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AMERICAS
ANTITRUST REVIEW 2020

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Preface

Global Competition Review's *Americas Antitrust Review 2020* is one of a series of regional reviews that have been conceived to deliver specialist intelligence and research to our readers – in-house counsel, government agencies and private practice lawyers – who must navigate the world's increasingly complex competition regimes.

Like its sister reports covering the Asia-Pacific, Europe, the Middle East and Africa, this book provides an unparalleled annual update from competition enforcers and leading practitioners on key developments in the field.

In preparing this report, Global Competition Review has worked with leading competition lawyers and government officials. Their knowledge and experience – and above all their ability to put law and policy into context – give the report special value. We are grateful to all of the contributors and their firms for their time and commitment to the publication.

Changes from the previous edition include adding a chapter on US class action defence, focusing on the perspective of plaintiffs. Along with the new topics, contributors' roles highlight trends in competition law. For example, the Federal Trade Commission chapter was penned by Daniel Francis, associate director for digital markets – an area of particular interest globally.

Although every effort has been made to ensure that all the matters of concern to readers are covered, competition law is a complex and fast-changing field of practice, and therefore specific legal advice should always be sought. Subscribers to Global Competition Review will receive regular updates on any changes to relevant laws over the coming year.

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United States: Pharmaceutical Antitrust

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Introduction

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

- antitrust claims under the rule of reason test announced by the US Supreme Court in *Federal Trade Commission* (FTC) *v Actavis* for innovator and generic settlements of pharmaceutical patent litigation involving alleged reverse payments or 'pay-for-delay';
- product-hopping antitrust claims against innovator pharmaceutical companies that introduce new versions of brand-name drugs facing generic competition;
- challenges to pharmaceutical manufacturers' pricing practices; and
- various other pharmaceutical antitrust challenges concerning biosimilar competition, certain contracting practices (eg, exclusive dealing and bundling), sham litigation and petitioning, and the US Food and Drug Administration's (FDA) risk evaluation and mitigation strategies programme.

Reverse payment case law under Actavis

The US Supreme Court's June 2013 decision in *FTC v Actavis* opened a floodgate for more than 25 separate antitrust cases that have been filed or revived under the Supreme Court's rule of reason approach to reverse payment claims announced in that decision. Reverse payment claims generally allege that an innovator pharmaceutical company provided financial inducement to a potential generic competitor to settle patent litigation concerning the innovator's drug product, or to obtain a later settlement entry date than the generic company otherwise would have accepted, absent the innovator's financial inducement. The majority opinion in *Actavis* rejected the deferential 'scope of the patent' test under which parties could settle for any entry date within the patent's term regardless of any contemporaneous financial consideration from the innovator to the generic,

but the majority opinion likewise rejected the FTC's proposed 'quick look' rule of presumptive unlawfulness for any alleged reverse payment settlement. Instead, the Supreme Court charted a middle course, holding that 'the FTC must prove its case as in other rule-of-reason cases'.[1]

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

While the Supreme Court repeatedly inveighed against 'large and unjustified' payments as the competitive concern, the justices nonetheless expressly reserved an option for innovators to provide financial settlement consideration to generic companies beyond the value of early entry alone:

> *Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.*[3]

Actavis expressly delegated to the lower courts the task of figuring out how to apply the rule of reason to alleged reverse payment settlements, and in the years since, we have seen conflicting district court decisions, the first jury verdict, the first appellate decisions and record-setting settlements. The FTC also recently reported that the number of pharmaceutical patent settlements have continued to increase, while the number of explicit 'reverse payments' have declined.[4] Despite this decline, there was an increase in pharmaceutical patent settlements in which 'it is not clear from the face of the agreement whether certain provisions act as compensation from the brand to the generic company' – referred to by the FTC as 'possible compensation'.[5] As discussed below, the only certainty thus far under *Actavis* is that the reverse payment waters are far from settled.

Pleading standards under Actavis

Following the Supreme Court's *Actavis* decision, two federal district courts concluded that a 'payment' under *Actavis* must be a cash transfer from a brand to a generic competitor, and thus rejected allegations that a no-authorised generic agreement (no-AG) was subject to *Actavis*.[6]

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

2 id at 2227.

3 id at 2236.

4 Eric Grannon and Adam M Acosta, 'FTC Publishes Annual MMA Report and Updated Filing Procedures', 10 June 2019, www.whitecase.com/publications/alert/ftc-publishes-annual-mma-report-and-updated-filing-procedures.

5 id.

6 *In re Lamictal Direct Purchaser Antitrust Litig*, 18 F Supp 3d 560, 567–69 (DNJ 2014); *In re Loestrin 24 FE Antitrust Litig*, 45 F Supp 3d 180, 193 (DRI 2014).

However, the US Court of Appeals for the Third Circuit in *Lamictal* – the first federal appellate court to apply *Actavis* to an alleged reverse payment of any kind – reversed, holding that:

> *this no-AG agreement falls under Actavis's rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition.*[7]

The Third Circuit reasoned that the no-AG agreement could potentially be worth hundreds of millions of dollars to the generic challenger and such an agreement 'may be as harmful as those resulting from reverse payments of cash'.[8] The US Court of Appeals for the First Circuit in *Loestrin* subsequently held that a similar no-AG agreement was subject to *Actavis*, explaining that a 'payment' includes 'a much broader category of consideration than cash alone'.[9]

Other federal district courts have also denied motions to dismiss, concluding that a payment under *Actavis* may include no-AG agreements as well as other non-cash transfers that have value, such as co-promotion, licensing and distribution agreements.[10] For example, in *Intuniv*, the US District Court for Massachusetts denied a motion to dismiss where the plaintiff alleged that in addition to a no-AG agreement, the first abbreviated new drug application (ANDA) filer for generic Intuniv paid the brand company too little under a licence agreement that permitted generic entry prior to patent expiration.[11] The court held that a 'sharply discounted royalty rate could permit the

7 *King Drug Co of Florence, Inc v SmithKline Beecham Corp*, 791 F.3d 388, 394 (3d Cir 2015).

8 id at 403–05.

9 *In re Loestrin 24 FE Antitrust Litig*, 814 F.3d 538, 550 (3d Cir 2016).

10 See, eg, *In re Zetia Ezetimibe Antitrust Litig*, No. 2:18-md-2836, 2019 US Dist LEXIS 59469, at *45 (ED Va 6 Feb 2019) (holding that the plaintiff plausibly alleged a 'large and unjustified' no-AG agreement despite defendants' arguments that the settlement agreement 'preserved Merck's ability to launch an AG and to compete with Glenmark through "conventional commercial conduct"'), adopted, 2:18-md-2836 (9 August 2019), ECF No. 489; *Sergeants Benevolent Ass'n Health & Welfare Fund v Actavis, PLC*, No. 15-cv-6549, 2016 US Dist LEXIS 128349, at *48–49 (SDNY 13 September 2016) (stating that case law 'suggests that early-entry terms are not reverse payments subject to antitrust scrutiny', but noting that there were allegations that 'the terms of the licenses were intentionally designed to keep competitors out of the market until the [brand] had successfully forced Namenda IR consumers to switch to Namenda XR'); *In re Solodyn Antitrust Litig*, No. 14-MD-2503, 2015 US Dist LEXIS 125999, at *33–43 (D Mass 14 August 2015) (holding that a settlement and licence agreement with upfront and milestone payments can constitute a payment under *Actavis*); *In re Aggrenox Antitrust Litig*, 94 F Supp 3d 224, 242 (D Conn 2015) (holding that a '"payment" is not limited to cash transfers'); *United Food & Commercial Workers Local 1776 v Teikoku Pharma USA, Inc*, 74 F Supp 3d 1052, 1070 (ND Cal 2014) ('A no-authorised-generic term can constitute a payment'); *Time Ins Co v AstraZeneca AB*, 52 F Supp 3d 705, 710 (ED Pa 2014) ('Reverse payments deemed anticompetitive pursuant to *Actavis* may take forms other than cash payments'); *In re Niaspan Antitrust Litig*, 42 F Supp 3d 735, 751 (ED Pa 2014) ('The term "reverse payment" is not limited to a cash payment'); *In re Nexium (Esomeprazole) Antitrust Litig*, 968 F Supp 2d 367, 392 (D Mass 2013) ('Nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment').

11 *Picone v Shire PLC*, No. 16-cv-12396, 2017 US Dist LEXIS 178150, at *10 (D Mass 20 October 2017).

generic company to keep a portion of the profits that it otherwise would have turned over to the brand company, had the royalty reflected the competitive market rate'.[12] This case has proceeded to discovery.

