United States: Pharmaceutical Antitrust

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In summary

The past year has continued to see an increase in US case law and other developments in the area of pharmaceutical antitrust. In this article we look at, among other things, 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', product-hopping antitrust claims against innovator pharmaceutical companies that introduce new versions of brand-name drugs facing generic competition, and pharmaceutical pricing developments.

Discussion points

- Recent dismissals of reverse payment allegations
- Increasing class certification scrutiny in pharmaceutical antitrust matters
- Challenges to pharmaceutical manufacturers' pricing practices
- The first pharmaceutical antitrust litigations concerning biosimilar competition

Referenced in this article

- *FTC v Actavis*
- *FTC v Abbvie*
- *In re Humira (Adalimumab) Antitrust Litigation*
- *In re Lamictal Direct Purchaser Antitrust Litigation*
- *Asacol, Thalomid/Revlimid, Intuniv* and *Niaspan*
- US Supreme Court
- Sherman Act

Reverse payment case law under Actavis

The US Supreme Court's June 2013 decision in *FTC v Actavis* opened a floodgate for more than 30 separate antitrust cases that have been filed or revived under the 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, but the majority opinion likewise rejected the FTC's proposed 'quick look' rule of presumptive unlawfulness. Instead, the Supreme Court charted a middle course, holding that 'the FTC must prove its case as in other rule-of-reason cases'.[1]

In doing so, the Supreme Court 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.*[2]

The Supreme Court 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. Moreover, California enacted a new reverse payment law, effective from January 2020, which deviates from the rule of reason standard announced in *Actavis* and codifies that certain alleged reverse payment settlements are to be treated as presumptively anticompetitive.[3] The law was unsuccessfully challenged at the district court level,[4] and the challenge was rejected for lack of standing by the US Court of Appeals for the Ninth Circuit in July 2020.[5] As further discussed below, the only certainty thus far is that the reverse payment waters are far from settled.

1 *FTC v Actavis, Inc*, 570 US 136, 159 (2013).

2 id. at 156.

3 See Kristen O'Shaughnessy et al, 'California's New Reverse Payment Law Departs from Supreme Court Standard in FTC v. Actavis', White & Case LLP, 17 October 2019, www.whitecase.com/publications/alert/californias-new-reverse-payment-law-departs-supreme-court-standard-ftc-v-actavis.

4 *Ass'n for Accessible Meds v Becerra*, No. 2:19-cv-2281, 2019 US Dist Lexis 223342 (ED Cal 31 December 2019).

5 *Ass'n for Accessible Meds v Becerra*, No. 20-15014 (9th Cir 24 July 2020), ECF No. 55-1.

Pleading standards under Actavis

Following the Supreme Court's *Actavis* decision, courts have concluded that a payment may include no authorised generic (no-AG) agreements as well as other non-cash transfers that have value, such as co-promotion, licensing and distribution agreements.[6] Courts, however, have grappled with how precisely a plaintiff must allege monetary estimates of value transferred to generic challengers.[7] For example, the court in *Intuniv* denied a motion to dismiss where the plaintiff alleged that in addition to a no-AG agreement, the first abbreviated new drug application filer for generic Intuniv paid the brand company too little under a licence agreement that permitted generic entry prior to patent expiry.[8] The court held that a 'sharply discounted royalty rate could permit the generic company to keep a portion of the profits that it otherwise would have turned over to the brand company, had the royalty reflected the competitive market rate'.[9] This case has proceeded through discovery, and the defendants' motion for summary judgment is pending.

In contrast, another court 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.[10] 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'.[11] An appeal by the FTC on that ruling, as well as a cross-appeal on a sham litigation judgment of US$448 against defendants, is pending in the US Court of Appeals for the Third Circuit. Oral argument was held in January 2020.

More recently, in June 2020, the court in *Humira* dismissed a reverse payment claim alleging that 'AbbVie paid biosimilar manufacturers in the form of European agreements that allowed the biosimilars to enter the European market' while agreeing to 'AbbVie-friendly' generic entry dates in the US.[12] The 'package deals' allegedly bought AbbVie 'more lucrative monopoly time in the

6 See, eg, *In re Loestrin 24 FE Antitrust Litig*, 814 F.3d 538, 550 (3d Cir 2016) ('[T]his no-AG agreement falls under *Actavis*'s rule'); *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 may constitute a payment); and *In re Aggrenox Antitrust Litig*, 94 F Supp 3d 224, 242 (D Conn 2015) (holding that a '"payment" is not limited to cash transfers').

