UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

IN RE: XYREM (SODIUM OXYBATE) ANTITRUST LITIGATION

This Document Relates To: All Actions

Master File No. 20-MD-02966-LHK

**ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS**

Re: Dkt. No. 109

**PUBLIC REDACTED VERSION**

In this multidistrict litigation, two sets of plaintiffs allege that certain manufacturers of the drug sodium oxybate (brand name Xyrem) have violated federal and state antitrust laws. The first set of plaintiffs, the Class Plaintiffs, comprise the following coalition of putative class representatives: (1) A.F. of L. – A.G.C. Building Trades Welfare Plan; (2) Blue Cross Blue Shield Association; (3) City of Providence, Rhode Island; (4) Government Employees Health Association, Inc.; (5) New York State Teamsters Council Health and Hospital Fund; (6) Self-Insured Schools of California; (7) UFCW Local 1500 Welfare Fund; and (8) Xyrem patient Ruth Hollman.

The second set of plaintiffs comprises United HealthCare Services, Inc., which brings an individual action against the same Defendants as the Class Plaintiffs.

Defendants are (1) Jazz Pharmaceuticals Plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz"); (2) Hikma Labs, Inc. (formerly known as Roxane Laboratories, Inc.), Hikma Pharmaceuticals USA Inc. (formerly known as West-Ward Pharmaceuticals Corp.), Eurohealth (USA), Inc., and Hikma Pharmaceuticals plc. (collectively, "Hikma"); and (3) Amneal Pharmaceuticals LLC, Par Pharmaceuticals, Inc., and Lupin Ltd, Lupin Pharmaceuticals Inc., and Lupin, Inc. (collectively, the "Later Generic Defendants").

Before the Court is Defendants' Motion to Dismiss Counts 1, 5–12, and 17 of the Consolidated Class Action Complaint and Counts 1, 5-9, and 11 of United Healthcare Services' Complaint. ECF No. 109 ("motion to dismiss" or "Mot."). Having considered the parties' briefing, the relevant law, and the record in this case, the Court GRANTS IN PART and DENIES IN PART Defendants' motion to dismiss.

## I. BACKGROUND

### A. Factual Background

At issue in this antitrust case is the drug sodium oxybate. Sodium oxybate is older than aspirin. United HealthCare Services' Compl. ¶ 1, No. 21-CV-02710, ECF No. 1 ("UHS"). Since the 1960s, sodium oxybate has been a treatment for narcolepsy. *Id.* ¶ 2. In 2002, a drug company named Orphan Medical obtained Food and Drug Administration ("FDA") approval to market sodium oxybate as a treatment for cataplexy—the sudden loss of muscle control while awake—associated with narcolepsy. *Id.* Orphan Medical named this treatment Xyrem. *Id.*

In 2005, Defendant Jazz Pharmaceuticals, Inc. ("Jazz")[1] acquired Orphan Medical. *Id.* ¶ 3. The acquisition was unprofitable at first. *Id.* By 2009, Jazz was on the verge of bankruptcy. *Id.* Jazz responded by replacing its management team and allegedly "embark[ing] on a multifaceted scheme to dramatically increase the price of Xyrem." *Id.* As Jazz's co-founder and Chief Executive Officer ("CEO") Bruce Cozadd stated publicly, Jazz had "substantial pricing power"

[1] Unless otherwise noted, the Court uses "Jazz" to refer to Defendants Jazz Pharmaceuticals, Inc., Jass Pharmaceuticals Ireland Limited, and/or Jazz Pharmaceuticals Public Limited Company. *See, e.g.*, UHS ¶ 3 n.1 (same naming convention).

because "nothing else [] does what [Xyrem] does. There is no substitute." *Id.* ¶ 111 (quoting Final Transcript, Jazz Pharmaceuticals Inc. at LCM Annual Healthcare Conference (Nov. 17, 2010), https://tinyurl.com/y4lchnrs). As Jazz's CEO further stated, "there's really no competition" for Xyrem. *Id.* ¶ 4 (quoting Conference Call Transcript; Jazz Pharmaceuticals, Inc. at Piper Jaffray Health Care Conference, Jazz Pharmaceuticals (Nov. 30. 2011), https://investor.jazzpharma.com/node/12191/html).

To reinforce Xyrem's market power, Jazz filed for and obtained three families of patents. UHS ¶ 80. None of the patents claim the active pharmaceutical compound in Xyrem (sodium oxybate) because the sodium oxybate was discovered long ago. *Id.* ¶ 81. Jazz instead patented (1) certain formulations and methods of treatment; (2) a drug distribution system; and (3) certain methods of administrating sodium oxybate. *Id.* ¶¶ 81–93. These patents had or have expiration dates between December 2019 and March 2033. *Id.*

Xyrem's lack of competition allowed Jazz to raise its price. Based largely on Xyrem price increases, Jazz's stock price grew about 5,000% from its 2009 low to November 2010 price of over $50 per share. *Id.* ¶ 111. Specifically, according to a Bloomberg report in May 2014, the price of Xyrem increased about 841% from 2007 through 2014. Consolidated Class Action Compl. ¶ 188, ECF No. 62 ("CAC"). These price increases boosted Jazz's profits because gross margins on Xyrem were over 90%. *Id.* ¶ 149.

The profitability of Xyrem did not go unnoticed. Between July 2010 and November 2017, nine manufacturers of generic drugs sought to enter Xyrem's market before the expiration of Xyrem patents. CAC ¶¶ 148, 183 (listing generic manufacturers). Specifically, these generic drug manufacturers filed Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to manufacture, market, and sell generic drugs that would be bioequivalent to Xyrem. *Id.* ¶¶ 148, 183. As a general matter, bioequivalent generic drugs are called "AB-rated" generics or commonly just "generics." UHS ¶ 47.

More than 11 years have passed since the first ANDA was filed on July 8, 2010. CAC ¶ 148. To date, however, no AB-rated generics for Xyrem are on the market. CAC ¶ 3. Nor will

any AB-rated generic be on the market until at least December 31, 2025 if Plaintiffs' allegations prove true. CAC ¶ 453. Instead, the generic drug companies have allegedly agreed to sell only "authorized" generics from January 1, 2023 until at least December 31, 2025. *Id.* These authorized generics will merely comprise *Xyrem*, manufactured by *Jazz*, that is *relabeled* and marketed by the generic drug companies. CAC ¶ 5 (citing FDA, *FDA List of Authorized Generic Drugs* (July 1, 2021), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs).

The Court describes this alleged series of events below in three parts. First, the Court summarizes the general difference between AB-rated generics and authorized generics. Second, the Court recounts nine ANDAs to manufacture, market, and sell an AB-rated generic version of Xyrem. Lastly, the Court outlines Jazz's allegedly anticompetitive scheme which successfully prevented generic entry into the market for sodium oxybate as a treatment for narcolepsy.

**1. Structure of the generic market: "AB-rated" generics vs. "authorized" generics**

As relevant here, a generic drug may be either an "AB-rated" generic or an "authorized" generic. An AB-rated generic is commonly called simply a "generic drug." *See FDA List of Authorized Generic Drugs*, *supra* (cited by CAC ¶ 5 & n.7). AB-rated generics are deemed by the FDA to be bioequivalent to the brand name drug. UHS ¶ 47; *accord* FDA, *Orange Book Preface* (41st ed. Jan. 1, 2021), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (detailing AB rating). Even so, AB-rated generics differ from the brand name drug in two ways. First, despite their bioequivalence, AB-rated generics "may have certain minor differences from the brand-name product, such as different inactive ingredients." *FDA List of Authorized Generic Drugs*, *supra*.

Second and most important, AB-rated generics are "developed and made by a company other than the company that makes the brand-name drug." *Id.* When a company enters a market with an AB-rated generic, the generic typically captures about 90% of the branded drug's sales within one year—and sells for about *15%* of the brand name drug's price. UHS ¶ 51; *accord* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* at 8 (Jan. 2010) (finding

same). Under the Hatch-Waxman Act, the first company that applies to produce an AB-rated generic (the "first filer") receives a "180-day period of exclusivity" during which "no other [non-AB-rated] generic can compete with the brand-name drug." *Federal Trade Commission* ("*FTC*") *v. Actavis, Inc.*, 570 U.S. 136, 143–44 (2013).

An authorized generic ("AG"), by contrast, "is essentially a brand-name drug *produced by a brand manufacturer* but *marketed* under a generic label." *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 380 (D. Mass. 2013) (emphasis added). "Other than the fact that [an AG] does not have the brand name on its label, it is the exact same drug product as the branded product." *FDA List of Authorized Generic Drugs*, *supra*. Thus, unlike AB-rated generics, AGs are marketed and sold "either by the brand manufacturer itself" or "another company *with the brand company's permission*." *Id.* (emphasis added); UHS ¶ 61 (same).

Importantly here, it is far more common that a third party markets an AG (with the brand manufacturer's permission) than the brand manufacturer doing so itself. For instance, the FTC has found that "out of 119 AG launches from 2001 to 2008, *only one* was distributed by a brand drug company without generic marketing." *In re Intuniv Antitrust Litig.* ("*Intuniv*"), 496 F. Supp. 3d 639, 671 (D. Mass. 2020) (emphasis added) (citing FTC, *Authorized Generic Drugs: Short-Term Effects & Long-Term Impact* (2011) ("FTC 2011 AG Study")); *see also* CAC ¶ 87 n.36 (same study). Moreover, at least one court has credited research that "out of the 529 AG launches since 2009 . . . only two were distributed by a brand company without generic expertise." *Intuniv*, 496 F. Supp. 3d at 671. In short, it is rare for a brand manufacturer to market and sell its own AG. Brand manufacturers instead tend to license marketing/relabeling rights to a third party.

Regardless of who markets them, AGs and AB-rated generics compete. AGs in fact enjoy an opportunity for competition that other generics lack. That unique opportunity is an AG's ability to compete with an AB-rated generic that is protected by the Hatch-Waxman Act's 180-day period of exclusivity during which no other AB-rated generic can compete. AGs are thus the "only potential source of generic price competition during the first-to-file generic manufacturer's 180-day exclusivity period." CAC ¶ 99. Typically, this competition between an AG and a first-filer's

AB-rated generic "reduc[es] the revenues generated by the first-filer's generic product by 40–52% during the 180-day exclusivity period." UHS ¶ 62 (citing FTC 2011 AG Study at iii). The competition also reduces generic prices by about 15%. CAC ¶ 99 (citing IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf). Drug purchasers benefit as a result.

In sum, AB-rated generics are manufactured and sold by generic drug manufacturers—and for about 15% of the brand name drug's price. AGs, by contrast, are often manufactured by the brand manufacturer itself because AGs are simply the brand name drug but relabeled. AGs are then marketed as a "generic" only with the brand manufacturer's permission (or, rarely, by the brand manufacturer itself). Lastly, when AB-rated generics and AGs compete during the first filer's 180-day exclusivity period, that competition lowers generic drug prices by about 15%.

**2. From 2010 through 2017, first Hikma and then Later Generic Defendants apply to manufacture, market, and sell a generic version of Xyrem.**

In July 2010, Defendant Hikma Labs, Inc. ("Hikma") submitted an Abbreviated New Drug Application ("ANDA") to manufacture, market, and sell an AB-rated generic version of Xyrem.[2] *Id.* ¶ 148. Under the Hatch-Waxman Act's procedures for generic drug applications, Hikma's ANDA certified that Jazz's Xyrem patents were either "'invalid or w[ould] not be infringed by the manufacture, use, or sale' of the drug described in the [ANDA]." *Actavis*, 570 U.S. at 143 (2013) (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) (summarizing ANDA process); *accord, e.g.*, CAC ¶ 149 (alleging same). This type of certification by a generic manufacturer against the patents of the brand-name manufacturer is called a "Paragraph IV certification." CAC ¶ 149.

[2] Unless otherwise noted, the Court uses "Hikma" to refer to Defendants Hikma Labs, Inc. (formerly known as Roxane Laboratories, Inc.), Hikma Pharmaceuticals USA Inc. (formerly known as West-Ward Pharmaceuticals Corp.), Eurohealth (USA), Inc., and/or Hikma Pharmaceuticals plc. *See, e.g.*, CAC ¶ 2 n.2 (same naming convention). The Hikma entities acquired the original ANDA applicant for the generic version of Xyrem—Roxane Laboratories, Inc.—in 2016. UHS ¶ 17.

