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United States: Pharmaceutical Antitrust

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In summary

The past year has continued to see an increase in US case law and other developments in the area of pharmaceutical antitrust. In this article we look at, among other things, antitrust claims under the rule of reason test announced by the US Supreme Court in Federal Trade Commission v Actavis for innovator and generic settlements of pharmaceutical patent litigation involving alleged reverse payments or 'pay-for-delay', product-hopping antitrust claims against innovator pharmaceutical companies that introduce new versions of brand-name drugs facing generic competition, and pharmaceutical pricing developments involving legislation, regulations and legal challenges in court.

Discussion points

- Recent decisions concerning reverse payment claims
- Challenges to pharmaceutical manufacturers' pricing practices
- The first pharmaceutical antitrust litigations concerning biosimilar competition

Referenced in this article

- FTC v Actavis
- FTC v AbbVie
- FTC v Impax
- In re Humira (Adalimumab) Antitrust Litigation
- US Supreme Court
- Sherman Act

Reverse payment case law under Actavis

The US Supreme Court's June 2013 decision in *FTC v Actavis* opened a floodgate for more than 30 separate antitrust cases that have been filed or revived under that decision. Reverse payment claims generally allege that an innovator pharmaceutical company provided financial inducement to a potential generic competitor to settle patent litigation concerning the innovator's drug product, or to obtain a later settlement entry date than the generic company otherwise would have accepted, absent the innovator's financial inducement. The majority opinion in *Actavis* rejected the deferential 'scope of the patent' test, but the majority opinion likewise rejected the FTC's 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 verdict, the first appellate decisions and record-setting settlements. Moreover, California enacted a new reverse payment law, effective from

January 2020, which deviates from the rule of reason standard announced in *Actavis* and codifies that certain alleged reverse payment settlements are to be treated as presumptively anticompetitive.[3] The law was unsuccessfully challenged at the district court level,[4] and the challenge was rejected for lack of standing by the US Court of Appeals for the Ninth Circuit in July 2020.[5] As further discussed below, the only certainty thus far is that the reverse payment waters are far from settled.

Pleading standards under Actavis

Following the Supreme Court's *Actavis* decision, 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, such as no authorised generic (no-AG), co-promotion, licensing and distribution agreements.[6] Courts, however, have grappled with how precisely a plaintiff must allege monetary estimates of value transferred to generic challengers,[7] with several courts expressly requiring 'plaintiffs plead information sufficient to estimate the value of the term, at least to the extent of determining whether it is "large" and "unjustified"'.[8] For example, in September 2020, the Third Circuit held that a supply agreement for TriCor, entered at the same time as a patent settlement for AndroGel, may plausibly constitute a reverse payment because the FTC had alleged that 'the royalty terms were "significantly worse for [the brand company]" than is usual in authorised-generic agreements', and the brand company 'expected to lose roughly US$100 million in TriCor revenues as a result of the deal', which the court called a 'sacrifice'.[9] At the same time, the generic company expected its 'net sales of authorised generic TriCor sales would be nearly US$175 million over a four-year period', exceeding what the generic company 'projected it was likely to earn by winning the infringement suit and marketing its generic version of AndroGel'.[10]

By contrast, in June 2020, the court in *Humira* dismissed a reverse payment claim alleging that 'AbbVie paid biosimilar manufacturers in the form of European agreements that allowed the biosimilars to enter the European market' while agreeing to 'AbbVie-friendly' generic entry dates in the US.[11] The 'package deals' allegedly bought AbbVie 'more lucrative monopoly time in the US (worth billions of dollars in revenue for AbbVie)'.[12] The district court, however, rejected this theory because the settlements increased competition 'by bringing competitors into the market when patents otherwise prohibited competition' and the 'settlement terms, when taken together, involve transfers of value from the patentee to the alleged infringer'.[13] An appeal is pending in the Seventh Circuit, and oral argument was held in February 2021.[14]

Finally, in July 2020, a magistrate judge in *Sensipar* issued an order recommending dismissal of alleged reverse payment claims because neither 'Teva's retained revenue' from its at-risk launch nor 'an acceleration provision allowing Teva to resume sales of its generic product if another generic launched before Teva's agreed-upon entry date' was an unlawful reverse payment under *Actavis*, either when considered alone or together.[15] But in November 2020, the district judge reversed, holding that '[a]lthough Teva paid Amgen US$40 million as part of the Amgen-Teva settlement of Amgen's patent infringement claims against Teva, that "forward" payment cannot be divorced from what Teva did *not* pay Amgen'.[16] By allegedly 'giving up its claim to all but US$40 million (and not even the full US$393 million of revenues Teva had earned from its at-risk launch), Amgen was permitting Teva to retain at least some of the profits Teva had earned at Amgen's expense', which 'constitutes a "transfer of value" to Teva that may be proven' to be 'large and unjustified'.[17] The court further explained that the acceleration provision may constitute an 'additional transfer of value' when factored into the overall settlement and rule of reason analysis.[18]

Summary judgment under Actavis

Courts have likewise grappled with how to apply *Actavis* at summary judgment when evaluating evidence. Several summary judgment decisions, such as *AndroGel, K-Dur, Loestrin, Modafinil, Namenda* and *Nexium*, have focused on whether business agreements executed contemporaneously with patent settlements are 'large and unjustified'. In several of these cases, district courts denied summary judgment based on various disputed factual issues unique to each case. Some of these courts, for example, analysed whether there was sufficient evidence to support allegations that the compensation for services was significantly above fair market value, the services were unnecessary or unwanted, the agreements for services included unusual terms, the brand company failed to follow certain industry or internal practices, and the extent to which such business agreements may be 'linked' to the patent settlement.[19]

For instance, in September 2020, the court in *Intuniv* denied summary judgment because there were disputed factual issues as to whether an authorised generic agreement constituted an unexplained large payment. Defendants argued that because 'it was more profitable for [brand company] Shire to collect royalties than to launch its own AG, Shire did not sacrifice' profits to delay generic entry.[20] But the court noted that 'the question is whether, by declining to launch its own AG, Shire sacrificed profits that it otherwise would have had by not launching its own generic or by not taking a larger percentage of royalties'.[21] Defendants also argued that, by securing its rights to launch its own AG, Shire did not sacrifice any profits, but Plaintiff was considered to have presented sufficient evidence to show 'that Shire had no intention of launching, and did not have the capacity to launch, an AG on its own'.[22] Thus, 'even assuming that Shire had retained its right to launch an AG, there would remain a dispute of fact concerning whether Shire sacrificed potential profits by limiting its ability to launch an AG with a third party'.[23]

In May 2021, the court in *Glumetza* examined what it characterised as 'one covenant not to compete, providing four more years of Glumetza monopoly, in exchange for a second covenant not to compete, one year without marketing an authorised generic'.[24] Yet the court recognised that such covenants are not dispositive under *Actavis* and 'that to traverse a motion for summary judgment raising defendants' patents as the procompetitive justification, plaintiffs, as several courts have held, must show "some evidence" of noninfringement or invalidity'.[25] The court ultimately determined that there were disputed factual issues for a jury to resolve. For example, defendants pointed to evidence that the underlying patent court 'adopted claim constructions which both undermined Lupin's invalidity argument and made a judgment of infringement very unlikely'.[26] At the same time, the court observed that if '*both* parties *knew* Lupin infringed and would be barred from marketing generic Glumetza', then there remained a question as to why 'brand defendants agreed to *expedite* Lupin's generic market entry', 'cede a year's worth of revenue that an authorised generic could recoup from Lupin', and 'pay three million dollars in Lupin's legal fees'.[27]

In June 2021, the court in *Opana* also denied summary judgment where a 'Broad Licence' provision was at issue providing that Impax had a licence 'to sell generic Opana ER even if Endo acquired additional patents'.[28] Defendants sought to use 'the Broad Licence as a counterbalance to the reverse payment', but the court reasoned that 'the Broad Licence is a concession in the same direction as the reverse payment – from Endo to Impax'.[29] The court explained that '[w]hile the Broad Licence has potentially beneficial effects to consumers, it does not counterbalance the US$102 million reverse payment from Endo to Impax', and 'the Broad Licence concession serves only to highlight how much Endo valued Impax's delayed start, suggesting monopolistic effects instead of procompetitive ones'.[30] Thus, a jury was to decide what competitive implications should be ascribed to the Broad Licence agreement as part of the rule of reason analysis.

