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 the three types of pharmaceutical antitrust cases that have been most active:

- US trial court and appellate court decisions adjudicating 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;
- so-called product-hopping antitrust claims against innovator pharmaceutical companies that introduce new versions of brand-name drugs facing generic competition; and
- challenges to pharmaceutical manufacturers' pricing practices.

Reverse payment case law under Actavis

The US Supreme Court's June 2013 decision in *FTC v Actavis* opened a floodgate for more than 20 separate antitrust cases that have been filed or revived under the 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 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 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 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, some federal courts diverged on what constitutes sufficient allegations of a reverse 'payment' to survive a motion to dismiss. Two federal district courts had concluded that a 'payment' under *Actavis* must be a cash transfer from a brand to a generic competitor.[4] Applying this rule in *Lamictal*, the US District Court for New Jersey granted a motion to dismiss where plaintiffs alleged that:

> *in exchange for dropping its challenge to GSK's patents, the settlement allowed Teva to market generic lamotrigine before the relevant patent expired and ensured that once it did so, its generic tablets and chewables would not face competition from GSK's own 'authorised generic' for a certain period of time.*[5]

On appeal, however, the US Court of Appeals for the Third Circuit – the first federal appellate court to address 'the no authorised generic' (no-AG) issue – 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.*[6]

The Third Circuit cited the plaintiffs' appeal brief, which used a comparable drug to argue that the no-AG agreement could potentially be worth hundreds of millions of dollars to the generic challenger, as a basis for holding that such an agreement 'may be as harmful as those resulting from reverse payments of cash'.[7] In addition to being the first appellate decision on the no-AG issue, *Lamictal* is the first federal appellate decision applying *Actavis* to an alleged reverse payment of any kind. GlaxoSmithKline and Teva filed a petition for a writ of certiorari with the US Supreme Court, asking the Court to address the uncertainty surrounding the types of agreements covered by its *Actavis* decision. The petition was denied in November 2016 after the US Solicitor General asked the Court to let the decision stand.[8]

In *Loestrin*, the US District Court for the District of Rhode Island also reached a 'no-payment' conclusion similar to the district court in *Lamictal*. The court granted a motion to dismiss, holding that there was no 'payment' under *Actavis* where plaintiffs alleged that the 'settlement involve[d] licenses and co-promotion arrangements

for other drugs and a "no authorised generic" agreement on the part of the brand manufacturer'.[9] The court reached this conclusion 'because [the brand's] "payment" for delay was not made in cash' and plaintiffs 'struggle[d] to affix a precise dollar value to it'.[10]

Plaintiffs appealed this ruling to the US Court of Appeals for the First Circuit, which reversed the district court's cash-only decision.[11] Agreeing with the Third Circuit in *Lamictal*, the First Circuit reasoned that 'the key word used throughout the [*Actavis*] opinion is "payment", which connotes a much broader category of consideration than cash alone'.[12] While the First Circuit recognised the difficulty in computing the value of non-cash payments, the court explained that antitrust litigation requires this type of 'elaborate inquiry into the reasonableness of a challenged business practice' and therefore is often 'extensive and complex'.[13] The court declined, however, to decide whether the provisions of the settlement agreements qualify as unlawful reverse payments under *Actavis*, instead remanding to the district court to address.

Other federal district courts have also concluded that a 'payment' under *Actavis* may include non-cash transfers that have value, such as co-promotion, licensing, distribution and no-AG agreements, and denied motions to dismiss on that basis.[14] The *Lidoderm* decision in the US District Court for the Northern District of California, for example, held that 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.[15] 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'.[16] Notably, other federal district courts have denied motions to dismiss under *Actavis* even when the plaintiffs failed to allege with specificity the monetary value of the non-cash transfer of value.[17]

In a consolidated appeal, the Third Circuit reversed a district court's dismissal of reverse payment claims in *Effexor* and *Lipitor*. The Third Circuit held that the plaintiffs were not required to plead a 'heightened pleading standard' that includes the district court's requirement of a reliable monetary estimate of the non-cash payments, after subtracting out legal fees and other services, to support an allegation that the payment was 'large'.[18] The court rejected the argument that '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'.[19] 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,'[20] 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'.[21]