Paragraph IV certifications have three important features, as detailed by the United States Supreme Court in *FTC v. Actavis*. The Court applies those features to the facts of this case. First, Hikma's Paragraph IV certification statutorily infringed Jazz's Xyrem patents. *Actavis*, 570 U.S. at 143 (citing 35 U.S.C. § 271(e)(2)(A)); *accord, e.g.*, CAC ¶ 150 (listing five patents).

Second, if Jazz responded with an infringement suit within 45 days, the FDA would be statutorily bound to "withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court." *Actavis*, 570 U.S. at 143. This statutory delay would hinder Hikma and future ANDA filers alike. That is, if Jazz's suit against Hikma—the first to file an ANDA for generic Xyrem—were to settle, a subsequent "generic that files a [P]aragraph IV after learning that the first filer has settled will (if sued by the brand-name) have to wait out a stay period of (roughly) 30 months before the FDA may approve its application, just as the first filer did." *Id.* at 155.

Third, if Hikma were to "overcome any patent obstacle and bring the generic to market," Hikma's generic would be the exclusive AB-rated generic for 180 days. *Id.* "[T]his 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'" *Id.* at 144 (quoting Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)); *accord, e.g.*, UHS ¶ 44 (alleging same). "The 180-day exclusivity period, however, can belong only to the first generic to file." *Actavis*, 570 U.S. at 144.

In sum, "[t]hese features together mean that a reverse payment settlement with the first filer (or . . . all of the initial filers) 'removes from consideration the most motivated challenger, and the one closest to introducing competition.'" *Id.* at 155 (quoting Hemphill, *supra*, at 1586). As explained below in Section I-A-3, a "reverse payment settlement" settles patent infringement litigation in a manner "virtually unheard of outside of pharmaceuticals." *Actavis*, 570 U.S. at 155. Specifically, a reverse payment settlement "requires the patentee to pay the alleged infringer, rather than the other way around." *Id.* at 141. In exchange, the alleged infringer agrees "not to produce the patented product" for some time. *Id.*

After Hikma's 2010 ANDA, eight other generic manufacturers filed ANDAs between 2012 and 2017. CAC ¶ 183. Each submitted a Paragraph IV certification that Jazz's Xyrem patents were invalid or would not be infringed. *Id.*

**3. Jazz's alleged anticompetitive scheme**

In response to these ANDAs, Jazz allegedly schemed to preserve its multi-billion-dollar Xyrem monopoly. CAC ¶¶ 148–292; UHS ¶¶ 98–223. Jazz's alleged scheme had three main parts that operated in roughly chronological but overlapping order: (a) abuse of an FDA drug safety program called "Risk Evaluation and Mitigation Strategy"; (b) sham litigation; and (c) reverse payments to four of the generic manufacturers. The Court describes each part of the scheme below.

**a. Jazz's alleged Risk Evaluation and Mitigation Strategy ("REMS") abuse**

In general, the FDA may require that risky drugs implement a safety program called a Risk Evaluation and Mitigation Strategy ("REMS"). CAC ¶ 163; *see also* FDA, *FAQs about REMS* (Jan. 26, 2018), https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems. REMS are proposed by a drug's manufacturer and then approved by the FDA. CAC ¶ 163. To receive FDA approval, a proposed REMS must balance (1) "the need to evaluate and mitigate risk of a drug to ensure that [the drug's] benefits outweigh its risks"; and (2) "the potential burdens of REMS elements on patient access and the health care delivery system." *Id.* "A REMS can include, *inter alia*, a medication guide, patient package inserts, and/or *restrictions on the distribution* of the drug." UHS ¶ 56 (emphasis added).

Most importantly here, the FDA ordinarily requires all manufacturers of a particularly risky drug—including the drug's generic manufacturers—to share one REMS. UHS ¶ 120; *see also* FDA, *Office of Surveillance & Epidemiology, Development of a Single, Shared System (SSS) Risk and Evaluation Mitigation Strategy* (Oct. 28, 2020) (detailing shared REMS requirement). Yet a "single, shared system" REMS has the potential for abuse. For instance, because REMS can restrict access to and distribution of a drug, the FDA has expressed concern that brand manufacturers abuse REMS to "delay the entry of generics." UHS ¶ 58 (quoting FDA Commissioner Scott Gottlieb, *FDA In Brief: FDA affirms its commitment to efficient adoption of*

*Risk Evaluation and Mitigation Strategy plans and to making sure they do not impede generic drug development* (Apr. 4, 2019), https://tinyurl.com/y4je3kau). The annual cost of REMS abuse is about $13.3 billion according to one estimate: $5.2 billion from the federal government, $5.8 billion from private insurance companies, $1.8 billion from consumers, and $500 million from small payors such as state and local governments. UHS ¶ 60 (citing Alex Brill, *Unrealized Savings from the Misuse of REMS and Non-REMS Barriers*, Matrix Global Advisors (Sept. 2018), https://tinyurl.com/y272qvlb).

Here, Plaintiffs allege that Jazz abused the FDA's REMS process. CAC ¶¶ 165–73; UHS ¶¶ 54–60, 98–101, 112–13, 118–37. This alleged abuse resulted in FDA approval of Jazz's allegedly anticompetitive REMS: a REMS that mandates dispensing all Xyrem and Xyrem generics through a single centralized pharmacy, Express Scripts Specialty Distribution Services, Inc. ("Express Scripts"). CAC ¶ 287.

According to Plaintiffs, Jazz's alleged abuse of the REMS process spanned nearly seven years beginning in late August 2008. *Id.* ¶ 166. From late August 2008 through February 2015, Jazz took allegedly inconsistent and dilatory positions before the FDA on Xyrem's distribution restrictions. At first, Jazz advocated for a single-pharmacy distribution protocol in its REMS. UHS ¶ 55. In August 2009, however, Jazz "submitted a REMS proposal that would, among other things, remove the restriction to a single pharmacy and instead allow certification of multiple pharmacies." *Id.* ¶ 98.

Yet in "early 2011"—months after the FDA rejected Jazz's application to allow Xyrem as a fibromyalgia treatment—Jazz again reversed course and proposed a single-pharmacy REMS. *Id.* ¶ 100, 112. In the words of Jazz's CEO, "any generic company—[Hikma] included—will have a difficult time setting up their own distribution system that, A, doesn't infringe our intellectual property, and B, would successfully accomplish the goals of this REMS." UHS ¶ 40 (quoting Bruce Cozadd, Conference Call Tr. at Piper Jaffray Health Care Conference (Nov. 30, 2011), https://tinyurl.com/y5m5rb7n).

The FDA initially resisted Jazz's single-pharmacy REMS. In December 2013, "the FDA

informed Jazz that the Agency was requiring a modification to the REMS under the FDA's statutory authority which, among other things, would have removed the single pharmacy restriction." UHS ¶ 127. Jazz formally disputed this FDA decision. *Id.* ¶ 132. By June 2014, the FDA had denied Jazz's dispute, and Jazz had further appealed to FDA's Director of the Office of New Drugs. *Id.* ¶ 132.

However, on February 27, 2015, the FDA approved Jazz's REMS application. *Id.* ¶ 135 (citing Letter from Billy Dunn, FDA Director of Neurology Products, to Jazz Pharmaceuticals (Feb. 27, 2015) (UHS Ex. C) ("FDA Dunn Letter")). In doing so, the FDA criticized Jazz's "repeated, lengthy delays" and Jazz's inconsistent position on whether "a single pharmacy is critical to the safe use of Xyrem." FDA Dunn Letter at 3. The FDA later recounted its reluctant approval of Jazz's REMS in a January 17, 2017 memorandum from Dr. Trueman W. Sharp, Deputy Director of the FDA's Office of Generic Drugs, to the manufacturers who had applied to make generic Xyrem (*i.e.*, filed ANDAs).

In that memo, the FDA wrote that it had approved Jazz's REMS to halt the "significant drain on [FDA] resources posed by the dispute." UHS ¶ 135 (quoting Memorandum from Trueman Sharp, Deputy Director for the Office of Generic Drugs, FDA, to ANDAs for sodium oxybate oral solution products, *et seq.* ("Sharp Memo") (Jan. 17, 2017) (UHS, Ex. B)). Even though it had approved Jazz's REMS, the FDA doubted both (1) the objective merits of Jazz's REMS; and (2) Jazz's subjective motivations in proposing a single-pharmacy REMS. As to the objective merits, the FDA reiterated concerns by Dr. John K. Jenkins, Director of the Office of New Drugs. Specifically, Dr. Jenkins noted the uniquely exclusionary nature of Xyrem REMS and its "burdens on patient access and the healthcare delivery system":

> Our action approving the REMS submitted by Jazz *should not be construed or understood as agreement* with Jazz that limiting dispensing to a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh the risks under section 505-1 of the FD&C Act. We continue to be concerned that limiting the distribution of Xyrem to one pharmacy *imposes burdens on patient access and the healthcare delivery system*. *No other currently approved REMS* requires a sponsor to limit dispensing to a single pharmacy.

Sharp Memo at 8 (emphasis added). As for subjective motivations, the FDA expressly "note[d] the inconsistent position Jazz has taken on [REMS safety]"—an inconsistency which "suggest[ed] [Jazz's] *knowledge* that this aspect of its REMS *could have the effect of preventing generic competition*." *Id.* at 26; *accord* at 12 (reiterating "Jazz's awareness that Xyrem REMS could have the effect of blocking or delaying approval of generic version of Xyrem"); UHS ¶ 136 (quoting same).

Generic manufacturers allegedly shared the FDA's fear that Jazz's REMS would block competition. After the FDA approved Jazz's REMS application in February 2015, generic manufacturers argued to the FDA that Jazz refused to negotiate in good faith to share access to Jazz's REMS. UHS ¶ 140; *see, e.g.*, CAC ¶¶ 200–08, 223, 227. A single, shared REMS is ordinarily required by the FDA for all versions of a risky drug—including AB-rated generics manufactured by generic manufacturers. CAC ¶ 73. Sharing a REMS entails co-administrating a safety system that gathers documentation on prescribers, dispensers, and patients. *Id. Id.* Here, that safety system also included the requirement that Xyrem and its generics be distributed exclusively through Express Scripts. CAC ¶ 287.

On January 17, 2017, in response to generic manufacturer's allegations, the FDA waived the single-pharmacy requirement for generic versions of Xyrem. In issuing this waiver, the FDA reiterated generic manufacturer's allegations that "Jazz ha[d] engaged in a strategy that 'entails serial attempts to impose unreasonable contractual terms and conditions on the ANDA [filers] while concurrently issuing self-serving statements to FDA and the ANDA [filers] about Jazz's commitment to the process." UHS ¶ 207 (quoting Sharp Memo at 11). The FDA then found that the "burden of creating a single, shared system outweighs the benefits." Sharp Memo at 13 (capitalization omitted). Among the burdens were Jazz's "obvious incentives" "to delay generic competition [] by failing to agree on [single, shared system] REMS terms." *Id.* at 17. The FDA thus concluded that allowing ANDA applicants to proceed with their own drug distribution systems would "remove a barrier to generic products coming to market." *Id.*

Among the ADNA applicants listed on the FDA's January 17, 2017 memo were Hikma and

Amneal. Sharp Memo at 1; *accord* UHS ¶ 201. Yet, to date, at least Hikma has allegedly no plans to develop an alternative to Jazz's REMS. CAC ¶ 223. The reason, Plaintiffs allege, is that Hikma would contractually forfeit its lucrative reverse settlement with Jazz if Hikma tried to compete with Jazz. *Id.* ¶ 219; UHS ¶ 169. In fact, sometime after Jazz and Hikma settled their patent litigation, Jazz's CEO allegedly said on an earnings call that although "Hikma has a license to launch its [AB-rated] generic product as of July 1, 2023, [Hikma] will not longer have the right to sell an AG product through the Xyrem REMS if [Hikma] elects to do so." CAC ¶ 219 & n.66 (quoting earnings call; no date provided).

