

United States: Pharmaceutical Antitrust

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The past year has seen an increase in US case law developments in the area of pharmaceutical antitrust. This chapter focuses on the four 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;
- alleged barriers to competition created when innovator companies deny generic companies access to sample product under REMS safety restrictions on distribution; 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 short time since, we have seen conflicting district court decisions, the first jury trial 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, federal courts have 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. In February 2016, 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 Court has not decided whether to grant the petition, but recently asked the US Solicitor General to weigh in on the issue.

In *Loestrin*, the US District Court in 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.’⁸ 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’.⁹

Plaintiffs appealed this ruling to the US Court of Appeals for the First Circuit, which reversed the district court’s cash-only decision.¹⁰ 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.’¹¹ 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.’¹² 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.¹³ 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.¹⁴ 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.’¹⁵ 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.¹⁶

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.’¹⁷ 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’.¹⁸ 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.’¹⁹ Other aspects of this case are pending on appeal in the US Court of Appeals for the Second Circuit.²⁰

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.²¹ 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 royalties on Teva’s profits.²² 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 us and then sell it to the public in competition with Abbott’.²³ The court concluded that the patentee ‘did not make any payment, reverse or otherwise, to the claimed infringer.’²⁴ 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.

Evaluating evidence 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.²⁵ 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.’²⁶ The court held that the burden then shifts to the defendant to show the payment is, on balance, pro-competitive, at which point plaintiffs must ‘raise a genuine dispute of material fact as to whether the reverse payment is unjustified or unexplained.’²⁷

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.’²⁸ 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.²⁹

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.’³⁰ While the court acknowledged:

Cephalon will have vigorous pro-competitive 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 or inducing the Generic Defendants to stay off of the market.’³¹

On the eve of trial, Cephalon settled with the FTC for a record-setting US\$1.2 billion fine, subject to a credit for settlements reached in related private actions,³² including a settlement with a class of direct purchasers for US\$512 million.³³ The size of 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.³⁴

Addressing a summary judgment motion in *Nexium*, the US District Court in Massachusetts likewise 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.³⁵ There was a variety of evidence that the court thought a

reasonable jury might rely on to reach such a conclusion, including:

- 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.’³⁶

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 AstraZeneca would not have agreed to an earlier settlement entry date even if there had not been a reverse payment, which ended the case despite the jury’s finding that AstraZeneca had market power and that there had been a ‘large and unjustified’ anticompetitive payment.³⁷ The plaintiffs’ motion for a new trial was denied, leading to the pending appeal in the US Court of Appeals for the First Circuit.³⁸

In *K-Dur*, the US District Court for the District of New Jersey similarly denied summary judgment for the 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.³⁹ Although the court recognised that 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’, plaintiffs have also offered evidence that counters defendants’ arguments and raises a genuine dispute of material fact.⁴⁰ In particular, 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.⁴¹ The court, however, rejected 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.⁴²

In contrast to the three 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.’⁴³ This decision is pending on appeal in the US Court of Appeals for the Third Circuit.⁴⁴

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-2014 cases: TriCor, Prilosec and Doryx

Prior to 2014, only three decisions dealt with product-hopping claims in the pharmaceutical context, all 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.⁴⁵ 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’ allegations sufficient to support their antitrust claims based on specific allegations about defendants’ conduct: defendants were alleged to have 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.⁴⁶

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.⁴⁷ 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.⁴⁸

In *Doryx*, the court denied defendants’ motion to dismiss on the grounds that the court would be required to consider facts beyond the pleadings to decide on the product-hopping issue.⁴⁹ However, the court noted that plaintiffs’ product-hopping theory was ‘novel at best’ and conveyed scepticism that product-hopping even constitutes anticompetitive conduct under the Sherman Act.⁵⁰ As detailed below, the *Doryx* court ultimately rejected plaintiffs’ theory of anticompetitive product-hopping and granted summary judgment for defendants.

Suboxone

Since December 2014, five additional decisions have added to the body of case law on pharmaceutical product-hopping, beginning with *Suboxone*. In *Suboxone*, plaintiffs alleged that defendants engaged in anticompetitive product-hopping by seeking to shift patients from its Suboxone tablets to its Suboxone film, which enjoyed a much longer term of patent exclusivity. According to plaintiffs, defendants shifted patients to the film by falsely disparaging and fabricating safety concerns about the tablet, and by removing the tablets from the market just as generic versions of Suboxone tablets were set to enter the market.

