Ten Years Post-Actavis: Lessons Learned and the Future of Reverse Payment Antitrust Cases

by Stephen Fink; Analysis Group, Inc.

ABA Antitrust Law Section (October 24, 2023)

Stephen Fink

Ten years have passed since the U.S. Supreme Court's 2013 landmark decision in *FTC v. Actavis*, which cleared the path for so-called "reverse payment" settlements between branded drug patent holders and generic manufacturers to face antitrust scrutiny.[1] In a 5-3 decision, Justice Breyer's majority opinion outlined how reverse payment settlements could be found to be anticompetitive even when the settlement terms do not exceed the scope of the patent. To make this determination, the court's majority held, these settlements should be evaluated individually, using the rule of reason antitrust standard to determine whether the procompetitive aspects of the settlement outweighed anticompetitive ones.

The majority opinion provided guidance on ways individual settlements could be evaluated under a rule of reason framework. The specifics, however, have been interpreted differently by practitioners and left open issues for continuing debate. In particular, the opinion noted that:

1. Specific terms and restraints in settlement agreements, particularly as they relate to the entry of generic competitors, have the potential for genuine adverse effects on competition.
2. Some antitrust consequences will sometimes prove unjustified (e.g., when the payment exceeds the saved litigation expenses or fair value for services).

3. If a reverse payment settlement can cause anticompetitive harm, the patent holder likely possesses the power to bring that harm about in practice, with the size of the payment serving as a strong indicator of such power.
4. An antitrust claim may be more administratively feasible than the lower court in *Actavis* believed.
5. The fact that a large, unjustified reverse payment risks antitrust liability does not prevent parties from settling their lawsuit.

With respect to the administrative feasibility of these cases, the majority opinion argued it would normally not be necessary to litigate the underlying patent validity to address the antitrust question, which the lower court memorably described as a "turducken" task of deciding a patent case within an antitrust case about the settlement of the patent case.[2] Instead, the majority opined that "an unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."[3] The majority explained further that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."[4]

In his dissenting opinion, Chief Justice Roberts argued that this approach would discourage the settlement of patent litigation, noting that the question raised in the case was fundamentally one of patent validity. The dissent also challenged the practicality of the majority's decision to analyze these settlements under the rule of reason standard. In particular, the Chief Justice claimed that district courts, when faced with a patent settlement that is alleged to be a reverse payment, would be required to weigh the likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations. In light of these challenges, Chief Justice Roberts offered two words of advice to the lower courts: "Good luck."[5]

So how have the district courts fared thus far overseeing these antitrust challenges? Over the past decade, there have been dozens of reverse payment class action cases brought by private litigants. Many of these cases have been dismissed at the class certification stage.[6] Many others have settled prior to or during trial.[7] But in the decade since the Supreme Court's *Actavis* decision, only three cases have actually proceeded through trial to a jury verdict.

This article reviews some of the key findings from these three cases, summarizes lessons from the proceedings, and considers what may be ahead.

In re: Nexium (Esomeprazole) Antitrust Litigation ("Nexium")

In 2014, *Nexium* became the first reverse payment case to proceed through trial after the *Actavis* decision.[8] In this case, the plaintiffs – which included a class of direct purchasers, a class of end-payors, and a group of pharmaceutical retail outlets – alleged that defendant AstraZeneca, the manufacturer of the heartburn medication Nexium, had made payments to Ranbaxy, a generic manufacturer that had challenged a set of AstraZeneca's Nexium patents.[9] The plaintiffs argued that these alleged payments stemmed from terms of the patent litigation settlement agreement, which included

a condition that AstraZeneca would refrain from launching an authorized generic version of the Nexium product. Under this "no-AG" clause, Ranbaxy would serve as AstraZeneca's subcontractor and manufacture certain quantities of branded Nexium, and also serve as AstraZeneca's distributor for authorized generic versions of two other AstraZeneca drugs.[10] The plaintiffs alleged that these terms were actually payments from AstraZeneca to Ranbaxy to delay Ranbaxy's generic Nexium entry for a period of approximately six years.[11]