**b. Jazz's alleged sham patent litigation against generic manufacturers**

Sham patent litigation comprised the second part of Jazz's alleged monopolistic scheme. According to Plaintiffs, Jazz filed many meritless patent infringement cases against drug manufacturers who had filed ANDAs to market generic versions of Xyrem. CAC ¶¶ 150–61; UHS ¶¶ 104–09, 121–26, 133–34, 139, 151–52, 155–57. These cases were allegedly brought in a vicious cycle. Jazz would allegedly "assert a patent position, glean defenses to that position in the litigation, file new 'follow-on' patents, and then file a new lawsuit asserting those patents." Opp'n at 5 (citing CAC ¶¶ 155–61; UHS ¶¶ 104–09).

Among others, the targets of Jazz's suits included (1) Hikma, the filer of the first generic Xyrem ANDA; and (2) three other manufacturers who filed ANDAs after Hikma. Those three other manufacturers (the "Later Generic Defendants") were Amneal Pharmaceuticals LLC ("Amneal"), Par Pharmaceuticals, Inc. ("Par"), and Lupin Ltd, Lupin Pharmaceuticals Inc., and Lupin, Inc. (together, "Lupin"). CAC ¶ 2 n.2; UHS ¶¶ 20–23. Jazz sued Hikma for patent infringement *nine* times between November 2010 and August 2016. CAC ¶¶ 151–62 (detailing suits). Also, between at least December 2012 and November 2017, Jazz brought more than eight other suits against the Later Generic Defendants and five other later generics. *Id.* ¶¶ 183–85 (listing suits).

Pursuant to the Hatch-Waxman Act, each lawsuit automatically stayed the FDA's approval process for generic Xyrem ANDAs by approximately 30 months. CAC ¶ 185; *see generally*

*Actavis*, 570 U.S. at 143, 155 (explaining stay required by 21 U.S.C. § 355(j)(5)(B)(iii)). These 30-month stays were statutorily automatic "irrespective of the[] [lawsuits'] prospects of success." CAC ¶ 185. Indeed, some of Jazz's asserted patents were eventually invalidated. In March 2017, the Patent Trial Appeal Board ("PTAB") invalidated as obvious one of Jazz's three asserted families of patents relating to REMS.[3] UHS ¶¶ 151–57. The Federal Circuit affirmed the PTAB invalidity rulings. *Id.* ¶ 157 (citing *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347 (Fed. Cir. 2018)).

**c. Jazz's reverse payment settlements with first-filer Hikma and then Later Generic Defendants Par, Lupin, and Amneal**

Lastly and most significantly, Plaintiffs allege that Jazz settled its patent cases with each Generic Defendant (Hikma, Amneal, Par, and Lupin) by way of unlawful "reverse payment" settlements. As the Supreme Court explained in *FTC v. Actavis*, a reverse payment settlement is one where "the patentee [] pay[s] the alleged infringer, rather than the other way around." *Actavis*, 570 U.S. at 141. In exchange, the alleged infringer delays entry into the patentee's market. *Id.* These reverse payment settlements (or "reverse settlements" for short) are "virtually unheard of outside of pharmaceuticals." *Id.* at 155 (quoting 1 Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, and Christopher R. Leslie, *IP and Antitrust* § 15.3 & n.161 (2d ed. Supp. 2011)). Such settlements also "sometimes violate the antitrust laws." *Id.* at 141.

Plaintiffs allege that Jazz's reverse settlements with each Generic Defendant violated the antitrust laws. CAC ¶¶ 209-76; UHS ¶¶ 161-210. According to Plaintiffs, the value of these settlements was in the hundreds of millions of dollars for first-filer Hikma and the tens of millions of dollars each for Later Generic Defendants Par, Lupin, and Amneal. CAC ¶¶ 229–38, 255, 262, 269–70; UHS ¶¶ 179–83, 206. In exchange for making these large reverse payments, Jazz allegedly delayed generic entry into the Xyrem market. *See, e.g.*, CAC ¶ 275–76. The alleged result has been supra-competitive prices and lower output. CAC ¶ 276.

[3] The invalidated REMS patents claimed methods of tracking drug prescriptions in a computer database. CAC ¶¶ 141–44.

Although Jazz's settlements allegedly all delayed generic entry, the settlements with Hikma versus the Later Generic Defendants conveyed value in somewhat different ways. In the Jazz-Hikma agreement, Jazz licensed Hikma as the exclusive third-party marketer of an authorized generic ("AG") version of Xyrem between at least January 1, 2023 and July 1, 2023. CAC ¶¶ 110, 221 & n.67. This Hikma AG would be (1) Xyrem manufactured by Jazz that (2) Hikma would relabel and market as a Hikma product that (3) Jazz's REMS pharmacy, Express Scripts, would distribute. *See, e.g.*, UHS ¶ 223 (alleging purchases "would follow the same route as Xyrem" and that Hikma will not take delivery); Hikma License Agreement §§ 1.3, 1.24, ECF No. 111-2 (providing that Hikma's AG will not bear Jazz's trademarks, such as the name Xyrem).

To incentivize this alleged "no-AG" agreement and convey further value to Hikma, Jazz made primarily the following three alleged reverse payments.

- First, Jazz promised not to license AG to any third party other than Hikma between at least January 1, 2023 and July 1, 2023. CAC ¶¶ 110, 221 & n.67.
- Second, Jazz created a royalty structure of escalating payments from Hikma to Jazz that undermined Jazz's economic interest in marketing its own AG. CAC ¶ 231.
- Third, the Jazz-Hikma agreement contained an "acceleration clause." *Id.* ¶ 232. An acceleration clause is a type of most-favored-entry clause that allows a generic manufacturer to enter a market sooner if certain contingencies occur. CAC ¶¶ 120–24 (citing Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, 16 J. Competition L. & Econ. 188, 188 (2020) (available on Lexis+)). In the Jazz-Hikma agreement, the acceleration clause allegedly allowed Hikma to immediately market Hikma Authorized Generic ("AG") if (1) a generic version of Xyrem were to market itself without Jazz's permission; or (2) anyone were to successfully invalidate or render unenforceable Xyrem's unexpired patent claims. CAC ¶ 225; *accord* Hikma AG Agreement § 2.8, ECF No. 110-14 (acceleration provisions). According to Plaintiffs, acceleration clauses like Hikma's deter generic entry by warning potential entrants that they will face competition if they actually enter. *Id.* ¶¶ 123–24 (citing congressional testimony and Drake & McGuire, *supra*). The prospect of competition reduces the expected payoff of breaking up any collusive scheme. *Id.* ¶ 123.

Together, these parts of the Jazz-Hikma agreement were allegedly "designed to, and do[] have, the effect that during at least the first six months of entry (before subsequent generics were allocated a slice of the market in their own separate pay-for-delay agreements, as discussed below [in Section

III-B]), the Hikma AG would be the only authorized generic." *Id.* ¶ 221. The alleged estimated value to Hikma of the Jazz-Hikma agreement is over $480 million just in the first six months after Hikma launches its AG. CAC ¶ 237 (estimating $480 million to $540 million); UHS ¶ 181 (estimating $705 million). Jazz's market capitalization also jumped by about $785 million after the Jazz-Hikma agreement was partially disclosed on April 6, 2017—a jump that Plaintiffs allege is attributable to investors' expectations that Xyrem would face reduced generic competition. UHS ¶ 185; CAC ¶ 246.

Jazz's settlements with the Later Generic Defendants made primarily the following three alleged reverse payments, as detailed in formerly confidential contracts that Defendants attached to their instant motion to dismiss:[4]

- First, Jazz made multi-million-dollar cash payments to each Later Generic Defendant—ostensibly for Jazz's avoided litigation costs. *See* Opp'n at 13 (citing Par Settlement Agreement § 3, ECF No. 110-15 (Ex. 4); Lupin Settlement Agreement § 3, ECF No. 110-17 (Ex. 7); Amneal Settlement Agreement § 3, ECF No. 110-19 (Ex. 10)).
- Second, Jazz allegedly gave each Later Generic Defendant a limited license to sell a constrained supply of AG. Each license (1) began only after the expiration of Hikma's 180-day exclusivity period in July 2023; (2) was capped at a low-single-digit market share; and (3) required a royalty payment, as a percentage of sales, that increased over time. *See, e.g.*, Lupin AG Agreement § 1.27, 5, ECF No. 110-18 (Exh. 8).
- Third, Jazz's agreements with each Later Generic Defendant contained acceleration clauses like the acceleration clause in the Jazz-Hikma agreement discussed above. *See, e.g.*, CAC ¶¶ 253, 260, 267 (alleging acceleration clauses); Section III-A-2-b-iii, *infra* (analyzing

[4] Defendants filed a request for judicial notice on April 22, 2021. ECF No. 111. Defendants seek judicial notice of (1) the contracts between Jazz, Hikma, and the Later Generic Defendants, which are incorporated by reference in the CAC and UHS complaint; (2) public filings with the Securities and Exchange Commission ("SEC"); and (3) an FTC blog post cited in CAC ¶ 110 n.48. Plaintiffs have not opposed Defendants' request. The Court may take judicial notice of matters that are either "generally known within the trial court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Moreover, courts may consider materials referenced in the complaint under the incorporation by reference doctrine, even if a plaintiff did not attach those materials to the complaint. *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005). Accordingly, the Court GRANTS Defendants' request for judicial notice, ECF No. 111.

Jazz-Hikma acceleration clause and acceleration clauses generally).

Plaintiffs estimate the value to the Later Generic Defendants of these agreements to be in the tens of millions of dollars. CAC ¶¶ 255, 262, 269-70; UHS ¶¶ 193, 198, 205, 206. As with the Jazz-Hikma agreement, Jazz's agreements with Par, Lupin, and Amneal allegedly "will not increase overall output, reduce price, or increase consumer choice." UHS ¶ 207. Rather, the agreements will allegedly "merely substitute Par, Lupin, and Amneal as the sellers of millions of dollars' worth of Xyrem for the sole purpose of paying them to delay market entry of less expensive generic sodium oxybate, preserving Jazz's massive monopoly profits in exchange for doling out a small slice of them to Par, Lupin, and Amneal." *Id.*

In Plaintiffs' telling, Jazz executives publicly alluded to these anticompetitive effects on at least two occasions. At a conference on December 4, 2019, Jazz's CEO stated that "in terms of *dynamics on price*, it's – th[e] [market] is *not what you would think of as a generic free for all*" because of the "*very limited volumes*" for Par, Lupin, and Amneal. CAC ¶ 273 (emphasis added by Plaintiffs).

Similarly, on November 14, 2018, a senior Jazz executive explained that "after th[e] the 6-month exclusivity period for the first-filer [Hikma], 3 of the second filers [allegedly Par, Lupin, and Amneal] get to come again with a limited generic. And they are *limited to low single-digit volume* of the previous year Xyrem sales. So again, relatively *low incursion on Xyrem* here." *Id.* ¶ 274 (emphasis added).

Plaintiffs allege that because of all these agreements, Jazz has avoided judicial scrutiny of its (invalid and unenforceable) patents to this day. *See, e.g.*, CAC ¶ 278; UHS ¶ 172. Indeed, Jazz remains the sole supplier of sodium oxybate even though Hikma filed its ANDA in July 2010—more than 11 years ago. CAC ¶¶ 296, 307; UHS ¶ 237.

**B. Procedural History**

This is a multidistrict litigation with two operative complaints across nine actions. One action is an individual action brought by Plaintiff United HealthCare Services, Inc., which "serve[s] some 70 million individual insureds" as "the largest single health insurance carrier and

services provider in the United States." UHS ¶ 7. The remaining actions are putative class actions brought by Class Plaintiffs, a coalition of four types of plaintiffs:

- Labor unions' health plans or welfare benefits funds, namely A.F. of L. – A.G.C. Building Trades Welfare Plan, New York State Teamsters Council Health and Hospital Fund, and UFCW Local 1500 Welfare Fund. These labor unions' funds bought or reimbursed Xyrem for their members.
- Associations of companies that provide health plans, namely Blue Cross Blue Shield Association and Government Employees Health Association. Together, these associations provide health benefits to more than 107 million people nationwide.
- Government entities, namely the Self-Insured Schools of California and the City of Providence, Rhode Island. These entities pay bought or reimbursed Xyrem for their employees and retirees.
- Xyrem patient Ruth Hollman, who has used Xyrem since 2009.