In *Actos*, however, the US District Court for the Southern District of New York dismissed plaintiffs' alleged reverse payment claims, holding that although 'some settlements with non-cash settlement terms may provide a basis for an *Actavis* reverse payment claim, the settlement agreements in this case do not'.[22] The settlements at issue involved acceleration clauses and licences for early generic entry, which the court said simply provided the generic companies with a 'compromise date of generic entry'.[23] Under these circumstances, the court reasoned that 'crediting Plaintiffs' unsupported assertions that the settlements were unlawful "payments" would suggest that any and all settlements between a brand and manufacturer are potentially unlawful – a result that the *Actavis* Court was unlikely to have intended'.[24] The plaintiffs did not appeal this ruling, but did appeal the dismissal of other antitrust claims related to false patent descriptions.[25]

One district court thus far has addressed whether antitrust plaintiffs can state a claim by alleging that a settling generic received a 'payment' under *Actavis* by paying the brand company too little for some product or service. The US District Court for the Eastern District of Pennsylvania in *FTC v AbbVie* granted a motion to dismiss on those facts, holding that a patent settlement signed contemporaneously with a supply agreement in which the generic paid the brand did not constitute an anticompetitive reverse payment.[26] The court concluded that there was no anticompetitive 'payment' where Teva paid Abbott to supply an authorised generic version of TriCor at a price based on Abbott's cost, plus a royalty on Teva's profits.[27] 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'.[28] The court concluded that the patentee 'did not make any payment, reverse or otherwise, to the claimed infringer'.[29] 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 continues to litigate its sham litigation claims against Abbott.

In contrast, the US District Court for the Southern District of New York refused to dismiss reverse payment claims in *Namenda II* where contemporaneously with the execution of the brand's settlements with each of the generics, the brand and generics entered into licensing agreements granting generic entry three months prior to patent expiry.[30] The defendants argued that such agreements do not constitute a reverse payment and the only consideration exchanged included payments to cover the settling parties' 'litigation costs and attorney fees'.[31] The court held that the plaintiffs plausibly alleged that the payments for litigation costs and attorney fees 'were actually commensurate with the legal fees they expected to pay over the course of the ANDA patent litigation' and that '[t]hese intrinsically fact-based determinations cannot be made on a pre-answer motion to dismiss' without the discovery needed to reveal whether the payments were 'commensurate with the legal fees they expected to pay over the course of the ANDA patent litigation, or constituted reasonable compensation for promoting brand-name Namenda IR to doctors and patients'.[32] As to the early-entry licences, the court said that although 'these payments appear to be proper under *Actavis*, the legality of these terms is better decided on a motion for summary judgment, after discovery has taken place'.[33] The court explained that *Actos*, *FTC v AbbVie*, and *Niaspan*, along with dicta from *Actavis*, 'suggests that early-entry terms are not reverse payments subject to antitrust scrutiny',[34] but noted that there were allegations in *Namenda II* 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'.[35] The court found those allegations to be 'idiosyncratic enough to distinguish the effects of the early-entry licenses' from those at issue in *Actavis* and *Actos*, thereby requiring discovery.[36]

Finally, two district courts dismissed reverse payment claims because of the lack of FDA approval. At issue in *Asacol* was the settlement of the *Asacol HD* patent litigation, which included two

'options'. First, the generic could enter the market with its own generic on 15 November 2015 (or earlier under certain conditions) if it received FDA approval of its ANDA, and in exchange the generic would pay the brand a 25 per cent royalty on net sales.[37] The brand would also maintain the option to supply an authorised Asacol HD generic to its affiliates (but not third-parties) during the generic's marketing exclusivity period.[38] Second, if the FDA did not approve the generic's ANDA, the generic could sell an authorised generic version of Asacol HD beginning 2 July 2016, and the brand would be barred from supplying an authorised generic to its affiliates or any third party for two years.[39] In exchange, the generic would pay 75 per cent of its profits to the brand.[40] The second option would terminate upon FDA approval of the ANDA.[41] The US District Court for the Southern District of New York dismissed the reverse payment claim in *Asacol* because the generic still had not obtained FDA approval and, therefore, the plaintiffs could not claim antitrust injury even if the generic could have negotiated an earlier entry date.[42] The plaintiffs also did not allege that either the brand or generic 'sought to delay or sabotage FDA approval' of the generic's ANDA.[43] Additionally, the plaintiffs argued that the generic could have negotiated an earlier date to sell an authorised generic of Asacol HD, but the court rejected that argument, reasoning that even if the generic could have negotiated an earlier authorised generic entry date, that option would have disappeared upon FDA approval of the ANDA.[44]