Finally, in June 2021, the court in *Namenda* held that there were disputed factual issues as to the value associated with a distribution and supply agreement negotiated at the time of the parties' patent settlement. In reaching this conclusion, the court rejected plaintiff's 'generic inducement test' where the 'trier of fact can consider only the generic's perspective' and 'it does not matter if [the brand company] expected to save money in the long run' under the distribution and supply agreement.[31] Instead, the court held that a 'factfinder must also be allowed to consider the net benefits to the branded manufacturer, which could include, among other things, reduced Medicaid liabilities and saved manufacturing costs – all in addition to the saved litigation costs from settling'.[32] *Actavis* made clear that 'litigation expenses saved through the settlement' and 'compensation for other services' are not exhaustive and that the factfinder may address other considerations.[33] 'The only consideration that cannot factor into whether the reverse settlement was made are the expected profits from delayed competition.'[34]

Other district courts have also denied summary judgment where factual and expert evidence adequately supported plaintiffs' causation theories of earlier generic entry that in the but-for world the generic challenger would have launched at risk, prevailed in the patent case, or entered into an alternative, 'no-payment' settlement agreement.[35] At the same time, other district courts, such as *AndroGel*, have rejected patent-based causation theories as unsupported and 'simply too procedurally burdensome and speculative' when there were no concrete developments in the underlying patent case in which to base such a causation theory.[36]

One of the most notable causation decisions is *Wellbutrin*, where the Third Circuit affirmed a grant of summary judgment for the defendants. The Third Circuit held that the plaintiffs 'did not take into account Andrx's blocking patent' and that it is not enough 'to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal'.[37] 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'.[38] Notably, the size of the reverse payment alone was an insufficient 'surrogate' for the weakness of the patent.[39] Additionally, the court 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.[40] 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'.[41]

Trials under Actavis

Several cases, such as *Modafinil* and *Solodyn*, have proceeded to trial since *Actavis* but were resolved by settlements mid-trial. Two reverse payment cases, however, have proceeded through trial to judgment, both of which were appealed. In *Nexium*, the private plaintiffs had calculated a reverse payment of US$22 million, argued that the contemporaneously executed business agreements 'provided a steady flow of revenue to Ranbaxy' during the same period it agreed not to launch its generic Nexium product and offered evidence that 'even if Ranbaxy had won its litigation instead of settling, Ranbaxy would not have secured such favourable arrangements'.[42] But at trial, the jury reached a verdict for the defendants despite finding that there had been a reverse payment. The jury found that, although AstraZeneca had market power and there had been a 'large and unjustified' payment, the reverse payment did not cause delayed generic entry because AstraZeneca would not have agreed to an earlier settlement entry date absent a reverse payment.[43] The US Court of Appeals for the First Circuit affirmed the jury's verdict for the defendants.[44]

More recently, following an administrative bench trial in the FTC's *Opana* suit, the FTC's chief administrative law judge (ALJ) concluded that an alleged reverse payment between Endo and Impax was not anticompetitive. Endo and Impax had settled the underlying patent litigation and entered into a settlement and licence agreement (SLA) and a development and co-promotion agreement (DCA).[45] The SLA included a no-AG provision and a potential cash credit to Impax if Opana sales fell below a certain threshold.[46] The DCA was executed contemporaneously with the SLA and provided an up-front payment of US$10 million for the development of a Parkinson's disease treatment, with potential payments up to US$30 million at certain milestones.[47]

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'.[48] Despite finding that the SLA was 'large and unjustified', the ALJ concluded that any anticompetitive harm was outweighed by pro-competitive benefits because 'Endo's acquisition of additional patents, and successful assertion of those additional patents in litigation, has led to all generic manufacturers, other than Impax, being enjoined from selling a generic version of Opana ER', and 'absent the SLA, such after-acquired patents also would have been successfully asserted to enjoin Impax from selling generic Opana ER'.[49]

The FTC Commission unanimously rejected the ALJ's decision, concluding that 'Impax failed to show that the challenged restraint furthered any cognisable procompetitive justifications', and 'even if Impax had satisfied this burden, Complaint Counsel identified a viable less restrictive alternative'.[50] In an April 2021 decision, the US Court of Appeals for the Fifth Circuit denied a petition for review and found that the Commission did not commit any legal errors and that substantial evidence supported the Commission's factual findings.[51] The Fifth Circuit observed that the settlement 'saved Endo only US$3 million in litigation expenses' and that only US$10 million in payments were associated with services, such that 'over US$100 million of Endo's payment remains unjustified'.[52] Impax's 'principal attack on the finding of anticompetitive effect [was] that the Commission needed to evaluate 'the patent's strength, which is the expected likelihood of the brand manufacturer winning the litigation', but the Fifth Circuit rejected that argument, holding that the FTC need not assess the 'likely outcome of the patent case'.[53] The Fifth Circuit also discounted the impact of the patents acquired after the settlement because 'the impact of an agreement on competition is assessed as of "the time it was adopted"'.[54] Ultimately, the Fifth Circuit concluded that substantial evidence supports the Commission's conclusion that the parties could have entered a less restrictive alternative settlement that did not include a payment.[55]

Product-hopping antitrust cases

Plaintiffs have also attempted to use antitrust laws to challenge brand manufacturers' introduction of new versions of existing drugs. In these product-hopping cases, plaintiffs allege that brand pharmaceutical manufacturers violate the antitrust laws by introducing new versions and discontinuing older versions of brand drugs in an alleged attempt to thwart generic competition and generic substitution laws.[56]

Pre-2015 decisions: *TriCor*, *Prilosec* and *Suboxone*

In one of the first 'product hopping' decisions, the district court in *TriCor* rejected the defendants' argument that any product change that is an improvement is per se legal under the antitrust laws.[57] Instead, the court concluded that the introduction of a new product should be assessed under the rule of reason approach, requiring the plaintiffs to demonstrate that the anticompetitive harm from the formulation change outweighed any benefits of introducing a new version of the product. The court in *TriCor* denied the defendants' motion to dismiss, finding the plaintiffs' specific allegations – that the defendants bought back supplies of the old formulation and changed product codes for the old products to 'obsolete' to prevent pharmacies from filling TriCor prescriptions with generic versions of the old formulation – sufficient to support the plaintiffs' antitrust claims.[58]

In *Prilosec*, the district court concluded that antitrust laws do not require new products to be superior to existing ones and that consumer choice plays into the analysis of a product-hopping claim.[59] In granting the defendants' motion to dismiss, the court found that where defendants left the old product on the market but heavily (and successfully) promoted their new product, the plaintiffs could not allege that the defendants interfered with competition because consumer choice was not eliminated.[60]

