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United States: Pharmaceutical Antitrust

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The past year has arguably seen more US case law developments in the area of pharmaceutical antitrust than ever before. This chapter focuses on the four types of pharmaceutical antitrust cases that have been most active this year:

- 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
- a spate of litigation alleging anti-competitive unilateral pricing practices by the leading suppliers of contact lenses.

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 decision 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 *Loestrin*, the US District Court in Rhode Island 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 authorized generic" [no-AG] agreement on the part of the brand manufacturer'.[5] 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'.[6] The dismissal was appealed and is now pending in the US Court of Appeals for the First Circuit.

The US District Court for New Jersey reached a similar no 'payment' conclusion in *Lamictal*, granting 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 "authorized generic" for a certain period of time.*[7]

On appeal, however, the US Court of Appeals for the Third Circuit – the only federal appellate court to address 'the no authorised generic' issue thus far – 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.*[8]

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'.[9] 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.

Some 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.[10] 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.[11] 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'.[12] 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.[13]

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 anti-competitive reverse payment.[14] The court concluded that there was no anti-competitive '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.[15] Despite 'something of large value passing 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'.[16] The court concluded that the patentee 'did not make any payment, reverse or otherwise, to the claimed infringer'.[17] The FTC is seeking final judgment on this issue to permit the agency to file an interlocutory appeal in the US Court of Appeals for the Third Circuit while the FTC's sham litigation claim against Abbott proceeds in the district court.[18]

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.[19] Rather, that court held that plaintiffs 'must present evidence of a large reverse payment as part of their initial burden of demonstrating anti-competitive effects under the rule of reason'.[20] 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'.[21]

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'.[22] 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.[23]

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'.[24] While the court acknowledged:

> *that 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 and/or inducing the Generic Defendants to stay off of the market.*[25]

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,[26] including a settlement with a class of direct purchasers for US$512 million.[27] 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.[28] Although the Commission unanimously approved seeking disgorgement, Commissioners Maureen Ohlhausen and Joshua Wright issued a statement conveying their 'continuing concerns about the lack of guidance the Commission has provided on the pursuit of this extraordinary remedy' and proposing that the evidence should have been analysed under 'the factors set forth in the since-withdrawn Commission policy statement on pursuing disgorgement in competition cases'.[29] In addition to the fine, the settlement also included a permanent injunction in which Teva, having acquired Cephalon, is prohibited from:

> *entering into any Brand/Generic Settlement that includes: (1) Payment by the NDA Holder to the ANDA Filer; and (2) an agreement by the ANDA Filer not to research, develop, manufacture, market or sell the Subject Drug Product for any period of time.*[30]

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.[31] 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'.[32]

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. Specifically, question four on the verdict form asked:

> *Had it not been for the unreasonably anti-competitive settlement, would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before 27 May 2014?*[33]

The jury's 'No' answer to that question ended the case despite the preceding 'Yes' answers on market power and whether there had been a 'large and unjustified' anti-competitive payment.[34] The plaintiffs in *Nexium* have a pending motion for a new trial.

State law developments under Actavis

A notable development in the state law context is the California Supreme Court's *In re Cipro I & II* decision, where the court essentially adopted *Actavis*'s rule of reason analysis.[35] Rejecting the lower court's scope of the patent analysis under California's state antitrust law, the Cartwright Act, the California Supreme Court revived claims that Bayer made anti-competitive payments to Barr of US$398.1 million in exchange for a delayed settlement entry date.[36]

In reaching this conclusion, the California Supreme Court clarified that in applying what it referred to as a 'structured' rule of reason analysis, plaintiffs must establish four elements:

> *(1) the settlement includes a limit on the settling generic challenger's entry into the market; (2) the settlement includes cash or equivalent financial consideration flowing from the brand to the generic challenger; and the consideration exceeds (3) the value of goods and services other than any delay in market entry provided by the generic challenger to the brand, as well as (4) the brand's expected remaining litigation costs absent settlement.*[37]

Although the court did not define 'equivalent financial consideration' as part of the second element, the California Supreme Court apparently wished to foreclose the 'cash only' reasoning that has been applied by some federal district courts under *Actavis*.

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 (ANDA) 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.[38] 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 anti-competitive 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.[39]

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.[40] 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.[41]

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.[42] However, the court noted that plaintiffs' product-hopping theory was 'novel at best' and conveyed scepticism that product hopping even constitutes anti-competitive conduct under the Sherman Act.[43] As detailed below, the *Doryx* court ultimately rejected plaintiffs' theory of anti-competitive product hopping and granted summary judgment for defendants.