Similarly, in *Solodyn*, the US District Court for the District of Massachusetts dismissed reverse settlement claims as to one category of generics – the legacy strength Solodyn generics – because generic Lupin did not receive FDA approval until a few days after the agreed-upon entry date in the settlement agreement.[45] Thus, the 'FDA's approval, not an agreement with Medicis, was the limiting factor in Lupin's ability to bring generic Solodyn in legacy strengths to market'.[46] The direct purchasers, however, adequately alleged delay of Lupin's market entry for its subsequent strength Solodyn generic products based on allegations 'that the cash payments agreed upon in the Lupin JDA – US$20 million upfront and up to US$35.5 million in milestone payments – far exceeded the value of the development services to be performed by Lupin pursuant to the Lupin JDA and served no purpose other than to compensate Lupin for keeping its generic Subsequent Strength Solodyn off the market'.[47] The court also found that the direct purchasers did not plausibly allege a sham litigation claim and also dismissed other allegations of exclusionary conduct.[48]

Evaluating evidence and remedies under Actavis

Turning to the summary judgment context, the US District Court for the Eastern District of Pennsylvania in the *In re Modafinil* litigation rejected the defendants' argument that *Actavis* places a threshold burden on plaintiffs to demonstrate a 'large and unjustified' reverse payment to trigger a rule of reason analysis.[49] Rather, that court held that plaintiffs 'must present evidence of a large reverse payment as part of their initial burden of demonstrating anticompetitive effects under the rule of reason'.[50] The court held that the burden then shifts to the defendant to show the payment is, on balance, procompetitive, at which point plaintiffs must 'raise a genuine dispute of material fact as to whether the reverse payment is unjustified or unexplained'.[51]

Applying this framework, the court held that there was sufficient evidence for a reasonable jury to find that a reverse payment exceeded the brand company's avoided litigation costs and 'was significant enough to induce a generic challenger to abandon its patent claim'.[52] The four settlement agreements at issue between Cephalon and the generic defendants – including litigation cost payments and various licensing agreements with royalty and milestone payments – allegedly exceeded US$164 million in payments to Teva, US$63 million to Barr, US$48 million to Mylan and US$25 million to Ranbaxy.[53]

The court emphasised that plaintiffs' experts 'concluded that the amounts paid to these Generic Defendants have come close to, or in some instances, greatly exceeded the profits they could have expected to earn through an at-risk launch'.[54] While the court acknowledged:

> *Cephalon will have vigorous procompetitive responses to all of this evidence, a jury presented with these facts could find that the side agreements between Cephalon and the Generic Defendants were a means of disguising payments for delay and/or inducing the Generic Defendants to stay off of the market.*[55]

On the eve of trial, Cephalon settled with the FTC, agreeing to injunctive relief that prohibited certain types of settlements and a record-setting US$1.2 billion fine, subject to a credit for settlements reached in related private actions,[56] including Teva, Cephalon and Barr's settlement with a class of direct purchasers for US$512 million and Mylan's settlement with the direct purchasers for US$96.5 million.[57] The fine was driven by the court's prior decision to permit the FTC to proceed with a disgorgement claim estimated to be between US$3.5 billion and US$5.6 billion.[58] Meanwhile, Ranbaxy did not settle and proceeded to trial. A federal district court jury heard opening arguments on 14 June 2017, but the parties settled mid-trial.[59]

In the ongoing *FTC v Actavis* litigation that followed from the Supreme Court's 2013 decision and remand, the scope of the Cephalon injunction became the focal point of a summary judgment motion filed by generic defendant Actavis. Teva Pharmaceutical Industries Ltd's acquisitions of Cephalon and Actavis Holdco US Inc raised the question of whether 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'.[60] The court ultimately denied summary judgment for Actavis, 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.*[61]

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'.[62] Additionally, in February 2017, the FTC voluntarily dismissed with prejudice its reverse payment claims against Par Pharmaceutical Companies, Inc and Paddock Holdings, LLC for zero damages, no liability, and no injunctive relief beyond that already agreed to previously by Par's corporate parent in a separate matter. In May 2016, a group of indirect purchasers also dismissed with prejudice their reverse payment claims against all defendants for zero compensation. These dismissals follow from an earlier grant of summary judgment against direct and indirect purchaser sham litigation claims. Summary judgment briefing on the remaining substantive reverse payment claims is expected in 2017.