In contrast, the US District Court for the Eastern District of Pennsylvania dismissed allegations that a settling generic company received a payment under *Actavis* by paying the brand company too little for a product or service. In *FTC v AbbVie*, the court considered a patent settlement for AndroGel signed contemporaneously with a supply agreement in which the generic company, Teva, paid the brand company, Abbott, to supply an authorised generic version of TriCor at a price based on Abbott's cost, plus a royalty on Teva's profits.[13] Despite 'something of large value pass[ing] from Abbott to Teva', the court reasoned that something of value flows both ways in any contract and reverse payments under *Actavis* are not so broad 'as to include the opportunity afforded Teva to buy TriCor in the supply contract before [the court] and then sell it to the public in competition with Abbott'.[14] As discussed below, an appeal by the FTC on that ruling is pending in the US Court of Appeals for the Third Circuit.

Litigants have also grappled with how precisely a plaintiff must allege monetary estimates of value transferred to generic challengers. For example, the US District Court for the Northern District of California in *Lidoderm* held that the plaintiffs sufficiently alleged a payment where the 'settlement states that the patentee shall give the infringer Brand Product of value totalling US$12 million per month' for a term of eight months.[15] The court held that the specific, quantifiable allegation of a reverse payment stated a claim under *Actavis*, observing that this 'term is not a complex, multifaceted payment; rather it is a simple transfer of a fungible product. Calculating its value is straightforward, and plaintiffs have plausibly alleged facts sufficient to support their calculations.'[16] In *Opana*, the US District Court for the Northern District of Illinois observed that while 'a plaintiff must provide at least a rough estimate of the value of the reverse payment and anticipated litigation costs, the court is also aware that a precise valuation may require discovery, as it will likely depend on evidence in defendants' exclusive possession and on expert analysis'.[17] And in the consolidated *Lipitor* and *Effexor* appeals, the US Court of Appeals for the Third Circuit rejected a 'heightened pleading standard' where 'the size of the reverse payment must be determined by the net reverse payment, which accounts for litigation costs and other discounting measures and justifications for the payment'.[18]

12 id at *35.

13 *FTC v AbbVie Inc*, 107 F Supp 3d 428, 430, 432–36 (ED Pa 2015).

14 id at 436.

15 *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v Teikoku Pharma USA, Inc*, 74 F Supp 3d 1052, 1070 (ND Cal 2014).

16 id.

17 *In re Opana ER Antitrust Litig*, 162 F Supp 3d 704, 718 (ND Ill 2016).

18 *In re Lipitor Antitrust Litig*, 868 F3d 231, 255 n.11 (3d Cir 2017); see also *In re Lipitor Antitrust Litig*, 722 F App'x 132, 135 (3d Cir 2016) (per curium) (rejecting a per se violation theory under California's Cartwright Act).

Finally, two district courts have dismissed reverse payment claims for the generic challenger's lack of approval by the FDA. In *Asacol*, the US District Court for Massachusetts dismissed a reverse payment claim because the generic company still had not obtained FDA approval by the settlement entry date and, therefore, the plaintiffs could not claim antitrust injury even if the generic could have negotiated an earlier entry date.[19] Similarly, in *Solodyn*, the US District Court for Massachusetts partially dismissed a reverse payment claim as to one of the settlement agreements at issue, because the generic did not receive FDA approval for one of the two drugs at issue until a few days after the agreed-upon settlement entry date.[20] As discussed below, both of these cases proceeded past summary judgment on other antitrust claims.

Evaluating evidence and remedies under Actavis

In the summary judgment context, some district courts have denied summary judgment where plaintiffs' causation theories of earlier generic entry were at issue. In *Solodyn*, for example, where the settlement and business agreements at issue allegedly totalled over US$63 million in payments,[21] the court held that the plaintiffs had presented sufficient evidence to support their at-risk launch theory that the generic defendant would have launched its product prior to the conclusion of the patent litigation absent the allegedly anticompetitive settlement.[22] The plaintiffs had raised a genuine dispute about the invalidity of the patent and non-infringement,[23] and there was evidence that the generic company obtained board approval to launch at risk, took orders from customers and manufactured a three-month supply.[24] The court also found the plaintiffs' other but-for theory – a no-payment settlement agreement with an earlier generic entry date – had sufficient support based on discussions of earlier generic launch dates during settlement negotiations, internal business documents and economic expert opinion.[25] The case proceeded to trial in early 2018, but Impax settled mid-trial with the remaining indirect purchasers for US$20 million.[26]

In *Lidoderm*, the US District Court for the Northern District of California reached a similar result as to a no-AG agreement allegedly worth around US$250 million.[27] The court permitted the plaintiffs' at-risk theory to proceed to trial based on contemporaneous evidence from the defendants as well as expert opinion about the patent's invalidity, but found 'that Watson could not have

19 *In re Asacol Antitrust Litig*, No. 1:15-cv-12730, 2016 US Dist LEXIS 94605, at *24 (D Mass 20 July 2016).

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

21 *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503, 2018 US Dist LEXIS 11921, at *20–21 (D Mass 25 January 2018).

22 id at *71–72.

23 id at *62–69.

24 id at *72.

25 id at *74–81.

26 Settlement Agreement at 8, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503 (D Mass 29 March 2018), ECF No. 1137.

27 See, eg, Compl paragraph 11, *California v Teikoku Seiyaku Co*, No. 18-cv-675 (ND Cal 31 January 2018), ECF No. 1.

won on non-infringement'.[28] The court also permitted the plaintiffs' no-payment settlement theory based on economic expert testimony that applied 'accepted principles in antitrust law and settlement analysis to evidence in this case'.[29] The court reasoned that the 'defendants do not point to any specific evidence considered or assumptions made by the experts that are contrary to evidence in the record'.[30] The defendants eventually settled with the remaining plaintiffs, a certified class of direct purchasers, for a total of US$166 million.[31]

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

> *in relation to this particular case, arguments which depend on determining what the ultimate outcome of the underlying patent litigation would have been are simply too procedurally burdensome and speculative to serve as valid theories of causation under Actavis.*[32]

The court, however, permitted the plaintiffs' no-payment settlement theory because they offered certain expert opinions about why the brand company 'crafted the settlement with *Actavis*'.[33] The expert testimony, for example, evaluated the merits of the underlying patent litigation to address what a competent patent attorney would have advised the defendants about their chances of winning, and other economic experts looked to the terms of the actual settlement agreement to conclude that 'it would have been economically rational for [the brand company] to settle even without a reverse payment' for an earlier generic entry date.[34] The district court, however, denied the direct purchasers' motion to certify a class of 33 proposed members for lack of numerosity because 'unlike the typical class action, in which there are a number of individual plaintiffs with relatively small claims, the plaintiffs' proposed class consists of very large, sophisticated companies with very large claims'.[35] The court explained that this 'means that even though these proposed plaintiffs are widely distributed, they also have the means and the motivation to join this action if they so choose'.[36] This appears to be only the second time that direct purchasers have been

28 *United Food & Commercial Workers Local 1776 v Teikoku Pharma USA*, 296 F Supp 3d 1142, 1156–58, 1160 (ND Cal 2017).

29 id at 1163.

30 id at 1163–64.

31 Notice of Motion and Motion at 2, *In re Lidoderm Antitrust Litig*, No. 14-md-2521 (ND Cal 20 March 2018), ECF No. 1004.

32 *In re AndroGel Antitrust Litig (No. II)*, No. 1:09-md-2084, 2018 US Dist LEXIS 99716, at *49–50 (ND Ga 14 June 2018).

33 id at *58.

34 id at *59.

35 *In re AndroGel Antitrust Litig*, No. 1:09-md-2084, 2018 US Dist LEXIS 117760, at *25 (ND Ga 16 July 2018).

36 id.

denied class certification in a reverse payment case.[37] The remaining private plaintiffs in the US District Court for the Northern District of Georgia have a February 2020 trial date. Following the denial of class certification, some of the formerly proposed class members filed complaints in the US District Court for the Eastern District of Pennsylvania in August 2019.