CAC ¶¶ 10–25.

This case's chronology is as follows. On December 16, 2020, the Judicial Panel on Multidistrict Litigation transferred six putative class actions to this Court. ECF No. 1. Two more putative class actions were transferred on January 4, 2021, followed by another putative class action on January 26, 2021. ECF No. 2, 38. On January 27, 2021, one of the nine transferred actions was voluntarily dismissed without prejudice in accordance with a tolling agreement. ECF No. 39. This dismissal left eight putative class actions.

On February 22, 2021, the Court appointed Interim Co-Lead Class Counsel and Plaintiffs' Steering Committee. ECF No. 59. For Interim Co-Lead Class Counsel, the Court appointed Dena Sharp of Girard Sharp LLP and Michael Buchman of Motley Rice LLC. For Plaintiffs' Steering Committee, the Court appointed Jessica R. MacAuley of Hagens Berman Sobol Shapiro LLP; Karin Garvey of Labaton Sucharow LLP; Joseph Saveri of Joseph Saveri Law Firm, Inc.; Kenneth Wexler of Wexler Wallace LLP; Clark Craddock of the Radice Law Firm; John Macoretta of Spector Roseman & Kodroff PC; and Mark Fischer of Rawlings & Associates, PLLC.

On March 8, 2021, the plaintiffs in the eight putative class actions (together, the "Class Plaintiffs") filed one of the operative complaints: the Consolidated Class Action Complaint

("CAC"). ECF No. 62. Class Plaintiffs comprise (1) A.F. of L. – A.G.C. Building Trades Welfare Plan; (2) Blue Cross Blue Shield Association; (3) City of Providence, Rhode Island; (4) Government Employees Health Association, Inc.; (5) New York State Teamsters Council Health and Hospital Fund; (6) Self-Insured Schools of California; (7) UFCW Local 1500 Welfare Fund; and (8) Ruth Hollman. CAC ¶¶ 10–25. Class Plaintiffs assert 17 claims against Defendants under both federal and state antitrust laws. CAC ¶¶ 352–518.

Defendants comprise three sets of entities known as (1) Jazz; (2) Hikma; and (3) the Later Generic Defendants. Each set of Defendants specifically comprises the following:

- The first set includes Jazz Pharmaceuticals Plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Limited (together, "Jazz"). CAC ¶ 1; UHS ¶ 3 n.1. Jazz owns patents that claim aspects of Xyrem and its use. CAC ¶ 80.
- The second set of Defendants—which together are known as "Hikma"—includes Hikma Labs, Inc. (formerly known as Roxane Laboratories, Inc.), Hikma Pharmaceuticals USA Inc. (formerly known as West-Ward Pharmaceuticals Corp.), Eurohealth (USA), Inc., and Hikma Pharmaceuticals plc. CAC ¶ 2 n.2; UHS ¶ 18. Hikma was the first to file an ANDA to market a generic version of Xyrem. CAC ¶ 2; UHS ¶ 101.
- The third set of Defendants includes Amneal Pharmaceuticals LLC ("Amneal"), Par Pharmaceuticals, Inc. ("Par"), and Lupin Ltd, Lupin Pharmaceuticals Inc., and Lupin, Inc. (together, "Lupin"). CAC ¶ 2 n.2; UHS ¶¶ 20–23. These Defendants were among the generic manufacturers who filed ANDAs after Hikma. CAC ¶ 183. Together, Amneal, Par, and Lupin are known as the "Later Generic Defendants." Collectively with Hikma, they are known as the "Generic Defendants."

On March 19, 2021, the Court noted that the CAC—which sets forth 17 causes of action against 12 Defendants—is unmanageably large. ECF No. 66. The Court thus ordered Class Plaintiffs and Defendants to jointly identify "10 selected causes of action" to be litigated through resolution. ECF No. 66 at 2. Class Plaintiffs and Defendants filed their joint notice identifying 10 selected causes of action (the "Selected Claims") on March 29, 2021. ECF No. 81. The Selected Claims are the following:

- CAC Count 1 – Violation of 15 U.S.C. § 1 (against Jazz and Hikma)
- CAC Count 5 – Violation of 15 U.S.C. § 1 (against all Defendants)

- CAC Count 6 – Violation of 15 U.S.C. § 2 (against Jazz)
- CAC Count 7 – Conspiracy and Combination in Restraint of Trade Under State Law (against Jazz and Hikma)
- CAC Count 8 – Conspiracy and Combination in Restraint of Trade Under State Law (against Jazz and Amneal)
- CAC Count 9 – Conspiracy and Combination in Restraint of Trade Under State Law (against Jazz and Lupin)
- CAC Count 10 – Conspiracy and Combination in Restraint of Trade Under State Law (against Jazz and Par)
- CAC Count 11 – Conspiracy and Combination in Restraint of Trade Under State Law (against all Defendants).
- CAC Count 12 – Monopolization and Monopolistic Scheme Under State Law (against Jazz)
- CAC Count 17 – For Declaratory and Injunctive Relief for Violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 16 of the Clayton Act, 15 U.S.C. §§ 1–2, 26 (against all Defendants)

Meanwhile, on March 24, 2021, Plaintiff United HealthCare Services, Inc. ("United") informed the Court that United's individual action against the same Defendants would soon be transferred to the instant multidistrict litigation. ECF No. 78. In response on March 30, 2021, the Court ordered the parties to address the overlap between (1) United's claims and (2) the Selected Claims. ECF No. 82. On April 2, 2021, United represented that its claims "largely overlap with the class action claims and advance materially the same theories of liability." ECF No. 84 at 1. United thus agreed to initially litigate through resolution only the claims that overlap with the Selected Claims. *Id.* at 2. United's complaint ("UHS") is at Case No. 21-CV-02710-LHK, ECF No. 1.

Accordingly, on April 7, 2021, the Court "order[ed] that U[nited] shall initially litigate only the Selected Claims. . . . After the resolution of the Selected Claims, the Court will discuss with U[nited] and [Class Plaintiffs] the remaining causes of action." ECF No. 85. United's claims relationship to the Selected Claims are as follows:

- UHS Count 1 overlaps with CAC Count 1 – Violation of 15 U.S.C. § 1 (against Jazz and Hikma)

- UHS Count 5 overlaps with CAC Count 5 – Violation of 15 U.S.C. § 1 (against all Defendants)
- UHS Count 6 overlaps with CAC Count 6 – Violation of 15 U.S.C. § 2 (against Jazz)
- UHS Counts 8 and 9 overlap with CAC Count 11 – Conspiracy and Combination in Restraint of Trade Under State Law (against all Defendants). However, UHS Count 9 is limited to the extent it overlaps with the Class Plaintiffs' Selected Claims.
- UHS Count 7 overlaps with CAC Count 12 – Monopolization and Monopolistic Scheme Under State Law (against Jazz)
- UHS Count 11 overlaps with CAC Count 17 – For Declaratory and Injunctive Relief for Violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 16 of the Clayton Act, 15 U.S.C. §§ 1–2, 26 (against all Defendants)

On April 22, 2021, Defendants filed the instant motion to dismiss the Selected Claims. ECF No. 109 ("motion to dismiss" or "Mot."). On May 20, 2021, Class Plaintiffs and United (together, "Plaintiffs") filed their consolidated opposition to Defendants' motion to dismiss. ECF No. 129 ("Opposition" or "Opp'n"). Defendants filed their reply on June 10, 2021. ECF No. 130 ("Reply").

## II. LEGAL STANDARD

### A. Motion to Dismiss Under Rule 12(b)(6)

Rule 8(a)(2) of the Federal Rules of Civil Procedure requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." A complaint that fails to meet this standard may be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6). The United States Supreme Court has held that Rule 8(a) requires a plaintiff to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id*. (internal quotation marks omitted). For purposes of ruling on a Rule 12(b)(6) motion, the Court "accept[s] factual allegations in the complaint as true and construe[s]

the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). The Court, however, need not "assume the truth of legal conclusions merely because they are cast in the form of factual allegations." *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir. 2011) (per curiam) (internal quotation marks omitted). Additionally, mere "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss." *Adams v. Johnson*, 355 F.3d 1179, 1183 (9th Cir. 2004).

**B. Leave to Amend**

If a court determines that a complaint should be dismissed, it must then decide whether to grant leave to amend. Under Rule 15(a) of the Federal Rules of Civil Procedure, leave to amend "shall be freely given when justice so requires," bearing in mind "the underlying purpose of Rule 15 to facilitate decisions on the merits, rather than on the pleadings or technicalities." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (alterations and internal quotation marks omitted). When dismissing a complaint for failure to state a claim, "a district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Id*. at 1130 (internal quotation marks omitted).

Accordingly, leave to amend generally shall be denied only if allowing amendment would unduly prejudice the opposing party, cause undue delay, or be futile, or if the moving party has acted in bad faith. *Leadsinger, Inc. v. BMG Music Publ'g*, 512 F.3d 522, 532 (9th Cir. 2008). At the same time, a court is justified in denying leave to amend when a plaintiff "repeated[ly] fail[s] to cure deficiencies by amendments previously allowed." *See Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 892 (9th Cir. 2010). Indeed, a "district court's discretion to deny leave to amend is particularly broad where plaintiff has previously amended the complaint." *Cafasso, U.S. ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1058 (9th Cir. 2011) (quotation marks omitted).

## III. DISCUSSION

Plaintiffs purchase or provide reimbursement for Xyrem nationwide. CAC ¶¶ 10–25 (Class Plaintiffs); UHS ¶¶ 6–10 (United HealthCare Services). Plaintiffs allege that Jazz has overcharged

for Xyrem and will continue to do so. UHS ¶ 5. Specifically, Plaintiffs allege that Jazz has unlawfully blocked generic entry into the Xyrem market through at least July 1, 2023. CAC ¶ 6. Plaintiffs thus seek treble damages and injunctive relief under federal and state antitrust laws, including Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1 and 2). Because Plaintiffs bring at least 17 claims against 12 Defendants, only 10 claims (the "Selected Claims") will be initially litigated through resolution. *See* Section I-B, *supra* (detailing Selected Claims).

Defendants move to dismiss the Selected Claims on six grounds. First, Defendants argue that Jazz's settlements with Hikma and each of the Later Generic Defendants (Amneal, Par, and Lupin) are not unlawful reverse settlements under *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). Second, Defendants argue that Plaintiffs inadequately plead an overarching antitrust conspiracy or unlawful market allocation. Third, Defendants argue that Plaintiffs fail to allege antitrust injury. Fourth, Defendants argue that Plaintiffs' monopolization claims under Sherman Act § 2 are barred by the *Noerr-Pennington* doctrine. Fifth, Defendants argue that Plaintiffs lack antitrust standing to pursue damages for violations of federal antitrust law. Lastly, Defendants argue that Plaintiffs' state law claims fail.

Ultimately, the Court mostly denies Defendants' motion to dismiss. The Court dismisses, however, the following four allegations or claims: (1) Plaintiffs' allegation that Defendants' market allocations are per se violations of the antitrust laws; (2) Plaintiffs' allegations against Jazz's citizen petitions to the FDA; (3) Plaintiffs' federal claims for damages; and (4) some claims brought under the laws of Illinois and Utah. Below, the Court analyzes the six asserted grounds for dismissal in turn. Each section of analysis begins with a header, which lists the Counts of the CAC and UHS complaint at issue in that section.

### A. Plaintiffs adequately plead unlawful reverse payments to Hikma (CAC Counts 1 and 7; UHS Counts 1, 5, and 8) and the Later Generic Defendants (CAC Counts 8–10; UHS Counts 5, 7, and 8).

Defendants argue that Plaintiffs inadequately plead that Jazz made unlawful reverse payments to Hikma and the Later Generic Defendants. As to Hikma, Defendants argue that Jazz's settlement was not a "no authorized generic" agreement ("no-AG" agreement). Specifically,

although Jazz promised that Hikma would be the exclusive third-party licensee of AG, Jazz could theoretically compete with Hikma AG by marketing a Jazz AG. As for the Later Generic Defendants, Defendants argue that Jazz did not make reverse payments to Amneal, Par, or Lupin.