Addressing a summary judgment motion in *Nexium*, the US District Court for the District of Massachusetts held that there was sufficient evidence on which a reasonable jury might conclude that the settlement between Ranbaxy and AstraZeneca – making Ranbaxy the exclusive authorised generic distributor of Nexium for six months after certain patents expired as well as providing 'lucrative' side manufacturing and distribution agreements – included improper reverse payments in exchange for delayed generic competition.[63] There was a variety of evidence that the court thought a reasonable jury might rely on to reach such a conclusion, such as:

- evidence that the settlement and side agreements were contemporaneously negotiated;
- evidence that the side agreements 'essentially provided a steady flow of revenue to Ranbaxy' during the same period it agreed not to launch its generic Nexium product; and
- evidence that 'even if Ranbaxy had won its litigation instead of settling, it would not have secured such favorable arrangements'.[64]

Nevertheless, when the case proceeded to trial – the first reverse payment trial since the Supreme Court's *Actavis* decision – the *Nexium* 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 even if there had not been a reverse payment.[65] The plaintiffs' motion for a new trial was denied, leading to an appeal in the US Court of Appeals for the First Circuit.[66]

On appeal, the First Circuit found no reversible error as to certain evidentiary rulings, the verdict form and jury instructions, or the district court's grant of judgment as a matter of law against plaintiffs' overarching conspiracy claim.[67] The final issue at the 'heart of the appeal' was whether the court's summary judgment decision erroneously rejected certain causation arguments.[68] The First Circuit held that any error that might have occurred was harmless because even if the district court had allowed the plaintiffs to present two of the causal theories at trial, the district court's judgment as a matter of law decision on plaintiffs' theory of invalidity eliminated the causation claim of at-risk entry by Ranbaxy or that Teva would have won its paragraph IV suit against AstraZeneca.[69] As to the other two causation theories where Ranbaxy allegedly could have negotiated an earlier entry date, the court found the exclusion of those theories to be harmless because the jury found 'that AstraZeneca would not have agreed to settlement terms with a license date earlier than 27 May 2014, the date on which two of its medical patents expired'.[70]

In *K-Dur*, the US District Court for the District of New Jersey denied summary judgment for reverse payment claims arising from Schering-Plough's and Upsher-Smith's settlement of the patent litigation for Schering's potassium supplement K-Dur. Plaintiffs alleged that the settlement included Schering paying first ANDA filer Upsher US$60 million for a licence to Niacor as well as other licences.[71] 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 also offered evidence that countered the defendants' arguments and raised a genuine dispute of material fact.[72] In particular, the plaintiffs' rebuttal included evidence that the licensing agreements lacked terms usually present in a pharmaceutical licensing agreement, that Schering did not conduct its typical due diligence before entering the agreement, and that the US$60 million payment was significantly above fair market value.[73] The court, however, rejected the plaintiffs' related conspiracy claims for Schering's settlement with second ANDA filer ESI-Lederle for lack of any direct or circumstantial evidence and 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 necessary to guarantee no generic competition.[74] Prior to trial, the case settled in April 2017 for a reported US$60 million.[75]

In contrast to the denials of summary judgment detailed above, the US District Court for the Eastern District of Pennsylvania granted summary judgment in *Wellbutrin* for lack of causation:

> *It is in keeping with the traditional rule of reason analysis to require the plaintiffs to show that the Wellbutrin settlement actually resulted in the delayed entry of Wellbutrin XL – that absent the Wellbutrin settlement, generic competition would have occurred earlier […]. There are no facts in the summary judgment record to support a contention that, absent the no authorised generic agreement, an alternate settlement would have been reached.*[76]

On appeal, the US Court of Appeals for the Third Circuit affirmed.[77] The court held that plaintiffs did not establish antitrust injury stemming from the alleged reverse payment settlement agreement because they failed to present evidence from which a reasonable jury could conclude that it is more likely than not that a generic would have entered the market earlier absent the settlement agreement, holding that '[a] plaintiff cannot satisfy the summary judgment burden based on speculation alone'.[78]

The court further held that it could not resolve whether generics would have prevailed in the underlying patent litigation absent the settlement agreement without considering the merits of the underlying patent dispute.[79] In concluding that plaintiffs had failed to present evidence from which a 'reasonable jury could conclude that [a generic] would have been more likely than not to prevail' in the patent litigation, the court credited patent expert opinion that the likelihood of generics prevailing in the underlying litigation was low, and the court rejected plaintiffs' argument that the size of the reverse payment alone is a sufficient 'surrogate' for the weakness of the patent where settlements are complex and 'risk aversion makes it difficult to use the size of a settlement as a proxy'.[80]

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-2016 cases: TriCor, Prilosec, Suboxone and Solodyn

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 *Tricor*, the court rejected defendants' assertions that any product change that is an improvement is per se legal under the antitrust laws.[81] Instead, the court concluded that the introduction of a new product should be assessed under the rule of reason approach, and thus plaintiffs would be required 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 defendants' motion to dismiss, finding plaintiffs' specific allegations – that 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.[82]

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.[83] In granting 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, plaintiffs could not allege that defendants interfered with competition, because consumer choice was not eliminated.[84]

In *Suboxone*, the 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]'.[85] 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 defendants removed the Suboxone tablets from the market, but less problematic than in *TriCor* because defendants did not buy back existing Suboxone tablets or label the tablets obsolete.[86] 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.[87] The case is still in discovery.