Suboxone

Since December 2014, four 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 anti-competitive 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.[44] 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]'.[45]

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.[46]

The court nonetheless found that plaintiffs had sufficiently pleaded 'other wrongful conduct' insofar as:

> *The threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film.*[47]

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*.[48] 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*[49] rule of reason framework for analysing the product-hopping claims (as had the courts in *TriCor* and *Suboxone*).[50] 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.[51] 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.[52]

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.[53] 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*[54] in its holding that:

> *neither product withdrawal nor product improvement alone is anti-competitive ... [but] when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act.*[55]

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.[56]

Defendants petitioned the Second Circuit for rehearing en banc.[57] That petition remains pending.

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.[58] 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.[59] The court also rejected plaintiffs' contention that the product reformulations were anti-competitive because they were insufficiently innovative, noting that no intelligible test for innovation 'sufficiency' had been offered and doubting that courts could ever fashion one.[60]

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, 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.[61]

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.[62] REMS programmes are intended to provide special safety measures and requirements for drugs that the US Food and Drug Administration (FDA) deems to present a grave risk of danger if misused or mishandled.[63] 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'.[64] Such elements to assure safe use (ETASU) may include restricted distribution, procurement and dispensing systems.[65]

Potential antitrust issues may arise when REMS measures prevent generic pharmaceutical companies from obtaining samples of brand drugs for purposes of deformulation 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 believes that such REMS-limited distribution arrangements may be used improperly to erect barriers to generic competition.[66]

Recent civil actions have addressed REMS-restricted distribution as an allegedly anti-competitive means of denying generic companies access to product samples. In two separate suits, generic manufacturer Mylan Pharmaceuticals Inc and follow-on class action plaintiffs alleged that Celgene Corporation violated federal and state antitrust laws by refusing to provide samples of its Thalomid and Revlimid brand products to generic companies for bioequivalence studies due to Celgene's REMS-limited distribution arrangements.[67] The FTC filed an amicus curiae brief in the *Mylan*

case arguing that there could potentially be an antitrust violation. 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'.[68] In Mylan's suit, the district court granted Celgene's motion to dismiss as to Mylan's allegations of conspiracy in restraint of trade, but denied the motion to dismiss as to Mylan's allegations of attempted monopolisation. The Third Circuit denied Celgene's petition for interlocutory appeal regarding the denial of dismissal of the monopolisation claims, which are currently proceeding in the district court. Celgene's motion to dismiss the class action case is pending.

In another REMS case, brand company Actelion Pharmaceuticals Ltd filed suit for declaratory relief against generic companies that had insisted on receiving samples of its product. Actelion asserted that it had 'a legal obligation to comply with the restricted distribution scheme of its REMS program, which does not allow it to provide samples of Tracleer to Apotex or Roxane', and that there was no 'legal obligation that forces a branded company such as Actelion to supply a drug product covered by a REMS to a potential generic competitor'.[69] The case was ultimately dismissed when the parties settled.

The FDA has proposed a potential remedy for the REMS controversy and has issued draft guidance describing how a prospective generic drug applicant may request a letter from the agency stating that the 'FDA will not consider it a violation of the REMS ... to provide a sufficient quantity of the RLD to the interested generic firm or its agent to allow the firm to perform the testing necessary to support its ANDA'.[70] Additionally, the FDA refers to the FTC any grievances the FDA receives from generic drug manufacturers claiming that a brand drug company has refused to provide sample product due to a REMS-restricted distribution system. The FTC has yet to take any action concerning alleged anti-competitive REMS practices beyond the agency's amicus curiae brief in the *Mylan v Celgene* case.[71]

Other developments: Contact lens antitrust litigation

Numerous actions have been filed in 2015 against Johnson & Johnson, Alcon Laboratories, Bausch & Lomb and CooperVision, accusing defendants of perpetuating illegal resale price maintenance (RPM) on contact lens sales.[72] Plaintiffs claim that defendants, which together account for approximately 97 per cent of contact lens sales revenue in the US, have employed unilateral pricing policies (UPPs) that artificially inflate contact lens prices in order to thwart deep discounts provided by retailers such as Wal-Mart, Costco, 1-800-Contacts and LensDiscounters.com. The suits were centralised by the Judicial Panel on Multi-District Litigation in the Middle District of Florida and are still in the early stages of litigation.[73]