7 See, eg, *In re Lipitor Antitrust Litig*, 868 F.3d 231, 255 n.11 (3d Cir 2017); *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) (*Lidoderm*); and *In re Opana ER Antitrust Litig*, 162 F Supp 3d 704, 718 (ND Ill 2016).

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

9 id. at *35.

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

11 id. at 436.

12 *In re Humira (Adalimumab) Antitrust Litig*, No. 19-CV-1873, 2020 US Dist Lexis 99782, at *57 (ND Ill 8 June 2020).

US (worth billions of dollars in revenue for AbbVie)'.[13] The district court, however, rejected this theory because the settlements increased competition 'by bringing competitors into the market when patents otherwise prohibited competition' and the 'settlement terms, when taken together, involve transfers of value from the patentee to the alleged infringer'.[14] Plaintiffs have indicated that they intend to appeal.[15]

Finally, in July 2020, a magistrate judge in *Sensipar* issued an order recommending dismissal because neither 'Teva's retained revenue' from its at-risk launch nor 'an acceleration provision allowing Teva to resume sales of its generic product if another generic launched before Teva's agreed-upon entry date' is an unlawful reverse payment under *Actavis*, either when considered alone or together.[16] The parties have 14 days to file objections to this order.

Evaluating evidence under Actavis

Some district courts have denied summary judgment where plaintiffs' causation theories of earlier generic entry were at issue. In *Solodyn*, for example, 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 settlement.[17] The plaintiffs had raised a genuine dispute about the invalidity of the patent and non-infringement,[18] 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.[19] 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.[20] The case proceeded to trial in early 2018, but Impax settled mid-trial with the remaining indirect purchasers.[21]

13 id. at *57–58.

14 id. at *58–61.

15 Status Report, *In re Humira (Adalimumab) Antitrust Litig*, No. 19-CV-1873 (29 June 2020), ECF No. 171.

16 *In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig*, No. 19-md-2895 (D Del 23 July 2020), ECF No. 160.

17 *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*, No. 14-md-2503, 2018 US Dist Lexis 11921, at *20–21 (D Mass 25 January 2018); see also *United Food & Commercial Workers Local 1776 v Teikoku Pharma USA*, 296 F Supp 3d 1142, 1156–58, 1160–64 (ND Cal 2017) (addressing similar causation theories).

18 *Solodyn*, 2018 US Dist Lexis 11921, at *62–69.

19 id. at *72.

20 id. at *74–81.

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

In contrast, the court 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.*[22]

The court, however, permitted the plaintiffs' no-payment settlement theory based on certain expert opinions about why the brand company 'crafted the settlement' and the perceived merits of the underlying patent litigation, whether 'it would have been economically rational for [the brand company] to settle even without a reverse payment', and other fact and expert evidence.[23] But following the denial of class certification discussed below, the remaining plaintiffs settled.

The district court in *Wellbutrin*, however, reached an entirely different result, granting summary judgment to the defendants for lack of causation.[24] On appeal, the US Court of Appeals for the Third Circuit affirmed, holding that 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'.[25] 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'.[26] Notably, the size of the reverse payment alone was an insufficient 'surrogate' for the weakness of the patent.[27] 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.[28] 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'.[29]

Other summary judgment decisions, such as *AndroGel*, *K-Dur*, *Loestrin*, *Modafinil*, *Namenda* and *Nexium*, have also focused on whether business agreements executed contemporaneously with patent settlements are 'large and unjustified'. In these cases, district courts denied summary judgment based on various disputed factual issues unique to each case. 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

22 *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).

23 id. at *58–59.

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

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

26 id. at 169.

27 id. at 168.

28 id. at 166–67.

29 id. at 167.

unwanted, the agreements for 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.[30]

While some cases, such as *Modafinil* and *Solodyn*, have proceeded to trial since the Supreme Court's *Actavis* decision, those cases were resolved by settlements mid-trial and only two reverse payment cases – *Nexium* and *Opana* – have proceeded through trial to judgment. In *Nexium*, the plaintiffs had calculated a reverse payment of US$22 million, argued that the contemporaneously executed business agreements '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'.[31] But at trial, 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.[32] The US Court of Appeals for the First Circuit affirmed the jury's verdict for the defendants.[33]

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 and licence agreement (SLA) and a development and co-promotion agreement (DCA).[34] 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.[35] The DCA was executed contemporaneously with the SLA and provided an up-front 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.[36]

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'.[37] Despite finding that the SLA was 'large and unjustified', the ALJ concluded that any anticompetitive harm was outweighed by pro-competitive benefits because 'Endo's acquisition of

30 *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 Loestrin 24 FE Antitrust Litig*, No. 13-md-2472, 2019 US Dist Lexis 220262, at *53–54, 62–70 (D RI 17 December 2019); *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); and *King Drug Co of Florence v Cephalon, Inc*, 88 F Supp 3d 402, 407–10, 419–21 (ED Pa 2015).