In contrast with the denials of summary judgment detailed above, the US District Court for the Eastern District of Pennsylvania in *Wellbutrin* granted summary judgment to the defendants for lack of causation where the settlement allegedly included a US$35 million payment and a no-AG agreement allegedly worth US$200 million, rejecting the plaintiffs' at-risk launch and no-payment settlement theories.[38] On appeal, the US Court of Appeals for the Third Circuit affirmed, holding that the plaintiffs did not establish antitrust injury because the plaintiffs 'did not take into account Andrx's blocking patent' and it is not enough 'to show that Anchen wanted to launch its drug; they must also show that the launch would have been legal'.[39] The plaintiffs' but-for theory that Anchen would have prevailed in the patent litigation failed because the 'unrebutted analysis was that Andrx would have an 80 per cent chance of proving infringement' and the parties did not 'identify any other evidence in the record that speaks to the possible outcomes of the *Anchen/Andrx* litigation'.[40] Notably, the size of the reverse payment alone was an insufficient 'surrogate' for the weakness of the patent.[41] The court also rejected the plaintiffs' but-for theory that Andrx had 'an independent economic interest' in providing a licence to Anchen and that licence negotiations were nearly complete days before the alleged reverse payment was made.[42] The court reasoned that the plaintiffs failed to point to evidence showing 'it is more likely than not that Anchen would have obtained a license' and it is possible that 'negotiations would have stalled and failed'.[43]

Other summary judgment decisions such as *AndroGel*, *K-Dur*, *Modafinil*, *Namenda* and *Nexium*, have also focused on whether business agreements executed contemporaneously with settlements are 'large and unjustified'. In these cases, district courts denied summary judgment based on an analysis of various disputed issues. Some of these courts, for example, analysed whether there was sufficient evidence to support allegations that the compensation for services was significantly above fair market value, the services were unnecessary or unwanted, the agreements for

37 id at *26 n.23 (citing *In re Modafinil Antitrust Litig*, 837 F.3d 238, 255–59 (3d Cir 2016) (vacating certification order in which the proposed class consisted of very large companies, and rejecting arguments about negative claims and retaliation); *King Drug Co of Florence v Cephalon, Inc*, No. 2:06-CV-1797, 2017 US Dist LEXIS 137601, at *8–11 (ED Pa 28 August 2017) (denying certification for similar reasons)).

38 *In re Wellbutrin XL Antitrust Litig*, 133 F Supp 3d 734, 754 n.28, 757–69 (ED Pa 2015).

39 *In re Wellbutrin XL Antitrust Litig*, 868 F.3d 132, 165 (3d Cir 2017).

40 id at 169.

41 id at 168.

42 id at 166–67.

43 id at 167.

services included unusual terms, the brand company failed to follow certain industry or internal practices, and the extent to which such business agreements may be 'linked' to the patent litigation settlement.[44]

Following these denials of summary judgment, several of these cases settled while others proceeded to trial. One notable settlement is the FTC's settlement in *Modafinil*. The brand company in that case settled with the FTC, agreeing to injunctive relief and a record-setting US$1.2 billion fine, subject to a credit for settlements reached in related private actions,[45] including prior direct purchaser settlements for US$512 million and US$96.5 million, and an end payer settlement of US$65.8 million.[46] The size of the fine resulted from the court's prior decision to permit the FTC to proceed with a disgorgement claim estimated between US$3.5 billion and US$5.6 billion.[47]

For the two reverse payment cases that have proceeded to trial since the Supreme Court's *Actavis* decision, the factfinders in both of those cases found for the defendants. In *Nexium*, the plaintiffs had calculated a reverse payment of US$22 million, argued that the contemporaneously executed business agreements 'essentially provided a steady flow of revenue to Ranbaxy' during the same period it agreed not to launch its generic Nexium product and offered evidence that 'even if Ranbaxy had won its litigation instead of settling, Ranbaxy would not have secured such favourable arrangements'.[48] But, in the first reverse payment trial since the Supreme Court's *Actavis* decision, the jury reached a verdict for the defendants despite finding that there had been a reverse payment. The jury found that although AstraZeneca had market power and there had been a 'large and unjustified' payment, the reverse payment did not cause delayed generic entry because AstraZeneca would not have agreed to an earlier settlement entry date absent a reverse payment.[49] The US Court of Appeals for the First Circuit affirmed the jury's verdict for defendants.[50]

More recently, following an administrative bench trial, the FTC's chief administrative law judge (ALJ) concluded that an alleged reverse payment between Endo and Impax was not anticompetitive. Endo and Impax had settled the underlying patent litigation and entered into a settlement

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

45 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.

46 Mot in Supp of Direct Purchaser Class Pls' Unopposed Mot for Cert of a Settlement at 1, *FTC v Cephalon, Inc*, No. 2:06-cv-01797 (ED Pa 17 April 2015), ECF No. 795; Memo of Law in Supp of Mot for Cert of Class at 1, *King Drug Co of Florence, Inc v Cephalon, Inc*, No. 2:06-cv-01797 (ED Pa 3 February 2017), ECF No. 1032-1; Order, *Vista Healthplan, Inc v Cephalon, Inc*, No. 2:06-cv-1933 (ED Pa 8 August 2019), ECF No. 592.

47 Order at 1, *FTC v Cephalon, Inc*, No. 2:08-cv-02141 (ED Pa 17 June 2015), ECF No. 376; FTC's Mem in Opp'n to Cephalon's Mot to Preclude the FTC's Disgorgement Claim at 5, *FTC v Cephalon, Inc*, No. 2:08-cv-02141 (ED Pa 17 June 2015), ECF No. 352.

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

49 id.

50 *In re Nexium (Esomeprazole) Antitrust Litig*, 842 F.3d 34 (1st Cir 2016).

and licence agreement (SLA) and a development and co-promotion agreement (DCA).[51] The SLA included a no-AG provision and a potential cash credit if Opana sales fell below a certain threshold, valued together at US$33 million to US$43 million.[52] The DCA was executed contemporaneous with the SLA and provided an upfront payment of US$10 million for the development of a Parkinson's disease treatment, with potential payments up to US$30 million at certain milestones.[53]

The ALJ concluded that the DCA 'was a bona fide product development collaboration, and that the US$10 million payment was justified by the profit-sharing rights given to Endo under the DCA'.[54] The ALJ rejected the FTC's evidence purportedly showing inadequate due diligence, unusual terms and 'linkage' to the SLA.[55] Rather, the ALJ found that:

- Endo and Impax had an established business interest in Parkinson's disease;
- the parties previously entered into risky early stage collaboration agreements;
- Endo analysed the merits of the deal;
- Impax continued its development efforts years after executing the DCA; and
- Endo did not consider the upfront payment to be uncharacteristically large.[56]

Despite finding that the SLA was 'large and unjustified', the ALJ concluded that any anticompetitive harm was outweighed by procompetitive benefits. The ALJ held that the 'evidence shows that Endo's acquisition of additional patents, and successful assertion of those additional patents in litigation, has led to all generic manufacturers, other than Impax, being enjoined from selling a generic version of Opana ER until the last of Endo's patents expires in 2029' and 'absent the SLA, such after-acquired patents also would have been successfully asserted to enjoin Impax from selling generic Opana ER'.[57]

The FTC commissioners subsequently rejected the ALJ's decision in a unanimous decision, concluding that 'Impax failed to show that the challenged restraint furthered any cognizable procompetitive justifications' and 'even if Impax had satisfied this burden, Complaint Counsel identified a viable less restrictive alternative that has been used to settle hundreds of similar pharmaceutical patent litigations'.[58] In June 2019, Impax filed a petition for review in the US Court of Appeals for the Fifth Circuit.

51 Initial Decision at 85, *In the matter of Impax Labs, Inc*, FTC Dkt No. 9373 (18 May 2018).

52 id at 114.

53 id at 120.

54 id at 132.

55 id at 133–35.

56 id at 132.

57 id at 145.

58 Opinion of the Commission at 42, *In the matter of Impax Labs, Inc*, FTC Dkt No. 9373 (28 March 2019).

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

Pre-2015 cases: TriCor, Prilosec and Suboxone

Only a handful of decisions have dealt with product-hopping claims in the pharmaceutical context, most of which were at the motion to dismiss stage. In the earliest of these decisions, the US District Court for Delaware in *TriCor* rejected the defendants' argument that any product change that is an improvement is per se legal under the antitrust laws.[59] Instead, the court concluded that the introduction of a new product should be assessed under the rule of reason approach, requiring the plaintiffs to demonstrate that the anticompetitive harm from the formulation change outweighed any benefits of introducing a new version of the product. The court in *TriCor* denied the defendants' motion to dismiss, finding the plaintiffs' specific allegations – that the defendants bought

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

back supplies of the old formulation and changed product codes for the old products to 'obsolete' to prevent pharmacies from filling TriCor prescriptions with generic versions of the old formulation – sufficient to support the plaintiffs' antitrust claims.[60]

In *Prilosec*, the US District Court for the District of Columbia 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.[61] In granting the defendants' motion to dismiss, the court found that where defendants left the old product on the market but heavily (and successfully) promoted their new product, the plaintiffs could not allege that the defendants interfered with competition, because consumer choice was not eliminated.[62]

In *Suboxone*, direct and indirect purchasers alleged that the defendants unlawfully shifted patients from Suboxone tablets to Suboxone film by falsely disparaging and fabricating safety concerns about the tablet, and by removing Suboxone tablets from the market just as generic versions of the tablets were set to enter the market. The US District Court for the Eastern District of Pennsylvania denied the defendants' motion to dismiss the product-hopping claims, holding that 'what is clear from the case law is that simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct [that stymies competition].'[63] The court determined that the defendants' conduct fell somewhere in between the conduct at issue in *TriCor* and *Prilosec*. The court found that the conduct was more problematic than in *Prilosec* because the defendants removed the Suboxone tablets from the market, but less problematic than in *TriCor* because the defendants did not buy back existing Suboxone tablets or label the tablets obsolete.[64] The court nonetheless found that the plaintiffs had sufficiently pleaded 'other wrongful conduct' insofar as removing the tablets from the market in conjunction with fabricating safety concerns could coerce patients to switch from the tablet to the film.[65]

Two appellate decisions: Namenda and Doryx

Namenda and *Doryx* were the first cases to address pharmaceutical product-hopping claims beyond the motion to dismiss stage. In *Namenda*, the US District Court for the Southern District of New York granted a motion for a preliminary injunction on a limited record related to product-hopping claims as to the defendants' plan to transition Alzheimer's patients from an older,

60 id at 423–24.