These lawsuits came shortly after a letter from the American Antitrust Institute (AAI) to the Department of Justice and Federal Trade Commission urging the agencies to take action against contact lens manufacturers over their pricing policies.[74] The AAI noted that the Obama administration had brought no RPM cases since the Supreme Court in *Leegin Creative Leather Products, Inc v PSKS, Inc*[75] abrogated the per se rule against RPMs. The landmark decision, the AAI argued, did not give RPMs a 'free pass' when the Court eliminated per se treatment of RPMs, but rather invited courts to analyse RPMs under the rule of reason.[76] The AAI urged that an investigation of contact lens pricing policies would be prudent due to the alleged harm to consumers, and because an investigation would be a good vehicle for the agencies to shape the law on RPMs post-*Leegin*.[77]

In a departure from *Leegin*'s holding that RPMs are not per se illegal, in March 2015 – on the heels of the first contact lens complaints – Utah passed legislation prohibiting contact lens manufacturers from controlling the prices that retailers charge for contact lenses.[78] Manufacturers quickly sued the Utah attorney general, challenging the constitutionality of the law because it impermissibly favoured Utah-based online contact lens seller 1-800-Contacts over out-of-state manufacturers, and interfered with interstate commerce. The federal district court in Utah denied the manufacturers' motion for a preliminary injunction to stay enforcement of the law.[79] The US Court of Appeals for the Tenth Circuit reversed and issued the preliminary injunction,[80] but a month later vacated its injunction, allowing the law to go into effect.[81] The parties continue to litigate over the propriety of the law.[82]

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 4 September 2014) ('*Actavis* requires cash consideration in order to trigger rule of reason scrutiny...'), appeal docketed, No. 14-2071 (1st Cir 14 October 2014); *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 *Loestrin*, 45 F Supp 3d at 193.
6 Id.
7 *Lamictal*, 18 F Supp 3d at 562, 567-69.
8 *King Drug Co of Florence, Inc v SmithKline Beecham Corp*, No. 14-1243, slip op. at 10 (3d Cir 26 June 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 48.
9 Id. at 33-34.
10 See, eg, *In re Aggrenox Antitrust Litig*, No. 3:14-MD-2516, 2015 WL 1311352, at *11 (D Conn 23 March 2015) (agreeing 'that "payment" is not limited to cash transfers.'); *United Food & Commercial Workers Local 1776 v Teikoku Pharma USA, Inc*, No. 14-MD-02521, 2014 WL 6465235, at *12 (ND Cal 17 November 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.').
11 *Lidoderm*, 2014 WL 6465235, at *12 (emphasis in original) (internal quotation marks omitted).
12 Id.; see also *Lidoderm*, 2014 WL 6465235, at *11 ('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), appeal docketed, No. 15-1274 (3d Cir 3 Febraury 2015) ('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.'); *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*.

13 See, eg, *Aggrenox*, 2015 WL 1311352, at *13 ('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.').

14 *FTC v AbbVie Inc*, No. 14-5151, 2015 WL 2114380, at *7 (ED Pa 6 May 2015).

15 *AbbVie*, 2015 WL 2114380, at *4.

16 Id. at *7.

17 Id. at *6.

18 On 1 July 2015, the FTC also filed a motion to reconsider the dismissal in AbbVie based on the Third Circuit's 26 June 2015 decision in *Lamictal*.

19 *King Drug Co of Florence v Cephalon, Inc*, No. 2:06-CV-1797, 2015 WL 356913, at *1 (ED Pa 28 January 2015) (*In re Modafinil Litigation*).

20 Id.

21 Id.

22 Id. at *12; see also *Aggrenox*, 2015 WL 1311352, at *12 ('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...').

23 *Cephalon*, 2015 WL 356913, at *3-5, *14.

24 Id. at *13.

25 Id. at *16.

26 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.

27 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.

28 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.

29 Separate Statement of Commissioners Maureen K Ohlhausen & Joshua D Wright, *FTC v Cephalon, Inc* at 1 (28 May 2015), available at https://www.ftc.gov/system/files/documents/cases/150528cephalonohlhausenwright.pdf.

30 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.

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

32 Id. (internal citations omitted).

33 Jury Verdict Form at 1, *In re Nexium (Esomeprazole) Antitrust Litig*, No. 1:12-md-2409 (D Mass 5 December 2014), ECF No. 1383.