In *Solodyn*, the plaintiffs alleged that the defendants' introduction and marketing of new strengths of Solodyn was anticompetitive because they improperly shifted the market away from the older strengths of Solodyn, which faced generic competition. However, the court dismissed the product-hopping claim, holding that because 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.[88]

Doryx

The *Doryx* court became the first court to evaluate product-hopping claims with the benefit of full discovery, at the summary judgment stage. In *Doryx*, the plaintiffs alleged that numerous product reformulations (including changes from capsules to tablets, changes to dosage strength and introduction of score lines), 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.[89] 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.[90]

Ultimately, after full discovery, the court then 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.[91] 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.[92] 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.[93] In 2016, the US Court of Appeals for the Third Circuit affirmed the lower court's grant of summary judgment in the defendants' favour.[94] The deadline for the plaintiffs to appeal the case to the Supreme Court has lapsed, and the suit is therefore terminated.

Namenda

In *Namenda I*, a federal district court in New York granted a motion for a preliminary injunction related to product-hopping claims related to defendants' plan to transition patients from an older, twice-daily drug to a newer, once-daily formulation.[95] 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 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.[96]

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.[97] Despite the continued availability to any patient with a need for the older formulation, the Second Circuit affirmed the district court order, and cited *Berkey Photo*[98] 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.[99] 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.[100]

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 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,[101] 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.[102]

Asacol

In *Asacol*, direct and indirect purchaser plaintiffs alleged that 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. 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.[103] However, the court allowed the plaintiffs' claims of 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.[104]

Challenges to pharmaceutical manufacturers' pricing practices

Over the past year, 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. Private litigation has ramped up as well, mostly in the form of claims alleging agreements to fix prices. The push for both state and federal legislation to address drug prices also has 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.

This section analyses the major developments in the area of drug pricing since our last update, with a specific focus on: (i) federal and state enforcement actions and congressional investigations; (ii) private litigation; and (iii) state and federal legislative and regulatory activity.

Federal and state enforcement actions and congressional investigations

Following a two-year investigation into the pharmaceutical industry, the US Department of Justice (DOJ) filed charges in December 2016 against two former Heritage Pharmaceuticals Inc executives.[105] The DOJ alleged that former Heritage CEO Jeffrey Glazer and former President Jason Malek conspired to fix prices with competitors and divide the customer base for doxycline 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.[106] In January 2017, Glazer and Malek each pleaded guilty to a two-count price-fixing felony charge in Pennsylvania federal court.[107] Both Glazer and Malek have signed cooperation agreements, and their testimony is expected play a role in ongoing antitrust investigations into the generic drug industry.[108] Heritage has initiated a racketeering suit against Glazer and Malek and announced that it is cooperating with the DOJ's ongoing investigation.[109] With the 'Yates Memo' encouraging the prosecution of individuals for corporate crimes, additional prosecutions of individual executives for price fixing may also be forthcoming. The DOJ's ongoing investigation has also resulted in a temporary stay of discovery in the ongoing private litigations challenging related conduct, as outlined below.

Following the January 2017 guilty plea 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.[110] 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 March 2017, an additional 20 states joined the Connecticut Attorney General's suit.[111] The defendants filed a motion to dismiss in June 2017, arguing that the states have no basis for injunctive relief because the complaint fails to allege any ongoing illegal conduct and no standing to recover damages in the form of disgorgement because the states only represent indirect purchasers.[112] The motion-to-dismiss briefing was completed in June of this year. Additionally, although other private litigations have been stayed pending the results of the DOJ's investigation, as outlined further below, the states' action has yet to be stayed.