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

32 id.

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

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

35 id. at 114.

36 id. at 120.

37 id. at 132.

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' and 'absent the SLA, such after-acquired patents also would have been successfully asserted to enjoin Impax from selling generic Opana ER'.[38]

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'.[39] In June 2019, Impax filed a petition for review in the US Court of Appeals for the Fifth Circuit and oral argument was held in June 2020.

Product-hopping antitrust cases

Plaintiffs have also attempted to use 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 and generic substitution laws.[40]

Pre-2015 decisions: 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 district court in *TriCor* rejected the defendants' argument that any product change that is an improvement is per se legal under the antitrust laws.[41] Instead, the court concluded that the introduction of a new product should be assessed under the rule of reason approach, requiring the plaintiffs to demonstrate that the anticompetitive harm from the formulation change outweighed any benefits of introducing a new version of the product. The court in *TriCor* denied the defendants' motion to dismiss, finding the plaintiffs' specific allegations – that the defendants bought back supplies of the old formulation and changed product codes for the old products to 'obsolete' to prevent pharmacies from filling TriCor prescriptions with generic versions of the old formulation – sufficient to support the plaintiffs' antitrust claims.[42]

In *Prilosec*, the district 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.[43] In granting the defendants' motion to dismiss, the court found that where defendants

38 id. at 145.

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

40 See Michael Gallagher et al., 'United States: Pharmaceutical Antitrust', *GCR Americas Antitrust Review 2020* at 116, Global Competition Review, 2019, www.whitecase.com/sites/default/files/2019-09/gcr-united-states-pharmaceutical-antitrust-2020.pdf (addressing the relevant regulatory background underlying product-hopping claims).

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

42 id. at 423–24.

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

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.[44]

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 district court denied the defendants' motion to dismiss the product-hopping claims, holding that 'what is clear from the case law is that simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct [that stymies competition].'[45] 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.[46] 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.[47]

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 district court 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, twice-daily drug to a newer, once-daily formulation.[48] 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.[49]

44 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').

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

46 id. at 681–82.

47 id. at 682–85.

48 *New York v Actavis, PLC*, No. 14-cv-7572, 2014 US Dist Lexis 172918, at *118–23 (SDNY 11 December 2014).

49 id. at *107–08.

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.[50] 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*[51] 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.[52] 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.[53]

The US Court of Appeals for the Third Circuit in *Doryx*, however, 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.[54] 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.[55]

After full discovery, the *Doryx* 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.[56] The court also rejected the plaintiffs' contention that the product reformulations were anticompetitive because they were insufficiently innovative, noting that no intelligible test for

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

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

52 787 F.3d at 653–54.

53 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)).

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

55 id. at *11.

56 *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.

innovation 'sufficiency' had been offered and doubting that courts could ever fashion one.[57] 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.[58] The US Court of Appeals for the Third Circuit affirmed the lower court's grant of summary judgment in the defendants' favour.[59]

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.[60]

In *Asacol*, 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.[61] 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 introducing the close substitute Delzicol.[62] 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.[63]

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 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

57 id. at *42.

58 id. at *40.

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

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

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

62 *In re Asacol Antitrust Litig*, No. 15-cv-12730, 2016 US Dist Lexis 94605 (D Mass 20 July 2016).

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

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.[64] The private plaintiffs' and the state attorneys generals' cases are coordinated for pretrial discovery,[65] and summary judgment motions are expected later in 2020.

Additionally, following an FTC investigation related to *Suboxone*, the FTC filed an antitrust action against Reckitt Benckiser in July 2019 concerning allegations of product hopping and sham petitioning. Reckitt settled the next day, agreeing to a 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.*[66]

The FTC settlement is reportedly 'part of a broader government settlement with Reckitt, which involves criminal and civil fraud claims'.[67] The FTC also reached a settlement with Indivior, a former subsidiary of Reckitt, in July 2020, which is also part of a broader government settlement.[68]

Finally, the court in *Loestrin* relied heavily on *Namenda* when denying the defendants' motion to dismiss the product-hopping claims.[69] 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.[70] At summary judgment, however, the *Loestrin* court rejected the plaintiffs' argument 'that no showing of anticompetitive conduct is required beyond the hard switch itself'; the court instead required plaintiffs to come forward with evidence of 'anticompetitive conduct to coerce consumers to

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

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

66 '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.