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

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

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

64 id at 681–82.

65 id at 682–85.

twice-daily drug to a newer, once-daily formulation.[66] Unlike in *TriCor* and *Suboxone*, in which the defendants fully removed the older formulation from the market, the *Namenda* defendants planned to continue making the older formulation available to any patient who had a medical need for it. Nonetheless, the *Namenda* court held that the 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.[67]

The defendants appealed the decision to the US Court of Appeals for the Second Circuit, raising an issue of first impression in the circuit courts regarding the circumstances under which alleged product hopping may violate the Sherman Act.[68] Despite the continued availability to any patient with a need for the older formulation, the Second Circuit affirmed the district court, and cited *Berkey Photo*[69] 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.[70] 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.[71]

The *Doryx* court became the first to evaluate product-hopping claims, with the benefit of full discovery, at the summary judgment stage. In *Doryx*, the plaintiffs alleged that numerous product reformulations (including changes from capsules to tablets, changes to dosage strength and introduction of score lines to the tablets), coupled with the subsequent discontinuation of older versions constituted anticompetitive product hopping. The court denied the defendants' motion to dismiss on the ground that it would be required to consider facts beyond the pleadings to decide the product-hopping issue.[72] However, the court noted that the plaintiffs' product-hopping theory was 'novel at best' and conveyed scepticism that product hopping even constitutes anticompetitive conduct under the Sherman Act.[73]

66 *New York v Actavis, PLC*, 14 Civ 7572, 2014 US Dist LEXIS 172918, at *118–23 (SDNY 11 December 2014).

67 id at *107–08.

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

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

70 787 F.3d at 653–54.

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

72 *Mylan Pharms, Inc v Warner Chilcott Pub*, No. 12-3824, 2013 US Dist LEXIS 152467 (ED Pa 11 June 2013).

73 id at *11.

Ultimately, after full discovery, the court granted summary judgment for the defendants and dismissed all claims, holding that the introduction of a reformulated drug and withdrawal of the older version was not exclusionary conduct where the generic was not foreclosed from competing.[74] The court also rejected the plaintiffs' contention that the product reformulations were anticompetitive because they were insufficiently innovative, noting that no intelligible test for innovation 'sufficiency' had been offered and doubting that courts could ever fashion one.[75] 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.[76] In 2016, the US Court of Appeals for the Third Circuit affirmed the lower court's grant of summary judgment in the defendants' favour.[77]

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

Since the *Namenda* and *Doryx* decisions, additional courts have addressed pharmaceutical product hopping at the motion to dismiss stage. The *Solodyn* court dismissed the plaintiffs' product-hopping claim, holding that because the defendants kept the older strengths of Solodyn on the market until two years after the older strengths faced generic competition, the introduction of newer strengths did not limit customer choice and was therefore not anticompetitive.[78]

In *Asacol*, proceeding before the US District Court for Massachusetts, the direct and indirect purchasers alleged that the defendants engaged in a product hop that thwarted generic competition for branded drug Asacol by first introducing and promoting Asacol HD (a high-dose version of Asacol), years later introducing the drug Delzicol with the same active ingredient and dose as Asacol, and shortly thereafter removing Asacol from the market prior to the entry of generic Asacol products. Relying on *Namenda*, the *Asacol* court dismissed the plaintiffs' claims of a product hop between Asacol and Asacol HD because Asacol continued to be sold side-by-side with Asacol HD for several years after Asacol HD was introduced.[79] However, the court allowed the plaintiffs' claims of a product hop from Asacol to Delzicol to survive the defendants' motion to dismiss, where the defendants allegedly withdrew Asacol from the market shortly after

74 *Mylan Pharms, Inc v Warner Chilcott Pub*, No. 12-3824, 2015 US Dist LEXIS 50026 (ED Pa 16 April 2015); see also id at *42 (noting that it had denied the motion to dismiss to consider the legality of the novel product-hopping theory with the benefit of a fully developed record, and that the record on summary judgment now underscored that the defendants did not violate the Sherman Act); see also id at *34.

75 id at *42.

76 id at *40.

77 *Mylan Pharms, Inc v Warner Chilcott Pub*, 838 F.3d 421 (3d Cir 2016).

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

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

introducing the close substitute Delzicol.[80] Following a settlement with direct purchasers, the court denied summary judgment as to the remaining indirect purchasers' claims based on disputed factual issues concerning coercion, causation and product market, but did not revisit the legal framework for product-hopping claims.[81]

On the eve of trial in *Asacol*, the US Court of Appeals for the First Circuit granted an interlocutory appeal concerning class certification and stayed the trial. The district court had certified an indirect purchaser class despite finding 'that approximately ten percent of the class had not suffered any injury' because the court 'determined that those uninjured class members could be removed in a proceeding conducted by a claims administrator' after trial.[82] In an October 2018 decision, however, the First Circuit decertified the indirect purchaser class because in the product-hopping context – where plaintiffs allege injury from being coerced to buy a newer formulation – individual testimony may be required at trial to determine whether certain plaintiffs were uninjured (ie, if they bought the newer formulation due to preference rather than coercion).[83] The First Circuit explained that 'there are apparently thousands who in fact suffered no injury' and 'plaintiffs do not propose to rely on unrebutted testimony to eliminate the question of injury-in-fact before trial'.[84] This left 'a fatal gap in the evidence for all but the few class members who [would] testify in person'.[85] Following remand, the defendants moved for summary judgment concerning injury-in-fact. Before the court issued a decision, the remaining three plaintiffs agreed to settle for a total of US$2.7 million.

Subsequent to the 2014 motion-to-dismiss decision in *Suboxone* related to the purchaser plaintiffs' complaints, state plaintiffs filed complaints with similar claims, and the court revisited its product-hopping analysis in light of the *Namenda*, *Doryx* and *Asacol* decisions that had been rendered since the earlier *Suboxone* decision. The court reached the same result as it did in its previous decision in which it analysed the product-hopping claims in view of *TriCor* and *Prilosec*, determining that the conduct was more akin to the claims allowed to proceed in *Namenda* than to claims dismissed in *Doryx* and *Asacol* because the old Suboxone product was withdrawn prior to generic entry.[86] The private plaintiffs' and the state attorneys generals' cases are coordinated for pre-trial discovery.[87] Additionally, following an FTC investigation related to *Suboxone*, the FTC filed an antitrust action against Reckitt Benckiser in the US District Court for the Western District of

80 *In re Asacol Antitrust Litig*, No. 15-md-2503, 2016 US Dist LEXIS 94605 (D Mass 20 July 2016).

81 *In re Asacol Antitrust Litig*, 323 FRD 451 (D Mass 2017).

82 *In re Asacol Antitrust Litig*, 907 F.3d 42, 45 (1st Cir 2018).

83 id at 53.

84 id 52–53.

85 id.

86 *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig*, No. 13-md-2445, 2017 US Dist LEXIS 627 (ED Pa 8 September 2017).

87 Order, *In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig*, No. 13-md-2445 (ED Pa 12 January 2017).

Virginia in July 2019 concerning allegations of product hopping and sham petitioning. The next day, the court approved a settlement where Reckitt agreed to a US$50 million fine and a permanent injunction. Notably, part of the injunction requires that:

> *If Reckitt introduces a reformulated version of an existing product, it must provide the FTC with information about that product and the reasons for its introduction. If generic companies file for FDA approval of competing versions of the branded drug, the order requires Reckitt to leave the original product on the market on reasonable terms for a limited period so that doctors and patients can choose which formulation of the drug they prefer.*[88]

The FTC settlement is reportedly 'part of a broader government settlement with Reckitt, which involves criminal and civil fraud claims'.[89]

Similarly, the US District Court for Rhode Island in *Loestrin* relied heavily on *Namenda* when denying defendants' motion to dismiss the product-hopping claims.[90] The court found that the removal of the earlier version of the drug prior to generic entry was distinguishable from the conduct in *Doryx* and *Solodyn* (product removed after generic competition) and *Prilosec* (no product removal), and in line with allegations in *Suboxone*, *TriCor* and *Asacol*, which survived motions to dismiss.[91] Summary judgment briefing is complete and the parties are awaiting a decision.