After deliberating for two and a half days, the jury found that AstraZeneca had exercised market power within the relevant market, that the AstraZeneca-Ranbaxy settlement agreement did include a large and unjustified payment, and that the settlement between the parties was "unreasonably anticompetitive."[12] However, the jury also found that the plaintiffs did not successfully prove that, absent the settlement, AstraZeneca and Ranbaxy would have agreed to an earlier generic entry date.[13] There was, therefore, no antitrust injury to the plaintiffs. The plaintiffs appealed the outcome to the U.S. Court of Appeals for the First Circuit, which upheld the jury's verdict in favor of the defense.[14]

Nexium highlights not only the complexity of these cases but also the challenge courts and parties face when trying these matters in front of a jury.[15] A key component to the case was the plaintiffs' decision to forego arguing that the generic manufacturers would have won the underlying patent litigation (i.e., proving a patent case inside of an antitrust case), arguing instead that, absent the challenged settlement agreement, the parties would have reached an alternative settlement permitting earlier generic entry.[16] Ultimately, the jury determined that the plaintiffs had not proven this element of their case; as a result, there was no finding that they had suffered any harm caused by the settlement agreement. *Nexium*, therefore, demonstrates that the burden is on private plaintiffs to prove not just an antitrust violation – harm to *competition* – but also harm to *plaintiffs*.[17] The failure to prove the latter part of this standard ultimately doomed the plaintiffs' case.

In re: Opana ER Antitrust Litigation ("Opana ER")

Allegations that Endo Pharmaceuticals entered into reverse payment settlements for its extended-release opioid pain medication tablet, Opana ER, resulted in two trials: one brought by the Federal Trade Commission ("FTC"), and one brought by private plaintiffs.[18] In these cases, the plaintiffs alleged that Endo and a generic manufacturer, Impax Laboratories, had settled the underlying patent litigation involving Opana ER with a series of reverse payments. The settlement terms involved a no-AG commitment by Endo in which it was required to provide monetary compensation to Impax under certain conditions, and an arrangement for Endo to pay Impax up to $40 million for an independent development and co-promotion deal.[19] The plaintiffs alleged that these settlement terms constituted reverse payments by Endo to Impax to delay its generic Opana ER entry for a period of approximately two and a half years.

The FTC's case resulted in a 2018 administrative bench trial in which the FTC's chief administrative law judge initially ruled in favor of Impax, finding that "the Endo-Impax Settlement was, on balance, procompetitive" because the settlement "granted Impax a broad patent license covering Endo's existing and subsequently-acquired Opana ER-related patents, which has enabled Impax to sell generic Opana ER without interruption since launching its product in January 2013, while all other potential generic drug manufacturers have been enjoined by patent litigation."[20] The Commission, however, reversed the administrative law judge's initial decision, and the U.S. Court of Appeals for the Fifth Circuit upheld the FTC's opinion.[21] The appeals court agreed with the FTC that "the fact that generic competition was possible, and that Endo was willing to pay a large amount to prevent that risk, is enough to infer anticompetitive effect."[22]

The private plaintiff case, however, resulted in a three-week jury trial that concluded in July 2022 with a verdict in favor of the defendants.[23] Although the jury found that Endo had market power for the brand name drug and did indeed make a reverse payment, the anticompetitive effects of the conduct were found to be outweighed by the procompetitive benefits, which included earlier access to generic Opana ER than otherwise would have been permitted.[24]

Opana ER highlights another dimension of the burden shift between the plaintiff and the defendant under the rule of reason framework set forth in *Actavis*. Here, the ability of the defense to demonstrate that the challenged settlements in fact allowed for generic entry years before the expiry of existing patents was critical in proving the procompetitive benefits of the agreement.

In re: HIV Antitrust Litigation

Most recently, in June 2023, an eight-person jury heard arguments on an alleged reverse payment settlement between Gilead Sciences and Teva regarding two HIV medications, Truvada and Atripla.[25] The plaintiffs – which included a class of indirect purchasers, as well as health plans and insurance providers – claimed that Gilead and Teva's 2014 settlement of their patent dispute constituted a reverse payment providing Teva with six months' contractual exclusivity on its generic versions of Truvada and Atripla in exchange for allowing Gilead to maintain a monopoly over both drugs until September 30, 2020.[26] This six-month period of exclusivity was tied to an "acceleration clause" that allegedly permitted Teva to enter as soon as any other generic.[27]

