2024); Michigan: HB 4276, 102nd Leg (Mich 2024); California: SB 786, 2024 Leg, Reg Sess (Cal 2024).

[189] See Oklahoma Pharmacy Audit Integrity Act, SB 1670, 2024 Leg, Reg Sess, Okla Sess L 332 (Okla 2024).

[190] See HB 190, 2024 Leg, Reg Sess (Ky 2024).

[191] See Kevin Adam, 'Growing Web of State Drug-Pricing Legislation Increases Challenges for Pharmaceutical Manufacturers and Other Industry Participants', White & Case LLP (19 May 2020), https://www.whitecase.com/insight-alert/growing-web-state-drug-pricing-legislation-increases-challenges-pharmaceutical; Michael Gallagher, Cassandra Calderon,

Constantin Nuernberger, 'States Remain the Drivers of New Drug Pricing Legislation As Washington Weighs In', White & Case LLP (23 August 2021), https://www.whitecase.com/insight-alert/states-remain-drivers-new-drug-pricing-legislation-washington-weighs.

[192] NY Assembly Bill A1707-A, 2023-2024 Reg Sess (2023).

[193] See, eg, Minnesota Patient Protection Act, Minn Stat Ann § 62J.841; Order, Association for Accessible Medicines v Ellison, No. 23-cv-02024 (D Minn 4 December 2023), ECF No. 42; Illinois Generic Drug Pricing Fairness Act, HB 3957, 103rd Gen Assembly, Ill Public Act 103-0367 (Ill 2023); Association for Accessible Medicines v Raoul, No. 24-cv-00544 (ND Ill 17 June 2024), ECF No. 31.

[194] In re EpiPen Epinephrine Injection, Mktg, Sales Pracs & Antitrust Litig, 44 F4th 959 (10th Cir 29 July 2022).

[195] See Complaint, Sanofi-Aventis US LLC v Mylan Inc, No. 3:17-cv-02763 (DNJ 24 April 2017), ECF No. 1.

[196] See In re EpiPen, 44 F4th 959, at 986–91, 1006.

[197] id., at 988.

[198] id., at 989.

[199] id., at 990.

[200] id., at 989; see also id., at 996–99.

[201] In re EpiPen Direct Purchaser Litig, No. 20-cv-0827, 2021 US Dist LEXIS 8362 (D Minn 15 January 2021).

[202] See In re EpiPen Direct Purchaser Litig, No. 20-cv-0827, 2022 US Dist LEXIS 63272 (D Minn 5 April 2022). Defendants had, in 2019, 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 pharmacy benefit managers. 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).

[203] See id., at *10–15.

[204] See, eg, Brief in Supp of Defendants' Motion to Dismiss Direct Purchaser Class Action at § II.A.2, In re Copaxone Antitrust Litig, No. 2:22-cv-1232 (DNJ 15 June 2022), ECF No. 40; Brief in Supp of Motion to Dismiss Third-Party Payor Class Action at § II.B,In re Copaxone Antitrust Litig, No. 2:22-cv-1232 (DNJ 15 June 2022), ECF No. 41.

[205] See Complaint, Mylan Pharmaceuticals Inc v Teva Pharms Indus, No. 2:21-cv-13087 (DNJ 29 June 2021), ECF No. 1.

[206] See id., at ¶¶ 6–7.

[207] See Complaint, FWK Holdings, LLC v Teva Pharms Industries, Ltd (In re Copaxone Antitrust Litig), No. 22-cv-01232 (DNJ 7 Mar 2022), ECF No. 1; Brief in Supp of Defs' Motion to Dismiss Third Party Payor Class Action, In re Copaxone Antitrust Litig TPP Class Action, No. 22-cv-01232 (DNJ 15 June 2022), ECF No. 41; Complaint, In re Copaxone Antitrust Litig DPP Class Action, No. 22-cv-01232 (DNJ 29 April 2022), ECF No. 31; Brief in Supp of Defs' Motion to Dismiss Direct Purchaser Class Action, In re Copaxone Antitrust Litig DPP Class Action, No. 22-cv-01232 (DNJ 15 June 2022), ECF No. 40.

[208] See Complaint ¶ 3, Camargo v Abbvie, Inc, No. 23-cv-02589 (ND Ill 25 April 2023), ECF No. 1.

[209] id. ¶ 14.

[210] See Mem In Supp Of Motion to Dismiss, Camargo v Abbvie Inc, No. 23-cv-02589 (ND Ill 23 June 2023), ECF No. 18.

[211] See Complaint ¶ 3, Ohio v Ascent Health Servs LLC, No. 23-CV-H-03-0179 (Ohio Ct Common Pleas 27 March 2023).

[212] id., at ¶ 5.

[213] id., at ¶ 8.