On a motion to dismiss, the Suboxone court refused to dismiss the product-hopping claims.⁵¹ Although the parties disagreed about whether the film was an improvement over the tablet, the court's decision did not turn on an analysis of the new drug's benefits. Rather, the court observed 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]'.⁵²

The court determined that 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.⁵³

The court nonetheless found that 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.⁵⁴

Namenda

A week after *Suboxone* was decided, a federal district court in New York granted a motion for a preliminary injunction related to product-hopping claims in *Namenda*.⁵⁵ At issue in *Namenda* was defendants' plan to transition patients from an older, twice-daily drug to a newer, once-daily formulation.

The *Namenda* court adopted the *Microsoft*⁵⁶ rule of reason framework for analysing the product-hopping claims (as had the courts in *TriCor* and *Suboxone*).⁵⁷ Unlike in *TriCor* and *Suboxone*, in which the defendants fully removed the older formulation from the market, the *Namenda* defendants planned to continue making the older formulation available to any patient who had a medical need for it. Nonetheless, the *Namenda* court determined that the patient population for Alzheimer's drug Namenda was particularly vulnerable to any change from one product to another, and 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.⁵⁸ Although the court acknowledged that generic competitors would not be foreclosed from entering the market with a generic version of the twice-daily drug when patent exclusivity ended, the court determined that conduct can be found to be exclusionary where competition is not totally foreclosed but where the market's ambit is restricted.⁵⁹

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.⁶⁰ 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*⁶¹ 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.⁶²

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.⁶³

Doryx summary judgment

In April 2015, the *Doryx* court delivered the first decision in a product-hopping case with the benefit of full discovery, when it granted summary judgment for defendants and dismissed all claims.⁶⁴ At issue in *Doryx* were numerous product reformulations (including changes from capsules to tablets, changes to dosage strength and introduction of score lines), coupled with subsequent discontinuation of older versions. The court in *Doryx* held 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.⁶⁵ The court also rejected 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.⁶⁶

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.⁶⁷ The *Doryx* case is currently pending on appeal in the US Court of Appeals for the Third Circuit.

Solodyn

Another recent decision in a product-hopping case was by the *Solodyn* court in September 2015.⁶⁸ In *Solodyn*, plaintiffs alleged that 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.

Product-hopping allegations are at issue in a number of other cases in which there has yet been no substantive decision on the merits of the product-hopping claims.⁶⁹

REMS antitrust cases

The US Congress authorised the Risk Evaluation and Mitigation Strategies (REMS) programme in the Food and Drug Administration Amendments Act of 2007.⁷⁰ REMS programmes are intended to provide special safety measures and requirements for drugs that the US FDA deems to present a grave risk of danger if misused or mishandled.⁷¹ The FDA can require a REMS programme if the agency determines that such safety measures are needed to ensure that a drug's benefits outweigh its risks. The FDA may require that REMS

for a reference listed drug (RLD) ‘include such elements as are necessary to assure safe use of the drug.’⁷² Such elements to assure safe use (ETASU) may include restricted distribution, procurement and dispensing systems.⁷³

Potential antitrust issues may arise when REMS measures prevent generic pharmaceutical companies from obtaining samples of brand drugs for purposes of reformulation and potential design-around to produce generic versions of the brand drug. The FDA is unequivocal that the agency does not intend for REMS to hamper generic competition. For some pharmaceutical companies, however, implementing REMS measures entails establishing a restricted distribution system for their drugs, making those drugs unavailable to generic companies through normal distribution channels.