After two days of deliberation, the jury found that the plaintiffs had not shown that Gilead had market power within the relevant markets for Truvada and Atripla, and, separately, that the plaintiffs had not shown that the settlement agreement included a "reverse payment" from Gilead to delay Teva's competing generics.[28]

Toward the end of their deliberations, the jury sent a note to U.S. District Judge Edward Chen that asked if they could skip the market power question if they had an answer to the question about whether the purchasers had proven that the settlement included a reverse payment.[29] While the jury was instructed that they did need to

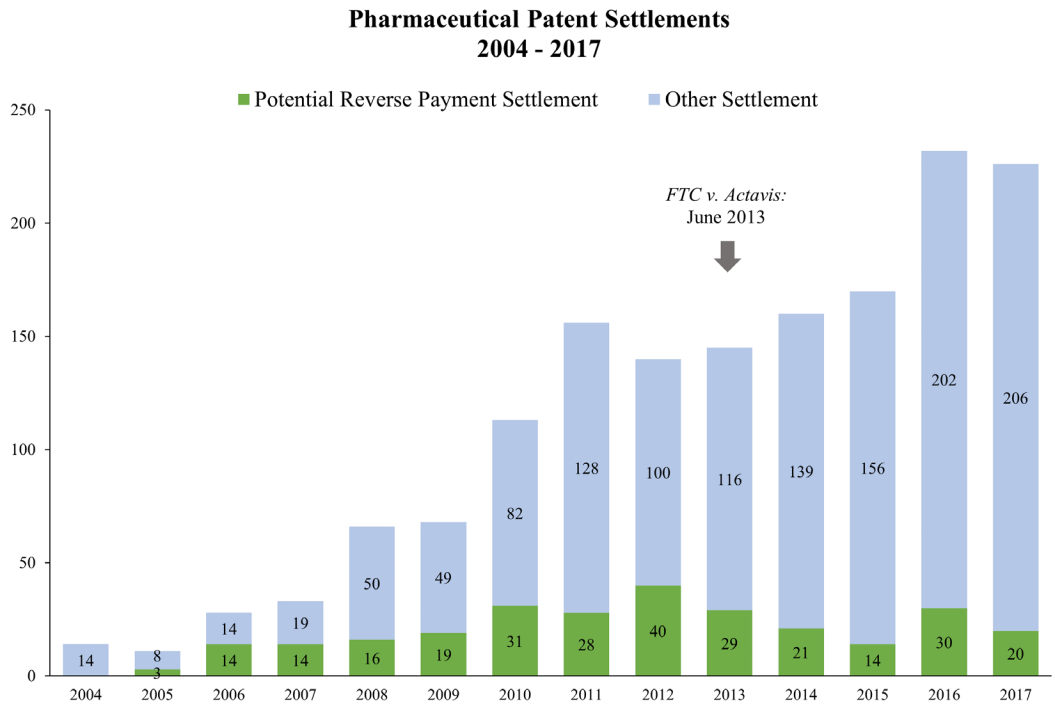
first answer the market power question – and ultimately found that Gilead lacked market power – this note suggests that the jury may have first reached a decision that the settlement did not include a payment for delay. Here, the defense had effectively countered the plaintiffs' arguments that, absent the patent settlement, the generic manufacturers would have entered into the marketplace earlier.

What the Next 10 Years May Look Like

The outcomes of these three jury trials in favor of the defense highlight the difficulty private plaintiffs face in clearing the requisite hurdles to reach a favorable ruling. Indeed, in each matter, the jury's verdict turned on a different legal or economic requirement. From establishing market power, to proving a large and unjustified reverse payment, to determining that the net effects of the settlement are anticompetitive, to showing that the plaintiffs were harmed, there are multiple dots that must be connected by plaintiffs' counsel under the rule of reason framework; otherwise, the defense will prevail. Proclaiming any trends from these trials should be done cautiously: each case is unique, and it may be that only those cases that had particularly favorable facts for the defendants were the ones to ultimately proceed through trial. However, the complexity of these matters and the need to communicate the legal and economic considerations effectively to juries are clear.