Challenges to pharmaceutical manufacturers' pricing practices

In recent years, enforcement agencies, private plaintiffs and politicians have continued to pressure brand and generic pharmaceutical manufacturers regarding drug prices. Federal and state investigations have resulted in criminal and civil enforcement actions, and private litigation has also ramped up, mostly in the form of claims alleging agreements to fix prices. The push for both state and federal legislation to address drug prices has also increased, with the majority of states proposing (and many passing) various price-transparency laws, which require drug manufacturers to disclose certain information to justify their prices, while the federal government continues to wrestle with proposed legislation of its own. Over the past two years specifically, as

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

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

90 *In re Loestrin 24 FE Antitrust Litig*, 261 F Supp 3d 307 (DRI 2017).

91 id.

litigation regarding the alleged price-fixing of generic drugs moves through the early stages of motions to dismiss and various discovery stays, much of the focus on drug prices has shifted to these potential legislative remedies.

Federal legislative and regulatory activity

Over the past two years, pressure for legislation on drug prices has mounted at the federal level. Following congressional hearings and investigations in 2018 and 2019, congressional interest in drug pricing has gained momentum, with Congress targeting certain conduct that some have argued underlie rising drug prices.[92] For example, the Patient Right to Know Drug Prices Act was enacted in October 2018, which prohibits health insurance plans or pharmacy benefit managers (PBMs) from preventing pharmacies from disclosing the 'differential between the enrollee's out-of-pocket cost under the plan or coverage' and the amount an individual would pay for the 'drug without using any health plan or health insurance coverage'.[93] The act also extends the requirement for reporting patent settlements to settlements between biologic and biosimilar manufacturers.[94] Several proposed laws have also been introduced but not enacted, such as the Protecting Consumer Access to Generic Drugs Act of 2019, which would provide the FTC with greater authority to challenge alleged pay-for-delay agreements, and the Biologic Patent Transparency Act of 2019, which would require manufacturers to make certain information available regarding patents for approved biologics.[95]

Most notably, the US Senate Committee on Health, Labour, Education and Pensions advanced the Lower Health Care Costs Act (the LHCC Act) to full Senate consideration with the Committee chairperson pushing for a floor vote by the end of July 2019, but none has occurred upon the submission of this chapter in August 2019.[96] The LHCC Act seeks to increase drug-price transparency and generic competition by preventing 'parking' of the 180-day exclusivity period for first generic ANDA filers. The bill includes two notable acts – the Creating and Restoring Equal Access to Equivalent Samples Act, giving generic drug developers more leverage to attain drug samples

92 See, eg, Zachary Brennan, 'House E&C Passes CREATES, Pay-for-Delay Bills', Regulatory Affairs Professional Society, 4 April 2019, www.raps.org/news-and-articles/news-articles/2019/4/house-ec-passes-creates-pay-for-delay-bills; Michael Cipriano, 'House Vs Senate Drug Pricing Bills: A Snapshot Of Differences', Pink Sheet, 28 May 2019, https://pink.pharmaintelligence.informa.com/PS125367/House-Vs-Senate-Drug-Pricing-Bills-A-Snapshot-Of-Differences; Michael Cipriano, 'Senate Drug Pricing Legislation Clears Committee With Generic Exclusivity "Parking" Provision Unchanged', Pink Sheet, 26 June 2019, https://pink.pharmaintelligence.informa.com/PS125538/Senate-Drug-Pricing-Legislation-Clears-Committee-With-Generic-Exclusivity-Parking-Provision-Unchange.

93 Silber et al, 'Pharmaceutical Antitrust Legislation to Watch', *Law360*, 28 May 2019, www.law360.com/lifesciences/articles/1163413/pharmaceutical-antitrust-legislation-to-watch?nl_pk=b31a56b3-e935-4098-ba64-ae64375aad5e&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences.

94 id.

95 id.

96 Michael Cipriano, 'Senate Drug Pricing Legislation Clears Committee With Generic Exclusivity "Parking" Provision Unchanged', Pink Sheet, 26 June 2019, https://pink.pharmaintelligence.informa.com/PS125538/Senate-Drug-Pricing-Legislation-Clears-Committee-With-Generic-Exclusivity-Parking-Provision-Unchange.

for bioequivalence testing from brand companies and passed unanimously by the house,[97] and the Fair Accountability and Innovative Research Drug Pricing Act, requiring drug manufacturers to report price increases of certain drugs to the US Department of Health and Human Services (HHS), which has stalled despite bipartisan support.[98] Additionally, the Affordable Prescriptions for Patients Act of 2019 was introduced in the Senate and would create a presumption that a manufacturer engaged in anticompetitive product hopping in certain situations where a drug is discontinued, but the portion of the originally introduced bill that would create a presumption of illegal 'patent thicketing' was dropped during committee review.[99]

The Trump administration has also issued a number of proposals and finalised some measures aiming to decrease drug prices. For example, the administration added a final rule to its American Patients First blueprint requiring drug companies to disclose to patients the list price for prescription drugs in television advertisements.[100] The HHS had relied on the Social Security Act to adopt this price-disclosure rule, but the day before the pricing regulation was to go into effect the US District Court for the District of Columbia struck it down. The court held that HHS does not have the statutory authority under the Social Security Act 'to issue a rule that compels drug manufacturers to disclose list prices' in such advertisements.[101] Given this holding, the district court did not reach plaintiffs' First Amendment challenge to the rule. Other notable measures proposed by the Trump administration include implementing certain price caps based on an international drug-price index,[102] seeking to make drug-price increases more transparent[103] and providing incentives to increase generic competition.[104]

State legislation

In the past year, there was also a surge of state legislation targeting drug prices. To date, 47 states have introduced 258 bills to decrease drug prices, and 29 states have enacted some type of drug-pricing legislation.[105] The measures focus on providing more transparency for pharmaceutical

97 Zachary Brennan, 'House E&C Passes CREATES, Pay-for-Delay Bills', Regulatory Affairs Professional Society, 4 April 2019, www.raps.org/news-and-articles/news-articles/2019/4/house-ec-passes-creates-pay-for-delay-bills.

98 Michael Cipriano, 'House Vs Senate Drug Pricing Bills: A Snapshot Of Differences', Pink Sheet, 28 May 2019, https://pink.pharmaintelligence.informa.com/PS125367/House-Vs-Senate-Drug-Pricing-Bills-A-Snapshot-Of-Differences.

99 Affordable Prescriptions for Patients Act of 2019, S 1416, 116th Cong (1st Sess 2019).

100 Billy Wynne and Josh LaRosa, 'The Drug Pricing Debate: Sizing Up Recent Actions and What May Come Next', Commonwealth Fund, 7 March 2019, www.commonwealthfund.org/blog/2019/drug-pricing-debate-sizing-recent-actions-and-what-may-come-next.

101 Opinion at 2, *Merck & Co v US Department of Health and Human Servs*, No. 19-cv-1738 (DDC 8 July 2019).

102 id.

103 id.

104 'Drug Pricing Legislative Summary', ASHP, 7 February 2018.

105 Lou Cannon, 'State Efforts to Rein In Drug Costs Have Mixed Success', *Law360*, 14 June 2019, www.law360.com/massachusetts/articles/1160846/state-efforts-to-rein-in-drug-costs-have-mixed-success?nl_pk=83c45a5f-fc9b-49ef-81ea-b6fb7f3943b7&utm_source=newsletter&utm_medium=email&utm_campaign=massachusetts.

prices, setting restrictions on PBMs and allowing drug importation. For example, some states have focused on a lack of transparency in drug pricing and enacted measures, including requiring drug manufacturers to disclose their listed wholesale acquisition cost,[106] report planned increases in drug prices,[107] and for PBMs to submit certain pricing reports that include rebate information.[108] Many states have also set restrictions and additional requirements for PBMs. For example, some states sucha as Minnesota require PBMs to obtain licences,[109] and others restrict them from penalising pharmacists for sharing costs with consumers.[110] States such as Arkansas and Louisiana enacted measures to prohibit PBMs from engaging in spread pricing[111] – where companies allegedly mark up the difference between the amount they reimburse pharmacies for drugs and the amount charged to clients. Some states have also enacted measures focused on the importation of drugs from foreign countries. For example, Florida's governor signed a bill to design a wholesale importation programme from Canada.[112] Although these state measures have sought to increase transparency, they do not expressly challenge or restrict price increases for specific drugs.