The FTC is concerned with alleged REMS abuses, taking the view that REMS may be misused as a strategy by branded pharmaceutical companies that may result in delaying or preventing generic entry.⁷⁴ The FTC is concerned that branded firms may use REMS-mandated distribution restrictions to ‘inappropriately limit access to product samples generic drug developers need for bioequivalence testing’ – a necessary step for FDA approval of generic drugs.⁷⁵

The FTC has filed amicus curiae briefs in civil litigation addressing REMS-restricted distribution as an allegedly anticompetitive means of denying generic companies access to product samples. In both amicus curiae briefs, the FTC asserted that the approval of generic drugs – dependent on the generic firm accessing the brand product – under the Hatch-Waxman Act facilitated generic competition and resulted in large savings for patients, healthcare plans, and federal and state governments.⁷⁶ In *Actelion*, which ultimately settled, the FTC argued that the ‘allegations in this case highlight a troubling phenomenon: the possibility that procedures intended to ensure safe distribution of certain prescription drugs may be exploited by brand companies to thwart generic competition.’⁷⁷

In *Mylan*, the FTC re-iterated its belief that such REMS-limited distribution arrangements may be used improperly to erect barriers to generic competition.⁷⁸ Although Congress ‘fail[ed] to create an explicit duty to sell samples’, the FTC stated, ‘If brand firms are able to block generic competition by denying access to the product samples needed to obtain FDA approval, this conduct may prevent the Hatch-Waxman framework from functioning as Congress intended.’⁷⁹ With monopolisation claims proceeding in the district court, the parties in *Mylan* are currently in the discovery period.

While the FTC has not taken any enforcement action concerning alleged anticompetitive REMS practices beyond the agency’s amicus curiae briefs,⁸⁰ the FDA had proposed a potential remedy through its draft guidance⁸¹ and recently US legislation has been introduced that attempts to mitigate REMS-related denial of access to product samples. On 14 June 2016,⁸² Senator Patrick Leahy (D-VT) introduced a bill called the Creating and Restoring Equal Access to Equivalent Samples Act of 2016 (or CREATES Act of 2016)⁸³ to ‘provide for certain causes of action relating to delays of generic drugs and biosimilar biological products’ to the Senate.⁸⁴ The bill provides for generic manufacturers, termed ‘eligible product developer’ within the bill, to bring a civil action against a brand company (licence holder) for a covered product if the brand company does not provide ‘sufficient quantities’ of its covered product to the generic manufacturer.⁸⁵ A brand company’s failure to provide ‘sufficient quantities’ can be for a covered product under the REMS program, or within another restricted distribution arrangement.⁸⁶ Remedies include ordering the license holder to provide the covered product on ‘commercially reasonable terms’ as well as attorney fees and costs and a monetary award ‘sufficient to deter the license holder’

to the generic manufacturer.⁸⁷ The proposed bill invokes section 5 of the FTC Act (15 USC 45) ‘to the extent that such section applies to unfair methods of competition’ and provides that the cause of action and remedies are not to be construed ‘to limit the operation of any provision of the antitrust laws.’⁸⁸

Challenges to pharmaceutical manufacturers’ pricing practices

The pricing decisions of both brand and generic pharmaceutical manufacturers have garnered substantial attention over the last year. Critics have challenged the initial price for new, patent-protected therapies, citing access and affordability concerns. Likewise, critics have challenged substantial price increases for generic products, and off-patent brand products that face little or no generic competition, claiming generally that such increases were unexplained by market circumstances or unjustified by the need to fund research and development costs. Collectively, these challenges by lawmakers, enforcement agencies, and private plaintiffs raise a number of issues, only some of which are addressed by the antitrust laws. Indeed, absent some form of exclusionary conduct, antitrust law typically is not concerned with manufacturers’ unilateral pricing practices.⁸⁹ Antitrust law concerns itself with market structure and conduct; pricing by itself has been considered economic regulation outside the antitrust laws. While serving as head of the DOJ’s Antitrust Division, Bill Baer summarised this view in remarks at the Annual International Bar Association Competition Conference in Italy.⁹⁰ Thus, while antitrust law may have a limited role in the ongoing public debate over drug pricing, much of which focuses on issues such as how limitations on unilateral pricing freedom would affect pharmaceutical manufacturers’ incentives to innovate, traditional forms of anticompetitive conduct in connection with pharmaceutical pricing have received antitrust scrutiny.