What may lie ahead over the next decade for these types of antitrust disputes? Available data published by the FTC suggest that, after reaching a high point in 2012, the "traditional" types of settlement agreements that include terms that constitute payments and have raised antitrust scrutiny have been generally decreasing since the *Actavis* decision. Through the end of 2020, the FTC published annual reports summarizing information on pharmaceutical patent litigation settlements that were required to be submitted under the Medicare Modernization Act.[30] These reports summarized the number of final Hatch-Waxman patent settlements that occurred in a given fiscal year, and categorized each settlement as either containing a payment or not. Figure 1 below shows the number of settlements reached in a given fiscal year, with the green portion of the bar representing the settlements with a payment and the blue portion representing the settlements without a payment.

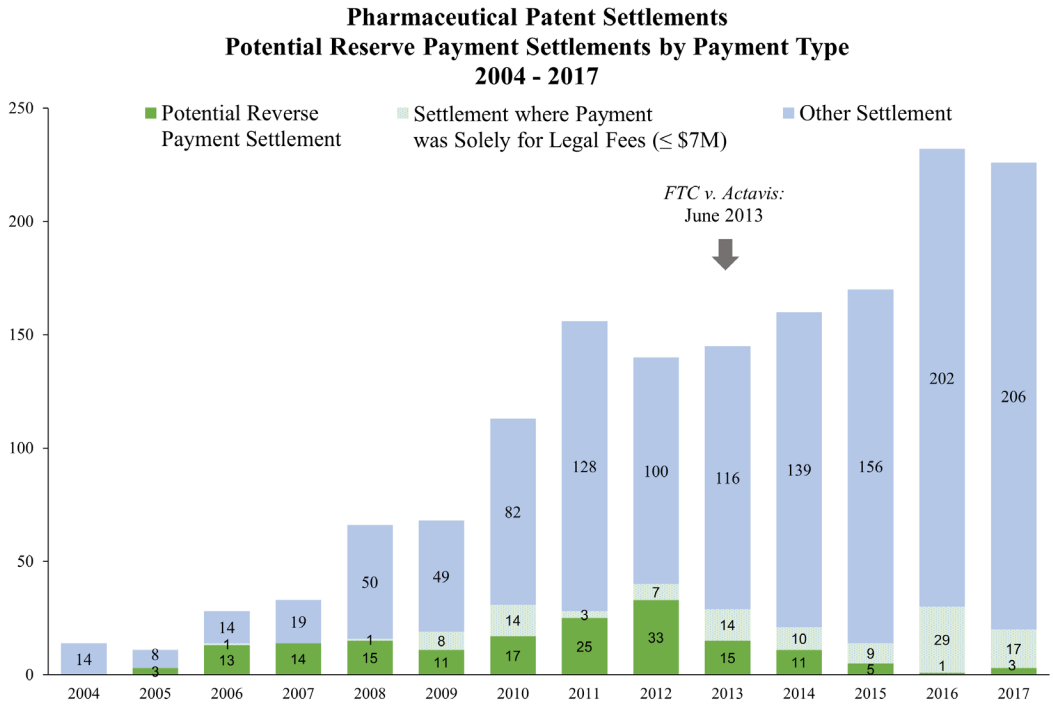
Figure 1



Source: FTC, "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2017," Exhibit 1.

As is evident in the chart, while the total number of settlements has generally increased since 2004, the number of settlements containing what the FTC categorizes as a payment has been generally trending downward since the 2013 Actavis decision. The FTC also distinguishes settlements with relatively small payments (less than $7 million) that are solely for saved litigation expenses, as these settlements are unlikely to raise antitrust concerns. When these settlements are accounted for, the decline in potential reverse payment settlements is even more pronounced, as shown in Figure 2 below.

Figure 2



Source: FTC, "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2017," Exhibit 1.