In *Suboxone*, direct and indirect purchasers alleged that the defendants unlawfully shifted patients from Suboxone tablets to Suboxone film by falsely disparaging and fabricating safety concerns about the tablet, and by removing Suboxone tablets from the market just as generic versions of the tablets were set to enter the market. The district court denied the defendants' motion to dismiss the product-hopping claims, holding that 'what is clear from the case law is that simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct [that stymies competition]'.[61] The court determined that the defendants' conduct fell somewhere in between the conduct at issue in *TriCor* and *Prilosec*. The court found that the conduct was more problematic than in *Prilosec* because the defendants removed the Suboxone tablets from the market, but less problematic than in *TriCor* because the defendants did not buy back existing

Suboxone tablets or label the tablets obsolete.[62] The court nonetheless found that the plaintiffs had sufficiently pleaded 'other wrongful conduct' insofar as removing the tablets from the market in conjunction with fabricating safety concerns could coerce patients to switch from the tablet to the film.[63]

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 district court granted a motion for a preliminary injunction on a limited record related to product-hopping claims as to the defendants' plan to transition Alzheimer's patients from an older, twice-daily drug to a newer, once-daily formulation.[64] Unlike in *TriCor* and *Suboxone*, in which the defendants fully removed the older formulation from the market, the *Namenda* defendants planned to continue making the older formulation available to any patient who had a medical need for it. Nonetheless, the *Namenda* court held that the plaintiff had met its burden of demonstrating a substantial risk that the plan to transition patients would harm competition because generics would not be able to take advantage of automatic state substitution laws to the extent generics hoped.[65]

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.[66] 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*[67] 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.[68] 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.[69]

The US Court of Appeals for the Third Circuit in *Doryx*, however, became the first to evaluate product-hopping claims, with the benefit of full discovery, at the summary judgment stage. In *Doryx*, the plaintiffs alleged that numerous product reformulations (including changes from capsules to tablets, changes to dosage strength and introduction of score lines to the tablets), coupled with the subsequent discontinuation of older versions, constituted anticompetitive product hopping. The court denied the defendants' motion to dismiss on the ground that the court would be required to consider facts beyond the pleadings to decide the product-hopping issue.[70] However, the court noted that the plaintiffs' product-hopping theory was 'novel at best' and conveyed scepticism that product hopping even constitutes anticompetitive conduct under the Sherman Act.[71]

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.[72] The court also rejected the plaintiffs' contention that the product reformulations were anticompetitive because they were insufficiently innovative, noting that no intelligible test for innovation 'sufficiency' had been offered and doubting that courts could ever fashion one.[73] As to the role of state substitution laws in the analysis of product-hopping claims, the court rejected the notion that the brand excluded competition by denying the generic the opportunity to take advantage of the 'regulatory bonus' afforded by state substitution laws. Rather, the court held that generics can compete without automatic substitution through advertising and cost competition, and concluded that brand manufacturers have no duty to facilitate generic manufacturers' business plans by keeping older versions of a drug on the market.[74] The US Court of Appeals for the Third Circuit affirmed the lower court's grant of summary judgment in the defendants' favour.[75]

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

Since the *Namenda* and *Doryx* decisions, additional courts have addressed pharmaceutical product hopping at the motion to dismiss stage. The *Solodyn* court dismissed the plaintiffs' product-hopping claim, holding that because the defendants kept the older strengths of Solodyn on the market until two years after the older strengths faced generic competition, the introduction of newer strengths did not limit customer choice and was therefore not anticompetitive.[76]

In *Asacol*, the direct and indirect purchasers alleged that the defendants engaged in a product hop that thwarted generic competition for branded drug Asacol by first introducing and promoting Asacol HD (a high-dose version of Asacol), years later introducing the drug Delzicol with the same active ingredient and dose as Asacol, and shortly thereafter removing Asacol from the market prior to the entry of generic Asacol products. Relying on *Namenda*, the *Asacol* court dismissed the plaintiffs' claims of a product hop between Asacol and Asacol HD because Asacol continued to be sold side-by-side with Asacol HD for several years after Asacol HD was introduced.[77] However, the court allowed the plaintiffs' claims of a product hop from Asacol to Delzicol to survive the defendants' motion to dismiss, where the defendants allegedly withdrew Asacol from the market shortly after introducing the close substitute Delzicol.[78] Following a settlement with direct purchasers, the court denied summary judgment as to the remaining indirect purchasers' claims based on disputed factual issues concerning coercion, causation and product market, but it did not revisit the legal framework for product-hopping claims.[79]

Subsequent to the 2014 motion to dismiss decision in *Suboxone* related to the purchaser plaintiffs' complaints, state plaintiffs filed complaints with similar claims, and the court revisited its product-hopping analysis in light of the *Namenda*, *Doryx* and *Asacol* decisions rendered since the earlier *Suboxone* decision. The court reached the same result as it did in its previous decision in which it analysed the product-hopping claims in view of *TriCor* and *Prilosec*, determining that the conduct was more akin to the claims allowed to proceed in *Namenda* than to claims dismissed in *Doryx* and *Asacol* because the old Suboxone product was withdrawn prior to generic entry.[80] The private plaintiffs' and the state attorneys general's cases are coordinated for pretrial discovery, and fully briefed summary judgment motions have been pending before the district court since June 2021.[81]

Additionally, following an FTC investigation related to *Suboxone*, the FTC filed an antitrust action against Reckitt Benckiser in July 2019 concerning allegations of product hopping and sham petitioning. Reckitt settled the next day, agreeing to a fine and a permanent injunction. Notably, part of the injunction requires that:

> "If Reckitt introduces a reformulated version of an existing product, it must provide the FTC with information about that product and the reasons for its introduction. If generic companies file for FDA approval of competing versions of the branded drug, the order requires Reckitt to leave the original product on the market on reasonable terms for a limited period so that doctors and patients can choose which formulation of the drug they prefer. [82]"

The FTC settlement is reportedly 'part of a broader government settlement with Reckitt, which involves criminal and civil fraud claims'.[83] The FTC also reached a settlement with Indivior, a former subsidiary of Reckitt, in July 2020, which is also part of a broader government settlement.[84]

Further, the court in *Loestrin* relied heavily on *Namenda* when denying the defendants' motion to dismiss the product-hopping claims.[85] The court found that the removal of the earlier version of the drug prior to generic entry was distinguishable from the conduct in *Doryx* and *Solodyn* (product removed after generic competition) and *Prilosec* (no product removal), and in line with allegations in *Suboxone*, *TriCor* and *Asacol*, which survived motions to dismiss.[86] At summary judgment, however, the *Loestrin* court rejected the plaintiffs' argument 'that no showing of anticompetitive conduct is required beyond the hard switch itself'; the court instead required the plaintiffs to come forward with evidence of 'anticompetitive conduct to coerce consumers to switch' products to prove their product-hopping claim.[87] The court found that there was competing evidence on the issue of coercion, which was 'all fodder for the jury' under the circumstances, and therefore allowed the product-hopping claim to proceed to trial.[88] The case settled prior to trial.