To provide context for the parties' arguments, the Court first describes the difference between a generic manufactured by a generic drug company ("AB-rated generic") and a "generic" that is identical to—and often manufactured and distributed by—the brand name drug company ("authorized generic"). The Court then analyzes the Jazz-Hikma agreement followed by Jazz's agreements with the Later Generic Defendants.

**1. Background: "authorized generics" are often just the brand name drug made by the brand name manufacturer—but relabeled.**

The Court first recounts the background on the generic drug market set forth in Section I-A-1, *supra*. As relevant here, a generic drug may be either an "AB-rated" generic or an "authorized" generic. An AB-rated generic is commonly called simply a "generic drug." *See FDA List of Authorized Generic Drugs*, *supra* (cited by CAC ¶ 5 & n.7). AB-rated generics are deemed by the FDA to be bioequivalent to the brand name drug. UHS ¶ 47; *accord* FDA, *Orange Book Preface* (41st ed. Jan. 1, 2021), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (detailing AB rating). Even so, AB-rated generics differ from the brand name drug in two ways. First, despite their bioequivalence, AB-rated generics "may have certain minor differences from the brand-name product, such as different inactive ingredients." *FDA List of Authorized Generic Drugs*, *supra*.

Second and most important, AB-rated generics are "developed and made by a company other than the company that makes the brand-name drug." *Id.* When a company enters a market with an AB-rated generic, the generic typically captures about 90% of the branded drug's sales within one year—and sells for about *15%* of the brand name drug's price. UHS ¶ 51; *accord* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* at 8 (Jan. 2010) (finding same). Under the Hatch-Waxman Act, the first company that applies to produce an AB-rated generic (the "first filer") receives a "180-day period of exclusivity" during which "no other [non-

AB-rated] generic can compete with the brand-name drug." *Federal Trade Commission* ("*FTC*") *v. Actavis, Inc.*, 570 U.S. 136, 143–44 (2013).

An authorized generic ("AG"), by contrast, "is essentially a brand-name drug *produced by a brand manufacturer* but *marketed* under a generic label." *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 380 (D. Mass. 2013) (emphasis added). "Other than the fact that [an AG] does not have the brand name on its label, it is the exact same drug product as the branded product." *FDA List of Authorized Generic Drugs*, *supra*. Thus, unlike AB-rated generics, AGs are marketed and sold "either by the brand manufacturer itself" or "another company *with the brand company's permission*." *Id.* (emphasis added); UHS ¶ 61 (same).

Importantly here, it is far more common that a third party markets an AG (with the brand manufacturer's permission) than the brand manufacturer doing so itself. For instance, the FTC has found that "out of 119 AG launches from 2001 to 2008, *only one* was distributed by a brand drug company without generic marketing." *In re Intuniv Antitrust Litig.* ("*Intuniv*"), 496 F. Supp. 3d 639, 671 (D. Mass. 2020) (emphasis added) (citing FTC, *Authorized Generic Drugs: Short-Term Effects & Long-Term Impact* (2011) ("FTC 2011 AG Study")); *see also* CAC ¶ 87 n.36 (same study). Moreover, at least one court has credited research that "out of the 529 AG launches since 2009 . . . only two were distributed by a brand company without generic expertise." *Intuniv*, 496 F. Supp. 3d at 671. In short, it is rare for a brand manufacturer to market and sell its own AG. Brand manufacturers instead tend to license marketing/relabeling rights to a third party.

Regardless of who markets them, AGs and AB-rated generics compete. AGs in fact enjoy an opportunity for competition that other generics lack. That unique opportunity is an AG's ability to compete with an AB-rated generic that is protected by the Hatch-Waxman Act's 180-day period of exclusivity during which no other AB-rated generic can compete. AGs are thus the "only potential source of generic price competition during the first-to-file generic manufacturer's 180-day exclusivity period." CAC ¶ 99. Typically, this competition between an AG and a first-filer's AB-rated generic "reduc[es] the revenues generated by the first-filer's generic product by 40–52% during the 180-day exclusivity period." UHS ¶ 62 (citing FTC 2011 AG Study at iii). The

competition also reduces generic prices by about 15%. CAC ¶ 99 (citing IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf). Drug purchasers benefit as a result.

In sum, AB-rated generics are manufactured and sold by generic drug manufacturers—and for about 15% of the brand name drug's price. AGs, by contrast, are often manufactured by the brand manufacturer itself because AGs are simply the brand name drug but relabeled. AGs are then marketed as a "generic" only with the brand manufacturer's permission (or, rarely, by the brand manufacturer itself). Lastly, when AB-rated generics and AGs compete during the first filer's 180-day exclusivity period, that competition lowers generic drug prices by about 15%.

**2. Plaintiffs adequately allege that the Jazz-Hikma agreement contains an implicit "no-AG" agreement (CAC Counts 1 and 7; UHS Counts 1, 5, and 8).**

With the above background in mind, the Court returns to the case at hand. The Court starts by analyzing the Jazz's settlement with Hikma (the "Jazz-Hikma agreement"). Plaintiffs argue that the Jazz-Hikma agreement contains an implicit "no-AG" agreement. Specifically, this alleged "no-AG" agreement is that Jazz will not sell an authorized generic of Xyrem for "at least the first six months that Hikma is eventually on the market" with the Hikma AG, which is Jazz's Xyrem under the label of Hikma AG. *E.g.*, CAC ¶ 221.

The parties do not dispute that if the Jazz-Hikma agreement is in fact a "no-AG" agreement, it warrants antitrust scrutiny under the Supreme Court's *Actavis* framework for reverse payments. *See, e.g.*, *Impax Lab'ys, Inc. v. Fed. Trade Comm'n*, 994 F.3d 484, 494 (5th Cir. 2021) (holding same and collecting cases); Mot. at 13 (not disputing that no-AG agreements "may trigger scrutiny under *Actavis*"). A 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." *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015). Indeed, as the leading antitrust treatise has explained, no-AG agreements "can in

fact be more anticompetitive than a large cash payment for delay." Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles & Their Application* ¶ 2045 (updated May 2021).

Defendants argue, however, that "this is not a 'no-AG' case." *Id.* For support, Defendants note that the Jazz-Hikma agreement "explicitly reserves Jazz's right to launch a Jazz AG." *Id.*

The Court addresses this defense of the Jazz-Hikma agreement in two parts. To start, the Court summarizes the leadup to the Jazz-Hikma agreement and the agreement's alleged "no-AG" effect. The Court then analyzes what allegedly evidences and incentivizes the no-AG agreement: at least three alleged reverse payments from Jazz to Hikma. These reverse payments suggest that Jazz "has serious doubts about [its] patent[s]' survival" and "in turn[] suggests that the payment[s]' objective is to maintain supracompetitive prices to be shared among [Jazz] and [Hikma] rather than face what might have been a competitive market." *Actavis*, 570 U.S. at 157.

**a. Alleged background and effect of Jazz-Hikma agreement**

The Court summarizes (i) Hikma's allegedly impending entry into the sodium oxybate market in Spring 2017; and (ii) how the Jazz-Hikma agreement replaced Hikma's impending manufacture of a new sodium oxybate generic with Hikma's mere resale of Jazz's Xyrem under Hikma's label. The alleged effect of this Jazz-Hikma agreement was to perpetuate Jazz's Xyrem monopoly. *See, e.g.*, UHS ¶¶ 172–85 (alleging harms).

**i. Hikma's impending entry into Xyrem market in Spring 2017**

Plaintiffs allege that in Spring 2017, Hikma's entry into Jazz's market was impending. CAC ¶ 209; UHS ¶ 161. Specifically, on January 17, 2017, the FDA granted Hikma final approval of its ANDA: Hikma's application to "manufacture, market, and sell an AB-rated generic version of Xyrem." CAC ¶¶ 148, 278.

This final approval was the culmination of nearly seven years of battle. Hikma's predecessor company, Roxane, had filed Hikma's ANDA in July 2010. *Id.* at ¶ 148. Jazz had fought back. Among other things, Jazz had (1) sued Roxane/Hikma nine times for patent infringement; and (2) received the FDA's reluctant permission to limit the distribution of sodium

oxybate oral solutions (*i.e.*, Xyrem and any generics) to a single pharmacy. *See* Section I-A-1 and 2, *supra* (detailing lawsuits and alleged abuse of FDA's REMS process). Yet by January 17, 2017, Jazz's Xyrem monopoly was allegedly at risk in two ways.

First, Jazz's Xyrem patents appeared vulnerable. Starting in July 2016—and continuing through March 2017—the Patent Trial and Appeal Board invalidated many Xyrem patents during *inter partes* review. CAC ¶ 197. Meanwhile, other patent litigation was still proceeding. In particular, "Hikma's challenge to Jazz's remaining Xyrem patents was set for trial only a few weeks away." CAC ¶ 209.

Second, on January 17, 2017, Hikma had received FDA approval to circumvent Jazz's single-pharmacy REMS. CAC ¶¶ 208–09. In issuing this approval, the FDA reiterated generic manufacturers' allegations that "Jazz ha[d] engaged in a strategy that 'entails serial attempts to impose unreasonable contractual terms and conditions on the ANDA [filers] while concurrently issuing self-serving statements to FDA and the ANDA [filers] about Jazz's commitment to the process." *Id.* at 207 (quoting Sharp Memo at 11). The FDA then found that the "burden of creating a single, shared system outweighs the benefits." Sharp Memo at 13 (capitalization omitted). Among the burdens were Jazz's "obvious incentives" "to delay generic competition [] by failing to agree on [single, shared system] REMS terms." *Id.* at 17. The FDA therefore concluded that allowing Hikma to proceed with its own drug distribution system would "remove a barrier to generic products coming to market." *Id.*

In sum, by Spring 2017, Hikma's launch of an AB-rated generic was allegedly impending. Hikma had received FDA approval of its ANDA and alternative distribution strategy that circumvented Jazz's single-pharmacy REMS. Moreover, trial on Xyrem's remaining patents was "weeks away." CAC ¶ 209. Thus, Hikma could either launch (A) after potentially prevailing at trial; or (B) before a final litigation outcome. *See generally, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 241 (3d Cir. 2017) (describing generic manufacturer's option to launch "at risk" during ongoing litigation). Either way, Hikma's "manufacture, market[ing], and s[ale] of an AB-rated generic version of Xyrem" did not seem far off. CAC ¶ 126.

An alleged chain of events would follow Hikma's launch of an AB-rated generic. Jazz would likely launch an AG to compete with Hikma during Hikma's 180-day exclusivity period. CAC ¶ 210. Then after that six-month period, other generic manufacturers would presumably enter the market. CAC ¶¶ 183, 195–96 (listing other ANDA filers and two settlements). In fact, as of January 2017, six ANDA filers allegedly were maintaining their patent cases against Jazz. *Id.* The expected outcome of all this competition would be the price of sodium oxybate oral solution—a treatment for narcolepsy—dropping about 85%. *See* Section III-A-1, *supra* (summarizing average price drop upon entry of AB-rated generic).

**ii. Jazz-Hikma agreement delays Hikma's entry; Hikma instead resells Jazz's sodium oxybate as Hikma's AG**

On April 5, 2017, Hikma and Jazz settled their patent litigation by way of an allegedly unlawful reverse settlement, which Plaintiffs call the "Jazz-Hikma agreement." UHS ¶¶ 163–64. As a result, Hikma did not "manufacture, market, [or] sell an AB-rated generic version of Xyrem." CAC ¶ 148. Nor has Hikma done so to date.

Plaintiffs allege that the Jazz-Hikma agreement was, in part, memorialized in three interdependent documents executed contemporaneously: (1) a "Settlement Agreement"; (2) a "License Agreement"; and (3) and an "AG Agreement." UHS ¶ 164. The Settlement Agreement between Jazz and Hikma was partially disclosed in Jazz's April 5, 2017 Form 8-K. CAC ¶ 215 (citing Jazz Pharmaceuticals plc, Form 8-K at 2 (Apr. 5, 2017)). Jazz and Hikma allegedly agreed to keep the other two documents secret. UHS ¶ 164. In response to Plaintiffs' instant lawsuit, however, Defendants have attached the Hikma License Agreement and Hikma AG Agreement to the instant motion to dismiss.

