United States: Pharmaceutical Antitrust

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Introduction

The past year has continued to see an increase in US case law developments in the area of pharmaceutical antitrust. This article focuses on four areas of pharmaceutical antitrust litigation that have been most active:

- US trial and appellate court decisions adjudicating antitrust claims under the rule of reason test announced by the US Supreme Court in *Federal Trade Commission* (FTC) *v Actavis* for innovator and generic settlements of pharmaceutical patent litigation involving alleged reverse payments or 'pay-for-delay';
- product-hopping antitrust claims against innovator pharmaceutical companies that introduce new versions of brand-name drugs facing generic competition;
- challenges to pharmaceutical manufacturers' pricing practices; and
- recent challenges regarding certain contracting practices (eg, exclusive dealing and bundling), including the first antitrust challenge concerning biosimilar competition, and the risk evaluation and mitigation strategies programme.

Reverse payment case law under Actavis

The US Supreme Court's June 2013 decision in *FTC v Actavis* opened a floodgate for more than 25 separate antitrust cases that have been filed or revived under the Supreme Court's newly announced rule of reason approach to claims 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 under which parties could settle for any entry date within the patent's term regardless of any contemporaneous financial consideration from the innovator to the generic, but the majority opinion likewise rejected the FTC's proposed 'quick look' rule of presumptive unlawfulness for any alleged reverse payment settlement. Instead, the Supreme Court charted a middle course, holding that 'the FTC must prove its case as in other rule-of-reason cases.'[1]

Actavis was categorical only in its rejection of the more presumptive rules that had been proposed to the court. *Actavis*'s adoption of the rule of reason followed from the Supreme Court's decidedly non-committal view that 'reverse payment settlements such as the agreement alleged in the complaint before us can sometimes violate the antitrust laws.'[2] Indeed, the majority opinion uses the word 'sometimes' six times in its analysis.

While the Supreme Court repeatedly inveighed against 'large and unjustified' payments as the competitive concern, the justices nonetheless 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.*[3]

Actavis expressly delegated to the lower courts the task of figuring out how to apply the rule of reason to alleged reverse payment settlements, and in the few years since, we have seen conflicting district court decisions, the first jury verdict under *Actavis*, the first appellate decisions and record-setting settlements with private plaintiffs as well as the FTC. As discussed below, the only certainty thus far under *Actavis* is that the reverse payment waters are far from settled.

Pleading standards under Actavis

Following the Supreme Court's *Actavis* decision, two federal district courts concluded that a 'payment' under *Actavis* must be a cash transfer from a brand to a generic competitor, and thus rejected allegations that a no-authorised generic agreement (no-AG) was subject to *Actavis*.[4] However, the US Court of Appeals for the Third Circuit in *Lamictal* – the first federal appellate court to apply *Actavis* to an alleged reverse payment of any kind – reversed, holding that:

> *this no-AG agreement falls under Actavis's rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition.*[5]

The Third Circuit reasoned that the no-AG agreement could potentially be worth hundreds of millions of dollars to the generic challenger and such an agreement 'may be as harmful as those resulting from reverse payments of cash'.[6] The defendants sought review by the US Supreme Court, asking the court to address the uncertainty surrounding the types of agreements covered by *Actavis*, but the petition was denied.[7]

Like the Third Circuit, the US Court of Appeals for the First Circuit in *Loestrin* subsequently held that a similar no-AG agreement was subject to *Actavis*, explaining that a 'payment' includes 'a much broader category of consideration than cash alone'.[8] While the First Circuit recognised the difficulty in computing the value of non-cash payments, the court explained that antitrust litigation requires such an 'elaborate inquiry into the reasonableness of a challenged business practice'.[9]

Other federal district courts have also denied motions to dismiss, concluding that a 'payment' under *Actavis* may include no-AG agreements as well as other non-cash transfers that have value, such as co-promotion, licensing and distribution agreements.[10] For example, in *Intuniv*, the US District Court for Massachusetts denied a motion to dismiss where the plaintiff alleged that in addition to a no-AG agreement, the first Abbreviated New Drug Application

(ANDA) filer for generic Intuniv paid the brand company too little under a licence agreement that permitted generic entry prior to patent expiration.[11] The court recognised that other 'courts have explicitly held that no-AG agreements can constitute illegal reverse payments',[12] and a 'sharply discounted royalty rate could permit the generic company to keep a portion of the profits that it otherwise would have turned over to the brand company, had the royalty reflected the competitive market rate'.[13] This case has proceeded to discovery.

In contrast, the US District Court for the Eastern District of Pennsylvania dismissed allegations that a settling generic company received a 'payment' under *Actavis* by paying the brand company too little for a product or service. In *FTC v AbbVie*, a patent settlement for AndroGel signed contemporaneously with a supply agreement in which the generic company, Teva, paid the brand company, Abbott, to supply an authorised generic version of TriCor at a price based on Abbott's cost, plus a royalty on Teva's profits.[14] Despite 'something of large value pass[ing] from Abbott to Teva', the court reasoned that something of value flows both ways in any contract and reverse payments under *Actavis* are not so broad 'as to include the opportunity afforded Teva to buy TriCor in the supply contract before [the court] and then sell it to the public in competition with Abbott'.[15] The FTC's motion to reconsider the dismissal – based on the subsequently decided Third Circuit decision in *Lamictal* – was denied, and the FTC's motion for partial final judgment under Rule 54(b) to appeal the dismissal was also denied. The FTC's remaining sham litigation claims proceeded to trial and on 29 June 2018 the court ordered disgorgement of US$448 million.[16]

Another issue that litigants have grappled with following *Actavis* is how precise must a plaintiff allege monetary estimates of value transferred between the patentee and generic challengers. For example, the US District Court for the Northern District of California in *Lidoderm* held that the plaintiffs sufficiently alleged a 'payment' where the 'settlement states that the patentee shall give the infringer Brand Product of value totalling US$12 million per month' for a term of eight months.[17] The court held that the specific, quantifiable allegation of a reverse payment stated a claim under *Actavis*, observing that this 'term is not a complex, multifaceted payment; rather, it is a simple transfer of a fungible product. Calculating its value is straightforward, and plaintiffs have plausibly alleged facts sufficient to support their calculations'.[18] In *Opana*, the US District Court for the Northern District of Illinois observed that while 'a plaintiff must provide at least a rough estimate of the value of the reverse payment and anticipated litigation costs, the court is also aware that a precise valuation may require discovery, as it will likely depend on evidence in defendants' exclusive possession and on expert analysis'.[19] In another example, the district court in *Loestrin*, after remand from the First Circuit, found that some plaintiffs 'value the sum of the deals' with the first ANDA filer to be worth 'tens or hundreds of millions' and other plaintiffs value it at US$216 to US$266 million.[20] The court explained that these figures are sufficiently 'precise estimates of value' at the pleading stage, noting that discovery would be needed for the plaintiffs to provide 'a step-by-step calculation of how they reached those figures'.[21]