Finally, in the follow-on indirect-purchaser action in *Namenda*, the court granted summary judgment for defendant on plaintiff's hard switch theory of liability because the plaintiff failed to 'demonstrate that it was personally harmed by the hard switch'.[89] Instead, the plaintiff simply relied on class-wide evidence and did not 'prove *its own case*, with evidence relating to *its own* customers, and *its own* reimbursements'.[90] Despite being afforded an opportunity to provide additional evidence, the court subsequently granted summary judgment for defendant in July 2021 because plaintiff again failed to 'identify which of [its] reimbursements were attributable to the "hard switch"'.[91]

Pharmaceutical manufacturer pricing practices

Federal legislation regarding drug pricing has largely stalled over the last few years, but the pace of change may increase under the Biden Administration. Into the third quarter of 2021, lawmakers have passed two new laws and proposed a package of additional ones, while the new Administration has issued an Executive Order and public statement pushing for regulatory change and legislative action. At the same time, state lawmakers continue to pass new laws targeting key issues in the ongoing drug-pricing debate, seemingly emboldened by a recent Supreme Court decision denying ERISA pre-emption of state laws regulating Pharmacy Benefit Manager (PBM) prescription drug payment rates to pharmacies. As few new theories challenging drug pricing have gained traction in courts, much of the focus on efforts to lower drug prices has continued to be potential legislative and regulatory remedies.

Legislation relating to pharmaceutical pricing

Federal legislation

While federal legislation regarding drug pricing took a back seat in 2020 during the covid-19 pandemic, lawmakers refocused on pricing in early 2021. With the Biden Administration came a number of bills targeting key issues in the ongoing drug-pricing debate. For example, the COVID-19 Stimulus Package passed in March 2021 eliminated the statutory cap on rebates that drug manufacturers pay to Medicaid, which means a manufacturer may be required to pay Medicaid when its drug is used.[92] Further, two bills signed into law in April 2021 seek to reduce prescription drug prices by supporting generic and biosimilar alternatives to branded drugs. The Ensuring Innovation Act clarified the technical qualifications for earning exclusivity as a 'new

chemical entity' (NCE) and codified the FDA's practice of awarding NCE exclusivity based on a drug's 'active moiety' rather than its 'active ingredient', arguably making it more difficult for pharmaceutical companies to obtain NCE exclusivity.[93] The Advancing Education on Biosimilar Act called for the government to provide educational materials to physicians and the public to increase awareness of biosimilar drugs.[94]

In addition to the two bills signed by President Biden, an April 2021 House Judiciary Antitrust Subcommittee hearing kick-started a discussion on changes to existing antitrust and patent laws to address prescription drug pricing. Federal lawmakers used the hearing to introduce a legislative package of four previously introduced bills that would revise aspects of antitrust and patent enforcement in the pharmaceutical industry: the Preserve Access to Affordable Generics and Biosimilars Act, the Affordable Prescriptions for Patients through Promoting Competition Act, the Stop STALLING Act, and the Affordable Prescriptions for Patients through Improvements to Patent Litigation Act.[95] On the antitrust front, these bills would create presumptions of anticompetitive conduct for certain 'reverse payment' patent settlements, instances of 'product hopping', and sham petitioning.[96] On the patent front, the bill would cap the number of patents in an infringement action resulting from the 'patent dance' information exchange created by the Biosimilar Products Competition Innovation Act (BPCIA).[97]

Congressional Democrats may also have found support from President Biden on a number of other developments. Among those developments is a bill revived earlier this year to empower Medicare to negotiate drug prices and to make those prices available to commercial plans,[98] a proposal to establish international reference pricing for newly launched specialty drugs, and other proposals intended to rein in drug prices.[99] President Biden's 9 July 2021 Executive Order continued to press for action on drug pricing. The Executive Order expressly supports 'aggressive legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and through other related reforms'.[100] The Executive Order also directs the FDA to work with states to import less-expensive pharmaceuticals from outside the US.[101] President Biden re-emphasised his Administration's focus on drug pricing with a 12 August 2021 statement calling on Congress to take certain steps, such as allowing Medicare to negotiate lower drug prices.[102]

Key stakeholders in the pharmaceutical industry, however, did come out ahead in at least some of the ongoing battles regarding drug pricing. For example, in the final months of his presidency, President Trump signed four executive orders seeking to (1) reduce the cost of insulin and injectable epinephrine to low-income individuals, (2) allow importation of drugs from other countries with lower prices, (3) eliminate the anti-kickback safe harbour protections for rebates paid to pharmacy benefit managers and insurers, and (4) establish a most-favoured-nation (MFN) pricing model for Medicare drug payments based on international reference prices.[103] Industry trade groups had mounted numerous legal challenges to some of those rules,[104] and President Biden halted the rulemaking procedure for all four late-issued rules shortly after taking office.[105]

State legislation

Drugmakers continued to face a growingly complex web of state drug price transparency and other laws over the past year. In 2020, states debated more than 400 bills that purported to reduce or control drug prices and enacted more than 20 of them.[106] These new state laws require pricing transparency from pharmaceutical manufacturers, mandate disclosures from pharmaceutical benefit managers (PBMs) and insurers, and cap consumer cost-sharing on certain drugs, among other changes.[107] As of June 2021, more than 500 state drug pricing bills have been introduced this year, several of which would go beyond mere reporting requirements and institute various degrees of price control.[108] The busy activities in state houses may be ascribed to local lawmakers' boosted confidence to enact such legislation, given the 2020 Supreme Court decision upholding an Arkansas law regulating PBM payments to pharmacies as a 'cost regulation' not preempted by ERISA.[109] The Court, in a unanimous opinion, reasoned that a state law may be 'impermissibly connected' with ERISA plans – and therefore pre-empted – only where the state law 'governs a central matter of plan administration or interferes with nationally uniform plan administration'.[110] The Arkansas Act did neither and 'merely increases costs or alters incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage'.[111]

Some states have diverged from the federal government approach to limit manufacturer co-pay assistance programmes for consumers, acting in several instances to ensure that those benefits reach consumers and are not co-opted by commercial health plans through the use of 'co-pay accumulator' programmes, which exclude manufacturer co-pay assistance from counting towards a consumer's deductible or out-of-pocket maximum. A total of 11 states require commercial health plans and self-funded non-ERISA plans to count the value of any co-pay assistance – manufacturer coupons, nonprofit assistance programmes or prescription discounters – toward patient deductibles.[112] For its part, the Centers for Medicare and Medicaid Services (CMS) continued to refine its policy allowing the use of co-pay accumulators as it finalised a rule that requires manufacturers to ensure co-pay assistance benefits for commercially-insured consumers are provided entirely to the consumer to qualify for certain regulatory exclusions.[113]

Litigation relating to pharmaceutical pricing

Litigation relating to drug pricing in the past year is marked by the impact of a Supreme Court decision on the availability of disgorgement as an FTC Act remedy, some early victories for drugmakers in dismissing consumers' RICO claims attacking allegedly 'high' drug prices, and novel theories challenging drug prices using a combination of the Anti-Kickback Statute, the Travel Act and the RICO Act.

Manufacturers view the Supreme Court's May 2021 decision in *AMG* as effectively barring claims of disgorgement in many antitrust claims. For example, in the sprawling multidistrict litigation in the Eastern District of Pennsylvania regarding alleged price-fixing of various generic drugs, generic drugmakers in a lead case moved to dismiss the state attorneys general's price-fixing claims, citing *AMG*'s ruling that the FTC Act does not grant authority under section 13(b) to seek equitable monetary relief such as restitution or disgorgement.[114] In response, the state attorneys general argued that they sought equitable monetary relief under the Clayton Act and specific state laws, rather than the FTC Act, and therefore the Supreme Court's decision did not affect their claims.[115] The drugmakers' motion to dismiss remains pending.