67 '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.

68 *FTC v Indivior Inc*, No. 1:20-cv-00036 (WD Va 24 July 2020), ECF No. 3.

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

70 id.

switch' products to prove their product-hopping claim.[71] The court found that there was competing evidence on the issue of coercion, which was 'all fodder for the jury' under the circumstances, and therefore allowed the product-hopping claim to proceed to trial.[72] The case settled prior to trial.

Class certification in pharmaceutical antitrust cases

Numerous recent circuit and district court decisions have signalled increasing scrutiny concerning class certification, and have denied certification because common issues failed to predominate, for a lack of numerosity and on other grounds.

In April 2020, the US Court of Appeals for the Third Circuit vacated an order certifying a class of direct purchasers in *Lamictal*. The Third Circuit held that the district court failed to conduct a 'rigorous analysis' and scrutinise the competing proof offered by the parties.[73] The plaintiffs argued that common evidence of injury predominated, relying on general pricing information and hypothetical average prices derived from economic literature, forecasts, transactional data and an expert model.[74] The brand company, however, offered evidence that it contracted with pharmacies and promised significant discounts and rebates for the brand Lamictal, and the generic company contended that it learned about the brand's contracting strategy and pre-emptively lowered its prices to compete.[75] According to the defendants' expert, by relying on averages and not accounting for the brand's individualised negotiations and the generic's response on pricing in the actual world, the plaintiffs masked that up to one-third of the proposed class likely paid less for their purchases than they would have paid absent the challenged settlement agreement.[76] The Third Circuit vacated the certification decision and remanded for the district court to address this competing evidence.

Additionally, on the eve of trial in *Asacol*, the US Court of Appeals for the First Circuit granted an interlocutory appeal concerning class certification. The district court had certified an indirect-purchaser class, despite finding 'that approximately 10 per cent of the class had not suffered any injury' as brand loyalists, because the court 'determined that those uninjured class members could be removed in a proceeding conducted by a claims administrator' after trial.[77] In an October 2018 decision, the First Circuit decertified the class because, in the product-hopping context – where plaintiffs allege injury from being coerced to buy a new formulation – individual testimony is required at trial to determine whether certain plaintiffs were injured.[78] The First Circuit explained

71 *In re Loestrin 24 Fe Antitrust Litig*, No. 13-md-2472, 2019 US Dist Lexis 220262, at *89–91 (DRI 17 December 2019).

72 id. at *92.

73 *In re Lamictal Direct Purchaser Antitrust Litig*, 957 F.3d 184, 195 (3d Cir 2020).

74 id. at 193.

75 id. at 193–94.

76 id.

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

78 See id. at 52.

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'.[79] This left 'a fatal gap in the evidence for all but the few class members who [would] testify in person'.[80]

The *Asacol* decision has been cited extensively, including in the recent *Thalomid/Revlimid*, *Intuniv* and *Niaspan* decisions, all of which denied class certification for indirect purchasers.[81] For example, in *Thalomid/Revlimid*, the court held 'that there are potentially uninjured class members remaining in the class – specifically, brand loyalists – and that identifying these members would require extensive individualized inquiry', such that class certification is inappropriate.[82] Similarly, in *Intuniv*, the court held that class certification should be denied because indirect purchasers 'have failed to put forth a reasonable and workable plan to weed out the more than 10,000 uninjured class members'.[83] And in the June 2020 *Niaspan* decision, the court drew upon both *Lamictal* and *Asacol* in denying class certification, holding that averages in plaintiffs' proposed 'yardstick model does not purport to show that all class members were injured' and 'hides several groups of uninjured class members who cannot be easily identified' and adequately removed from the class.[84]

Class certification was also denied in *AndroGel* and *Modafinil* because direct purchasers failed to establish that 'the class is so numerous that joinder of all members is impracticable'.[85] These decisions are in stark contrast to earlier direct-purchaser class certification decisions, which merely noted that class members were geographically dispersed to conclude that joinder would be impracticable.[86]

In *AndroGel*, the district court denied a motion to certify a class of 33 direct purchasers that were challenging alleged reverse payment settlements. Rather than simply accepting that the proposed class was geographically dispersed, the court found that 'unlike the typical class action, in which there are a number of individual plaintiffs with relatively small claims, the plaintiffs' proposed class consists of very large, sophisticated companies with very large claims'.[87] The court

79 id. at 52–53.