In the consolidated *Lipitor* and *Effexor* appeals, the Third Circuit reversed the lower court's dismissals, rejecting a 'heightened pleading standard' where 'the size of the reverse payment must be determined by the net reverse payment, which accounts for litigation costs and other discounting measures and justifications for the payment'.[22] The court explained that to 'plausibly allege an unjustified reverse payment, an antitrust plaintiff need only allege the absence of a "convincing justification" for the payment',[23] and '*Actavis* does not require antitrust plaintiffs to come up with possible explanations for the reverse payment and then rebut those explanations in response to a motion to dismiss'.[24] The brand company petitioned the US Supreme Court to review the decision, arguing that the Third Circuit's decision let the plaintiffs 'cherry-pick isolated terms in otherwise routine patent litigation settlement agreements' to pursue an antitrust challenge,[25] but the petition was denied in February 2018 and the cases have proceeded to discovery.[26]

In a subsequent appeal in *Lipitor*, the Third Circuit affirmed the dismissal of reverse payment claims asserted under California's Cartwright Act.[27] The Third Circuit held that 'a reverse settlement may not be attached on a per se basis', recognising that the California Supreme Court's *In re Cipro I & II* decisions[28] adopted *Actavis* and applied it to the Cartwright Act.[29] The plaintiff's 'attempts to escape *Cipro*'s reach by arguing that the agreement between Pfizer and Ranbaxy was not a reverse payment at all' was based on the theory that the agreements allegedly 'only covered the time period following the expiration of the *Lipitor* patent'.[30] The court disagreed, explaining that 'the settlement agreement's basic attributes, which cannot be ignored, reveal that it was a straightforward reverse settlement', that Lipitor was covered by at least five other patents during the relevant period and whether Ranbaxy could have designed around these later-expiring patents to produce a non-infringing generic version of Lipitor is a relevant consideration under the rule of reason.[31]

Finally, two district courts have dismissed reverse payment claims for lack of approval by the US Food and Drug Administration (FDA). In *Asacol*, the US District Court for Massachusetts dismissed a reverse payment claim because the generic company still had not obtained FDA approval by the settlement entry date and, therefore, the plaintiffs could not claim antitrust injury even if the generic could have negotiated an earlier entry date.[32] Similarly, in *Solodyn*, the US District Court for the District of Massachusetts partially dismissed a reverse payment claim as to one of the settlement agreements at issue, because the generic did not receive FDA approval for one of the two drugs at issue until a few days after the agreed-upon settlement entry date.[33] As discussed below, both of these cases proceeded past summary judgment on other antitrust claims.

Evaluating evidence and remedies under Actavis

Turning to the summary judgment context, two district courts have denied summary judgment where the plaintiffs' causation theories of earlier generic entry were at issue. In *Solodyn*, where the settlement and business agreements at issue allegedly totalled over US$63 million in payments,[34] the court held that the plaintiffs had presented sufficient evidence to support their at-risk launch theory that the generic defendant would have launched its product prior to the conclusion of the patent litigation absent the allegedly anti-competitive settlement.[35] The plaintiffs had raised a genuine dispute about the invalidity of the patent and non-infringement,[36] and there was evidence that the generic company obtained board approval to launch at risk, took orders from customers and manufactured a three month supply.[37] The court also found the plaintiffs' other but-for theory – a no-payment settlement agreement with an earlier generic entry date – had sufficient support based on discussions of earlier generic launch dates during settlement negotiations, internal business document, and economic expert opinion.[38] The case proceeded to trial in early 2018, but Impax settled mid-trial with the remaining the end-payor plaintiffs for US$20 million.[39]

In *Lidoderm*, the US District Court for the Northern District of California reached a similar result as to a no-AG agreement allegedly worth around US$250 million.[40] The court permitted the plaintiffs' at-risk theory to proceed to trial based on contemporaneous evidence from the defendants as well as expert opinion about the patent's invalidity, but found 'that Watson could not have won on non-infringement'.[41] The court also permitted the plaintiffs' no-payment settlement theory based on economic expert testimony that applied 'accepted principles in antitrust law and settlement analysis to evidence in this case'.[42] The court reasoned that the 'defendants do not point to any specific evidence considered or assumptions made by the experts that are contrary to evidence in the record.[43] The defendants eventually settled with the remaining plaintiffs, a certified class of direct purchasers, for a total of US$166 million.[44]

Unlike *Solodyn* and *Lidoderm*, the US District Court for the Northern District of Georgia in *AndroGel*, rejected the plaintiffs' at-risk launch theory because:

> *in relation to this particular case, arguments which depend on determining what the ultimate outcome of the underlying patent litigation would have been are simply too procedurally burdensome and speculative to serve as valid theories of causation under Actavis.*[45]

The court, however, permitted the plaintiffs' no-payment settlement theory because they offered certain expert opinions about why the brand company 'crafted the settlement with *Actavis*'.[46] The expert testimony, for example, evaluated the merits of the underlying patent litigation to address what a competent patent attorney would have advised the defendants about their chances of winning, and other economic experts looked to the terms of the actual settlement agreement to conclude that 'it would have been economically rational for [the brand company] to settle even without a reverse payment' for an earlier generic entry date.[47] As to the FTC's related case on remand from the Supreme Court, the court observed that the FTC only needs to prove an antitrust violation and the plaintiffs satisfied their prima facie burden of showing antitrust harm with evidence of a US$12 million payment, expert testimony that the contemporaneously executed business agreement at issue 'was out of step with industry practice and the Generics' regular business practices', and other evidence from the negotiation and implementation of that business agreement.[48] No trial date has been scheduled.