In the suit filed by the FTC and seven state attorneys general against Martin Shkreli and Vyera Pharmaceuticals LLC regarding Daraprim, however, seven states agreed not to seek civil penalties or forfeitures in exchange for the defendants' agreement to withdraw their jury demands.[116] Separately, Shkreli and Vyera Pharmaceuticals were hit with the first private antitrust suit, initiated by Blue Cross and Blue Shield, asserting similar allegations to those made by the FTC and state attorneys general – namely that Vyera monopolised the relevant market through the use of exclusive contracts that purportedly blocked potential generic competitors from access to suppliers of the active pharmaceutical ingredient and engaged in other allegedly anticompetitive conduct.[117]

In a 2019 case in the US District Court for the District of New Jersey, drugmakers successfully tossed for lack of standing the federal 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.[118] The class plaintiffs' second try at reframing federal RICO claims by seeking injunctive relief under RICO likewise failed in 2020, with the court finding no RICO private right of equitable relief.[119] It remains to be seen whether the patients' third attempt at alleging state RICO claims in April 2021 will survive dismissal.[120]

By contrast, a 2021 decision by the US District Court for the District of Minnesota permitted drug wholesalers who purchased EpiPen from Mylan at list price to sue Mylan for Anti-Kickback Statute violations marks a potential new liability theory in drug-pricing litigation.[121] The wholesalers alleged that the rebates Mylan paid to PBMs to maintain favourable formulary status were kickbacks in violation of the Anti-Kickback Statute.[122] To overcome the issue that private litigants cannot sue directly under the Anti-Kickback Statute, the wholesalers alleged that violations of the Anti-Kickback Statute constitute bribery in violation of the Travel Act, a statute that qualifies as a predicate for RICO claims.[123] After the District Court of Minnesota accepted the wholesalers' argument that Anti-Kickback Statute violations may be deemed bribery in contravention of the Travel Act, which would in turn entail RICO claims, this novel liability theory has been adopted by at least another court, namely the US District Court for New Jersey in the direct purchasers' insulin-pricing case where the court relied on the Minnesota decision and refused to toss the RICO claims.[124]

The federal government's 340B Drug Pricing Programme also created controversies. The programme 'mandates that pharmaceutical manufacturers provide outpatient drugs to certain healthcare providers – known as eligible covered entities – at significant discounts'.[125] Over time, pharmacy chains and PBMs – such as Walgreens, CVS Health, Express Scripts, OptumRx and Walmart – have allegedly dominated the 340B contract pharmacy relationships with hospitals and other 340B-qualified healthcare providers.[126] The former profit from per-prescription fees paid by 340B-qualified entities, fees that are 'much higher than a pharmacy's typical gross profit from a third-party payer', whereas patients have not benefited from the 340B discounts.[127] As a result, certain drugmakers have limited 340B discounts for prescription drugs dispensed via contract pharmacies.[128] These developments have given rise to lawsuits: drugmakers recently challenged the US Department of Health and Human Services' December 2020 advisory opinion that any pharmacy contracting with 340B hospitals can get the same drug discounts those hospitals get.[129] The US District Court for the District of Delaware shot down the HHS's attempt to dismiss the lawsuit and found that the agency's 340B advisory opinion was 'legally flawed'.[130]

Other notable antitrust challenges involving pharmaceuticals

In addition to the above areas that have been most active, we also have seen recent antitrust decisions concerning biosimilar competition and drug exclusivity arrangements that are particularly notable.

Biosimilar antitrust litigation

In 2009, Congress passed the Biologics Price Competition and Innovation Act to provide an abbreviated FDA approval pathway for biosimilar versions of a biological drug,[131] opening the door to a new regime of pharmaceutical competition.

In September 2017, in the first antitrust case between a biologic originator and a biosimilar manufacturer, Pfizer sued Johnson & Johnson (J&J) and Janssen for allegedly employing a 'multifaceted scheme' to thwart biosimilar competition through imposing exclusionary contracts on both health insurers and healthcare providers (eg, hospitals and clinics).[132] The court denied the defendants' motion to dismiss Pfizer's complaint, holding that the complaint plausibly asserts 'detailed allegations regarding J&J's exclusionary terms with many of the nation's largest insurers, the incentive structure that forces end payors and providers into accepting those terms, Pfizer's efforts to compete, including its guarantees that Inflectra would cost less than Remicade, and [alleged] how market participants on many levels are injured from J&J's ability to sell Remicade without having to compete with Inflectra and other biosimilars'.[133] Indirect purchaser class-action and opt-out complaints followed the Pfizer lawsuit and are proceeding through discovery. Pfizer resolved and dismissed its claims in July 2021.

In a separate set of biosimilar suits filed in early 2019, class-action plaintiffs also began filing antitrust complaints concerning AbbVie's biological drug Humira, which is one of the best-selling prescription drugs in the world, with more than US$130 billion in estimated total sales. The complaints allege that AbbVie prevented biosimilar competition by employing a 'patent thicket' – defined by plaintiffs as 'an unlawful scheme whereby [AbbVie] secured over 100 patents designed solely to insulate Humira from any biosimilar competition' – and then entering into illegal market division agreements.[134] In June 2020, the district court granted a motion to dismiss, recognising that the 'patent thicket' claim is a 'new kind of antitrust claim' that 'brings together a disparate set of aggressive but mostly protected actions'.[135] The court held that the 'allegations – even when considered broadly and together for their potential to restrain trade – fall short of alleging the kind of competitive harm remedied by antitrust law'.[136] The plaintiffs have appealed to the Seventh Circuit and oral argument was held in February 2021.[137]

Exclusivity agreements

Certain contracting practices in the pharmaceutical industry have also come under antitrust scrutiny.

For instance, in early 2021, the US Court of Appeals for the Third Circuit addressed allegations concerning an exclusive supply agreement for the active pharmaceutical ingredient (API) in vasopressin, a blood pressure treatment.[138] Plaintiff Fresenius alleged that while seeking to submit an ANDA for vasopressin, it realised that the only suppliers of the API were subject to exclusive-dealing arrangements with Par Pharmaceutical.[139] These arrangements allegedly are part of Par's efforts to '"lock up difficult-to-source API" to prevent competitors from entering the IVI market'.[140] The district court granted Par's motion for summary judgment, concluding that the existence of Par's patents on its brand vasopressin product broke the chain of causation and that Fresenius' theory that it would have successfully challenged those patents was 'unduly speculative' because 'there was never an underlying patent challenge or an underlying ANDA from which a jury could make a reasoned decision on how such hypothetical patent action on invalidity or infringement would have been resolved'.[141] But the Third Circuit reversed, holding that the district court should have analysed whether a reasonable jury could have found that Par's patents would have blocked Fresenius's entry.[142] The court noted, however, that '[o]n remand, the District Court may choose to consider whether the exclusivity agreement even constitutes anticompetitive conduct because if it does not, then no patent analysis is needed'.[143] The Third Circuit provided guidance on how the trial court should examine the legality of the exclusivity agreements at issue and pointed to record evidence relevant to the question of whether Fresenius has shown 'substantial foreclosure of the market for the relevant product'.[144] Following remand, the parties have filed supplemental summary judgment briefs with the district court, which remain pending.