Challenges to brand-name drug pricing

Recent innovations have brought to market an increasing number of specialty and other patent-protected therapies with costs that can run to tens of thousands of dollars annually for a single patient. Complaints about the cost for these therapies have arisen despite the potential life-saving benefits provided by some patented therapies. For example, lawmakers, consumer and payer-supported trade groups, and others have criticised the prices for the new generation of hepatitis C vaccines, despite the fact that these new vaccines may cure the disease within several weeks and replace a prior standard-of-care drug regimen that was both costly and ineffectual as a cure.⁹¹ The recent legal challenges to the cost of innovative drug therapies have cited cost as a barrier to access for patients and relied on consumer protection and other laws – not antitrust.⁹²

Far more attention in the past year has been focused on price increases on off-patent, brand-name drugs. Much of this scrutiny came after press reports about Turing Pharmaceuticals’ acquisition, and subsequent fiftyfold price increase, of the off-patent, branded drug Daraprim, which is used to treat parasitic infections and prevent nervous-system infections in those with HIV. In the last two years, two separate congressional committees have launched investigations into brand pricing practices – more specifically, off-patent, brand-name drugs recently acquired by the company and then subjected to a price increase.⁹³ Similarly, state and federal enforcers have directed their attention to price increases for off-patent brands. Earlier this year, it became clear that the FTC is investigating Turing Pharmaceuticals, reportedly in connection with Turing’s pricing practices.⁹⁴ The New York Attorney General

has also been investigating Turing concerning Daraprim, focusing on the company's limited distribution through a specialty pharmacy, and whether that limitation unlawfully impedes generic competition by restricting access to the samples generic manufacturers use to conduct tests for regulatory approval.⁹⁵ And in 2015, federal prosecutors in both New York and Massachusetts issued subpoenas to Valeant Pharmaceuticals regarding its pricing practices, as well as other aspects of its business, such as distribution methods and patient-assistance programs.⁹⁶

Valeant's distribution and pricing have also drawn the attention of private plaintiffs. In May of 2016, Valeant was sued by a proposed class of indirect purchasers alleging the company and its executives violated the Racketeer Influenced and Corrupt Organizations Act by allegedly shielding the company's drugs from competition through the mail-order pharmacy, Philidor, which plaintiffs claim altered prescriptions and manipulated prices to favour Valeant's drugs.⁹⁷ Plaintiffs allege Philidor and Valeant worked together to prevent competition at Philidor's network of pharmacies and fraudulently inflated the prices of Valeant's products.

Challenges to price increases of generic drugs

Recent price increases by generic drug manufacturers have also attracted the attention of federal and state enforcement agencies, federal legislators, and private plaintiffs. Starting in 2014, DOJ's Antitrust Division issued grand jury subpoenas to a number of generic manufacturers, reportedly seeking marketing and pricing information for the antibiotic doxycycline hyclate, the heart drug digoxin, and other products, as well as communications with competitors about such products.⁹⁸ That same year, the Connecticut Attorney General subpoenaed a similar group of generic manufacturers for information regarding digoxin as part of an investigation into alleged collusion among those manufacturers.⁹⁹

Separately, the Senate Committee on Health, Education, Labor and Pensions, led in part by Senator Bernie Sanders, and the House Committee on Oversight and Government Reform initiated an investigation of their own into generic drug pricing, but on a broader scale. The congressional investigation requested pricing information for 10 generic drugs from 14 different manufacturers.¹⁰⁰ A November 2014 congressional hearing followed where the generic drug manufacturers were asked to explain rising drug prices.¹⁰¹ And earlier this year, the Senate Special Committee on Aging inquired into the rising cost of naloxone, a drug used to reverse the effects of opioids, asking five manufacturers to explain their price changes on the product.¹⁰²

Private plaintiffs followed the initial investigation with a lawsuit alleging a price-fixing conspiracy. In March 2016, a union health plan filed a proposed indirect-purchaser class action claiming a group of generic manufacturers conspired to raise prices for generic versions of digoxin and doxycycline hyclate. The complaint alleges that between October 2013 and April 2014, the average price of doxycycline hyclate increased from US\$20 to US\$1849, and the price of digoxin increased from US\$0.11 to US\$1.10. The complaint makes general allegations of possible coordination between the defendants, but otherwise alleges parallel price increases in what have become oligopolistic product markets after exit by some generic manufacturers.¹⁰³ Yet it is well established that conscious parallel conduct does not fall within the purview of the Sherman Act.¹⁰⁴ The suit, which alleges violations of sections 1 and 2 of the Sherman Act, as well as violations of state antitrust, consumer protection, and common law unjust-enrichment laws, is based on the same allegations underlying the DOJ, Connecticut AG, and congressional investigations.