Following summary judgment, the district court denied the direct purchaser plaintiffs' motion to certify a class of 33 proposed members for lack of numerosity. Despite the plaintiffs' argument about geographic dispersion of the class, the court reasoned that 'unlike the typical class action, in which there are a number of individual plaintiffs with relatively small claims, the plaintiffs' proposed class consists of very large, sophisticated companies with very large claims'.[49] The court explained that this 'means that even though these proposed plaintiffs are widely distributed, they also have the means and the motivation to join this action if they so choose . . . .'[50] The court rejected the plaintiffs' arguments about negative value claims and retaliation, and also observed that other courts have declined to certify classes in similar situations.[51]

In contrast, the US District Court for the Eastern District of Pennsylvania in *Wellbutrin* granted summary judgment to the defendants for lack of causation where the settlement allegedly included a US$35 million payment and a no-AG agreement allegedly worth US$200 million, rejecting the plaintiffs' at-risk launch and no-payment settlement theories.[52] On appeal, the US Court of Appeals for the Third Circuit affirmed, holding that the plaintiffs did not establish antitrust injury because the plaintiffs 'did not take into account Andrx's blocking patent' and it is not enough 'to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal'.[53] 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'.[54] Notably, the size of the reverse payment alone was an insufficient 'surrogate' for the weakness of the patent.[55] The court 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.[56] The court reasoned that the plaintiffs failed to point to evidence showing 'it is more likely than not that Anchen would have obtained a license' and it is possible that 'negotiations would have stalled and failed'.[57]

Other summary judgment decisions have focused on whether business agreements executed contemporaneous with settlements are 'large and unjustified'. For example, the US District Court for the District of New Jersey in *K-Dur* denied summary judgment where the parties settled and Schering agreed to pay Upsher, the first ANDA filer, US$60 million for a licence to Niacor as well as other licences.[58] Although the court recognised that the defendants 'have offered evidence that could persuade a reasonable jury that Schering paid fair market value for Niacor, and that the payment at issue in the *Schering/Upsher* settlement did not compensate Upsher for delaying its market entry', the plaintiffs had evidence that the licensing agreements lacked terms usually present in such a licensing agreement, lacked due diligence and the payment was significantly above fair market value.[59] The court, however, granted summary judgment in favour of Schering as to the plaintiffs' related claims for Schering's settlement with the second ANDA filer *ESI/Lederle* because 'one party's motivations in entering into a settlement are not evidence of a conspiracy', even where settlement with both Upsher and ESI was allegedly necessary to guarantee no generic competition.[60] After summary judgment, the remaining parties settled for US$60 million.[61]

In *Modafinil*, the four settlement agreements at issue included various licensing agreements with royalty and milestone payments, ranging from US$25 million to over US$164 million.[62] The court denied summary judgment, reasoning that while Cephalon will have vigorous pro-competitive responses, the plaintiffs had evidence of the patent's weakness, expert opinion about 'unnecessary and unwanted' services, evidence that payments were two to three times higher than normal and demonstrated disregard for corporate principles and due diligence.[63] Cephalon later settled with the FTC, agreeing to injunctive relief and a record-setting US$1.2 billion fine, subject to a credit for settlements reached in related private actions,[64] including prior settlements for US$512 million and US$96.5 million.[65] The size of the fine was driven by the court's prior decision to permit the FTC to proceed with a disgorgement claim estimated between US$3.5 billion and US$5.6 billion.[66] Meanwhile, Ranbaxy proceeded to trial, but the parties settled mid-trial.[67] The remaining parties are scheduled for trial in October 2018.

Notably, in late 2017, the scope of the *Cephalon* injunction became the focal point of a summary judgment motion in *FTC v Actavis*. Following Teva Pharmaceutical Industries Ltd's acquisitions of Cephalon and Actavis Holdco US Inc, Actavis argued that the FTC's case against Actavis 'is now moot because it has since become covered by the *Teva* Injunction and any additional relief

sought by the FTC is merely redundant'.[68] The court disagreed, reasoning that:

> *The FTC has outlined three potential types of relief it seeks in addition to the activities enjoined in the Teva Injunction: (1) a ban on no-AG agreements, (2) an advance notice provision, and (3) an extended injunction period beyond the expiration of the Teva Injunction. Contrary to Actavis' argument, the court explained, none of these remedies are redundant, and all three are well within the Court's authority to grant.*[69]

The court, however, cautioned that 'the mootness doctrine inquires into a court's authority to order a remedy, not the likelihood or appropriateness of that remedy under particular circumstances'.[70]

In *Nexium*, the court denied summary judgment where the plaintiffs had calculated the reverse payment to be US$22 million and the business agreements at issue were negotiated contemporaneous with the settlement, 'essentially provided a steady flow of revenue to Ranbaxy' during the same period it agreed not to launch its generic Nexium product, and 'even if Ranbaxy had won its litigation instead of settling, Ranbaxy would not have secured such favourable arrangements'.[71] But in the first reverse payment trial since the Supreme Court's *Actavis* decision – 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.[72] The jury's verdict was affirmed on appeal.[73]

More recently, following a bench trial, 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).[74] The SLA included a no-AG provision and a potential cash credit in the event that Opana sales fell below a certain threshold, valued together at US$33 to US$43 million.[75] The DCA was executed contemporaneous with the SLA and provided an upfront 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.[76]

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'.[77] The ALJ rejected the FTC's evidence purportedly showing inadequate due diligence, unusual terms and linkage to the SLA.[78] Rather, the ALJ found that:

- Endo and Impax had an established business interest in Parkinson's disease;
- the parties previously entered into risky early stage collaboration agreements;
- Endo analysed the merits of the deal;
- Impax continued its development efforts years after executing the DCA; and
- Endo did not consider the upfront payment to be uncharacteristically large.[79]

Despite finding that the SLA was 'large and unjustified', the ALJ concluded that any anticompetitive harm was outweighed by pro-competitive benefits. The ALJ held that the 'evidence shows that 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 until the last of Endo's patents expires in 2029' and 'absent the SLA, such after-acquired patents also would have been successfully asserted to enjoin Impax from selling generic Opana ER'.[80] In May 2018, the FTC filed a notice of appeal, which is pending before the FTC commission.[81]

Product-hopping antitrust cases

In recent years, plaintiffs have begun using the antitrust laws to challenge brand manufacturers' introduction of new versions of existing drugs. In these so-called 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.

Regulatory background

Under the Hatch-Waxman Act, generic manufacturers seeking FDA approval to market a generic version of a drug can submit an abbreviated new drug application demonstrating that the generic is bioequivalent to the brand drug (ie, the generic product delivers the active ingredient into the bloodstream in a similar concentration over a similar amount of time as the brand drug), thereby forgoing the need to conduct the lengthy and expensive clinical trials undertaken by the brand manufacturer. Generic drugs with bioequivalence are typically AB-rated to the brand drug, which means that the drug is deemed pharmaceutically equivalent in terms of dosage strength and drug formulation (eg, capsule, tablet, oral liquid).

States have enacted drug substitution laws that govern when a generic version of a drug may or must be substituted for the brand drug by the pharmacist, many of which link the substitutability of the generic drug to its AB-rating. In lieu of traditional forms of marketing, generic manufacturers typically rely on these state substitution laws to automatically substitute their generic products for the brand product. To the extent the brand manufacturer introduces a newer, improved formulation of a drug that is not deemed pharmaceutically equivalent to the older version against which the generic drugs are AB-rated, generic manufacturers may not be able to take advantage of state substitution laws to automatically obtain sales when a physician writes a prescription for the newer version. Plaintiffs in product-hopping cases claim that this forecloses competition.