Federal and state enforcement actions

Following a two-year investigation into the pharmaceutical industry, the US Department of Justice (DOJ) filed criminal charges in December 2016 against two former Heritage Pharmaceuticals Inc executives.[113] The DOJ alleged that Heritage's former CEO Jeffrey Glazer and former president Jason Malek conspired to fix prices with competitors and divide the customer base for doxycycline hyclate and glyburide. More specifically, prosecutors alleged that Glazer and Malek sought to allocate customers for doxycycline from April 2013 to December 2015 and for glyburide from April 2014 to December 2015, effectively forcing consumers to pay collusive and non-competitive prices.[114] In January 2017, Glazer and Malek each pleaded guilty to a two-count price-fixing felony charge in

106 See, eg, HB 19-1131, 2019 Leg, 1st Reg Sess (Colo 2019); HB 1131, 86th Leg, 83rd Sess (Tex 2019); HB 1224, 2019 Leg, Reg Sess (Wash 2019).

107 See, eg, HB 2658, 2019 Leg, Reg Sess (Or 2019); HB 1224, 2019 Leg, Reg Sess (Wash 2019).

108 See, eg, SB 378, 2019 Leg, 80th Sess (Nev 2019); HB 370, 2019 Leg, Reg Sess (Utah 2019); SF 278, 91st Leg, Reg Sess (Minn 2019); SB 520 (Ark 2019); HF 489, SF 347, SF 563 (Iowa 2019).

109 SF 278, 91st Leg, Reg Sess (Minn 2019); see also SB 1507, Leg Sess (NY 2019); S 359, Gen Ass, 123d Sess (SC 2019); SB 489, Reg Sess (W Va 2019).

110 See also S Carolina S 359 (SC 2019); HB 63, 65th Leg (Wyo 2019); SB 415, Reg Sess (NM 2019); AB 141, 80th Sess (Nev 2019).

111 SB 520, 92d Gen Ass, Reg Sess (Ark 2019); SB 41, SB 239, Reg Sess (La 2019); see also SB 1507, Leg Sess (NY 2019).

112 CS/HB 19 (Fla 2019); see also SB19-005, Reg Sess (Col 2019).

113 'Former Top Generic Pharmaceutical Executives Charged with Price-Fixing, Bid-Rigging and Customer Allocation Conspiracies', DOJ Press Release, 14 December 2016, www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer.

114 Def Glazer's Information, *United States v Glazer*, No. 2:16-cr-00506 (ED Pa 12 December 2016), ECF No. 1; Def Glazer's Plea Agreement, *United States v Glazer*, No. 2:16-cr-00506 (ED Pa 9 January 2017), ECF No. 18; Def Malek's Information, *United States v Malek*, No. 2:16-cr-00508 (ED Pa 13 December 2016), ECF No. 1; Def Malek's Plea Agreement, *United States v Malek*, No. 2:16-cr-00508 (ED Pa 9 January 2017), ECF No. 17.

Pennsylvania federal court.[115] Both Glazer and Malek have signed cooperation agreements, and their testimony may play a role in ongoing antitrust investigations into the generic drug industry.[116] Heritage has initiated a racketeering suit against Glazer and Malek and announced that it is cooperating with the DOJ's ongoing investigation.[117] With the 'Yates Memo' encouraging the prosecution of individuals for corporate crimes, additional prosecutions of individual executives for price fixing may also be forthcoming.

Following the January 2017 guilty pleas by the two Heritage executives, the Connecticut attorney general and 19 states filed a civil complaint in the US District Court for the District of Connecticut against Heritage, Mylan, Teva and three smaller pharmaceutical corporations, charging that these companies colluded to dramatically increase the price of doxycycline hyclate and glyburide.[118] The complaint, which seeks both disgorgement and a permanent injunction, alleges that generic manufacturers used frequent industry conferences, trade shows and dinners to meet with competitors and agree, in one form or another, to raise prices for certain generic doxycycline and glyburide. In October 2017, the litigation expanded further, growing to a total of 46 state attorneys general, 12 additional drug companies and 13 more generic drugs. With the exception of one defendant, motions to dismiss were denied in October 2018.[119]

In May 2019, 44 state attorneys general sued 20 generic manufacturers in the US District Court for Connecticut alleging the defendants conspired to fix the prices for a number of generic drugs.[120] Unlike the 2016 cases, this complaint focuses more on the conduct of certain executives, a number of whom are named as defendants.[121] The case was recently transferred to the US District Court for the Eastern District of Pennsylvania for pre-trial proceedings.

115 id.

116 'AG Jepsen: States Reach Settlements, Cooperation Agreements with Two Former Executives in Generic Drug Multistate Investigation', Press Release from State of Connecticut Office of Attorney General George Jepsen, 24 May 2017, www.portal.ct.gov/AG/Press-Releases-Archived/2017-Press-Releases/AG-Jepsen-States-Reach-Settlements-Cooperation-Agreements-with-Two-Former-Executives-in-Generic-Drug.

117 Antonio José Vielma, 'Two executives charged in generic drug price-fixing federal investigation: Report', CNBC (14 December 2016), www.cnbc.com/2016/12/14/us-files-first-charges-in-generic-drug-price-fixing-probe-report.html (quoting Heritage's full statement).

118 *Pls States' Compl, Connecticut v Aurobindo Pharma USA, Inc*, No. 3:16-cv-2056 (D Conn 15 December 2016), ECF No. 1.

119 Opinion, *In re: Generic Pharmaceuticals Pricing Antitrust Litig*, 16-MD-2724 (ED Pa 16 October 2018); Dani Kass, '20 Drugmakers Must Face Generic Price-Fixing MDL', 17 October 2018, www.law360.com/articles/1092947/20-drugmakers-must-face-generic-price-fixing-mdl.

120 Compl, *Connecticut v Teva Pharma USA, Inc*, No. 2:19-cv-710 (D Conn 10 May 2019), ECF No. 1; Spencer Parts, 'New state generics complaint is tougher on execs', *Global Competition Review*, 14 May 2019, https://globalcompetitionreview.com/article/usa/1192731/new-state-generics-complaint-is-tougher-on-execs.

121 Spencer Parts, 'New state generics complaint is tougher on execs', *Global Competition Review*, 14 May 2019, www.globalcompetitionreview.com/article/usa/1192731/new-state-generics-complaint-is-tougher-on-execs.

Private litigation

To date, there have only been a handful of recent private litigations concerning price-fixing allegations for drugs. The *In re Propranolol Antitrust Litigation* filed in the US District Court for the Southern District of New York involves the generic blood pressure medication propranolol hydrochloride – the generic equivalent of the branded drug Inderal. In that case, the direct and indirect purchasers' consolidated class action complaint alleges that several generic drug manufactures entered into separate price-fixing conspiracies for the capsule and tablet forms of generic propranolol. In April 2017, the court largely denied the defendants' motion to dismiss. The court held that a conspiracy could be inferred based on 'conscious parallelism' where interdependent conduct was accompanied by circumstantial evidence and 'plus factors', and the court stated that the plaintiffs had sufficiently alleged the following:

- a motive to increase prices;
- that the price increases were against the defendants' own self-interest;
- that the defendants communicated at trade association meetings; and
- that there were ongoing state and federal investigations into the manipulation of generic drug prices, including the price of propranolol.[122]

The court dismissed several state law claims, finding that, among other things, indirect purchasers lacked standing to bring consumer protection claims under the laws of those states in which they did not directly purchase, pay or reimburse for propranolol. This litigation was subsequently transferred to the multi-district litigation in the US District Court for the Eastern District of Pennsylvania. The court denied additional motions to dismiss in October 2018.

Brand-name drug manufacturers have also been the target of putative class actions alleging collusive price fixing. In the US District Court for the Central District of California, a proposed class of consumers filed an action against Novo Nordisk, alleging the company inflated the list price of Type 2 diabetes medicine, Victoza, in an effort to subsidise higher rebates to PBM OptumRX.[123] The theory is that, because PBMs demand rebates from drug makers in exchange for more favourable formulary placement, Novo responded by increasing its drug price to cover the rebates and maintain its profit margins, and those higher prices were passed along to consumers. The suit alleges that this purported need to fund rebates to OptumRx explains the increase of Victoza from about US$400 a package to more than US$900 a package between 2009 and 2017. This matter was transferred to the US District Court for New Jersey in 2017.