Follow-on class action suits have been filed by individuals, other union health plans, the City of Providence, and direct purchasers.¹⁰⁵

Notes

- 1 *FTC v Actavis*, 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 *Loestrin*, 45 F Supp 3d at 193.
- 9 *Id.*
- 10 *In re Loestrin 24 Fe Antitrust Litig*, 814 F.3d 538, 542 (1st Cir 2016).
- 11 *Id.* at 550.
- 12 *Id.* at 552.
- 13 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 anticompetitive 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*, No. 2:16-cv-01440 (ED Pa).
- 14 *Lidoderm*, 74 F Supp 3d at 1070 (emphasis in original) (internal quotation marks omitted).
- 15 *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 WL 4988410, at *20 (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*.
- 16 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’).
- 17 *In re Actos End Payor Antitrust Litig*, No. 13-CV-9244, 2015 US Dist. LEXIS 127748, at *63 (SDNY 22 September 2015).
- 18 Id. at *45-58.
- 19 Id. at *63.
- 20 *In re Actos End Payor Antitrust Litig*, No. 13-CV-9244, 2015 US Dist. LEXIS 127748, at *63 (SDNY 22 September 2015), appeal docketed, No. 15-3364 (22 October 2015).
- 21 *FTC v AbbVie Inc*, 107 F Supp 3d 428, 432-36 (ED Pa 2015).
- 22 Id. at 430.
- 23 Id. at 436.
- 24 Id.
- 25 *King Drug Co of Florence v Cephalon, Inc*, 88 F Supp 3d 402, 405 (ED Pa 2015) (*In re Modafinil Litigation*).
- 26 Id.
- 27 Id.
- 28 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...’).
- 29 *Cephalon*, 88 F Supp 3d at 407-10, 418.
- 30 Id. at 417.
- 31 Id. at 421.
- 32 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.
- 33 Mot. in Support 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.
- 34 Order at 1, *FTC v Cephalon, Inc*, No. 2:08-cv-02141 (ED Pa 17 June 2015), ECF No. 376; Pl. 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.
- 35 *In re Nexium (Esomeprazole) Antitrust Litig*, 42 F Supp 3d 231, 264 (D Mass 2014).
- 36 Id. (internal citations omitted).
- 37 Id.
- 38 Am. Mem. & Order Denying Mot. for New Trial, *In re Nexium (Esomeprazole) Antitrust Litig*, No. 1:12-md-2409 (D Mass 7 August 2015), ECF No. 1545, appeal docketed, Nos. 15-2005, 15-2006, 15-2007 (1st Cir 11 September 2015).
- 39 *In re K-Dur Antitrust Litig*, No. 01-CV-1652, 2016 US Dist. LEXIS 22982, at *49-50 (D NJ 25 February 2016).
- 40 Id. at *53-54.
- 41 Id. at *54-62.
- 42 Id. at *72-80.
- 43 *In re Wellbutrin XL Antitrust Litig*, No. 08-2431, 2015 US Dist. LEXIS 127373, at *62 (ED Pa 23 September 2015), appeal docketed, No. 15-2875 (3d Cir 10 August 2015).
- 44 *In re Wellbutrin XL Antitrust Litig*, No. 08-2431, 2015 US Dist. LEXIS 127373 (ED Pa 23 September 2015), appeal docketed, No. 15-2875 (3d Cir 10 August 2015).
- 45 *Abbott Labs v Teva Pharm USA, Inc (TriCor)*, 432 F Supp 2d 408, 422 (D Del 2006).
- 46 Id. at 423-24.
- 47 *Walgreen Co v AstraZeneca Pharm LP (Prilosec)*, 534 F Supp 2d 146, 151 (DDC 2008).
- 48 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’).
- 49 *Mylan Pharms, Inc v Warner Chilcott plc (Doryx)*, 2013 WL 5692880 (ED Pa 12 June 2013).
- 50 Id. at *2.
- 51 *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig*, 64 F Supp 3d 665 (ED Pa 2014).
- 52 Id. at 682.
- 53 Id. at 681-82.
- 54 Id. at 682-84.
- 55 *New York v Actavis plc (Namenda)*, 2014 WL 7015198 (SDNY 11 December 2014).
- 56 *United States v Microsoft*, 253 F.3d 34 (DC Cir 2001).
- 57 2014 WL 7015198, at *38-39.
- 58 Id. at *39.
- 59 Id.
- 60 *New York v Actavis plc*, 787 F.3d 638, 643 (2d Cir 2015).
- 61 *Berkey Photo, Inc v Eastman Kodak Co*, 603 F.2d 263 (2d Cir 1979).
- 62 787 F.3d at 653-54 (emphasis in original).
- 63 See id. at 653-59.
- 64 *Mylan Pharms, Inc v Warner Chilcott plc*, 2015 WL 1736957 (ED Pa 16 April 2015); see also id. at *15 (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).
- 65 Id. at *12.
- 66 Id. at *15.
- 67 Id. at *14.
- 68 *Solodyn*, 2015 WL 5458570 (D Mass 16 September 2016).
- 69 See *JM Smith Corp v Actavis plc*, 15-cv-7488 (SDNY) (Namenda); *In re Loestrin 24 Fe Antitrust Litig*, No. 13-md-2472 (D RI); *Hartig Drug Co Inc v Senju Pharmaceutical Co*, 14-cv-0719 (D Del) (*Zymar/Zymaxid*); see also *In re Opana ER Antitrust Litig*, 14-cv-10150 (ND Ill) (product-hopping theory advanced as evidence that reverse payment agreement caused injury in fact, not as independent claim).
- The Zymar/Zymaxid* court dismissed the case based on lack of subject matter jurisdiction, and did not reach the merits of the claims alleged, 122 F Supp 3d 202 (D Del 2015). That case has been appealed to the US Court of Appeals for the Third Circuit.
- 70 Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub L No. 110-85, tit. IX, 121 STAT. 823, 922-62 (2007), codified at 21 USC section 355-1 (2010).
- 71 Safety risks that REMS requirements aim to mitigate include serious infections, allergic reactions, liver damage and severe birth defects. FDA, A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS), at 3, FDA.GOV, available at www.fda.gov/AboutFDA/Transparency/Basics/