Pre-2015 cases: TriCor, Prilosec and Suboxone

Only a handful of decisions have dealt with product-hopping claims in the pharmaceutical context, most of which were at the motion to dismiss stage. In the earliest of these decisions, *Tricor*, the court rejected the defendants' assertions that any product change that is an improvement is per se legal under the antitrust laws.[82] 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 their antitrust claims.[83]

In *Prilosec*, the 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.[84]

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.[85]

In *Suboxone*, the purchaser plaintiffs alleged that the defendants unlawfully shifted patients from Suboxone tablets to Suboxone film by falsely disparaging and fabricating safety concerns about the tablet, and by removing Suboxone tablets from the market just as generic versions of the tablets were set to enter the market. The court denied the defendants' motion to dismiss 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]'.[86] The court determined that the defendants' conduct fell somewhere in between the conduct at issue in *TriCor* and *Prilosec*. 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.[87] 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.[88] The case is still in discovery.

Two appellate decisions: Namenda and Doryx

Namenda I and *Doryx* were the first cases to address pharmaceutical product-hopping claims beyond the motion to dismiss stage. In *Namenda I*, the US District Court for the Southern District of New York granted a motion for a preliminary injunction on a limited record related to product-hopping claims as to the defendants' plan to transition patients from an older, twice-daily drug to a newer, once-daily formulation.[89] Unlike in *TriCor* and *Suboxone*, in which the defendants fully removed the older formulation from the market, the *Namenda I* defendants planned to continue making the older formulation available to any patient who had a medical need for it. Nonetheless, the *Namenda I* court held that the plaintiffs had met their 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.[90]

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 product-hopping may violate the Sherman Act.[91] Despite the continued availability to any patient with a need for the older formulation, the Second Circuit affirmed the district court, and cited *Berkey Photo*[92] 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.[93] 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.[94]

The *Doryx* court 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), coupled with the subsequent discontinuation of older versions constituted anticompetitive product-hopping. The court denied the defendants' motion to dismiss on the grounds that it would be required to consider facts beyond the pleadings to decide the product-hopping issue.[95] 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.[96]

Ultimately, after full discovery, the 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.[97] 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.[98] 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.[99] In 2016, the US Court of Appeals for the Third Circuit affirmed the lower court's grant of summary judgment in the defendants' favour.[100]

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.[101]

In *Asacol*, the purchaser plaintiffs alleged that the defendants engaged in a product hop that thwarted generic competition for branded drug Asacol by first introducing and promoting Asacol HD (a high-dose version of Asacol), years later introducing the drug Delzicol with the same active ingredient and dose as Asacol, and shortly thereafter removing Asacol from the market prior to the entry of generic Asacol products. Relying on *Namenda I*, 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.[102] 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 withdrew Asacol from the market shortly after introducing the close substitute Delzicol.[103] The court did not revisit the legal framework for product-hopping claims at summary judgment, and the case is now trial-ready.

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 that had been 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.[104]

Challenges to pharmaceutical manufacturers' pricing practices

In recent years, enforcement agencies, private plaintiffs and legislators – with help from the media – have continued to pressure brand and generic pharmaceutical manufacturers regarding high drug prices. Federal and state investigations have resulted in criminal and civil enforcement actions, and private litigation has also ramped up, mostly in the form of claims alleging agreements to fix prices. The push for both state and federal legislation to address drug prices has also increased, with numerous states proposing (and some passing) various price-transparency laws, which require drug manufacturers to disclose certain information to justify their prices, while the federal government continues to wrestle with proposed legislation of its own. Over the past year specifically, as litigation regarding the alleged price fixing of generic drugs moves through the early stages of motions to dismiss and various discovery stays, much of the focus on drug prices has shifted to these potential legislative remedies.

This section analyses the major developments in the area of drug pricing since our last update, with a specific focus on:

- federal and state legislative and regulatory activity;
- federal and state enforcement actions and congressional investigations; and
- private litigation regarding drug prices.

Federal legislative and regulatory activity

Over the last year, pressure for legislation on drug prices has mounted at the federal level. And while there have been a number of bills introduced in the house and senate targeting issues concerning drug prices – including proposals such as allowing for the importation of drugs from foreign countries, allowing Medicare to negotiate prices under Part D, and providing incentives to increase competition in the generic marketplace – to date, none of those bills have been successful.[105] The Fair Accountability and Innovative Research (FAIR) Drug Pricing Act is widely considered to be the most notable congressional attempt to require enhanced transparency from drug companies regarding drug prices.[106] Under the bill, which was drafted by Tammy Baldwin (Democrat, Wisconsin) and John McCain (Republican, Arizona), a pharmaceutical company seeking to raise the price of a drug by 10 per cent or more in a single year, or by 25 per cent over three years, would be required to provide extensive reports detailing justifications for the increase. The bill also would require drug companies to inform the US Department of Health and Services 30 days in advance of any price increase and provide them with transparency reports that would be posted publicly. Although drug companies are not prohibited from raising prices, the legislation provides for a fine of US$100,000 per day for failure to comply with FAIR's reporting requirements. Despite being introduced in the first half of 2017, however, the bill has languished. In fact, in May 2018, Senators Baldwin and McCain sent President Trump a letter urging him to follow through on his campaign promise to lower drug prices by backing FAIR.[107]

In May 2018, the Trump administration unveiled its plans to assist with lowering prescription drug prices in the United States.[108] The proposed plan, titled the 'American Patients First Plan',[109] included a number of high-level ideas on lowering drug prices, such as:

- possibly allowing Medicare to pay different amounts for the same drug, depending on the illness treated;
- 'value-based purchasing' for federal programmes;
- making generic drugs free for some low-income elderly patients on Medicare;
- passing on a portion of the rebates typically paid to insurers or pharmacy benefit managers to consumers;
- raising prices for drugs in foreign countries to reduce prices in the United States; and
- lifting restrictions on pharmacists communicating to patients about less-expensive alternatives.[110]

President Trump also targeted supposed efforts by brand manufacturers to limit the availability of brand drugs to generic manufacturers for testing, which he implied could delay potential generic competition. As discussed below, the FDA has also addressed similar alleged conduct related to the Risk Evaluation and Mitigation Strategy (REMS) requirements.

State legislation

In the last year, a number of states have passed new laws targeting issues concerning drug pricing,[111] two of which are particularly notable because they went well beyond some of the general price-transparency laws that were passed over the past few years in states such as Vermont, Florida, California and Nevada.