80 id. at 53.

81 See also *In re Loestrin 24 Fe Antitrust Litig*, 410 F Supp 3d 352, 404 (DRI 2019) (denying class certification of a consumer class but permitting a third-party payor class).

82 *In re Thalomid & Revlimid Antitrust Litig*, No. 14-6997, 2018 US Dist Lexis 186457, at *44 (DNJ 30 Oct 2018).

83 *In re Intuniv Antitrust Litig*, No. 1:16-cv-12396, 2019 US Dist Lexis 141643, at *27 (D Mass 21 Aug 2019).

84 *In re Niaspan Antitrust Litig*, No. 13-md-2460, 2020 US Dist Lexis 97215, at *71–72 (ED Pa 2 June 2020).

85 Fed R Civ P 23(a)(1).

86 See, eg, *In re Nexium Esomeprazole Antitrust Litig*, 296 FRD 47, 53 (D Mass 2013) (concluding 'that litigating the same exact claims in multiple courts across the country is impracticable' (*internal citation and quotations omitted*)).

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

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'.[88] The plaintiffs did not appeal.

Similarly, the US Court of Appeals for the Third Circuit in *Modafinil* vacated a class certification order because the district court inappropriately 'considered the late stage of the litigation as relevant' to whether certification should be granted and 'failed to properly consider the ability and motivation of the plaintiffs to proceed as joined, as opposed to individual, parties'.[89] Despite the geographical dispersion of the proposed 22-member class, the Third Circuit observed that the proposed class members appeared likely to proceed as joined parties. This was in part because of the sizable claims of the proposed class members, including three absent class members that each had claims estimated at over US$1 billion even before trebling.[90] Accordingly, they could 'hardly be considered as candidates who need the aggregative advantages of the class device'.[91] On remand, the district court denied certification for similar reasons.[92]

Pharmaceutical manufacturer pricing practices

The growing pressure on brand and generic pharmaceutical manufacturers' pricing practices from enforcement agencies, private plaintiffs and politicians has continued over the past year. Federal and state investigations have resulted in criminal and civil enforcement actions, and private litigation has progressed, mostly in the form of claims alleging agreements to fix prices on generic drugs. The push for both state and federal legislative solutions on drug pricing has also increased, with the majority of states proposing (and many passing) drug pricing laws, while the federal government continues to wrestle with proposed legislation of its own, which was largely tabled following the onset of the covid-19 pandemic. As generic price-fixing litigation continues to move through discovery, much of the focus on drug prices has shifted to potential legislative remedies.

Legislation relating to pharmaceutical pricing

Drug pricing remains an important legislative issue, but over the past year, individual states rather than the federal government have charged ahead with new legislation. Indeed, although federal legislators proposed a number of bills over the past year regarding drug prices, including a Democrat-backed bill led by US House Speaker Nancy Pelosi (District of California),[93] momentum at the federal level has largely stalled, particularly in light of the ongoing covid-19 pandemic. For example, the Coronavirus Aid, Relief, and Economic Security Act signed by President Trump on 27 March 2020 makes no mention of drug pricing specifically, focusing instead on drug shortages

88 id.

89 *In re Modafinil Antitrust Litig*, 837 F.3d 238, 259 (3d Cir 2016).

90 id. at 258.

91 id.

92 *King Drug Co of Florence v Cephalon Inc*, No. 2:06-CV-1797, 2017 US Dist Lexis 137601, at *23–29 (ED Pa 28 August 2017).

93 See 'H.R. 3 – The Lower Drug Costs Now Act', Speaker.gov, www.speaker.gov/LowerDrugCosts.

and risk management, nor does the Health and Economic Recovery Omnibus Emergency Solutions Act passed by the House on 15 May 2020, which largely targets covid-19 relief and providing assistance to state and local governments.[94] As the pandemic continues and the November 2020 presidential election approaches, the likelihood of federal drug-pricing legislation in 2020 becomes less likely. The exception may be the potential for legislative limits on pricing of covid-19 treatments.