These findings may suggest that, overall, the number of antitrust reverse payment matters could decline in the next 10 years. However, as industry participants have modified their settlement negotiation tactics to avoid being flagged as including a potentially anticompetitive reverse payment, it is quite possible that other types of settlement terms will be targeted by plaintiffs. For example, patent settlements commonly include "acceleration clauses," whereby the settling generic is allowed to enter earlier than the agreed-to date in certain circumstances, such as if a third party wins a patent litigation. According to the FTC's review of settlements in fiscal year 2017, of the 192 settlements that restricted the generic manufacturers from selling their product for some period of time, 181 (or 94 precent) included an acceleration clause.[31] These settlement terms have been criticized by some as being anticompetitive reverse payments, in which the generic patent challengers accept later entry dates given the right to accelerate entry, and the entry clause potentially deters other third parties from attempting to enter earlier.[32] Of course, any potential anticompetitive effects of these clauses would, under rule of reason analysis, need to be balanced against the fact that these terms allow for even earlier generic entry then initially agreed to in the settlement, arguably a procompetitive outcome. It is worth noting that plaintiffs are already pursuing cases, including *In re: HIV Antitrust Litigation*, where these acceleration clauses are alleged to be anticompetitive reverse payments.[33]

Ultimately, pharmaceutical reverse payment litigation as we know it will likely continue to evolve in the coming years. It is also to be determined how the *Actavis* rule of reason framework will apply to patent settlements involving biologics and biosimilar

manufacturers, as these large-molecule drug products face a different regulatory framework than small-molecule pharmaceuticals.[34] It remains to be seen how the *Actavis* decision will hold up given the dynamics of this legal area.

Endnotes

1 *Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136 (2013). For a deeper discussion of the details of the *Actavis* case and the Court's opinions, see American Bar Association, Section of Antitrust Law, "Win, Lose, or Draw? A Decade of Pharma Antitrust Since *FTC v. Actavis*," *Our Curious Amalgam* podcast (August 21, 2023), available at https://ourcuriousamalgam.com/episode/235-pharma-antitrust-ftc-actavis/.

2 *Fed. Trade Comm'n v. Watson*, 677 F.3d 1298, 1315 (11th Cir. 2012). A turducken is a dish created by stuffing a deboned chicken into a deboned duck, which is then stuffed into a deboned turkey. It is arguably delicious.

3 *Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. at 157.

4 *Id*. at 158.

5 *Id*. at 173 (Roberts, C.J., dissenting).

6 See, e.g., I*n re: Niaspan Antitrust Litigation*, No. 21-2895 (E.D. Pa. 13 August 2019); *In re: Lamictal Direct Purchaser Antitrust Litigation*, No. 2:12-cv-00995 (D.N.J. 1 February 2023).

7 See, e.g., Memorandum and Order, *In re: Namenda Indirect Purchaser Antitrust Litigation*, No. 1:15-cv-06549 (S.D.N.Y. 23 March 2023), ECF No. 967; Final Approval Order of Plaintiff's Settlement with Defendant Actavis and Shire, and Order Granting Final Judgement, *In re: Intuniv Antitrust Litigation*, No. 1:16-cv-12396 (D. Mass. 6 January 2022), ECF No. 385; Order on Motion for Settlement, *In re: Aggrenox Antitrust Litigation*, No. 3:14-md-02516 (D. Conn. 19 September, 2017), ECF No. 685.

8 Jury Verdict, *In re: Nexium (Esomeprazole) Antitrust Litig*, No. 1:12-md-02409 (D. Mass. 5 December 2014), ECF No. 1383.

9 For a summary of the case facts and allegations, see *In re: Nexium (Esomeprazole) Antitrust Litig*, 842 F.3d 34 (1st Cir. 2016).

10 *Id.*

11 Consolidated Amended Class Action Complaint and Demand for Jury Trial, *In re: Nexium (Esomeprazole) Antitrust Litig*, No. 1:12-md-02409 (D. Mass. 22 January 2013), ECF 95.

12 Jury Verdict, *In re: Nexium (Esomeprazole) Antitrust Litig*, No. 1:12-md-02409 (D. Mass. 5 December 2014), ECF No. 1383.

13 *Id.*

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

15 As Judge Young reflected after the trial, "I did not try this case very well. I did try it fairly." Amended Memorandum and Order, *In re: Nexium (Esomeprazole) Antitrust Litig*, No. 1:12-md-02409 (D. Mass. 7 August 2015), ECF No. 1545.

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

17 Dan Butrymowicz, "Antitrust Violation vs. Injury-in-Fact: A distinction that makes a difference," *FTC Bureau of Competition*, February 26, 2016, available at https://www.ftc.gov/enforcement/competition-matters/2016/02/antitrust-violation-vs-injury-fact-distinction-makes-difference/.