First, and likely most notable, is Maryland's HB 631, often referred to as the 'price gouging' law. In summary, HB 631, 'An Act concerning Public Health – Essential Off-Patent or Generic Drugs – Price Gouging – Prohibition', prohibits generic drug manufacturers, or wholesale distributors, from making 'unconscionable' increases in the price of an 'essential off-patent or generic drug'. The law authorised the Maryland Medical Assistance Program (MMAP) to notify the Maryland Attorney General of a price increase for a drug when:

- the wholesale acquisition cost (WAC) of a prescription drug increased by at least 50 per cent within the preceding one-year period, or when the price paid by MMAP would increase by at least 50 per cent within the preceding one-year period; and
- the WAC for either a 30-day supply or a full course of treatment exceeded $80.

The law provides the Maryland Attorney General power to bring civil claims for violations of the law.[112] In July 2017, the Association for Accessible Medicines (AAM) filed suit seeking declaratory and injunctive relief against the implementation and enforcement of HB 631, claiming that the law was unconstitutional because it both violated the dormant commerce clause, by regulating commerce entirely outside Maryland, and was impermissibly vague in violation of due process. The district court ruled for the state, upholding HB 631 as constitutional, and AAM appealed to the Fourth Circuit. In a 13 April 2018 decision, the Fourth Circuit reversed, concluding that HB 631 'effectively seeks to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland', in violation of the dormant commerce clause.[113] Moving forward, it remains to be seen how, if at all, other states will seek to target similar conduct without running afoul of constitutional restrictions.

The other notable state law development is Vermont's Senate Bill 175 that allows for the importation of prescription drugs from Canada, in an effort to reduce prescription drug prices in the state. Passed in May 2018, Senate Bill 175 requires:

> [Vermont's] *Agency of Human Services, in consultation with interested stakeholders and appropriate federal officials,* [to] *design a wholesale prescription drug importation program that complies with the applicable requirements of 21 USC § 384, including the requirements regarding safety and cost savings.*[114]

Senate Bill 175 includes a number of elements, but most notably the bill designates the state of Vermont to be a licensed drug wholesaler, or to contract with a licensed wholesaler, to use regulated Canadian prescription-drug suppliers to secure prescription drugs that meet FDA standards. While federal law generally bars importation of prescription drugs into the United States,[115] supporters of the bill contend that section 804 of the Federal Food, Drug, and Cosmetic Act provides an exception,[116] teeing up what might be a dispute between Vermont and the FDA.

Federal and state enforcement actions

Following a two-year investigation into the pharmaceutical industry, the US Department of Justice (DOJ) filed criminal charges in December 2016 against two former Heritage Pharmaceuticals Inc executives.[117] The DOJ alleged that Heritage's former CEO Jeffrey Glazer and former president Jason Malek conspired to fix prices with competitors and divide the customer base for doxycycline hyclate and glyburide. More specifically, prosecutors asserted that Glazer and Malek sought to allocate customers for doxycycline from April 2013 to December 2015 and for glyburide from April 2014 to December 2015 with competing pharmaceutical corporations, effectively forcing consumers to pay collusive and non-competitive prices.[118] In January 2017, Glazer and Malek each pleaded guilty to a two-count price-fixing felony charge in Pennsylvania federal court.[119] Both Glazer and Malek have signed cooperation agreements, and their testimony may play a role in ongoing antitrust investigations into the generic drug industry.[120] Heritage has initiated a racketeering suit against Glazer and Malek and announced that it is cooperating with the DOJ's ongoing investigation.[121] With the 'Yates Memo' encouraging the prosecution of individuals for corporate crimes, additional prosecutions of individual executives for price fixing may also be forthcoming.

Following the January 2017 guilty pleas by the two Heritage executives, the Connecticut Attorney General and 19 states filed a civil complaint in US District Court for the District of Connecticut against Heritage, Mylan, Teva and three smaller pharmaceutical corporations, charging that these companies colluded to dramatically increase the price of doxycycline hyclate and glyburide.[122] The complaint, which seeks both disgorgement and a permanent injunction, alleges that generic manufacturers used frequent industry conferences, trade shows and dinners to meet with competitors and agree, in one form or another, to raise prices for certain generic doxycycline and glyburide. In October 2017, the litigation expanded further, growing to a total of 46 state attorneys general, 12 additional drug companies and 13 more generic drugs. In early 2018, Eastern District of Pennsylvania Judge Cynthia M Rufe extended a stay of discovery in the case pending an ongoing DOJ investigation. Motions to dismiss are still pending as of July 2018.

Another area of focus in the last year has been investigations into patient-assistance programmes, which generally provide cost-sharing assistance to insured patients with high prescription-drug expenses. These programmes, largely funded by drug manufacturers, are often criticised for being a means of inflating drug prices. Moreover, these programmes, originally criticised by the Department of Health and Human Services' Office of the Inspector General, have caught the attention of the DOJ, which subpoenaed more than 20 manufacturers regarding their patient-assistance practices in the last few years. Following these investigations, starting at the end of 2017, Aegerion Pharmaceuticals, Inc and United Therapeutics both reached settlements with the DOJ regarding their patient-assistance programmes.[123]

Private litigation

To date, there have only been a handful of private litigations targeting high drug prices. The only case to reach the motion-to-dismiss stage involves the generic blood pressure medication propranolol hydrochloride – the generic equivalent of the branded drug Inderal. In that case, the direct and indirect purchasers' consolidated class action complaint alleges several generic drug manufactures entered separate price-fixing conspiracies for the capsule and tablet forms of generic propranolol. In April 2017, the court largely denied the defendants' motion to dismiss. The court held that a conspiracy could be inferred on the basis of 'conscious parallelism' where interdependent conduct was accompanied by circumstantial evidence and 'plus factors', which it concluded the plaintiffs had sufficiently pleaded, including:

- a motive to increase prices;
- that the price increases were against the defendants' own self-interest;
- that the defendants communicated at trade association meetings; and
- that there were ongoing state and federal investigations into the manipulation of generic drug prices, including the price of propranolol.[124]

The court dismissed several state-law claims, finding that, among other things, indirect purchasers lacked standing to bring consumer-protection claims under the laws of those states in which they did not indirectly purchase, pay, or reimburse for propranolol. This litigation subsequently was transferred to the multi-district litigation in the US District Court for the Eastern District of Pennsylvania.[125]

Brand name drug manufacturers also have been the target of putative class action lawsuits alleging collusive price fixing. In California, a proposed class of consumers filed an action against Novo Nordisk, alleging the company inflated the list price of Type 2 diabetes medicine, Victoza, in an effort to subsidise higher rebates to pharmacy benefit manager (PBM) OptumRX.[126] The theory is that, because PBMs demand rebates from drug makers in exchange for more favourable formulary placement, Novo responded by increasing its drug price to cover the rebates and maintain its profit margins, and those higher prices were passed along to consumers. The suit alleges that this purported need to fund rebates to OptumRx explains the increase of Victoza from about US$400 a package to more than US$900 a package between 2009 and 2017.