Progress on the administrative side has also been a mixed bag as the changes proposed by President Trump and his administration in their 'blueprint' to lower drug prices have met different fates. Although the Trump administration's proposal to index drug pricing to an international benchmark never really got off the ground, two other proposals resulted in rules adopted by the Centers for Medicare & Medicaid Services (CMS) – only one, however, has survived legal challenges. In June 2020, the US Court of Appeals for the DC Circuit affirmed a district court's decision to vacate CMS's 2019 Drug Price Transparency Rule,[95] which would have required pharmaceutical manufacturers to disclose price information in television advertisements for certain prescription drugs and biological products.[96] On the other hand, in June 2020, a district court upheld CMS's Price Transparency Rule, set to take effect in 2021, requiring insurers and hospitals to disclose the actual prices for common tests and procedures, which the Trump administration has argued will promote competition and lower healthcare costs.[97] Additionally, on 24 July 2020, President Trump signed four Executive Orders directing the US Secretary of Health and Human Services to take steps to lower costs for certain prescription drugs, such as insulin and epinephrine.[98]

At the state level, however, the story has been different. In 2020 alone, states have considered over 400 proposed drug-pricing bills, with more than 20 signed into law.[99] Although these state laws do not specifically challenge or restrict the prices charged for prescription drugs, they target many of the key issues underlying the drug-pricing debate, such as requiring pricing transparency from pharmaceutical manufacturers, mandating disclosures from pharmaceutical benefit managers (PBMs) and insurers, and capping consumer cost-sharing on certain drugs.[100] This increasingly complex web of state laws, and their various non-uniform reporting requirements, present a host of new challenges and potential pitfalls for companies at every level of

94 See the Coronavirus Aid, Relief, and Economic Security Act, 15 USCS § 9001; and the Health and Economic Recovery Omnibus Emergency Solutions Act, HR 6800.

95 *Merck & Co, Inc v United States HHS*, No. 19-5222, 2020 US App Lexis 18857, at *23 (DC Cir 16 June 2020).

96 *Merck & Co v United States HHS*, 385 F Supp 3d 81, 98 (DDC 2019); 84 Fed Reg 20, 732 (10 May 2019).

97 *Aha v Azar*, No. 1:19-cv-3619, 2020 US Dist Lexis 110130, *57 (DDC 23 June 2020).

98 'Trump Administration Announces Historic Action to Lower Drug Prices for Americans', Press Release, US Department of Health and Human Services, 24 July 2020, www.hhs.gov/about/news/2020/07/24/trump-administration-announces-historic-action-lower-drug-prices-americans.html.

99 See, eg, Michael Gallagher and Kevin C Adam, 'Growing Web of State Drug-Pricing Legislation Increases Challenges for Pharmaceutical Manufacturers and Other Industry Participants', White & Case LLP, 19 May 2020, www.whitecase.com/publications/alert/growing-web-state-drug-pricing-legislation-increases-challenges-pharmaceutical.

100 id.

the pharmaceutical distribution and sales chain.[101] Indeed, within the past year, California fined more than a dozen pharmaceutical manufacturers US$17.5 million for failing to properly report price increases, and Nevada similarly issued approximately US$17 million in fines to more than 20 pharmaceutical manufacturers.[102] While 'high' prices alone do not give rise to antitrust liability, companies at all levels of the pharmaceutical distribution and payment chain need to understand this developing body of state laws and pay close attention to its impact on pricing decisions to manage compliance and minimise risk.

This state legislative progress has not been unchecked by legal challenges. For example, in a case brought by a pharmaceutical manufacturer trade association, the US Court of Appeals for the Fourth Circuit in 2018 struck down Maryland's law prohibiting 'unconscionable price increases' as unconstitutional.[103] Currently pending before the US Supreme Court is the Pharmaceutical Care Management Association's lawsuit arguing that Arkansas' law regulating PBM drug reimbursement is pre-empted by the Employee Retirement Income Security Act.[104] A lawsuit seeking to block similar provisions in Oklahoma's Patient's Right to Pharmacy Choice Act is pending in the US District Court for the Western District of Oklahoma.[105] The Pharmaceutical Research and Manufacturers Association's (PhRMA) challenge to a California law requiring notice of certain price increases survived a motion to dismiss, and a summary judgment motion is pending in the US District Court for the Eastern District of California.[106] PhRMA also recently sued to block a Minnesota law requiring insulin manufacturers to provide product free of charge in certain instances, arguing that the law is an unconstitutional takings and violates the commerce clause.[107] While these and other challenges proceed, the web of state drug pricing laws will likely continue to expand, giving rise to new issues and legal disputes along the way.