- ucm325201.htm (last updated 9 June 2015) (FDA Overview).
- 72 21 USC section 355-1(f)(1).
- 73 21 USC section 355-1(f)(3); FDA Overview at 12-15.
- 74 Prepared Statement of the FTC Before the US House of Representatives Committee on the Judiciary, Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Oversight of the Enforcement of the Antitrust Laws at p. 10 (May 15, 2015), https://www.ftc.gov/system/files/documents/public_statements/642691/150515antitrustoversight.pdf.
- 75 Prepared Statement of the FTC Before the US House of Representatives Committee on the Judiciary, Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Oversight of the Enforcement of the Antitrust Laws at p. 10 (May 15, 2015), https://www.ftc.gov/system/files/documents/public_statements/642691/150515antitrustoversight.pdf.
- 76 FTC Brief as Amicus Curiae at 3-4, *Mylan Pharms Inc v Celgene Corp*, No. 2:14-cv-02094-ES-MAH, 2014 WL 2968348 (DNJ filed 3 April 2014) (FTC Mylan Amicus Br); FTC Brief as Amicus Curiae at 3-4, *Actelion Pharms Ltd v Apotex Inc*, No. 1:12-cv-05743-NLH-AMD (DNJ filed 14 September 2012) (FTC Actelion Amicus Br).
- 77 FTC Actelion Amicus Br at 1
- 78 See FTC Mylan Amicus Curiae at 12-13 (explaining that distribution restrictions may prevent generic firms from purchasing brand products from wholesale distributors and that allowing brand firms to prevent generic competition simply by denying access to product samples needed for bioequivalence testing 'threatens to undermine the careful balance created by the Hatch-Waxman Act and potentially preserve a brand firm's monopoly indefinitely')
- 79 See FTC Mylan Amicus Br at 16-17.
- 80 Notably, an adviser to FTC Commissioner Joshua Wright stated: 'bringing an antitrust action against brand-name drug makers for using restrictive drug-safety protocols to avoid competition would be difficult, and that antitrust law may not be the best tool to redress harm'. Harry Phillips, FTC adviser: REMS case would be 'very difficult', *GCR* (19 November 2014).
- 81 FDA, How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD Guidance for Industry – Draft Guidance, 79 Fed Reg 72185, 72185 (5 December 2014). The FDA has not finalised a date for publishing the final guidance.
- 82 CREATES Act of 2016, S 3056, 114th Cong (2016). The bi-partisan bill is co-sponsored by Senators Chuck Grassley (R-IA), Amy Klobuchar (D-MN), and Mike Lee (R-UT). See Congress.gov, S.3056-A bill to provide for certain causes of action relating to delays of generic drugs and biosimilar biological products, <https://www.congress.gov/bill/114th-congress/senate-bill/3056/actions>.
- 83 CREATES Act of 2016, S 3056, 114th Cong (2016) at section 1.
- 84 S 3056, 114th Cong (2016).
- 85 Id. at section 3.
- 86 Id.
- 87 Id.
- 88 Id.
- 89 See, eg, *Verizon Commc'ns Inc v Law Offices of Curtis V Trinko, LLP*, 540 US 398, 407 (2004) ('The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices-at least for a short period-is what attracts 'business acumen' in the first place; it induces risk taking that produces innovation and economic growth').
- 90 Bill Baer, Reflections on the Role of Competition Agencies When Patents Become Essential, 19th Annual International Bar Association Competition Conference (11 Sept 2015), <https://www.justice.gov/opa/file/782356/download>.
- 91 Michael Hiltzik, Is that \$100,000 hepatitis treatment worth the price? Yes, but can society afford it?, *LA Times* (15 Jan 2016), <http://www.latimes.com/business/hiltzik/la-fi-mh-that-hepatitis-treatment-20160111-column.html>.