In another matter, a plaintiff union fund alleged that Mallinckrodt entered into an anticompetitive 'distribution scheme' with Express Scripts, under which Express Scripts became the sole distributor of Acthar, the only therapeutic adrenocorticotropic hormone product sold in the US.[145] In an August 2020 decision, the district court granted the defendants' motions to dismiss the antitrust allegations challenging the exclusive distributorship, concluding that the plaintiff failed to plausibly allege an adverse effect on competition where 'there [was] no indication that Express Scripts actually took any steps to harm or exclude any of Acthar's potential competitors'.[146] The court, however, did not dismiss certain antitrust and unjust enrichment claims against Mallinckrodt, which stem from the company allegedly acquiring the rights to a potential competitor product to keep it off the market.[147] Currently before the court is a motion to transfer the case to the District of Delaware, where Mallinckrodt's Chapter 11 bankruptcy cases are pending.

There has also been a number of cases of late involving antitrust challenges to pharmaceutical manufacturers securing exclusive formulary position by paying rebates.[148] These cases come at the same time as the FTC is reportedly taking a closer look at rebating practices, such as so-called 'rebate walls'.[149] This is an area to follow in the coming years as these cases and potential enforcements actions develop.[150]

Notes

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

[2] id. at 156.

[3] See Kristen O'Shaughnessy et al, 'California's New Reverse Payment Law Departs from Supreme Court Standard in FTC v. Actavis', White & Case LLP, 17 October 2019, www.whitecase.com/publications/alert/californias-new-reverse-payment-law-departs-supreme-court-standard-ftc-v-actavis.

[4] Ass'n for Accessible Meds v Becerra, No. 2:19-cv-2281, 2019 US Dist Lexis 223342 (ED Cal 31 December 2019).

[5] Ass'n for Accessible Meds v Becerra, No. 20-15014 (9th Cir 24 July 2020), ECF No. 55-1.

[6] See, eg, *I*n re Loestrin 24 FE Antitrust Litig, 814 F.3d 538, 550 (3d Cir 2016) ('[T]his no-AG agreement falls under Actavis's rule'); Picone v Shire PLC, No. 16-cv-12396, 2017 US Dist Lexis 178150, at *10 (D Mass 20 October 2017) (holding no-AG agreement and a 'sharply discounted royalty rate' may constitute a payment); In re Solodyn Antitrust Litig, No. 14-MD-2503, 2015 US Dist Lexis 125999, at *33–43 (D Mass 14 August 2015) (holding that a settlement and licence agreement with upfront and milestone payments may constitute a payment); In re Aggrenox Antitrust Litig, 94 F Supp 3d 224, 242 (D Conn 2015) (holding that a '"payment" is not limited to cash transfers').

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

[8] *Loestrin*, 814 F.3d at 552 (quoting In re Actos End Payor Antitrust Litig, 2015 US Dist LEXIS 127748, at *61–62 (SDNY 22 Sept 2015)); see also *Opana*, 2016 US Dist. LEXIS 23319, at *29 (ND Ill 25 February 2016).

[9] FTC v AbbVie Inc, 976 F.3d 327, 357 (3d Cir 2020).

[10] id.

[11] In re Humira (Adalimumab) Antitrust Litig, No. 19-CV-1873, 2020 US Dist Lexis 99782, at *57 (ND Ill 8 June 2020).

[12] id. at *57–58.

[13] id. at *58–61.

[14] UFCW Local 1500 Welfare Fund, et al v AbbVie Inc, et al, No. 20-2402 (7th Cir filed 30 July 2020).

[15] In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig, No. 19-md-2895 (D Del 23 July 2020), ECF No. 160.

[16] In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig, MDL No 2895, 2020 US Dist LEXIS 223786, at *17 (D Del 30 November 2020).

[17] id. at *18.

[18] id. at *20.

[19] In re AndroGel Antitrust Litig (No. II), No. 1:09-md-2084, 2018 US Dist Lexis 99716, at *42–43 (ND Ga 14 June 2018); In re K-Dur Antitrust Litig, No. 01-cv-1652, 2016 US Dist Lexis 22982, at *54–62 (DNJ 25 February 2016); In re Loestrin 24 FE Antitrust Litig, No. 13-md-2472, 2019 US Dist Lexis 220262, at *53–54, *62–70 (D RI 17 December 2019); In re Namenda Direct Purchaser Litig, 331 F Supp 3d 152, 198–99 (SDNY 2018); *In re Nexium (Esomeprazole) Antitrust Litig*, 42 F Supp 3d 231, 263–64 (D Mass 2014); King Drug Co of Florence v Cephalon, Inc, 88 F Supp 3d 402, 407–10, 419–21 (ED Pa 2015).

[20] In re Intuniv Antitrust Litig, 496 F Supp 3d 639, 661 (D Mass 2020).

[21] id. at *661–62.

[22] id. at *662.

[23] id.

[24] *I*n re Glumetza Antitrust Litig, No. 19-05822, 2021 US Dist LEXIS 87085, at *33 (ND Cal 6 May 2021).

[25] id. at *36.

[26] id. at *38.

[27] id. at *39–40.

[28] In re Opana ER Antitrust Litig, MDL No. 2580, 2021 US Dist LEXIS 105342, at *83 (ND Ill 4 June 2021).

[29] id. at *84.

[30] id. at *85.

[31] In re Namenda Indirect Purchaser Antitrust Litig, No. 1:15-cv-6549, 2021 US Dist LEXIS 110081, at *75 (SDNY 11 June 2021).

[32] id. at *76.

[33] id. at *77.

[34] id. at *78.

[35] See, eg, In re Glumetza Antitrust Litig, No. 19-05822, 2021 US Dist LEXIS 87085, at *44–55 (ND Cal 6 May 2021); In re Intuniv Antitrust Litig, 496 F Supp 3d 639, 672–77 (D Mass 2020); In re Solodyn (Minocycline Hydrochloride) Antitrust Litig, No. 14-md-2503, 2018 US Dist Lexis 11921, at *20–21 (D Mass 25 January 2018); United Food & Commercial Workers Local 1776 v Teikoku Pharma USA, 296 F Supp 3d 1142, 1156–58, 1160–64 (ND Cal 2017).

[36] In re AndroGel Antitrust Litig (No. II), No. 1:09-md-2084, 2018 US Dist Lexis 99716, at *49–50 (ND Ga 14 June 2018). But see Fresenius Kabi USA, LLC v Par Sterile Prods, LLC, 841 F App'x 399, 404 (3d Cir 2021) ('The analysis of such a hypothetical infringement suit or patent challenge may in some cases be predicted based on binding legal precedents, including statutory and case law. Whether the record permits the District Court to engage in such an analysis of course will be for it to decide'.)

[37] In re Wellbutrin XL Antitrust Litig, 868 F.3d 132, 165 (3d Cir 2017). But see In re Opana ER Antitrust Litig, MDL No. 2580, 2021 US Dist LEXIS 105342, at *89 (ND Ill 4 June 2021) ('Because Endo did not acquire its additional patents until years after the agreement was signed, the additional patents do not break the causal chain.').

[38] In re Wellbutrin XL Antitrust Litig, 868 F.3d 132, 169 (3d Cir 2017).

[39] id. at 168-69.

[40] id. at 166–67.

[41] id. at 167.

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

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

[44] In re Nexium (Esomeprazole) Antitrust Litig, 842 F.3d 34 (1st Cir 2016).

[45] Initial Decision at 85, In the Matter of Impax Labs, Inc, FTC Dkt No. 9373 (11 May 2018).

[46] id. at 114.

[47] id. at 120.

[48] id. at 132.

[49] id. at 145.