In another case in the US District Court for New Jersey, a proposed consumer class action alleged that Novo, Lilly and Sanofi increased insulin prices in lockstep, sharing the increased profits with the three largest PBMs, CVS Health, Express Scripts and OptumRX, through rebates.[124]

122 *In re Propranolol Antitrust Litig*, 249 F Supp 3d 712 (SDNY April 2017).

123 Class Action Compl & Demand for Jury Trial, *Ruth Johnson v OptumRX Inc*, No. 8:17-cv-00900 (CD Cal 23 May 2017), ECF No. 1.

124 Class Action Compl & Demand for Jury Trial, *Boss v CVS Health Corporation*, No. 3:17-cv-01823 (DNJ 17 March 2017), ECF No. 1.

The suit alleges that consumers were then obligated to pay far higher out-of-pocket expenses to subsidise this scheme. A Pennsylvania county's public retirement system also filed a similar class action against Novo, asserting that Novo engaged in 'collusive price fixing' to preserve high insulin prices.[125] In February 2019, certain indirect purchaser claims (including Racketeer Influenced and Corrupt Organizations Act claims) were dismissed, and the remainder of the case is now in the early stages of discovery.[126]

Additionally, over the past two years, more than 80 named plaintiffs, including proposed classes of direct and indirect purchasers, have filed private suits against more than 20 different generic manufacturers targeting alleged agreements to raise prices. These proposed classes, like the state attorneys general, allege that generic manufacturers engaged in a number of separate conspiracies through trade association conferences and other meetings to inflate the prices of almost 20 different generic drugs between 2012 and 2015, including digoxin, doxycycline, clobetasol, desonide, fluocinonide, econazole, levothyroxine and propranolol. In April 2017, the Judicial Panel on Multidistrict Litigation transferred and consolidated these actions in the US District Court for the Eastern District of Pennsylvania for pre-trial proceedings.[127] The court denied motions to dismiss in the autumn of 2018, and the cases remain in the early stages of discovery.

In January 2017, the FTC and five states sued Mallinckrodt in the US District Court for the District of Columbia for allegedly monopolising the market for Acthar, an epilepsy drug for infants, by purchasing the US rights to competing drug Synacthen Depot.[128] The FTC alleged that Mallinckrodt then raised the price of Acthar by 85,000 per cent between 2001 and 2017.[129] Several days after the complaint was filed, Mallinckrodt settled with the FTC and five states, agreeing to disgorgement of US$100 million and to license the right to develop Synacthen Depot in the United States.[130] In August 2019, Humana filed a follow-on suit in the US District Court for the Western District of California alleging, among other claims, related anticompetitive conduct.[131]

Other antitrust concerns involving pharmaceuticals

In addition to the above areas that have been most active, we have recently seen the first antitrust challenges concerning biosimilar competition, various antitrust challenges to certain contracting practices (eg, exclusive dealing and bundling), some notable developments in sham litigation and petitioning cases, and concerns with respect to the FDA's Risk Evaluation and Mitigation Strategies (REMS) programme.

125 Compl & Demand for Jury Trial, *Lehigh Cnty Employees' Retirement Sys v Novo Nordisk A/S*, No. 3:17-cv-00209 (DNJ 1 November 2017), ECF No. 1.

126 *In re Insulin Pricing Litig*, No. 3:17-cv-0699, 2019 US Dist LEXIS 25185, at *7 (DNJ 15 February 2019).

127 See Transfer Order, *In re Generic Digoxin & Doxycycline Antitrust Litig*, MDL No. 2724 (ED Pa 6 April 2017), ECF No. 291; *In re Generic Drug Pricing Antitrust Litig*, MDL No. 2724 (ED Pa 5 August 2016), ECF No. 1.

128 Compl, *FTC v Mallinchrodt*, No. 1:17-cv-120 (DDC 18 January 2017), ECF No. 1.

129 id.

130 Stipulated Order for Permanent Injunction and Equitable Monetary Relief, *FTC v Mallinchrodt*, No. 1:17-cv-120 (DDC 30 January 2017), ECF No. 15.

131 *Humana Inc v Mallinckrodt*, No. 2:19-cv-6926 (WD Cal 8 August 2019), ECF No. 1.

Biosimilar antitrust cases

In 2009, Congress passed the Biologics Price Competition and Innovation Act to provide an abbreviated FDA approval pathway for biosimilar versions of a biologic drug.[132] To receive FDA approval, the biosimilar manufacturer must demonstrate its proposed biosimilar is 'highly similar' to the reference biologic and has 'no clinically meaningful differences from the reference product in terms of safety, purity, and potency'.[133] Unlike generic medicines approved under the Hatch-Waxman Act, biosimilars are not automatically substitutable with the reference biologic without physician intervention.[134]

In September 2017, in the first antitrust case between a biologic originator and a biosimilar manufacturer, Pfizer sued Johnson & Johnson (J&J) and Janssen in the US District Court for the Eastern District of Pennsylvania. The complaint alleges that the defendants employed a 'multi-faceted scheme' to thwart biosimilar competition through imposing exclusionary contracts on both health insurers and healthcare providers (eg, hospitals and clinics).[135] The court denied defendants' motion to dismiss Pfizer's complaint, holding that the complaint plausibly asserts 'detailed allegations regarding J&J's exclusionary terms with many of the nation's largest insurers, the incentive structure that forces end payors and providers into accepting those terms, Pfizer's efforts to compete, including its guarantees that Inflectra would cost less than Remicade, and [alleged] how market participants on many levels are injured from J&J's ability to sell Remicade without having to compete with Inflectra and other biosimilars'.[136] Direct and indirect purchaser class action and opt-out complaints followed the Pfizer lawsuit and these cases have proceeded to discovery.

In a separate set of biosimilar suits filed in early 2019, class action plaintiffs also began filing antitrust complaints concerning AbbVie's biologic drug Humira, which is presently the best-selling prescription drug in the world with over US$130 billion in estimated total sales. The complaint alleges that AbbVie has prevented biosimilar competition by employing a 'patent thicket' – defined by plaintiffs as 'an unlawful scheme whereby [AbbVie] secured over 100 patents designed solely to insulate Humira from any biosimilar competition' – and then entering into illegal market division agreements.[137] An amended consolidated complaint is due in August 2019.

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

133 'What Does It Mean to Have "No Clinically Meaningful Differences"?', Biosimilar and Interchangeable Products, FDA, www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm.

134 See 'Considerations in Demonstrating Interchangeability with a Reference Listed Product', Guidance for Industry, FDA (2019).

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

136 *Pfizer Inc v Johnson & Johnson*, 333 F Supp 3d 494, 502 (ED Pa 2018).

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

Contracting practices in antitrust cases

Various other contracting practices have also recently come under antitrust scrutiny.

For example, in *Rotavirus*, the plaintiffs claim that 'before the threat of competition from GSK, Merck had contracts that offered "bundled" discounts that would condition prices on loyalty to a bundle of Merck vaccines', and with the anticipation of competition 'Merck added a condition to its contracts that required customers to buy all or nearly all of their pediatric rotavirus vaccines from Merck or face substantial price penalties on all other Merck vaccines'.[138] This allegedly resulted in 'reducing GSK's incentive to compete based on price' and allowed Merck 'to charge artificially-inflated prices for [its] rotavirus vaccine'.[139] In a one-page order, the US District Court for the Eastern District of Pennsylvania denied a motion to dismiss,[140] apparently rejecting defendants' arguments and concluding that the complaint plausibly alleged harm to competition and substantial foreclosure of a relevant antitrust market.[141] The case is stayed while the defendants seek to compel arbitration.

Another notable example is the *EpiPen* antitrust litigation. Among other allegations, the plaintiffs allege that Mylan provided exclusionary rebates that 'caused PBMs to begin to restrict the epinephrine auto-injector category' and 'to block [Sanofi's epinephrine drug] Auvi-Q from the market'.[142] Mylan, for example, allegedly offered large rebates to third-party payers that expressly conditioned rebates on exclusivity, imposed contractual exclusivity provisions on school programmes and offered consumers zero-dollar co-pays that in conjunction with rebates drove up competitor costs.[143] The US District Court for Kansas granted Mylan's motion to dismiss Sanofi's complaint in part, reasoning that 'Sanofi's exclusive dealing claims based on discounts or rebates that Mylan offered to state or state agencies' should be dismissed on *Noerr-Pennington* grounds.[144] The court reached a similar conclusion as to the consumer plaintiffs, rejecting their argument that, unlike Sanofi's claims, the class claims 'are premised on Mylan's misclassification of the EpiPen' to influence 'state-based Medicaid agencies to exclude Auvi-Q'.[145] The court explained that 'the benefit managers understood that Mylan had misclassified the EpiPen' and 'nothing about the misclassification affected the decision-making abilities of benefit managers

138 Compl paragraphs 4, 6, *In re Rotavirus Vaccines Antitrust Litig*, No. 18-cv-1734 (ED Pa 15 June 2018), ECF No. 12.

139 id.