[214] Complaint, International Union of Operating Engineers Local No. 478 Health Fund v Eli Lilly and Co, No. 24-cv-00743 (D Conn 22 April 2024).

[215] ibid.

[216] See Amanda Bronstad, 'Eli Lilly's $35 Insulin Cap Could Unravel, as $13.5M Class Action Settlement Falls Apart', ALM Media (26 April 2024), https://www.benefitspro.com/2024/04/26/as-eli-lillys-insulin-pricing-settlement-unravels-lawyers-vow-to-push-ahead-412-166663/.

[217] See MDL Transfer Order, Case transferred to District of New Jersey, International Union of Operating Engineers Local No. 478 Health Fund v Eli Lilly and Co, No. 24-cv-00743 (D Conn 20 May 2024), ECF No. 19.

[218] See FTC v Endo Pharms Inc, 82 F4th 1196 (DC Cir 2023).

[219] id., at 1201–02.

[220] ibid.

[221] id., at 1203.

[222] id., at 1202, 1206.

[223] id., at 1205.

[224] id., at 1206.

[225] ibid.

[226] Section 340B(a)(4) of the Public Health Service Act lists the covered entities that can participate in the programme, which include HRSA-supported health centres, state AIDS drug assistance programmes, Medicare or Medicaid Disproportionate Share Hospitals, children's hospitals and more. The full list of covered entities can be found at

https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf.

[227] 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.

[228] See, eg, Sanofi-Aventis US, LLC v US Dep't of Health and Hum Servs, 570 F Supp 3d 129, 153-54 (DNJ 2021) (citing AstraZeneca Pharms LP v Becerra, 543 F Supp 3d 47 (D Del 2021)), reversed and remanded by Sanofi Aventis US LLC v United States HHS, 58 F4th 696 (3d Cir 2023); see also Health and Human Servs, Notice of Withdrawal of Advisory Opinion, at 1 (18 June 2021), https://www.hhs.gov/sites/default/files/notice-of-withdrawal-of-ao-20-06-6-18-21.pdf.

[229] See Sanofi-Aventis US LLC v US Dep't of Health and Hum Servs, 570 F Supp 3d 129 (DNJ 2021) (holding manufacturers cannot unilaterally impose restrictions on offers to covered entities); Novartis Pharms Corp v Espinosa, 2021 US Dist Lexis 214824 (DDC 5 November 2021) (vacating violation letters and finding that 340B does not prohibit manufacturers from imposing conditions on the use of contract pharmacies); Eli Lilly and Co v Becerra, No. 1:21-cv-0081 (SD Ind 29 October 2021), ECF No. 144 at 57, 59 (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).

[230] Sanofi Aventis US LLC v US Dep't of Health and Human Servs, 58 F4th 696, 703–07 (3d Cir 2023).

[231] See Opinion at 20, Novartis Pharmaceuticals Corp v Johnson, No. 21-5299 (DC Cir 21 May 2024), consolidated with No. 21-5304, ECF No. 62.

[232] American Hospital Ass'n v Becerra, 596 US 724 (2022).

[233] Pharm Research & Manufs of Am v Becerra, 2022 US Dist LEXIS 88736, at *14 (DDC 17 May 2022).

[234] ibid. (emphasis in original).

[235] id., at *15.

[236] See Compl, Johnson & Johnson Healthcare Sys Inc v Save on SP, LLC, No. 22-cv-02632 (DNJ 4 May 2022), ECF No. 1.

[237] See Johnson & Johnson Health Care Sys v Save on SP, LLC, 2023 US Dist LEXIS 12619 (DNJ 25 January 2023).

[238] White & Case LLP represents several of the parties in cases discussed in this article, including FTC v Actavis, AndroGel, Aggrenox, Asacol, Bystolic, Doryx, EpiPen, Humira, K-Dur, Lidoderm, Lipitor, Loestrin, Namenda, Remicade, Xyrem, Zytiga, In re Generic Pharmaceuticals Pricing Antitrust Litigation and In re HIV Antitrust Litigation. No statement in this article may be imputed to any client in those actions or any other client of White & Case LLP. No client of White & Case LLP contributed to this article.

WHITE & CASE

Adam Acosta	adam.acosta@whitecase.com
Eric Grannon	egrannon@whitecase.com
Kristen O'Shaughnessy	kristen.oshaughnessy@whitecase.com
Gina Chiappetta	gina.chiappetta@whitecase.com
Daniel Grossbaum	dan.grossbaum@whitecase.com
Cansu Gunel	cansu.gunel@whitecase.com
Eugene Hutchinson	eugene.hutchinson@whitecase.com

3000 El Camino Real, 2 Palo Alto Square, Suite 900, Palo Alto CA 94306, United States

Tel: +1 650 213 0303

https://www.whitecase.com/