Under this "Jazz-Hikma agreement," Jazz granted Hikma the right to sell an authorized generic version of Xyrem for an initial term of six months starting on January 1, 2023. *Id.* Specifically, Hikma agreed to buy Xyrem *from Jazz*—through *Jazz's* REMS—and resell that Xyrem under the label of a Hikma AG. UHS ¶ 167. Sales of this Hikma AG are also distributed through Xyrem's single pharmacy, Express Scripts. *Id.* In fact, Plaintiffs allege that Hikma would

never take delivery of its AG from Jazz. *Id.*

In short, on April 5, 2017, after nearly seven years of trying to bring an AB-rated generic to market, Hikma agreed to buy and relabel Xyrem rather than manufacture a generic version of Xyrem. By agreeing to this, Hikma delayed its allegedly impending entry into Jazz's market over six years until at least July 1, 2023 (*i.e.*, the end of the six month term for Hikma's AG). CAC ¶ 214. That impending entry had been supported by (1) the possible vulnerability of Xyrem's patents; and (2) the FDA approving Hikma's plan to distribute through a pharmacy other than Express Scripts. *See* Section III-A-2-a-i, *supra* (detailing same).

In Plaintiffs' view, Hikma would not have agreed to Jazz's plan without a compelling economic reason. CAC ¶ 218. The key reason alleged here is that Jazz made a "no-AG" commitment to Hikma. That is, during at least the first 180 days that Hikma AG would be on the market, Jazz allegedly promised that Jazz would not license any other company to market an AG. CAC ¶ 215. The Hikma AG Agreement attached to Defendants' motion to dismiss confirms Jazz's commitment. *See* Hikma AG Agreement § 2.2, ECF No. 110-14 (Jazz promising not to "grant[] a license or sublicense to a Third Party to market an Authorized Generic" for approximately six months). Jazz would instead be content to (1) supply the Xyrem that Hikma would advertise and relabel as Hikma AG; and (2) receive an escalating royalty on sales, as analyzed in III-A-1-b-ii, *infra* (analyzing royalty structure).

With no competition from another AG for at least 180 days, Plaintiffs allege that Hikma could sell its AG at a supra-competitive price—and kick back some supra-competitive profits to Jazz. CAC ¶¶ 215, 239. In fact, Plaintiffs estimate Hikma's sales using the typical market share captured by AGs within 180 days of launch. The resulting estimate is that Hikma AG will generate over $480 million in sales between January 1, 2023 and July 1, 2023 alone. *See* CAC ¶ 237 (estimating $480 million to $540 million); UHS ¶ 181 (estimating $705 million).

If proven, this alleged "no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic." *King Drug*, 791 F.3d at 405. The no-AG agreement thus "may represent an unusual, unexplained transfer of value from the patent holder to

the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition." *King Drug*, 791 F.3d at 394.

In fact, as the leading antitrust treatise has explained, no-AG agreements "can in fact be more anticompetitive than a large cash payment for delay." Areeda & Hovenkamp, *supra*, ¶ 2045. The reason is that no-AG agreements replace "a generic duopoly" with a "a generic monopoly," which results in "higher prices." *King Drug*, 791 F.3d at 394. Here, the Jazz-Hikma agreement ensures that Hikma AG is the only "generic" for 180 days. Furthermore, Hikma AG is simply relabeled Xyrem manufactured by Jazz. The no-AG agreement thus allows Jazz to maintain its monopoly in exchange for sharing some monopolistic profits with Hikma. Put simply, "until generic *production* commences," no-AG agreements are "simply naked restraints on trade." Areeda & Hovenkamp, *supra*, ¶ 2045 & nn.186–87.

**b. Alleged reverse payments from Jazz to Hikma**

In short, the alleged no-AG agreement "uses valuable licensing in such a way as to induce a patent challenger's delay." *King Drug*, 791 F.3d at 406. Yet as the parties note, Jazz's alleged "no-AG" agreement had an explicit caveat. Jazz's written agreement merely promised not to "grant[] a license or sublicense to a Third Party to market an Authorized Generic." Hikma AG Agreement § 2.2, ECF No. 110-14. Jazz still reserved its right to market its *own* Jazz AG. *See* Hikma License Agreement §§ 1.14, 2.4, ECF No. 111-2 (expressly retaining rights to "Market," defined as "use, advertise, market, sell, or offer to sell"). That is, at least under Jazz's written agreements, there theoretically could be two AGs between January 1, 2023 and July 1, 2023: Hikma AG and Jazz AG. Defendants thus argue that Plaintiffs fail to plausibly allege the existence of a no-AG agreement between Jazz and Hikma. Mot. at 14.

The Court disagrees. Plaintiffs plausibly allege the existence of an implicit or *de facto* no-AG agreement between Jazz and Hikma. As circumstantial evidence of an implicit no-AG agreement, Plaintiffs rely on explicit parts of the Jazz-Hikma agreement. These parts of the Jazz-Hikma agreement allegedly (1) disincentivize Jazz from marketing its own AG; and (2) further compensate Hikma in order "to maintain supracompetitive prices to be shared among the patentee

[here, Jazz] and the challenger [here, Hikma] rather than face what might have been a competitive market." *Actavis*, 570 U.S. at 157.

Plaintiffs specifically identify three parts of the Jazz-Hikma agreement that disincentivize a Jazz AG and convey value to Hikma. The first is Jazz's promise not to license Jazz's AG through any third party for six months. The second is the royalty structure, which escalates kickbacks from Hikma to Jazz to undermine Jazz's economic interest in competing to sell Jazz's own AG. The third is the Jazz-Hikma agreement's "acceleration clause," a type of most-favored-entry clause that allows Hikma to sell AG immediately if (1) a generic version of Xyrem were to market itself without Jazz's permission; or (2) anyone were to successfully invalidate or render unenforceable Xyrem's unexpired patent claims. *See* Hikma AG Agreement § 2.8, ECF No. 110-14 (acceleration provisions). In Plaintiffs' view, the acceleration clause deters potential generic entrants by triggering competition if they actually enter.

Together, these parts of the Jazz-Hikma agreement were allegedly "designed to, and do[] have, the effect that during at least the first six months of entry (before subsequent generics were allocated a slice of the market in their own separate pay-for-delay agreements, as discussed below [in Section III-A-2]), the Hikma AG would be the only authorized generic." CAC ¶ 221. The alleged estimated value to Hikma of the Jazz-Hikma agreement is over $480 million just in the first six months after Hikma launches its AG (which is relabeled Xyrem made by Jazz). CAC ¶ 237 (estimating $480 million to $540 million); UHS ¶ 181 (estimating $705 million). Jazz's market capitalization also jumped by about $785 million after the Jazz-Hikma agreement was partially disclosed on April 6, 2017—a jump that Plaintiffs allege is attributable to investors' expectations that Xyrem would face reduced generic competition. UHS ¶ 185; CAC ¶ 246. Ultimately, in exchange for Hikma delaying its AB-rated generic, Jazz has allowed Hikma to relabel and sell Jazz Xyrem as Hikma AG.

Below, the Court details the three parts of the Jazz-Hikma agreement that disincentivize a Jazz AG and convey value to Hikma.

**i. Reverse payment 1 of 3: Delay on third party licensing**

First, Jazz promised not to license its AG through any other third party for Hikma's first 180 days selling Hikma AG—which, as stated, would simply be Jazz Xyrem but relabeled. This no *third-party* licensing period spans at least January 1, 2023 and July 1, 2023. CAC ¶ 6; *accord, e.g.*, Hikma License Agreement § 2.4 (expressly noting that Jazz's rights "specifically exclud[e] granting a license or sublicense to a Third Party for an Authorized Generic" for the "Initial Sales Period"); Hikma AG Agreement § 1.27 (defining Initial Sales Period as six-months from AG Launch Date). Jazz reserved the theoretical option of marketing and labeling an AG itself. Yet, as Plaintiffs plausibly allege, it is highly unlikely that Jazz would launch its own AG. Evidencing this *de facto* no-AG agreement are (1) Jazz's statements on its in-house manufacturing capacity; and (2) industry custom.

Jazz's statements suggest that its in-house manufacturing capacity is limited. Consequently, products that are manufactured by Jazz—including Xyrem, Hikma AG, and the Later Generic Defendants' AGs—must largely share the same limited output of sodium oxybate oral solution. *See* Section III-A-3, *infra* (detailing Jazz's licensing AGs to Later Generic Defendants). Statements to this effect are in Jazz's annual report (SEC Form 10-K) and the Jazz-Hikma AG Agreement. Specifically:

- Jazz's latest annual report shows that Jazz currently does not sell any AGs. Rather, "Jazz currently only sells branded (commercialized) products in the United States." CAC ¶ 221 n.67 (citing Jazz Pharmaceuticals plc, 2020 Annual Report (Form 10-K) at 6–11 (Feb 23, 2021)). As the FTC has found, "if [a] brand company does not market generics in the United States," a commitment from the brand manufacturer not to use a third party to distribute an authorized generic for a period of time . . . could have the same effect as an *explicit* no-AG agreement." FTC, *Overview of Agreements Filed in FY 2016: A Report by the Bureau of Competition* at 2 (May 2019) (emphasis added) ("2019 FTC Report").
- Jazz's annual report also states that Jazz's "ability to develop and supply products in a *timely and competitive* manner *depends primarily on third party suppliers* being able to meet our ongoing commercial and clinical trial needs for [active pharmaceutical ingredient], other raw materials, packaging materials and finished products." CAC ¶ 221 n.67 (quoting Annual Report at 16). Thus, by Jazz's own admission, Jazz would need to "depend[] primarily on third party suppliers" to develop and supply a new product such as a generic version of Xyrem. *Id.* Supplying an AG in-house would not be "timely and

competitive." *Id.*

- The Jazz-Hikma AG Agreement further evinces Jazz's manufacturing constraints. Jazz and Hikma explicitly planned for the possibility of a supply shortage. Hikma AG Agreement § 3.3 contains a provision titled "Allocation if Supply Shortage." The provision allocates sodium oxybate between Jazz and Hikma in the event of "a shortage of any materials" or "insufficient [Drug Enforcement Administration] quota to Manufacture [Hikma]'s requirements for the [Hikma] Authorized Generic." *Id.*

Given these documents, it is plausible that Jazz cannot manufacture enough sodium oxybate to supply Xyrem, Hikma AG, *and* a theoretical Jazz AG—let alone those three labels *plus* the three additional AGs that Jazz will begin to supply for Amneal, Par, and Lupin on July 1, 2023. *See* Section III-A-3, *infra* (detailing Jazz's settlements with Later Generic Defendants). In other words, Jazz's statements suggest that Jazz only manufactures enough for its Xyrem label.

Industry custom confirms that Jazz likely faces manufacturing constraints. It is not customary in the pharmaceutical industry for a brand manufacturer (such as Jazz) to launch its own AG. CAC ¶¶ 87, 110, 221 n.67 (citing FTC studies). Indeed, the FTC has found that "[t]he *most common* form of possible compensation" in settlements between brand and generic manufacturers "is a commitment from the brand manufacturer *not to use a third party* to distribute an authorized generic for a period of time, such as during first-filer exclusivity." 2019 FTC Report at 2. These commitments often "have the same effect as an explicit no-AG commitment." *Id.*; *see* CAC ¶ 110 (citing same). Specifically, the FTC has found that "out of 119 AG launches from 2001 to 2008, *only one* was distributed by a brand drug company without generic marketing." *In re Intuniv Antitrust Litig.* ("*Intuniv*"), 496 F. Supp. 3d 639, 671 (D. Mass. 2020) (emphasis added) (citing FTC 2011 AG Study); *see also* CAC ¶ 87 n.36 (citing FTC 2011 AG Study). Moreover, at least one court has credited research that "out of the 529 AG launches since 2009 . . . only two were distributed by a brand company without generic expertise." *Intuniv*, 496 F. Supp. 3d at 671. Thus, it is at least plausible that Jazz—like almost all other brand drug companies—would not launch its own AG. All told, Plaintiffs plausibly allege that Jazz's promise to not license Jazz's AG through a third party for six months functioned to delay *any* Jazz AG for six months.