[50] Opinion of the Commission at 42, In the Matter of Impax Labs, Inc, FTC Dkt No. 9373 (28 March 2019).

[51] Impax Labs, Inc v FTC, 994 F.3d 484, 488 (5th Cir 2021).

[52] id. at 494–95.

[53] id. at 495.

[54] id. at 496.

[55] id. at 498–500.

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

[57] Abbott Labs v Teva Pharms USA, Inc, 432 F Supp 2d 408, 422 (D Del 2006).

[58] id. at 423–24.

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

[60] See id. at 152 (further holding that 'the fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action').

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

[62] id. at 681–82.

[63] id. at 682–85.

[64] New York v Actavis, PLC, No. 14-cv-7572, 2014 US Dist Lexis 172918, at *118–23 (SDNY 11 December 2014).

[65] id. at *107–08.

[66] New York v Actavis, PLC, 787 F.3d 638, 643 (2d Cir 2015).

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

[68] 787 F.3d at 653–54.

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

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

[71] id. at *11.

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

Sherman Act); see also id. at *34.

[73] id. at *42.

[74] id. at *40.

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

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

[77] In re Asacol Antitrust Litig, No. 15-cv-12730 (D Mass 10 February 2017), ECF No. 279.

[78] In re Asacol Antitrust Litig, No. 15-cv-12730, 2016 US Dist Lexis 94605 (D Mass 20 July 2016).

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

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

[81] See In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig, No. 13-md-2445 (ED Pa).

[82] 'Reckitt Benckiser Group plc to Pay $50 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone', FTC Press Release, 11 July 2019, www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc; see also Stipulated Order for Permanent Injunction and Equitable Relief, *FTC v Reckitt Benckiser Grp*, No. 1:19-cv-28 (WD Va 12 July 2019), ECF No. 3.

[83] 'Reckitt Benckiser Group plc to Pay $50 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone', FTC Press Release, 11 July 2019, www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc.

[84] FTC v Indivior Inc, No. 1:20-cv-00036 (WD Va 24 July 2020), ECF No. 3.

[85] In re Loestrin 24 FE Antitrust Litig, 261 F Supp 3d 293, 307 (DRI 2017).

[86] id.

[87] In re Loestrin 24 Fe Antitrust Litig, No. 13-md-2472, 2019 US Dist Lexis 220262, at *89–91 (DRI 17 December 2019).

[88] id. at *92.

[89] In re Namenda Indirect Purchaser Antitrust Litig, No. 1:15-cv-6549, 2021 US Dist LEXIS 110081, at *126 (SDNY 11 June 2021).

[90] id. (emphasis in original).

[91] In re Namenda Indirect Purchaser Antitrust Litig, No. 1:15-cv-6549 (SDNY 26 July 2021), ECF No. 694.

[92] Patient Protection and Affordable Care Act, Pub L No. 111-148, 124 Stat 119, 309 (2010); see Michael Gallagher and Eugene Hutchinson, 'Elimination of Medicaid Rebate Cap in the Latest COVID-19 Relief Package—The First Legislative Action on Drug Pricing Under the Biden Administration', White & Case LLP, 9 March 2021, https://www.whitecase.com/publications/alert/elimination-medicaid-rebate-cap-latest-covid-19-relief-package-first-legislative.

[93] The Ensuring Innovation Act, S 415, 117th Cong § 1(a)(1) (2021); see Michael Gallagher and Kevin Adam, 'President Biden Signs Legislation Boosting Generic and Biosimilar Drugs', White & Case LLP, 3 May 2021, https://www.whitecase.com/publications/alert/president-biden-signs-legislation-boosting-generic-and-biosimilar-drugs-help.

[94] Advancing Education on Biosimilars Act, S 164, 117th Cong § 2 (2021).

[95] Preserve Access to Affordable Generics and Biosimilars Act, S 64, 116th Cong (2019), https://www.congress.gov/bill/116th-congress/senate-bill/64/text; Affordable Prescriptions for Patients through Promoting Competition Act, HR 4398, 116th Cong (2019), https://www.congress.gov/bill/116th-congress/house-bill/4398/text; Stop STALLING Act, HR 2374, 116th Cong (2020), https://www.congress.gov/bill/116th-congress/house-bill/2374/text; Affordable Prescriptions for Patients through Improvements to Patent Litigation Act, HR 3991, 116th Cong (2019), https://www.congress.gov/bill/116th-congress/house-bill/3991/text.

[96] See Michael Gallagher et al, 'Federal Lawmakers Turn Their Sights to Drug Pricing, Introducing a Package of Bills Seeking Changes to Antitrust and Patent Law', White & Case LLP, 25 May 2021, https://www.whitecase.com/publications/alert/federal-lawmakers-turn-their-sights-drug-pricing-introducing-package-bills.

[97] id.

[98] Press Release, Chairman Frank Pallone, Jr, House Comm on Energy & Com, Pallone Remarks at Legislative Hearing to Lower the Cost of Prescription Drugs (4 May 2021), https://energycommerce.house.gov/newsroom/press-releases/pallone-remarks-at-legislative-hearing-to-lower-the-cost-of-prescription; Lower Drug Costs Now: Expanding Access to Affordable Health Care, Health, Emp, Lab, and Pensions Subcomm of the Comm on Educ and Lab (5 May 2021), https://edlabor.house.gov/hearings/lower-drug-costs-now-expanding-access-to-affordable-health-care; Elijah E Cummings Lower Drug Costs Now Act, HR 3, 116th Cong (2020), https://www.congress.gov/bill/116th-congress/house-bill/3/text.

[99] See The Biden Plan to Protect & Build on the Affordable Care Act, Sec III, https://joebiden.com/healthcare/; Juliette Cubanski et al, A Status Report on Prescription Drug Policies and Proposals at the Start of the Biden Administration, Kaiser Family Foundation (12 February 2021), https://www.kff.org/medicare/issue-brief/a-status-report-on-prescription-drug-policies-and-proposals-at-the-start-of-the-biden-administration/.

[100] Michael Gallagher et al, 'What Does President Biden's 9 July 2013 Executive Order on Competition Mean for the Pharma Industry?', White & Case LLP, 13 July 2021, https://www.whitecase.com/publications/alert/what-does-president-bidens-july-9-2021-executive-order-competition-mean-pharma.

[101] id.

[102] See Remarks by President Biden on How His Build Back Better Agenda Will Lower Prescription Drug Prices (12 August 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/08/12/remarks-by-president-biden-on-how-his-build-back-better-agenda-will-lower-prescription-drug-prices/.

[103] Michael Gallagher et al, 'Uncertainty on Drug Pricing Remains Following Trump Administration Executive Orders', White & Case LLP, 29 July 2020, https://www.whitecase.com/publications/alert/uncertainty-drug-pricing-remains-following-trump-administration-executive-orders?s=drug%20 pricing.

[104] See, eg, Brendan Pierson, 'Federal judge blocks Trump administration drug pricing rule', Reuters (23 December 2020), https://www.reuters.com/article/us-usa-trump-drug-pricing-idUSKBN28X2II.

[105] See Memorandum from Ronald A Klain, Assistant to the President and Chief of Staff to the Heads of Executive Dep't and Agencies on Regulatory Freeze Pending Review (20 January 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/, https://www.federalregister.gov/documents/2021/03/23/2021-05981/implementation-of-executive-order-on-access-to-affordable-life-saving-medications-final-rule-delay.