Similarly, in New Jersey, a proposed consumer class action alleged that Novo, Lilly and Sanofi increased insulin prices in lockstep, sharing the increased profits with the three largest PBMs, CVS Health, Express Scripts and OptumRX, through rebates.[127] The suit asserts that consumers were then obligated to pay far higher out-of-pocket expenses to subsidise this scheme. A Pennsylvania county's public retirement system also filed a similar class action against Novo, asserting that Novo engaged in 'collusive price fixing' to preserve high insulin prices.[128]

In Massachusetts, a class action against Novo, Lilly and Sanofi alleged that these companies engaged in price fixing, raising their

list price in lockstep to ensure that large PBMs received rebates.[129] However, this case also included a Racketeer Influenced and Corrupt Organizations Act (RICO) claim. The suit alleges that the three companies formed an enterprise designed to inflate the list prices of drugs and to exploit the drug pricing system in a way that guaranteed them higher profits while passing on the increased costs to consumers, and that such conduct constitutes the kind of ongoing criminal organisation envisioned by RICO.

Finally, over the past two years, more than 80 named plaintiffs, including proposed classes of direct and indirect purchasers, have filed private suits against more than 20 different generic manufacturers targeting alleged agreements to raise prices. These proposed classes, like the State attorneys general, allege that generic manufacturers engaged in a number of separate conspiracies through trade association conferences and other meetings to inflate the prices of almost 20 different generic drugs between 2012 and 2015, including digoxin, doxycycline, clobetasol, desonide, fluocinonide, econazole, levothyroxine and propranolol. In April 2017, the Judicial Panel on Multidistrict Litigation transferred and consolidated these actions in the US District Court for the Eastern District of Pennsylvania for pretrial proceedings.[130] While it remains to be seen to what extent the scheduling of these private litigations will diverge from the state attorneys general action, if at all, discovery is also stayed pending the completion of the DOJ's investigation.

Other antitrust concerns involving pharmaceuticals

In addition to the above areas that have been most active, antitrust concerns have arose in other areas as well. Specifically, antitrust allegations have recently been asserted regarding certain contracting practices (eg, exclusive dealing and bundling), biosimilar manufacturer responses to biosimilar competition, and with respect to the REMS programme.

Contracting practices in antitrust cases

Various contracting practices have come under antitrust scrutiny. For example, the plaintiffs in *Restasis* allege that in addition to anticompetitive conduct related to patent procurement and litigation, the brand company 'entered into an unlawful contract with the Saint Regis Mohawk Tribe (the Tribe) to transfer ownership of the follow-on patents to the Tribe and then petitioned the [Patent Trial and Appeal Board] to dismiss its review for lack of subject-matter jurisdiction based on the Tribe's sovereign immunity' in an attempt to maintain a monopoly and insulate the follow-on patents from review.[131] Motions to dismiss are fully briefed and pending as of July 2018.[132]

In *Rotavirus*, the plaintiffs claim that '[b]efore the threat of competition from GSK, Merck had contracts that offered "bundled" discounts that would condition prices on loyalty to a bundle of Merck vaccines. In preparation for GSK's introduction of a competing rotavirus vaccine, Merck added a condition to its contracts that required customers to buy all or nearly all of their pediatric rota virus vaccines from Merck or face substantial price penalties on all other Merck vaccines', thereby 'reducing GSK's incentive to compete based on price' and allowing Merck 'to charge artificially-inflated prices for rotavirus vaccine'.[133] A consolidated class action complaint was filed in June 2018 and no dispositive motions have been filed yet.

Another notable example is the *EpiPen* antitrust litigation. Among other allegations, the plaintiffs allege that Mylan engaged in exclusionary rebates that 'caused PBMs to begin to restrict the epinephrine auto-injector category' and 'to block [Sanofi's epinephrine drug] Auvi-Q from the market'.[134] In particular, Mylan allegedly offered large rebates to third-party payors that expressly conditioned rebates on exclusivity, imposed contractual exclusivity provisions on school programmes, and offered consumers $0 co-pays that in conjunction with rebates drove up competitor costs.[135] The district court granted Mylan's motion to dismiss Sanofi's complaint in part, reasoning that 'Sanofi's exclusive dealing claims based on discounts or rebates that Mylan offered to state or state agencies' should be dismissed on *Noerr-Pennington* grounds.[136] The case is proceeding on two separate tracks, one involving Sanofi only and one including the consumer class cases. The motions to dismiss the consumer plaintiffs are still pending as of July 2018.

Biosimilar antitrust cases

The FDA and private litigants have also begun to raise antitrust concerns related to biologic manufacturers' contracting with insurers and providers.[137] Congress passed the Biologics Price Competition and Innovation Act to provide an abbreviated FDA approval pathway for biosimilar versions of a biologic drug.[138] To receive FDA approval, the biosimilar manufacturer must demonstrate its proposed biosimilar is 'highly similar' to the reference biologic and has 'no clinically meaningful differences from the reference product in terms of safety, purity, and potency'.[139] Unlike generic medicines approved under the Hatch-Waxman Act, biosimilars are not automatically substitutable with the reference biologic without physician intervention.[140]

In September 2017, in the first antitrust case between a biologic originator and a biosimilar manufacturer, Pfizer sued Johnson & Johnson and Janssen in the US District Court for the Eastern District of Pennsylvania. The complaint alleges that the defendants employed a 'multifaceted scheme to ensure that biosimilars would never become viable competitors' to Remicade by 'imposing a web of exclusionary contracts on both health insurers and healthcare providers (eg, hospitals and clinics) to maintain [their] stranglehold' in the marketplace.[141] Direct and indirect purchaser class action complaints followed the Pfizer lawsuit. The defendants' motions to dismiss were fully briefed in June 2018 and remain pending.

REMS antitrust cases

In past years, the FTC and some private litigants have expressed concerns about brand pharmaceutical companies using the FDA's REMS programme to allegedly prevent some generic companies from obtaining certain drug samples needed for bioequivalence testing. While this has been an area of continuing interest for the FTC and private litigants,[142] there have been no significant case law developments in this area during the past year.