Defendants also fail to show that Jazz has the marketing expertise or economic incentive to

sell an AG. Empirically, brand name manufacturers almost never launch their own AG. *See Intuniv*, 496 F. Supp. 3d at 671 (citing FTC 2011 AG Study and other research). Instead, brand name manufacturers generally rely on companies that specialize in generic drugs to market an AG. *Id.* Here, at the motion to dismiss stage, it is plausible that Jazz would follow prevailing industry practice and not launch a Jazz AG.

In sum, it is plausible that Jazz's agreement to delay licensing Jazz AG through a third party delayed Jazz's ability to compete with Hikma and the other Generic Defendants. That delay would give Hikma at least a 180-day monopoly on the only Xyrem "generic"—specifically, an authorized generic manufactured by Jazz, but marketed by Hikma. The result will be "simply a horizontal market division" between Hikma (which will sell Jazz's Xyrem marketed as Hikma AG) and Jazz (which will sell Xyrem but no Jazz AG). Areeda & Hovenkamp, *supra*, ¶ 2045. This plausible no-AG agreement would constitute a transfer of value from Jazz to Hikma. *See, e.g.*, *Impax Lab'ys*, 994 F.3d at 494 (holding same and collecting cases); Areeda & Hovenkamp, *supra*, ¶ 2045 (arguing that no-AG agreements "can in fact be more anticompetitive than a large cash payment for delay").

**ii. Reverse payment 2 of 3: Escalating royalty payments**

Second, Plaintiffs allege escalating royalty payments from Hikma to Jazz that undermine Jazz's economic interest in selling its own AG. For support, Plaintiffs cite the royalty structure in the Hikma AG Agreement, one of the three contracts that partially constitute the Jazz-Hikma agreement. *See* Opp'n at 10–11 (citing Hikma AG Agreement § 5.2.1); *see also, e.g.*, UHS ¶ 166 (alleging that Hikma agreed to pay a "meaningful royalty" that increases with sales); CAC ¶ 231 (same). Under this AG Agreement, Hikma will pay increasingly higher percentages of revenue to Jazz as Hikma's market share increases. Specifically, Hikma will pay (1) a [redacted] royalty on sales up to [redacted] market share; (2) a [redacted] royalty on incremental sales up to [redacted] market share; (3) a [redacted] royalty on incremental sales up to [redacted] market share; (4) a [redacted] royalty on incremental sales up to [redacted] market share; (5) and a [redacted] royalty on incremental sales up to a [redacted] market share. Hikma AG Agreement § 5.2.1.

In turn, Hikma's market share is defined as Hikma's percentage of total units sold by Jazz and Hikma. *Id.* ¶¶ 1.53, 1.55, 5.2.1. Hikma takes "market share" as it sells more bottles of Hikma AG. Conversely, as Jazz sells bottles of its branded product (*i.e.*, Xyrem) or a theoretical Jazz AG, Hikma's market share and incremental royalty rate decrease. In sum, the more AG that Hikma sells, the more Hikma pays Jazz. All the while, Hikma AG is merely relabeled Xyrem that is manufactured by Jazz.

Plaintiffs allege that this royalty structure discourages Jazz from launching an AG in three ways. First, if Jazz were to launch its own AG, the resulting price competition would lower prices for all sodium oxybate products—branded and generic. *See, e.g.*, CAC ¶¶ 96–98 (citing, *e.g.*, Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 Health Affairs 790, 796 (2007)). Second, Jazz's competing AG would reduce Hikma's market share and selling price. In turn, that competition from Jazz would reduce Hikma's incremental royalty rate, Hikma's sales, and Hikma's royalty payments to Jazz. *See, e.g.*, UHS ¶¶ 61–63 (citing, *e.g.*, FTC 2011 AG Study). Third, a Jazz AG would cannibalize sales of Jazz's more profitable Xyrem-branded product. *See, e.g.*, CAC ¶ 83 (alleging that generics are "50% to 80% (or more) less expensive than their brand counterparts"). In fact, the FTC's 2011 AG Study found that within six months after the launch of a generic, the market share of the branded drug is "less than 20 percent." FTC 2011 AG Study at 67; *see* CAC ¶ 91 (quoting same).

The Court agrees that Plaintiffs' allegations as to escalating royalties are plausible. Supporting this conclusion are findings by other courts and the FTC. Courts, for their part, have held that royalty payments may be "effectively a kickback." *FWK Holdings LLC v. Shire PLC*, No. 16-CV-12653-ADB, 2017 WL 11449668, at *8 (D. Mass. Oct. 10, 2017). In *FWK Holdings*, for instance, the court found plausible the allegation that "royalty payment[s] . . . both incentivized [the brand name manufacturer] not to launch an AG and evidence[d] the substantial value [the generic manufacturer] secured through the no-AG agreement." *Id.* Similarly, in *Intuniv*, the court held at summary judgment that royalty payments by a generic manufacturer could "effectively incentivize [the brand name manufacturer] to stay out of the generic market." 496 F. Supp. 3d at

670. The *FWK Holdings* and *Intuiniv* courts thus rejected the argument that "a royalty payment cannot form the basis of a reverse payment claim." *Id.* at *9; *accord Intuniv*, 496 F. Supp. 3d at 670 (rejecting argument that "there is no evidence that the royalty provision acted as an enforcement mechanism for an implicit no-AG agreement"). That failed argument is the same argument Jazz makes against Plaintiffs' royalty allegations here. *See* Reply at 8 (arguing that "royalties are not 'reverse payments'").

The FTC, for its part, has found that a "common form of possible compensation" in reverse settlements is a "royalty structure" like the one here. 2019 FTC Report at 2. Specifically, a royalty structure "may achieve the same effect as an explicit no-AG commitment." *Id.* This *de facto* no-AG agreement may be achieved where a result of the "brand [manufacturer] launch[ing] an authorized generic" would be that "the generic [company]'s obligation to pay royalties is reduced." *Id.*

Here too, if Jazz were to launch its own AG, Hikma's royalty obligations to Jazz would decrease. *See, e.g.*, UHS ¶¶ 61–63 (summarizing allegations). The reason, as discussed above, is the following chain of events plausibly triggered by a Jazz AG. A Jazz AG would plausibly (1) take market share from Hikma AG, which is merely relabeled Jazz Xyrem; and (2) compete on price with Hikma AG. Lowering Hikma AG market share would reduce Hikma's incremental royalty rate. Price competition would lower the prices of Hikma AG, the Jazz AG, and Xyrem—thereby potentially reducing the revenue of all three products. Together, lower incremental royalty rate and lower Hikma AG revenue would reduce Hikma's royalty payments. *Id.*

In sum, Plaintiffs plausibly allege that the Jazz-Hikma agreement's escalating royalty structure incentivized Jazz to delay its own AG.

**iii. Reverse payment 3 of 3: Acceleration clause**

Third, Plaintiffs allege that the Jazz-Hikma agreement contains a type of most-favored-entry clause called an "acceleration clause" or "poison pill," which hinders entry by later generics. *See, e.g.*, CAC ¶ 120, 225; UHS ¶ 177 (describing Hikma acceleration clause). The acceleration clause allows Hikma to immediately launch its AG if (1) a generic version of Xyrem were to

market itself without Jazz's permission; or (2) anyone were to successfully invalidate or render unenforceable Xyrem's unexpired patent claims. CAC ¶ 225 (quoting alleged clause); *accord* Hikma AG Agreement § 2.8 (acceleration clause). Otherwise, the Jazz-Hikma agreement provides that Hikma may launch Hikma AG, which is relabeled Jazz Xyrem, on January 1, 2023. Hikma AG Agreement § 1.5.

This acceleration clause adds value to Hikma in two ways. First, the clause plausibly disincentivizes other generic manufacturers from litigating their patent claims and coming to market as soon as possible. *Id.* The clause has this anticompetitive harm because, if another generic manufacturer successfully enters the market, that manufacturer immediately faces competition from Jazz's Xyrem and Hikma AG. Competition reduces a prospective entrant's expected profits. *E.g.*, *Musical Instruments*, 798 F.3d at 1193 n.8. The prospective entrant is less likely to enter as a result.

For instance, as the head of one of the world's largest generic manufacturers testified to Congress on March 31, 2009, acceleration clauses are "the primary anticompetitive aspects of settlements." Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 111th Cong., at 228 (Mar. 31, 2009) (statement of Bernard Sherman, CEO, Apotex, Inc.; CAC ¶ 123 (quoting same). Specifically, the CEO of Apotex testified:

> At first blush, the acceleration of [a generic's] entry into the market . . . may sound like a good outcome for consumers because it expedited access to the generic. However, *no subsequent filer is going to take up the patent fight knowing it will get nothing if it wins*. Consumers are the biggest losers under this system. . . . Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. . . . And settlements that delay consumer access to the generic will, in turn, increase.

111th Cong., at 218 (emphasis changed); CAC ¶ 123 (quoting same). In short, acceleration clauses may "very substantially diminish[], if not altogether eliminate[], the incentive for later generic filers to enter" before the scheduled entry date protected by the clause. *In re Loestrin 24 Fe Antitrust Litig.* ("*Loestrin*"), 261 F. Supp. 3d 307, 333 (D.R.I. 2017) (crediting allegation at motion

to dismiss); *In re Loestrin 24 Fe Antitrust Litig.* ("*Loestrin*"), 433 F. Supp. 3d 274, 321 (D.R.I. 2019) (same at summary judgment).

Second, Hikma's acceleration clause—coupled with acceleration clauses in each of Jazz's agreements with the Later Generic Defendants (*see* Section III-A-3, *infra*)—plausibly operates as a cartel enforcement mechanism. *See* Hikma AG Agreement § 2.8 (acceleration clause); Par AG Agreement § 2.7 (same); Lupin AG Agreement § 2.7.1, ECF No. 110-18 (same); Amneal AG Agreement § 2.7.1, ECF No. 110-20 (same).

The acceleration clauses so operate by creating a "powerful threat": the "threat of reversion to competitive behavior." Robert C. Marshall & Leslie M. Marx, *The Economics of Collusion: Cartels and Bidding Rings* at 136 (2012). As explained by economists Robert Marshall and Leslie Marx, reversions to competitive behavior deny firms collusive profits and are thus well-documented as "punishment for deviations from collusion." *Id.* (citing Congressional testimony and economic studies).

Here, the acceleration clauses allow Hikma, Amneal, Par, and Lupin to revert to competitive behavior (*i.e.*, quickly market an AG) if *any* generic manufacturer defects from the alleged scheme to delay and restrain generic output. These acceleration clauses allegedly all function like the Hikma clause just described. CAC ¶¶ 225, 232, 253, 260, 267; UHS ¶¶ 177, 188, 191, 196, 203 (describing acceleration clauses). Specifically, each Later Generic Defendant contractually received a default launch date of July 1, 2023 for their AGs. CAC ¶¶ 250, 257, 264. That default launch date coincides with the end of Hikma's exclusive licensing period for Hikma's AG. However, if a third party sells a generic without Jazz's permission before July 1, 2023, Hikma and each Later Generic Defendant may immediately start selling its AG to compete with that unauthorized entrant. *See* Par AG Agreement § 2.7 (acceleration provision); Lupin AG Agreement § 2.7.1 (same); Amneal AG Agreement § 2.7.1 (same). Consequently, any unauthorized generic entrant faces the unprofitable prospect of immediately competing with Hikma, Amneal, Par, and Lupin.