[106] Nicholas Florko, 'State legislatures are lapping the federal government on drug pricing – even amid the coronavirus', STAT+, 14 April 2020, https://www.statnews.com/2020/04/14/states-drug-pricing-policies/?utm_source=STAT+Newsletters&utm_campaign=e907cd26ff-Daily_Recap&utm_medium=email&utm_term=0_8cab1d7961-e907cd26ff-151170305.

[107] See '2021 State Legislative Action to Lower Pharmaceutical Costs', National Academy For State Health Policy, 22 June 2021, https://www.nashp.org/rx-legislative-tracker/; Michael Gallagher and Kevin Adam, 'Growing Web of State Drug-Pricing Legislation Increases Challenges for Pharmaceutical Manufacturers and Other Industry Participants', White & Case LLP, 19

May 2020, https://www.whitecase.com/publications/alert/growing-web-state-drug-pricing-legislation-increases-challenges-pharmaceutical.

[108] J Mark Gidley et al, 'What's next for drug pricing in the US?', White & Case LLP, 8 June 2021, https://www.whitecase.com/publications/insight/whats-next-drug-pricing-us.

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

[110] Rutledge v Pharm Care Mgmt Ass'n, 141 S Ct 474, 477 (2020) (quoting *Gobeille v Liberty Mut Ins Co*, 577 US 312, 320 (2016)).

[111] id. (quoting *NY State Conference of Blue Cross & Blue Shield Plans v Travelers Ins Co*, 514 US 645, 668 (1995)).

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

[113] See 'Medicaid Program: Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements', Federal Register, 31 December 2020, https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and.

[114] *AMG Capital Mgmt, LLC v FTC*, 141 S Ct 1341 (2021); see Notice of Supplemental Authority in Support of Defendants' Joint Motions to Dismiss Plaintiffs' Federal and State Law Claims and Defendants' Motion For Leave to File a Response in Further Support of Their Notice of Supplemental Authority, *Connecticut et al v Teva Pharmaceuticals USA, Inc*, No. 2:19-cv-02407 (ED Pa 5 May 2021), ECF Nos. 243, 245.

[115] See States' Motion for Leave to File Response to Defendants' Notice of Supplemental Authority and States' Motion for Leave to File Sur-Reply to Defendants' Response in Further Support of Their Notice of Supplemental Authority, *Connecticut et al v Teva Pharmaceuticals USA, Inc*, No. 2:19-cv-02407 (ED Pa 14 May 2021), ECF Nos. 244, 246.

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

[117] See Compl, *BCBSM, Inc d/b/a* Blue Cross and Blue Shield of Minnesota v Vyera Pharmaceuticals, LLC et al, No. 1:21-cv-01884 (SDNY 4 March 2021), ECF No. 1.

[118] In re Insulin Pricing Litig, No. 3:17-cv-0699, 2019 US Dist LEXIS 25185 (DNJ 15 February 2019).

[119] In re Insulin Pricing Litig, No. 3:17-cv-699, 2020 US Dist LEXIS 29345 (DNJ 20 February 2020).

[120] See Third Amended Class Action Compl, *In re Insulin Pricing Litig*, No. 3:17-cv-0699 (DNJ 20 April 2021), ECF No. 411.

[121] In re EpiPen Direct Purchaser Litig, No. 20-cv-02827, 2021 WL 147166 (D Minn 15 January 2021).

[122] Consolidated Class Action Compl, *In re EpiPen Direct Purchaser Litig*, No. 20-cv-00827 (D Minn 14 August 2020), ECF No. 76.

[123] id.; see also Allan Thoen and Callan Stein, 'EpiPen Ruling Could Embolden Private Anti-Kickback Claims', Law360.com, 1 March 2021, https://www.law360.com/articles/1359903/epipen-ruling-could-embolden-private-anti-kickback-claims.

[124] See supra note 121; see also Thoen and Stein supra note 123; *Rochester Drug Co-Operative, Inc v Eli Lilly & Co* (*In re Direct Purchaser Insulin Pricing Litig*), No. 3:20-cv-3426, 2021 US Dist LEXIS 128571, at *59 (DNJ 9 July 2021).

[125] 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?m=1.

[126] id.

[127] id; 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.

[128] See supra note 125.

[129] See, eg, AstraZeneca Pharmaceuticals LP v Azar et al, No. 21-cv-00027 (D Del 16 June 2021).

[130] id. at 17.

[131] The Biologics Price Competition and Innovation Act was enacted as part of the Patient Protection and Affordable Care Act, Pub Law No. 111-148, 124 Stat 119 (2009).

[132] Compl at paragraph 55, *Pfizer, Inc v Johnson & Johnson*, No. 2:17-cv-4180 (ED Pa 20 September 2017), ECF No. 1.

[133] Pfizer Inc v Johnson & Johnson, 333 F Supp 3d 494, 502 (ED Pa 2018).

[134] See, eg, Class Action Compl paragraph 6, *UFCW Local 1500 Welfare Fund v AbbVie*, No. 1:19-cv-1873 (ND Ill 18 March 2019), ECF No. 1.

[135] In re Humira (Adalimumab) Antitrust Litig, 465 F Supp 3d 811, 827 (ND Ill 8 June 2020).

[136] id.

[137] UFCW Local 1500 Welfare Fund v AbbVie, No. 20-2402 (7th Cir filed 30 July 2020).

[138] Fresenius Kabi USA, LLC v Par Sterile Prods, LLC, 841 F App'x 399 (3d Cir 2021).

[139] Fresenius Kabi USA, LLC v Par Sterile Prods, LLC, No. 16-4544, 2017 US Dist LEXIS 19084, at *3–4 (DNJ 10 February 2017).

[140] id. at *4.

[141] Fresenius Kabi USA, LLC v Par Sterile Prods, LLC, No. 16-4544, 2020 US Dist LEXIS 32034, at *8–9, *14–15 (DNJ 25 February 2020).

[142] 841 F App'x at 403–04.

[143] id. at 404 n.12.

[144] Id.

[145] United Ass'n of Plumbers & Pipefitters Local 322 of S NJ v Mallinckrodt ARD, LLC, No. 20-188, 2020 US Dist LEXIS 148343, at *4, *8 (DNJ 18 August 2020).

[146] id. at *39–42.

[147] id. at *45–48, *57–58.

[148] See, eg, Mylan Pharmaceuticals Inc v Teva Pharmaceuticals Industries Ltd et al, No. 2:21-cv-13087 (DNJ).

[149] Brenda Sandburg, 'US FTC Removing 'Handcuffs' To Pursue Pharma Companies, PBMs For Antitrust Violations', PinkSheet (21 July 2021); see also Statement of Acting Chairwoman Rebecca Kelly Slaughter, Regarding the FTC's Report to Congress on Rebate Walls (28 May 2021) ('The Commission should consider ways to build on this work by addressing emerging and evolving practices that have the potential to harm consumers. We must carefully scrutinize anticompetitive exploitation of market power throughout the pharmaceutical supply and payment chains, including the rebating practices discussed in the Commission report'.).

[150] White & Case LLP was counsel of record for two pharmaceutical company defendants in the US Supreme Court in *FTC v Actavis*. In addition, White & Case LLP represents several of the parties in the following cases discussed in this article: AndroGel, Aggrenox, Asacol, Doryx, Effexor, EpiPen, Humira, K-Dur, Lidoderm, Lipitor, Loestrin, Namenda, Remicade and In re Generic Pharmaceuticals Pricing Antitrust Litigation. No statement in this article may be imputed to any client in those actions or any other client of White & Case LLP. No client of White & Case LLP contributed to this article.

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