Congress has initiated a new investigation and continued existing ones. In September 2016, the House Committee on Oversight and Government Reform questioned the CEO of Mylan over the company's decision to raise the list price of EpiPen more than US$500 since 2007.[113] In December 2016, US Senators Susan Collins and Claire McCaskill released a report on price hikes for generic drugs that summarised findings from congressional hearings in late 2015 and early 2016.[114] The Senators criticised what they refer to as a 'hedge fund' model of pharmaceutical commercialisation: 'investing in (buying up the rights to a drug), dramatically increasing the price, and then collecting the increased revenue (the 'return' on the investment). In essence, this strategy allowed pharmaceutical corporations to raise prices without the need to invest in production or R&D'.[115] The report concluded by observing that the companies called before Congress may not have violated existing antitrust laws though: 'It

is possible that the business model pursued by the Valeants and Turings of the world was attractive in part because it was legal.'[116]

Private litigation

Over the last year, 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 18 generic drugs between 2012 and 2015, including digoxin, doxycycline, clobestasol, desonide, flucinonide, econazole, levothyroxine and propranolol. In April 2017, the Judicial Panel on Multidistrict Litigation (JPML) transferred cases and centralised these actions in the US District Court for the Eastern District of Pennsylvania for coordinated or consolidated pretrial proceedings.[117] On 22 May 2017, as the result of a stipulated agreement between the DOJ and the named plaintiffs designed to prevent any interference with the DOJ's ongoing criminal investigations, Judge Cynthia Rufe of the Eastern District of Pennsylvania entered an order staying all discovery in the private litigations consolidated before her by the JPML.[118] Under that order, plaintiffs are prohibited from serving discovery requests on the defendants until 15 September 2017.

Of these cases, the only one to reach the motion-to-dismiss stage to date 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 plaintiffs had sufficiently pleaded, including: (i) a motive to increase prices; (ii) that the price increases were against the defendants' own self-interest; (iii) that the defendants communicated at trade association meetings; and (iv) that there were ongoing state and federal investigations into the manipulation of generic drug prices, including the price of propranolol.[119] 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 MDL in the Eastern District of Pennsylvania.[120]

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) Optum RX.[121] 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 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.[122] The suit asserted 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.[123]

A Massachusetts 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.[124] 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 increased costs to consumers, and that such conduct constitutes the kind of ongoing criminal organisation envisioned by RICO.

Federal legislative and regulatory activity

The Fair Accountability and Innovative Research (FAIR) Drug Pricing Act is the most prominent congressional attempt to require enhanced transparency from drug companies.[125] Under the bill, which was drafted by Tammy Baldwin (D-Wisconsin) and John McCain (R-Arizona) and has some bipartisan support, 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.

With President Donald Trump also making reduced drug prices a central campaign promise, it remains to be seen whether the executive branch may also be supportive of the FAIR Drug Pricing Act and similar legislation. Notably, in June 2017, President Trump released a draft executive order targeting drug prices.[126] The proposed order addresses updating global trade agreements, scaling back the 340B pricing programme (which requires most drug companies to provide discounts of around 20 to 50 per cent to hospitals and clinics that treat low-income and uninsured patients), moving towards value-based drug pricing, and limiting out-of-pocket costs. Absent from the draft order, however, were two reform proposals that have been referenced by the Trump administration – Medicare negotiation of drug prices and importation of drugs from other countries.

President Trump's new FDA Commissioner, Scott Gottlieb, already has started to deliver on commitments made during his confirmation hearings to undertake steps to address high drug costs.[127] Commissioner Gottlieb publicly acknowledged that the FDA lacks the authority to regulate drug prices, but explained that the FDA has other tools available to impact drug prices and deter sudden price hikes. Further, on 27 June 2017, the FDA released a list of 267 off-patent and off-exclusivity drugs without an approved generic substitute.[128] The FDA published the list 'to improve transparency and encourage the development and submission' of ANDAs for drugs without direct generic competition. At the same time, the FDA announced it would prioritise ANDAs for drugs with less than three approved ANDAs.[129] The FDA continues to develop its Drug Competition Action Plan, which Commissioner Gottlieb

announced in June 2017, and convened a July 2017 meeting to hear stakeholder input on steps available to the FDA to support generic competition.[130]

State legislation

In 2017, legislatures in 29 different states have considered additional transparency and pricing requirements. These proposed laws generally target drug price increases, requiring public disclosure of manufacturing costs and other information to justify price increases above a certain threshold. While four states (Vermont, Florida, Maryland and Nevada) have passed legislation that requires this additional transparency, 19 states have pending legislation; so far, seven states have rejected all proposed pricing legislation.

In 2016, Vermont was the first state to pass legislation that penalised drug corporations for raising wholesale acquisition cost (WAC) of a drug too quickly and failing to disclose justifications for that price change.[131] More specifically, under 18 VSA section 4635(d), Vermont will identify annually up to 15 drugs that the state 'spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months'.[132] The Vermont's Office of the Attorney General will require the manufacturers of those drugs to provide a justification for the increase, and failing to supply the requested information may result in a fine of up to US$10,000 per violation.