The FDA, however, has recently taken several steps to combat purported misuse of the REMS programme. In July 2017, the FDA issued draft guidance – the Development of a Shared System REMS[143] and the Waivers of the Single, Shared System REMS Requirement[144] – creating policies designed to assist in the development and approval of generic drugs. FDA commissioner Scott Gottlieb has also spoken on the issue, observing that it is problematic when brand companies use REMS 'requirements to block timely generic entry. . . . REMS shouldn't become a tool that drug companies can use to delay or block competition from generic products or hinder their ability to enter the market'.[145] In May 2018, commissioner Gottlieb and the FDA took additional action, releasing a list of drug manufacturers suspected of using REMS to delay potential generic entry, based on the number of inquiries and safety-determination letters contending misuse of REMS.[146, 147]

Notes

1 *FTC v Actavis, Inc*, 133 S Ct 2223, 2237 (2013).
2 Id at 2227.
3 Id at 2236.
4 *In re Lamictal Direct Purchaser Antitrust Litig*, 18 F Supp 3d 560, 567–69 (DNJ 2014); *In re Loestrin 24 LE Antitrust Litig*, 45 F Supp 3d 180, 193 (DRI 2014).
5 *King Drug Co of Florence, Inc v SmithKline Beecham Corp*, 791 F.3d 388, 394 (3d Cir 2015). The Third Circuit also rejected the district court's alternative reason for dismissal – that the no-AG agreement was justified because the consideration exchanged was reasonably related to the removal of uncertainty created by the patent dispute – because 'without proper justification, the brand cannot pay the generic simply to eliminate the risk of competition'. Id at 411.
6 Id at 403–05.
7 *SmithKline Beecham Corp v King Drug Co of Florence, Inc*, 137 S Ct 446 (2016); Br of the US as Amicus Curiae, *SmithKline Beecham Corp v King Drug Co of Florence, Inc*, No. 15–1055 (October 2016).
8 *Loestrin*, 814 F.3d at 550.
9 Id at 552.
10 See, eg, *Sergeants Benevolent Ass'n Health & Welfare Fund v Actavis, PLC*, No. 15-cv-6549, 2016 US Dist LEXIS 128349, at *48–49 (SDNY 13 September 2016) (stating that case law 'suggests that early-entry terms are not reverse payments subject to antitrust scrutiny', but noting that there were allegations that 'the terms of the licenses were intentionally designed to keep competitors out of the market until the [brand] had successfully forced Namenda IR consumers to switch to Namenda XR'); *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 can constitute a 'payment' under *Actavis*); *In re Aggrenox Antitrust Litig*, 94 F Supp 3d 224, 242 (D Conn 2015) (holding that a '"payment" is not limited to cash transfers'); *United Food & Commercial Workers Local 1776 v Teikoku Pharma USA, Inc*, 74 F Supp 3d 1052, 1070 (ND Cal 2014) ('[A] no-authorised-generic term can constitute a payment'.); *Time Ins Co v AstraZeneca AB*, 52 F Supp 3d 705, 710 (ED Pa 2014) ('[R]everse payments deemed anticompetitive pursuant to *Actavis* may take forms other than cash payments'); *In re Niaspan Antitrust Litig*, 42 F Supp 3d 735, 751 (ED Pa 2014) ('[T]he term "reverse payment" is not limited to a cash payment'); *In re Nexium (Esomeprazole) Antitrust Litig*, 968 F Supp 2d 367, 392 (D Mass 2013) ('Nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment').
11 *Picone v Shire PLC*, No. 16-cv-12396, 2017 US Dist LEXIS 178150, at *10 (D Mass 20 October 2017).
12 Id at *23.
13 Id at *35.
14 *FTC v AbbVie Inc*, 107 F Supp 3d 428, 430, 432–36 (ED Pa 2015).
15 Id at 436.
16 Findings of Fact and Conclusions of Law, *FTC v AbbVie, Inc*, No. 14-cv-5151 (ED Pa 29 June 2018), ECF No. 439.
17 *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).
18 Id.
19 *In re Opana ER Antitrust Litig*, 162 F Supp 3d 704, 718 (ND Ill 2016).
20 *In re Loestrin 24 Fe Antitrust Litig*, 261 F Supp 3d 307, 338 (DRI 2017).
21 Id.
22 *In re Lipitor Antitrust Litig*, 868 F3d 231, 255 n.11 (3d Cir 2017).
23 Id at 256.
24 Id.
25 *Petition for Writ of Certiorari, Pfizer Inc v Rite Aid Corp*, No. 17–752, at 1 (S Ct 20 November 2017).
26 *Pfizer Inc v Rite Aid Corp*, No. 17–752, 2018 US LEXIS 1227, at *1 (S Ct 20 February 2018).
27 *In re Lipitor Antitrust Litig*, 722 F App'x 132, 135 (3d Cir 2016) (per curium).
28 *In re Cipro Cases I & II*, 61 Cal 4th 116 (Cal 2015).
29 *Lipitor*, 722 F App'x at 137.
30 Id.
31 Id.
32 *In re Asacol Antitrust Litig*, No. 1:15-cv-12730, 2016 US Dist LEXIS 94605, at *24 (D Mass 20 July 2016).
33 *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503, 2015 US Dist LEXIS 125999, at *41 (D Mass 14 August 2015).
34 *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503, 2018 US Dist LEXIS 11921, at *20–21 (D Mass 25 January 2018).
35 Id at *71–72.
36 Id at *62–69.
37 Id at *72.
38 Id at *74–81.
39 Settlement Agreement at 8, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503 (D Mass 29 March 2018), ECF No. 1137.
40 See, eg, Complaint paragraph 11, *Lidoderm*, No. 18-cv-675 (ND Cal 31 January 2018), ECF No. 1.
41 *United Food & Commercial Workers Local 1776 v Teikoku Pharma USA*, 296 F Supp 3d 1142, 1156-58, 1160 (ND Cal 2017).
42 Id at 1163.
43 Id at 1163–64.
44 Notice of Motion and Motion at 2, *In re Lidoderm Antitrust Litig*, No. 14-md-2521 (ND Cal 20 March 2018), ECF No. 1004.
45 *In re AndroGel Antitrust Litig* (No. II), No. 09-md-2084, 2018 US Dist LEXIS 99716, at *49–50 (ND Ga 14 June 2018).
46 Id at *58.
47 Id at *59.
48 Id at *42–43.
49 *In re AndroGel Antitrust Litig*, No. 1:09-md-2084, 2018 US Dist LEXIS 117760, at *25 (ND Ga 16 July 2018).
50 Id.
51 Id at *26 n.23 (citing *In re Modafinil Antitrust Litig*, 837 F.3d 238, 255-59 (3d Cir 2016) (vacating certification order in which the proposed class consisted of very large companies, and rejecting arguments about negative claims and retaliation); *King Drug Co of Florence v Cephalon, Inc*, No. 2:06-CV-1797, 2017 US Dist LEXIS 137601, at *8–11 (ED Pa 28 August 2017) (denying certification for similar reasons)).
52 *In re Wellbutrin XL Antitrust Litig*, 133 F Supp 3d 734, 754 n.28, 757–69 (ED Pa 2015).
53 *In re Wellbutrin XL Antitrust Litig*, 868 F.3d 132, 165 (3d Cir 2017).
54 Id at 169.
55 Id at 168.
56 Id at 166–67.
57 Id at 167.
58 *In re K-Dur Antitrust Litig*, No. 01-cv-1652, 2016 US Dist LEXIS 22982, at *49–50 (DNJ 25 February 2016).
59 Id at *54–62.
60 Id at *72–80.
61 *In re K-Dur Antitrust Litig*, No. 01-cv-1652, ECF No. 1037, 1038, 1044, 1045.
62 *King Drug Co of Florence v Cephalon, Inc*, 88 F Supp 3d 402, 407–10, 418 (ED Pa 2015).
63 Id 419–21.