18 Complaint, *In the Matter of Impax Laboratories, Inc.*, Dkt. No. 9373 (F.T.C. January 23, 2017), available at https://www.ftc.gov/system/files/documents/cases/docket_no_9373_impax_part_3_administrative_complaint_redacted_public_version_1-23-17.pdf; In re: Opana ER Antitrust Litigation, MDL No. 2580, No. 1:14-14-cv-10150 (N.D. Ill.).

19 Complaint, *In the Matter of Impax Laboratories, Inc.*, Dkt. No. 9373 (F.T.C. January 23, 2017), available at https://www.ftc.gov/system/files/documents/cases/docket_no_9373_impax_part_3_administrative_complaint_redacted_public_version_1-23-17.pdf.

20 While Endo settled with FTC, Impax remained in the case. See Initial Decision, *In the Matter of Impax Laboratories, Inc.*, Dkt. No. 9373 (F.T.C. May 18, 2018), available at https://www.ftc.gov/system/files/documents/cases/d09373initialdecisionpublic.pdf.

21 Opinion of the Commission, *In the Matter of Impax Laboratories, Inc.*, Dkt. No. 9373 (April 3, 2019), available at https://www.ftc.gov/system/files/documents/cases/d09373_impax_laboratories_opinion_of_the_commission_-_public_redacted_version_redacted_0.pdf; Impax Labs., Inc. v. FTC, 994 F.3d 484 (5th Cir. 2021).

22 *Id*. at 495.

23 *In re: Opana ER Antitrust Litigation*, MDL No. 2580, No. 1:14-14-cv-10150 (N.D. Ill.).

24 Lauraann Wood, "Jury Hands Endo Win In Opana Pay-For-Delay Case," *Law360*, July 1 2022, available at https://www.law360.com/articles/1508192/jury-hands-endo-win-in-opana-pay-for-delay-case.

25 Bonnie Eslinger, "Gilead, Teva Defeat $3.6B HIV Drug Antitrust Case At Trial," *Law360*, June 30, 2023, available at https://www.law360.com/articles/1694505/gilead-teva-defeat-3-6b-hiv-drug-antitrust-case-at-trial.

26 *Id*.

27 Bonnie Eslinger, "Gilead Didn't Pay Teva In HIV Drug IP Deal, Economist Says," *Law360*, June 26, 2023, available at https://www.law360.com/articles/1692847.

28 Bonnie Eslinger, "Gilead, Teva Defeat $3.6B HIV Drug Antitrust Case At Trial," *Law360*, June 30, 2023, available at https://www.law360.com/articles/1694505/gilead-teva-defeat-3-6b-hiv-drug-antitrust-case-at-trial.

29 Bonnie Eslinger, "How A 3-Firm 'Joint Effort' Beat A $3.6B Pharma Antitrust Suit," *Law360*, July 5, 2023, available at https://www.law360.com/articles/1695763.

30 Brad Albert, Armine Black, and Jamie Towey, "MMA Reports: No tricks or treats—just facts," Federal Trade Commission, October 27, 2020, available at https://www.ftc.gov/enforcement/competition-matters/2020/10/mma-reports-no-tricks-or-treats-just-facts.

31 FTC, "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2017," available at https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf.

32 Keith M. Drake and Thomas McGuire, "Most-Favored Entry Clauses In Drug Patent Litigation Settlements As A Potential Reverse Payment," National Bureau Of Economic Research Working Paper 29801, February 2022, available at https://www.nber.org/papers/w29801.

33 See, e.g., Order Granting in Part and Denying in Part Motion to Dismiss, *In re: Xyrem (Sodium Oxybate) Antitrust Litigation,* No. 20-MD-02966 (N.D. Cal. 13 August 2021), ECF 138.

34 Richard Mortimer and Brian Ellman, "The Economics of Biosimilar Drugs and New Considerations in Intellectual Property and Antitrust Litigation," *Public Domain: The Newsletter of the ABA Section of Antitrust Law's Intellectual Property Committee*, July 2018, available at https://www.analysisgroup.com/globalassets/content/insights/publishing/aba_economics-of-biosimilar-drugs.pdf.