With the passage of 2017 FL H 589, Florida sought to expand its online drug price database. This law required pharmacies dispensing the 300 most frequently prescribed medicines to disclose pricing data on each drug every month to the Agency for Health Care Administration (AHCA). The AHCA is then mandated to post this information online.[133] Maryland also passed a bill (Maryland HB 631) that imposes fines on generic drug manufacturers: (i) who raise WAC of their products by 50 per cent or more in one year; (ii) if the drug's WAC is more than US$80; or (iii) if three or fewer drug makers are actively manufacturing and marketing the drug.[134] Additionally, in June 2017, Nevada passed its own price-transparency bill (known as SB 265), which has been described as one of the strictest in the country.[135] Unlike other bills that focus on drug prices generally, the Nevada bill focuses only on two specific groups of drugs used to treat diabetes: insulin and biguanides.[136] The bill has a number of specific requirements, including requiring diabetes drug makers that have raised list prices by a 'certain amount to disclose information about the costs of making and marketing the drugs, along with what rebates they provide'.[137]

REMS antitrust cases

In past years, the FTC and some private litigants have expressed concerns about brand pharmaceutical companies using the FDA's Risk Evaluation and Mitigation Strategies (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,[138] there have been no significant developments in this area during the past year.[139]

Notes

1 *FTC v Actavis, Inc*, 133 S Ct 2223, 2237 (2013).

2 Id. at 2227.

3 Id. at 2236.

4 *In re Loestrin Antitrust Litig*, 45 F Supp 3d 180, 195 (DRI 2014) ('Actavis requires cash consideration in order to trigger rule of reason scrutiny…'), rev'd, No. 14-2071 (1st Cir 22 February 2016); *In re Lamictal Direct Purchaser Antitrust Litig*, 18 F Supp 3d 560, 569 (DNJ 2014) ('[T]his Court will not extend the holding of Actavis to the non-monetary facts before it.'), rev'd, No. 14-1243 (3d Cir 26 June 2015).

5 *Lamictal*, 18 F Supp 3d at 562, 567-69.

6 *King Drug Co of Florence, Inc v SmithKline Beecham Corp*, 791 F.3d 388, 394 (3d Cir 2015) (*In re Lamictal*). 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. Citing *Actavis*, the Third Circuit held that 'without proper justification, the brand cannot pay the generic simply to eliminate the risk of competition'. Id. at 411.

7 Id. at 403-05.

8 *SmithKline Beecham Corp v King Drug Co of Florence, Inc*, 137 S Ct 446 (7 November 2016); Br of the US as Amicus Curiae, *SmithKline Beecham Corp v King Drug Co of Florence, Inc*, No. 15-1055 (October 2016).

9 Loestrin, 45 F Supp 3d at 193.

10 Id.

11 *In re Loestrin 24 Fe Antitrust Litig*, 814 F.3d 538, 542 (1st Cir 2016).

12 Id. at 550.

13 Id. at 552.

14 See, eg, *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) (agreeing 'that '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) (*Lidoderm*) ('[A] no-authorized-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 anti-competitive pursuant to *Actavis* may take forms other than cash payments'.); *In re Niaspan Antitrust Litig*, 42 F Supp 3d 735, 751 (ED Pa 5 September 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'.). In March 2016, the FTC filed its first-ever reverse payment case involving a no-AG provision in *FTC v Endo Pharmaceuticals Inc, et al.*, No. 2:16-cv-01440 (ED Pa).

15 *Lidoderm*, 74 F Supp 3d at 1070.

16 Id.; see also *In re Opana ER Antitrust Litig*, No. 14-C-10150, 2016 US Dist LEXIS 16700, at *27-28 (ND Ill 10 February 2016) (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'); *Lidoderm*, 74 F Supp 3d at 1069 ('I agree that in order to determine if a term is a large and unjustified payment, as *Actavis* requires, courts must be able to calculate its value'.); *In re Effexor XR Antitrust Litig*, No. 11-5479, 2014 US Dist LEXIS 142206, at *60 (DNJ 6 October 2014) ('In applying *Actavis* here, the non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors'.), appeal docketed, No. 15-1274 (3d Cir 3 February 2015); *In re Lipitor Antitrust Litig*, 46 F Supp 3d 523, 547 (DNJ 2014) ('Plaintiffs failed to plausibly allege an estimate of the monetary value of the non-monetary payment, and the amount of legal fees of Ranbaxy should have been subtracted from same'.), appeal docketed, No. 14-4202 (3d Cir 24 October 2014). On 8 July 2015, the Third Circuit

consolidated the appeals in *Effexor* and *Lipitor*, and oral argument occurred on 19 May 2017.