- 92 See *Southeastern Pennsylvania Transportation Authority v Gilead Sciences, Inc*, 102 F Supp 3d 688 (ED Pa 2015) (dismissing state law claims and discrimination claims under federal Patient Protection and Affordable Care Act alleging that price unlawfully precluded patient access to Gilead's Hepatitis C drug); see also 22 January 2016 Letter from Massachusetts Attorney General to Gilead Sciences, Inc., <http://www.mass.gov/ago/docs/policy/2016/letter-to-gilead-1-22-16.pdf>.
- 93 Developments in the Prescription Drug Market: Hearing Before the H. Comm. on Oversight and Government Reform (4 February 2016, 9:00 AM), <https://oversight.house.gov/hearing/developments-in-the-prescription-drug-market-oversight/>. (focusing on Valeant Pharmaceuticals, Retrophin, Inc, and Rodelis Therapeutics, in addition to Turing).
- 94 Nate Raymond & David Ingram, Exclusive: US FTC Probes Turning Over Drug Prices, Shkreli's Lawyer Says, Reuters (22 January 2016, 4:43 PM), <http://www.reuters.com/article/us-usa-crime-shkreli-idUSKCN0V026V>.
- 95 Andrew Pollack, New York Attorney General Examining Whether Turning Restricted Drug Access, *NY Times* (12 October 2015), http://www.nytimes.com/2015/10/13/business/new-york-attorney-general-examining-if-turing-restricted-drug-access.html?_r=0.
- 96 Andrew Pollack, Valeant Under Investigation for its Drug Pricing Practices, *NY Times* (14 October 2015), <http://www.nytimes.com/2015/10/15/business/valeant-under-investigation-for-its-drug-pricing-practices.html>.
- 97 Complaint at 13-20, *Air Conditioning & Refrigeration Industry Health and Welfare Trust Fund et al*, 3:16-cv-03087 (D NJ Filed 27 May 2016).
- 98 See eg, *Endo International PLC*, Quarterly Report on Form 10-Q, filed on EDGAR on 9 November 2015, <http://www.sec.gov/Archives/edgar/data/1593034/000159303415000034/endorp-9302015x10q.htm>; *Impax Laboratories*, Notice on Form 8-K, filed on EDGAR on 07/14/2014; *Lannett Company, Inc.*, Annual Report on Form 10-K, filed on EDGAR on 30 June 2015, http://www.sec.gov/Archives/edgar/data/57725/000110465915062047/a15-13005_110k.htm; *Mylan N.V.*, Report on Form 8-K, filed on EDGAR on 4 December 2015, [http://www.sec.gov/Archives/edgar/data/1578845/000156459015006357/agn-10q_20150630.htm](http://www.sec.gov/Archives/edgar/data/cuments%20requested%20by%20the%20committeee.eform%20is%20a%20press%20release%20on%20Valeant%20ons%20as%20of%20yet%20-%20the%20and%20price-fixing%20conspiracies.essiv1623613/000119312515394875/d225442d8k.htm); *Par Pharmaceutical Companies, Inc.*, Annual Report on Form 10-K, filed on EDGAR on 13 March 2015, <http://www.sec.gov/Archives/edgar/data/878088/000087808815000002/prx-20141231x10k.htm>; see also *Sun Pharma gets US subpoena over pricing of generic drugs*, *Business Standard* (29 May 2016), http://www.business-standard.com/article/companies/sun-pharma-gets-us-subpoena-over-pricing-of-generic-drugs-116052900049_1.html.
- 99 See eg, *Impax Laboratories, Inc*, Annual Report on Form 8-K, filed on EDGAR on 14 July 2014, <http://d1lge852tjjqow.cloudfront.net/NasdaqGlobal-IPXL/81a4ea5e-c19f-4711-90b2-fc53fb02a2e5.pdf>; *Lannett Company, Inc.*, Annual Report on Form 8-K, filed on EDGAR on 16 July 2014, http://www.sec.gov/Archives/edgar/data/57725/000110465914051861/a14-17295_18k.htm.
- 100 Ranking Member Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs, <http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file> (last visited 29 March 2016); see also Press Release, Senator Bernie