Finally, one key area to watch in the coming year is the brewing debate over manufacturer copay assistance programmes and the use of 'copay accumulator' programmes, which insurers allegedly use to prevent manufacturer copay assistance from counting towards patient deductibles or out-of-pocket maximums. Specifically, CMS recently updated its rules for qualified health plans to permit the use of copay accumulator programmes, even when a generic counterpart is not

101 id.

102 id.

103 *Ass'n for Accessible Meds v Frosh*, 887 F.3d 664, 672–73 (4th Cir 2018) ('The Act instructs prescription drug manufacturers that they are prohibited from charging an "unconscionable" price in the initial sale of a drug, which occurs outside Maryland's borders. Maryland cannot, even in an effort to protect its consumers from skyrocketing prescription drug costs, impose its preferences in this manner.').

104 See *Rutledge v Pharmaceutical Care Management Ass'n*, 140 S Ct 812 (2020); see also *Pharm Care Mgmt Ass'n v Rutledge*, 891 F.3d 1109 (8th Cir 2018) (holding the Employee Retirement Income Security Act pre-empts state statute regulating PBMs' drug-reimbursement rates).

105 *Pharmaceutical Care Management Ass'n v Mulready*, No. 5:19-cv-00977 (WD Okla 2019).

106 See *Pharmaceutical Research Mfrs of America v David*, No. 2:17-cv-02573 (ED Cal 2018).

107 See *Pharmaceutical Research Mfrs of America v Williams et al*, No. 20-cv-01497 (D Minn 2020).

available for the brand name drug.[108] By contrast, in subsequent proposed rule-making regarding the determination of prices reported to the government (best price and average manufacturer price), CMS criticised copay accumulators that apply copay assistance 'to the benefit of the plan, instead of entirely to the patient', and proposed rules requiring manufacturers to ensure copay assistance benefits are provided entirely to the consumer in order to qualify for certain regulatory exclusions.[109] Additionally, one pharmaceutical manufacturer recently filed a federal declaratory judgment action seeking to overturn as erroneous and unconstitutional the federal government's position that a proposed copay assistance programme would violate anti-kickback and beneficiary inducement laws if provided to Medicare recipients.[110] The impact of these developments on manufacturer copay assistance programmes remains to be seen.

Litigation relating to pharmaceutical pricing

There have been few major developments in the past year in litigation over pharmaceutical manufacturer pricing. The cases that are pending do not actually challenge the price of drugs themselves – that is, that prices are too high or that price increases were too drastic. While some recent scholarship has pushed for recognising high prices alone as a Sherman Act, section 2 violation,[111] courts have not recognised such a claim. Rather, the pending cases target drug prices indirectly by challenging conduct that plaintiffs claim give rise to supracompetitive prices, such as reverse payment patent settlements, product hopping and other generic delay theories.

The sprawling generic drug price-fixing litigation in the US District Court for the Eastern District of Pennsylvania is the most notable legal action involving drug prices. Over the past year, while the cases have worked their way through discovery, there have been several important developments. First, another executive pleaded guilty to conspiring to fix prices.[112] The guilty plea follows from the earlier guilty pleas of two Heritage executives in 2017; a fourth executive at another manufacturer is awaiting trial.[113] Second, two generic manufacturers entered deferred prosecution agreements and agreed to pay criminal penalties to resolve criminal charges and

108 See 'Copay Maximizers Are Displacing Accumulators—But CMS Ignores How Payers Leverage Patient Support', Drug Channels, 19 May 2020, www.drugchannels.net/2020/05/copay-maximizers-are-displacing.html.

109 See 'Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements', Federal Register, 19 June 2020, www.federalregister.gov/documents/2020/06/19/2020-12970/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and#p-120;%20www.drugchannels.net/2020/05/copay-maximizers-are-displacing.html.

110 See *Pfizer Inc v US Dep't of Health and Human Services*, No. 1:20-cv-04920 (SDNY 2020).

111 Harry First, 'Excessive Drug Pricing as an Antitrust Violation', 82 *Antitrust Law Journal* 701, 2019.

112 See, eg, Riley Griffin and David McLaughlin, 'Former Sandoz Executive Pleads Guilty in U.S. Price-Fixing Probe', Bloomberg, 14 February 2020, www.bloomberg.com/news/articles/2020-02-14/former-sandoz-executive-pleads-guilty-in-u-s-price-fixing-probe.