64 Stipulated Order for Permanent Injunction & Equitable Monetary Relief at 10, *FTC v Cephalon, Inc*, No. 2:08-cv-02141 (ED Pa 17 June 2015), ECF No. 405.
65 Mot in Supp of Direct Purchaser Class Pls' Unopposed Mot for Cert of a Settlement at 1, *FTC v Cephalon, Inc*, No. 2:06-cv-01797 (ED Pa 17 April 2015), ECF No. 795; Memo of Law in Supp of Mot for Cert of Class at 1, King Drug Co of Florence, Inc, No. 2:06-cv-01797 (ED Pa 3 February 2017), ECF No. 1032-1.
66 Order at 1, *FTC v Cephalon, Inc*, No. 2:08-cv-02141 (ED Pa 17 June 2015), ECF No. 376; FTC's Mem in Opp'n to Cephalon's Mot to Preclude the FTC's Disgorgement Claim at 5, *FTC v Cephalon, Inc*, No. 2:08-cv-02141 (ED Pa 17 June 2015), ECF No. 352.
67 Order of Dismissal, *Apotex, Inc v Cephalon, Inc*, No. 2:06-cv-2768 (ED Pa 7 July 2017), ECF No. 1265.
68 *FTC v Actavis, Inc*, No. 1:09-cv-955, 2017 US Dist LEXIS 84438, at *17 (ND Ga 1 June 2017).
69 Id.
70 Id at *19–20.
71 *In re Nexium (Esomeprazole) Antitrust Litig*, 42 F Supp 3d 231, 264 (D Mass 2014).
72 Id.
73 *In re Nexium (Esomeprazole) Antitrust Litig*, 842 F.3d 34 (1st Cir 2016).
74 Initial Decision at 85, *In the matter of Impax Labs, Inc*, FTC Dkt No. 9373 (18 May 2018).
75 Id at 114.
76 Id at 120.
77 Id at 132.
78 Id at 133–35.
79 Id at 132.
80 Id at 145.
81 Complaint Counsel's Notice of Appeal at 1, *In the matter of Impax Labs, Inc*, FTC Dkt No. 9373 (18 May 2018).
82 *Abbott Labs v Teva Pharm USA, Inc*, 432 F Supp 2d 408, 422 (D Del 2006).
83 Id at 423–24.
84 *Walgreen Co v AstraZeneca Pharm LP*, 534 F Supp 2d 146, 151 (DDC 2008).
85 Id at 152 (further holding that '[t]he 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').
86 *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig*, 64 F Supp 3d 665, 682 (ED Pa 2014).
87 Id at 681–82.
88 Id at 682–84.
89 *New York v Actavis, PLC*, No. 14-7572, 2014 US Dist LEXIS 172918 (SDNY 11 December 2014).
90 Id at *107–08.
91 *New York v Actavis, PLC*, 787 F.3d 638, 643 (2d Cir 2015).
92 *Berkey Photo, Inc v Eastman Kodak Co*, 603 F.2d 263 (2d Cir 1979).
93 787 F.3d at 653–54.
94 See id at 653–59. In a subsequent, separate action, direct purchaser plaintiffs in *Namenda II* alleged that the defendants' mere announcement of their intent 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 *Namenda I* had prevented the defendants from withdrawing the older drug from the market, the court in *Namenda II* allowed the 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 the *Namenda II* court subsequently held that the defendants were precluded from arguing certain issues related to the product-hopping allegations that were already determined by the *Namenda I* court (*In re Namenda Direct Purchaser Antitrust Litig*, No. 15-cv-7488, 2017 US Dist LEXIS 83446, at *50–51 (SDNY 23 May 2017)).
95 *Mylan Pharms, Inc v Warner Chilcott plc*, No. 12-3824, 2013 US Dist LEXIS 152467 (ED Pa 12 June 2013).
96 Id at *11.
97 *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 in order 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.
98 Id at *42.
99 Id at *40.
100 *Mylan Pharms, Inc v Warner Chilcott Pub*, 838 F.3d 421 (3d Cir 2016).
101 *In re Solodyn (Mincocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503, 2015 US Dist LEXIS 125999 (D Mass 14 August 2015).
102 *In re Asacol Antitrust Litig*, No. 15-cv-12730 (D Mass 10 February 2017), ECF No. 279.
103 *In re Asacol Antitrust Litig*, No. 15-md-2503, 2016 US Dist LEXIS 94605 (D Mass 20 July 2016).
104 *Wisconsin v Indivior Inc (In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig)*, No. 13-md-2445, 2017 US Dist LEXIS 627 (ED Pa 8 September 2017).
105 'Drug Pricing Legislative Summary', ASHP, 7 February 2018.
106 J Carlisle Larsen, 'New Bill in Congress Seeks to Make Drug Price Increases More Transparent', Wisconsin Public Radio, 9 June 2017, www.wpr.org/new-bill-congress-seeks-make-drug-price-increases-more-transparent.
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108 'Remarks by President Trump on Lowering Drug Prices', Whitehouse.gov, 11 May 2018, https://www.whitehouse.gov/briefings-statements/remarks-president-trump-lowering-drug-prices/.
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113 *Ass'n for Accessible Meds v Frosh*, 887 F.3d 664, 672 (4th Cir 2018).
114 S 175, 2018 Leg, 1st Spec Sess, Section 4651(a) (Vt 2018), https://legislature.vermont.gov/assets/Documents/2018/Docs/ACTS/ACT133/ACT133%20As%20Enacted.pdf
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147 White & Case, LLP represents defendants in the following cases discussed in this academic article: *FTC v Actavis (AndroGel), Aggrenox, Asacol, Doryx, Effexor, K-Dur, Lidoderm, Lipitor, Loestrin, Namenda I, Namenda II and Remicade*. 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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