34 Id.

35 *In re Cipro Cases I & II*, No. S198616, 2015 WL 2125291, at *1, *25 (Cal 7 May 2015).

36 Id. at *3, *26.

37 Id. at *17, *25 (emphasis in original).

38 *Abbott Labs v Teva Pharm USA, Inc* (*TriCor*), 432 F Supp 2d 408, 422 (D Del 2006).

39 Id. at 423-24.

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

41 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.').

42 *Mylan Pharms, Inc v Warner Chilcott plc* (*Doryx*), 2013 WL 5692880 (ED Pa 12 June 2013).

43 Id. at *2.

44 *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig*, 64 F Supp 3d 665 (ED Pa 2014).

45 Id. at 682.

46 Id. at 681-82.

47 Id. at 682-84.

48 *New York v Actavis plc* (*Namenda*), 2014 WL 7015198 (SDNY 11 December 2014).

49 *United States v Microsoft*, 253 F.3d 34 (DC Cir 2001).

50 2014 WL 7015198, at *38-39.

51 Id. at *39.

52 Id. at *39.

53 *New York v Actavis plc*, 787 F.3d 638, 643 (2d Cir 2015).

54 *Berkey Photo, Inc v Eastman Kodak Co*, 603 F.2d 263 (2d Cir 1979).

55 787 F.3d at 653-54 (emphasis in original).

56 See id. at 653-59.

57 Defendants-Appellants' Petition for Rehearing En Banc, *New York v Actavis plc*, No. 14-4624 (2d Cir 5 June 2015), ECF No. 363.

58 *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).

59 Id. at *12.

60 Id. at *15.

61 Id. at *14.

62 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).

63 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) (hereinafter FDA Overview).

64 21 USC section 355-1(f)(1).

65 21 USC section 355-1(f)(3); FDA Overview at 12-15.

66 See FTC Brief as Amicus Curiae at 12-13, *Mylan Pharms Inc v Celgene Corp*, No. 2:14-cv-02094-ES-MAH, 2014 WL 2968348 (DNJ filed 3 April 2014) (*FTC Amicus Br*) (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').

67 *Mylan Pharms Inc v Celgene Corp*, No. 2:14-cv-02094-ES-MAH (DNJ filed 3 April 2014); *Int'l Union of Bricklayers & Allied Craft Workers Local 1 Health Fund v Celgene Corp*, No. 2:14-cv-06997 (DNJ filed 7 November 2014).

68 See FTC Amicus Br. at 16-17.

69 *Actelion Pharms Ltd v Apotex Inc*, No. 1:12-cv-05743-NLH-AMD (DNJ filed 14 September 2012).

70 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.

71 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).

72 See, eg, *Costco Wholesale Corp v Johnson & Johnson Vision Care, Inc*, No. 3:15-00941 (ND Cal); *Machikawa v CooperVision, Inc*, No. 3:15-01001 (ND Cal); *Miller v Alcon Labs, Inc*, No. 3:15-01028 (ND Cal).

73 *In re Disposable Contact Lens Antitrust Litig*, MDL No. 2626 (MD Fla).

74 Letter from American Antitrust Institute, to DOJ and FTC (24 October 2014), available at www.antitrustinstitute.org/sites/default/files/AAI%20Letter%20on%20RPM%20in%20Contact%20Lenses.pdf (AAI Letter).

75 551 US 877 (2007).

76 AAI Letter at 1 (citing *Leegin*, 551 U.S. at 898-99).

77 AAI Letter at 2.

78 SB 169, 2015 Gen Stat section 2(2).

79 *Johnson & Johnson Vision Care Inc v Reyes*, No. 15-cv-257 (D Utah 11 May 2015).

80 *Johnson & Johnson Vision Care Inc v Reyes*, No. 15-4071 (10th Cir 18 May 2015).

81 *Johnson & Johnson Vision Care Inc v Reyes*, No. 15-4071 (10th Cir 12 June 2015).

82 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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Eric Grannon is based in the Washington, DC office of White & Case LLP, where he helps clients with antitrust matters including civil and criminal defence as well as counselling for mergers and acquisitions and settlements of pharmaceutical patent litigation. He returned to White & Case after serving as counsel to the assistant attorney general in charge of the Antitrust Division of the Department of Justice in 2003–2004, where he helped formulate US antitrust enforcement policy and manage the civil and criminal investigations and court cases brought by the Antitrust Division.

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With 38 offices in 25 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.

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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.

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