140 Order, *In re Rotavirus Vaccines Antitrust Litig*, No. 18-cv-1734 (ED Pa 23 January 2019), ECF No. 53.

141 Mem in Supp of Mot to Dismiss, *In re Rotavirus Vaccines Antitrust Litig*, No. 18-cv-1734 (ED Pa 30 July 2018), ECF No. 22-1.

142 Consumer Class Action Compl paragraphs 1–9, 178–79, *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices, and Antitrust Litig*, No. 17-md-2785 (D Kan 17 October 2017), ECF No. 60.

143 Memorandum and Order, *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices, and Antitrust Litig*, No. 17-md-2785 (D Kan 21 December 2017), ECF No. 98.

144 Mem and Order, *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices, and Antitrust Litig*, No. 17-md-2785 (D Kan 21 December 2017), ECF No. 98 at 41.

145 *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices, and Antitrust Litig*, 336 F Supp 3d 1256, 1291 (D Kan 2018).

when they chose which EAI [auto-injector] devices to include in the formularies'.[146] Other antitrust claims have proceeded to discovery and the cases are proceeding on separate tracks for the Sanofi and consumer complaints.

Finally, in *Restasis*, Shire alleges that Allergan entered into an anticompetitive exclusive-dealing agreement and used '"bundling" rebates across its products, including Restasis, to secure exclusivity on top plans' formularies' to effectively block Shire from dry-eye disease competition.[147] The US District Court for New Jersey granted defendants' motion to dismiss because 'Plaintiff's product market of Medicare Part D is unduly narrow because it excludes others, notably commercial payers, to whom Plaintiff can sell Xiidra', its dry-eye drug.[148] The court also held that Shire did not plausibly allege anticompetitive conduct because the 'Plaintiff has not alleged that Defendants have a monopoly over the glaucoma drugs which it bundles with Restasis, the product competing with Plaintiff's Xiidra', and the 'Plaintiff has not asserted that either government or commercial payers must have Restasis (or other Defendant products)'.[149] Shire was granted leave to file an amended complaint, and direct and indirect purchasers have filed suits alleging various other anticompetive conduct related to *Restasis*. In June 2019, however, the court ordered a stay and administratively terminated Shire's case due to the recent transfer of ownership of the Xiidra franchise to Novartis.

Sham allegations

While many pharmaceutical antitrust cases include sham allegations, the US Court of Appeals for the Third Circuit's recent *FTC v Shire ViroPharma* decision is particularly notable as it limits the scope of the FTC Act. Shire allegedly inundated the FDA with meritless filings to delay approval of generic Vancocin. Nearly five years later and after Shire divested itself of Vancocin, the FTC filed suit against Shire under section 13(b) of the FTC Act asserting allegations of sham petitioning.[150] The Third Circuit held that section 13(b)'s express requirement that the defendant 'is violating' or 'is about to violate' the law cannot be reconciled with the FTC's 'expansive view' that section 13(b) includes 'showing a past violation and reasonable likelihood of recurrent future conduct'.[151] For this reason, the Third Circuit affirmed the district court's dismissal of the FTC's claims.

Also notable is *FTC v AbbVie*, in which the US District Court for the Eastern District of Pennsylvania dismissed the reverse payment claims as discussed above, but permitted the FTC's sham litigation claims to proceed to trial. At summary judgment, the court held that the defendants' underlying patent suit for AandroGel was objectively baseless because they had secured the relevant patent after 'amending their patent application from an initially broad claim covering all penetration enhancers to a narrow claim covering only one penetration enhancer', while the

146 id.

147 *Shire US, Inc v Allergan, Inc*, No. 17-7716, 2019 US Dist LEXIS 49837, at *8–9 (DNJ 22 March 2019).

148 id at *30–31.

149 id at *47–48.

150 *FTC v Shire Viropharma Inc*, 917 F.3d 147, 149 (3d Cir 2019).

151 id at 149–50.

generic companies used different penetration enhancers in their products.[152] Following a bench trial, the court further found that the patent litigation was subjectively baseless because the attorneys responsible for bringing the suit 'knew that Teva and Perrigo used penetration enhancers for their generic products which were distinct', 'understood that prosecution history estoppel barred the infringement suits' and 'were very experienced patent attorneys, who also knew the extensive financial benefits to defendants if generic versions of AndroGel were kept or delayed from entry'.[153] While the court ordered disgorgement of US$448 million, this amount was far less than the US$1.35 billion sought by the FTC.[154] Cross-appeals concerning the dismissed reverse payment claims and the sham litigation rulings are pending in the US Court of Appeals for the Third Circuit.[155]

Finally, in *Meijer v Ranbaxy*, plaintiffs alleged that generic defendants 'hastily submitted multiple ANDAs with incorrect or fraudulent information, thereby wrongfully locking in the exclusivity periods and deterring other potential generic drug manufacturers from entering the market'.[156] The US District Court for Massachusetts largely denied a motion to dismiss, addressing 'a question of first impression' concerning these allegations of fraud on the FDA and whether Ranbaxy had market power even though its product never reached the market.[157] The court held that it is plausible that Ranbaxy 'reduced output and restricted competition in hopes of gaining future profits' and 'had the power to exclude competitors while its ANDA was pending, because of its first-filer status'.[158] Other follow-on actions have been transferred to this court and a motion to dismiss a consolidated indirect purchaser complaint is pending.

REMS antitrust cases

The FDA's REMS programme subjects certain medications with serious safety risks to additional safety requirements to help ensure the benefits of the medication outweigh its risks. The FDA, the FTC and some private litigants have expressed concerns about brand pharmaceutical companies using the FDA's REMS programme to allegedly prevent some generic companies from obtaining certain drug samples needed for bioequivalence testing. For example, in July 2018, the FTC issued

152 *FTC v AbbVie Inc*, 329 F Supp 3d 98, 117 (ED Pa 2018).

153 id at 125–26.

154 id at 138–43.

155 *FTC v AbbVie, Inc*, No. 18-02621 (3d Cir 23 July 2018).

156 *Meijer, Inc v Ranbaxy Inc*, No. 15-11828, 2016 US Dist LEXIS 120780, at *12 (D Mass 16 June 2016), adopted by 2016 US Dist LEXIS 120998 (7 September 2016).

157 id at *50.

158 id.

a comment to an HHS publication, in which the FTC called for legislative and regulatory action to combat the potential misuse of REMS.[159] And in May 2018, the FDA released a list of drug manufacturers suspected of using REMS to delay potential generic entry.[160]

Furthermore, in a first-of-its-kind case, Mylan sued Celgene for allegedly withholding samples of Celgene's cancer drugs Thalomid and Revlimid under the REMS programme.[161] In October 2018, the US District Court for New Jersey granted summary judgment for Celgene in part, holding that 'until the FDA approved Mylan's [drug study] protocols and Celgene was so notified, it had a legitimate business justification for refusing to sell Mylan samples', but also held that 'Celgene's conduct after FDA approval requires factfinding'.[162] Mylan's claims were further limited by the court because, unlike the Thalomid claims, Mylan 'proffered no damages model for its Revlimid claims that contemplates an ANDA filing after FDA approval of its study protocols' and did not offer 'any evidence that Mylan could have developed its study protocols for its lenalidomide [Revlimid] ANDA sooner than it actually did'.[163] Celgene later settled with Mylan in July 2019 for US$62 million.[164]

159 'FTC Submits Statement to HHS on Its Blueprint to Lower Drug Prices', FTC Press Release, 17 July 2018, www.ftc.gov/news-events/press-releases/2018/07/ftc-submits-statement-hhs-its-blueprint-lower-drug-prices.

160 'Reference Listed Drug (RLD) Access Inquiries', US Food & Drug Admin, May 2018, www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm.

161 *Compl, Mylan Pharms Inc v Celgene Corp*, No. 2:14-cv-02094 (DNJ 3 April 2014), ECF No. 1.

162 Opinion at 55, *Mylan Pharms Inc v Celgene Corp*, No. 2:14-cv-02094, (DNJ 3 October 2018), ECF No. 287.

163 id at 39.

164 White & Case, LLP represents some of the parties in the following cases discussed in this academic article: *AndroGel*, *Aggrenox*, *Asacol*, *Doryx*, *Effexor*, *EpiPen*, *Humira*, *K-Dur*, *Lidoderm*, *Lipitor*, *Loestrin*, *Namenda*, *Remicade* and *In re Generic Pharmaceuticals Pricing Antitrust Litigation*. No statement in this article may be imputed to any client in those actions or any other client of White & Case LLP. No client of White & Case LLP contributed to this article.

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