Sanders, Congress Investigating Why Generic Drug Prices are Skyrocketing, (2 October 2014), <http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing>.

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- 102 Chairman Collins, Ranking Member McCaskill Seek Information from Companies on Efforts to Preserve Accessibility of Opioid Overdose Reversal Drug, Special Committee on Aging (6 June 2016), <http://www.aging.senate.gov/press-releases/chairman-collins-ranking-member-mccaskill-seek-information-from-companies-on-efforts-to-preserve-accessibility-of-opioid-overdose-reversal-drug>.
- 103 Complaint at 2, *Int'l Union of Operating Engineers Local 30 Benefits Fund v Lannett Co, Inc*, No. 2:16-CV-00990 (ED Pa filed 2 March 2016).
- 104 *Bell Atl Corp v Twombly*, 550 US 544, 557 (2007); *Brooke Grp Ltd v Brown & Williamson Tobacco Corp*, 509 US 209, 227 (1993).
- 105 White & Case LLP represents defendants in the following cases discussed in this article: *FTC v Actavis*, *Aggrenox*, *Effexor*, *Lipitor*, *Loestrin*, *Doryx* and *Namenda*. No statement in this academic 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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With 37 offices in 26 countries, White & Case LLP is a truly global law firm, uniquely positioned to help our clients achieve their ambitions in today's G20 world. As a pioneering international law firm, our cross-border experience and diverse team of local, US and English-qualified lawyers consistently deliver results for our clients. As a full-service firm in both established and emerging markets, we work with some of the world's most established banks and businesses as well as start-up visionaries, governments and state-owned entities.

Our global competition group consistently ranks as one of the top antitrust practices in the world, with more than 190 experienced competition practitioners in 22 of our offices across 14 countries worldwide. Our experience includes government and private litigation, trials and appeals, mergers, acquisitions and joint ventures, and numerous precedent-setting wins for our clients. In the pharmaceutical sector, we have unparalleled experience. According to Global Competition Review in 2016, 'No firm is more prolific or successful in handling major antitrust litigation targeting the pharmaceutical industry than White & Case'.

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.