17 See, eg, *Aggrenox*, 94 F Supp 3d at 244-45 ('I cannot conclude simply from the absence of precise figures that the pleadings represent formulaic recitations of elements and allegations that fail to rise above the speculative…'); *Niaspan*, 42 F Supp 3d at 752 ('[A] no-AG provision works exactly as would a payment of cash. One can logically infer that, all else equal, with a no-AG provision, a generic would be willing to agree to a later entry date than it would otherwise agree to in order to settle a patent-infringement case'.).

18 *In re Effexor XR Antitrust Litig and In re Lipitor Antitrust Litig*, Nos. 14-4202, 14-4203, 14-4204, 14-4205, 14-4206, 14-4602, at 54-56 (3d Cir 21 August 2017).

19 Id. at 59 n.11.

20 Id. at 60.

21 Id. at 62.

22 *In re Actos End Payor Antitrust Litig*, No. 13-CV-9244, 2015 US Dist LEXIS 127748, at *63 (SDNY 22 September 2015).

23 Id. at *45-58.

24 Id. at *63.

25 In February 2017, the US Court of Appeals for the Second Circuit affirmed the dismissal of the false patent description claims where 'plaintiffs' theory presupposes that these [generic] applicants were aware of Takeda's allegedly false patent descriptions when they filed their applications,' but reversed as to one generic company where plaintiffs' theory 'does not require any knowledge of the false patent descriptions'. *In re Actos End-Payor Antitrust Litig*, 848 F.3d 89, 93 (2d Cir 2017).

26 *FTC v AbbVie Inc*, 107 F Supp 3d 428, 432-36 (ED Pa 2015).

27 Id. at 430.

28 Id. at 436.

29 Id.

30 *Sergeants Benevolent Ass'n Health & Welfare Fund v Actavis, PLC*, No. 15-cv-6549, 2016 US Dist LEXIS 128349, at *43-44 (SDNY 13 September 2016).

31 Id. at *44.

32 Id. at *45-46.

33 Id. at *47.

34 Id. at *48-49.

35 Id. at *49.

36 Id.

37 *In re Asacol Antitrust Litig*, No. 1:15-cv-12730, 2016 US Dist LEXIS 94605, at *18 (D Mass 20 July 2016).

38 Id.

39 Id.

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41 Id.

42 Id. at *24.

43 Id.

44 Id. at *25.

45 *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503, 2015 US Dist LEXIS 125999, at *41 (D Mass 14 August 2015).

46 Id.

47 Id. at *42.

48 Id. at *45-53.

49 *King Drug Co of Florence v Cephalon, Inc*, 88 F Supp 3d 402, 405 (ED Pa 2015) (*In re Modafinil Litigation*).

50 Id.

51 Id.

52 Id. at 417; see also *Aggrenox*, 94 F Supp 3d at 243 ('I agree with the defendants that payments smaller than avoided litigation costs are presumptively not large and unexplained under *Actavis*, and represent a de facto safe harbor…').

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61 Id.

62 Id. at *19-20.

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67 *In re Nexium (Esomeprazole) Antitrust Litig*, 842 F.3d 34, 39-40 (1st Cir 21 November 2016).

68 Id. at 39.

69 Id. at 62.

70 Id. at 64.

71 *In re K-Dur Antitrust Litig*, No. 01-CV-1652, 2016 US Dist LEXIS 22982, at *49-50 (DNJ 25 February 2016).

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73 Id. at *54-62.

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83 *Walgreen Co v AstraZeneca Pharm LP (Prilosec)*, 534 F Supp 2d 146, 151 (DDC 2008).

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91 *Mylan Pharms, Inc v Warner Chilcott Pub*, 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 defendants did not violate the Sherman Act); see also id. at *34.
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139 White & Case LLP represents defendants in the following cases discussed in this academic article: *FTC v Actavis*, *Aggrenox*, *Asacol*, *Effexor*, *K-Dur Lipitor*, *Loestrin*, *Doryx*, *Namenda I* and *Namenda II*. 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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A key feature of our practice is in handling matters of first impression relating to the cutting-edge, fast-moving area at the intersection between IP and antitrust in the pharmaceutical industry. Our work on behalf of pharmaceutical clients includes defense against challenges to 'reverse payment' patent settlement agreements, 'product-hopping', claims of Walker Process fraud before the US Patent and Trademark Office, 'sham' IP enforcement and US Food and Drug Administration petitioning, and other allegations of improper conduct to delay or inhibit competition. In the US, we have extensive experience litigating claims brought by both private class action and opt-out plaintiffs as well as the US Federal Trade Commission and US Department of Justice.