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

an additional generic manufacturer (the fifth overall) was indicted.[114] Also, in June 2020, the state attorneys general expanded their litigation once again, filing another complaint accusing 26 companies and 10 individuals of fixing prices for more than 80 generic topical products, such as creams, gels, lotions, ointments and shampoos.[115]

The most notable new drug-pricing case this year is a suit filed by the Federal Trade Commission and seven state attorneys general against Martin Shkreli and Vyera Pharmaceuticals LLC, formerly known as Turing Pharmaceuticals LLC, regarding Daraprim (pyrimethamine), a drug used for treating the parasitic infection toxoplasmosis.[116] Although the case has been described by the media as targeting the price increases of Daraprim, the conduct at issue is actually Turing/Vyera's alleged efforts to control drug supply through the use of exclusive contracts that purportedly blocked potential generic competitors from access to suppliers of the active pharmaceutical ingredient. A motion to dismiss is pending and the case has proceeded with initial discovery.

Biosimilar antitrust litigation

In 2009, Congress passed the Biologics Price Competition and Innovation Act to provide an abbreviated FDA approval pathway for biosimilar versions of a biological drug,[117] opening the door to a new regime of pharmaceutical competition.

In September 2017, in the first antitrust case between a biologic originator and a biosimilar manufacturer, Pfizer sued Johnson & Johnson (J&J) and Janssen for allegedly employing a 'multi-faceted scheme' to thwart biosimilar competition through imposing exclusionary contracts on both health insurers and healthcare providers (eg, hospitals and clinics).[118] The court denied the 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'.[119] Direct and indirect purchaser class action and opt-out complaints followed the *Pfizer* lawsuit and these cases have proceeded to discovery.

114 See 'Fifth Pharmaceutical Company Charged In Ongoing Criminal Antitrust Investigation,' Dep't of Justice, 30 June 2020, www.justice.gov/opa/pr/fifth-pharmaceutical-company-charged-ongoing-criminal-antitrust-investigation.

115 See Compl, *Connecticut et al v Sandoz, Inc et al*, No. 3:20-cv-00802 (D Conn 10 June 2020).

116 See Compl, *FTC v Vyera Pharmaceuticals, LLC*, No. 1:20-cv-00706 (27 January 2020).

117 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).

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

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

In a separate set of biosimilar suits filed in early 2019, class action plaintiffs also began filing antitrust complaints concerning AbbVie's biological drug Humira, which is presently the best-selling prescription drug in the world with over US$130 billion in estimated total sales. The complaints allege 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.[120] In June 2020, the district court granted a motion to dismiss, recognising that the 'patent thicket' claim is a 'new kind of antitrust claim' that 'brings together a disparate set of aggressive but mostly protected actions'.[121] The court held that the 'allegations – even when considered broadly and together for their potential to restrain trade – fall short of alleging the kind of competitive harm remedied by antitrust law'.[122] As noted above, the plaintiffs intend to appeal.[123]

120 See, eg, 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.

121 *In re Humira (Adalimumab) Antitrust Litig*, No. 19-CV-1873, 2020 US Dist Lexis 99782, at *26–27 (ND Ill 8 June 2020).

122 id.

123 White & Case, LLP represents some of the parties in the following cases discussed in this article: *AndroGel*, *Aggrenox*, *Asacol*, *Doryx*, *Effexor*, *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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For more than two decades, Mr Gallagher has litigated jury and non-jury cases before federal and state trial and appellate courts throughout the United States.

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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, settlements of pharmaceutical patent litigation and strategic planning. 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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Mr Grannon served as lead trial counsel defending two pharmaceutical companies in *FTC v Actavis*, as well as counsel of record for those companies before the US Supreme Court. He has counselled more than 40 pharmaceutical patent settlements that have avoided challenge by the Federal Trade Commission and private plaintiffs. His other recent successes on behalf of clients include defeating class certification for direct purchasers, obtaining the dismissal of indirect-purchaser actions, winning summary judgment and successfully moving to bifurcate a trial into two phases, all in different pharmaceutical antitrust cases. He has also helped pharmaceutical clients obtain merger clearance in the United States.

In 2020, *Chambers USA* said: 'Eric Grannon "has a willingness to provide straightforward advice but also to think outside the box and help with creative solutions", reports a client. He is noted for his trial skills, representing pharmaceutical sector clients in complex antitrust litigation. He has particular experience defending pay for delay allegations.'

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