All told, the Hikma acceleration clause has plausibly deterred generic entry. Indeed, this

conclusion tracks research on the empirical result of acceleration clauses in the pharmaceutical industry. Health economists Thomas G. McGuire and Keith M. Drake have found that acceleration clauses have never promoted earlier generic entry where, as here, the first-filer (Hikma) has retained its 180-day period of exclusivity. Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, 16 J. Competition L. & Econ. 188, 188 (2020) (available on Lexis+); *see* CAC ¶ 124 (citing same); *see generally Actavis*, 570 U.S. at 144 (summarizing 180-day period of exclusivity under Hatch-Waxman Act). Specifically, "[a]mong the 54 cases in which the first filer retained sole rights to the 180-day exclusivity period, there were no cases of early generic entry. In other words, there were no cases in which the first-filer's entry was accelerated, and there were no cases in which a different generic entered before the entry date set in the first-filer's settlement." Drake & McGuire, *supra*, at 194.

Accordingly, like other courts analyzing acceleration clauses at the motion to dismiss stage, the Court holds that acceleration clauses plausibly cause anticompetitive harm as part of an alleged reverse payment scheme. *See, e.g.*, *In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.*, No. 19-CV-1460-LPS, 2020 WL 7022364, at *6 (D. Del. Nov. 30, 2020) (denying motion to dismiss because "acceleration provision [] could be proven to constitute value transferred"); *Loestrin*, 261 F. Supp. 3d at 334 (same because acceleration clause is "cognizable as a component of a complex settlement agreement"); *Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 610 (N.D. Cal. 2020) (same because acceleration clause, also known as a most favored entry clause, limits "entry, *i.e.*, when competition is allowed into a market"). Indeed, several courts have denied *summary judgment* against acceleration clause allegations despite "various [assertions of] broad procompetitive justifications" for such clauses. *Loestrin*, 433 F. Supp. 3d at 321; *see, e.g.*, *In re Namenda Indirect Purchaser Antitrust Litig.*, No. 15-CV-6549-CM, 2021 WL 2403727, at *26, *29 (S.D.N.Y. June 11, 2021) (denying summary judgment based on "potential anticompetitive impact from [] acceleration clause").

Defendants respond that Jazz's acceleration clauses failed to actually deter generic entry. Reply at 8–9. For support, Defendants note that after Jazz and Hikma settled, between nine to 18

months passed before the Later Generic Defendants settled with Jazz. *Id.* at 9 (citing CAC ¶¶ 249, 263; UHS ¶¶ 190, 199). Thus, in Defendants' view, the Later Generic Defendants should have settled sooner if Jazz's acceleration clauses in fact deterred generic entry.

Defendants' argument lacks merit for three reasons. First, Plaintiffs allege—and Defendants do not dispute—that "several other generics [] abandoned their challenges to the Xyrem patents" after the Hikma settlement. CAC ¶ 247 & n.68 (citing settlements with Wockhardt Bio AG, Ranbaxy Laboratories Limited, and Ranbaxy Inc.). These generic manufacturers plausibly abandoned their patent challenges because the acceleration clauses "very substantially diminished, if not altogether eliminated," the expected payoff from entering the Xyrem market with an AB-rated generic. *Loestrin*, 261 F. Supp. 3d at 333 (crediting same reasoning). Thus, even if Jazz's acceleration clauses failed to *completely* deter all potential generics, the clauses at least plausibly deterred some generics.

Second, Defendants cite only one authority for the proposition that continued litigation requires dismissal of acceleration clause allegations—and that authority is inapposite. Mot. at 26. Specifically, Defendants cite *In re Actos End Payor Antitrust Litigation*, No. 13-CV-9244-RA, 2015 WL 5610752, at *15 (S.D.N.Y. Sept. 22, 2015), *aff'd in part, vacated in part*, 848 F.3d 89 (2d Cir. 2017). There, the district court relied on at least two grounds absent here. The first ground was that "[s]ignificantly, [p]laintiffs d[id] not allege that the [g]eneric [d]efendants shared in the [brand name manufacturer]'s monopoly profits by charging supracompetitive prices when they entered the market." *Actos*, 2015 WL 5610752, at *15. Here, by contrast, Plaintiffs allege in detail that Hikma—along with the other Generic Defendants—"shar[ed] supra-competitive pricing of Xyrem products." CAC ¶ 259; *see, e.g.*, *id.* ¶¶ 190 (graph of allegedly supra-competitive pricing history), 273–75 (quoting Jazz CEO discussing elevated prices, "very limited volumes," and successfully avoiding "a generic free for all").

*Actos*'s other inapposite ground for dismissal was that, as of 2015, "no other court ha[d] found an acceleration clause to constitute a reverse payment." *Actos*, 2015 WL 5610752, at *16. "In fact," the *Actos* court reasoned, "acceleration clauses were pleaded as an alleged 'payment' in

*In re Loestrin*, but th[at] [c]ourt summarily rejected plaintiffs' theory." *Id.* n.13 (citing *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 191 (D.R.I. 2014), *vacated and remanded*, 814 F.3d 538 (1st Cir. 2016)). Since 2015, however, many courts have denied motions to dismiss or summary judgment because "acceleration provision[s] [] could be proven to constitute value transferred" in a reverse payment scheme. *In re Sensipar*, 2020 WL 7022364, at *6; *see, e.g.*, *In re Namenda Indirect Purchaser Antitrust Litig.*, 2021 WL 2403727, at *26, *29 (denying summary judgment based on "potential anticompetitive impact from [] acceleration clause"). For instance, the *Loestrin* case on which the *Actos* court relied was vacated and remanded by the First Circuit. *See In re Loestrin 24 Fe Antitrust Litig*., 814 F.3d 538 (1st Cir. 2016). Then, both on remand and at summary judgment, the *Loestrin* court which had erroneously dismissed the acceleration clause allegations allowed them to proceed to trial. *See In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d at 334 (denying motion to dismiss on remand); *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d at 321 (denying summary judgment). Thus, both the factual and legal premises of *Actos* are inapplicable here. Jazz's acceleration clauses plausibly convey value as part of an alleged reverse payment scheme.

Lastly, Defendants' argument threatens to create an antitrust loophole at the motion to dismiss stage. Under Defendants' reasoning, a generic manufacturer need only let a lawsuit sit idle for several months to defeat any allegation that an acceleration clause deterred generic entry. Similarly, a generic manufacturer could litigate feebly so that it intentionally fails to trigger any acceleration clause. *Cf., e.g.*, *Miller & Lux v. E. Side Canal & Irrigation Co.*, 211 U.S. 293, 303 (1908) (identifying and criticizing a collusive lawsuit); *IP and Antitrust* § 3.03 & n.155 (same in patent context). Thus, the time lapsed on a lawsuit should be insufficient to show whether an acceleration clause deterred the vigorous prosecution of that lawsuit.

In sum, Plaintiffs have plausibly alleged at least three reverse payments in the Jazz-Hikma agreement: (1) Jazz's six-month delay on third-party licensing; (2) the escalating royalty structure for Hikma's AG sales; and (3) an acceleration clause that deters generic entry and enforces collusion among all Defendants. The alleged estimated value to Hikma of the Jazz-Hikma

agreement is over $480 million just in the first six months after Hikma launches its AG. CAC ¶ 237 (estimating $480 million to $540 million); UHS ¶ 181 (estimating $705 million). This is more than enough to support a reverse payment claim under *Actavis*. *See, e.g.*, *Actavis*, 570 U.S. at 145 (reversing dismissal of claims challenging payments as small as $12 million to one defendant); *Impax*, 994 F.3d at 494 (affirming reverse payment claim against payment that increased generic's profits by $24.5 million). Accordingly, the Court denies Defendants' motion to dismiss Plaintiffs' reverse payment claims (CAC Counts 1 and 7; UHS counts 1, 5, and 8).

**3. Plaintiffs adequately allege that Jazz's settlements with the Later Generic Defendants contain reverse payments (CAC Counts 8–10; UHS Counts 5, 7, and 8).**

Plaintiffs also allege that the Later Generic Defendants (Par, Lupin, and Amneal) received large unjustified payments from Jazz. These reverse payments took three forms. First, Jazz made multi-million-dollar cash payments to each Later Generic Defendant—ostensibly for Jazz's avoided litigation costs. *See* Opp'n at 13 (citing Par Settlement Agreement § 3, ECF No. 110-15 (Ex. 4); Lupin Settlement Agreement § 3, ECF No. 110-17 (Ex. 7); Amneal Settlement Agreement § 3, ECF No. 110-19 (Ex. 10)). Jazz paid $[redacted] to Par, Lupin, and Amneal respectively. *See* Par Settlement Agreement § 3; Lupin Settlement Agreement § 3; Amneal Settlement Agreement § 3.

Second, Jazz gave each Later Generic Defendant a limited license to sell a constrained supply of AG. Specifically, each license (1) began only after the expiration of Hikma's 180-day exclusivity period in July 2023; (2) was capped at a low-single-digit market share; and (3) required a royalty payment, as a percentage of sales, that increased over time. *See, e.g.*, Lupin AG Agreement § 1.27, 5, ECF No. 110-18 (Exh. 8).

Third, Jazz's agreements with each Later Generic Defendant contained acceleration clauses like the acceleration clause in the Jazz-Hikma agreement discussed above. *See, e.g.*, CAC ¶¶ 253, 260, 267 (alleging acceleration clauses); Section III-A-2-b-iii, *supra* (analyzing Jazz-Hikma acceleration clause and acceleration clauses generally). The acceleration clauses appear in the contracts that Defendants have attached to their motion to dismiss. *See, e.g.*, Par AG Agreement

§ 2.7; Lupin AG Agreement § 2.7.1; Amneal AG Agreement § 2.7.1.

Plaintiffs estimate the value to the Later Generic Defendants of these agreements to be in the tens of millions of dollars. CAC ¶¶ 255, 262, 269–70; UHS ¶¶ 193, 198, 205, 206. In exchange for these reverse payments, Plaintiffs allege that the Later Generic Defendants agreed to (1) surrender their patent challenges; and (2) delay and limit the entry of generic versions of Xyrem. *See* CAC ¶¶ 247–46 (allegations of quid pro quo). Had the Later Generic Defendants not entered reverse settlements, the Later Generic Defendants would have allegedly entered the market long before 2023. UHS ¶ 188.

Defendants offer two arguments for dismissing the reverse payment allegations against the Later Generic Defendants, but neither is persuasive. Defendants first argue that Jazz did not make any reverse payments to the Later Generic Defendants. Instead, in Defendants' telling, "Jazz's agreements with the Later Generic[] [Defendants] simply permit those companies to enter the market before patent expiry, first with volume-limited AG sales and then with full entry 2.5 years later."

This first argument mischaracterizes Plaintiffs' factual allegations, which the Court must accept as true and construe in the light most favorable to Plaintiffs at the motion to dismiss stage. *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Those allegations, as detailed above, are that Jazz (1) paid each Later Generic Defendant millions of dollars; (2) gave each Later Generic Defendant a limited license to sell a constrained supply of AG; and (3) agreed to acceleration clauses that disincentivized entry by any generic and served as a cartel enforcement mechanism. The value of each of Jazz's agreements with the Later Generic Defendants is allegedly "at least" in the "tens of millions of dollars." *E.g.*, CAC ¶¶ 255, 262, 269-70; UHS ¶¶ 193, 198, 205, 206. Moreover, Jazz's alleged cash payment of "many millions of dollars" to a generic manufacturer is what the *Actavis* Court described as the paradigmatic reverse payment. *Actavis*, 570 U.S. at 140. Defendants are thus wrong that Plaintiffs have not alleged any "payments." Mot. at 19.

Defendants' other argument is that, even if Plaintiffs have alleged reverse payments, those

payments are not "large" and "unexplained." Mot. at 19. Specifically, in Defendants' view, "[t]here is simply no way to plausibly value the volume-limited AG sales provisions." This argument fails on two independent grounds. To start, the volume-limited AG licenses are only one of the three forms of reverse payment summarized above. Defendants thus ignore the alleged cash payments and acceleration clauses—either of which may constitute actionable reverse payments. *See Actavis*, 570 U.S. at 140 (discussing cash payment); Section III-A-1-a, *supra* (discussing acceleration clauses).

In addition, Defendants' demand for a more precise valuation of non-cash payments (such as the AG licenses) is unjustified. As the Third Circuit recently explained in reversing a district court's dismissal of a reverse payment claim, a plaintiff can meet *Actavis*'s "pleading standard without describing in perfect detail the world without the reverse payment, *calculating reliably the payment's exact size*, or preempting every possible explanation for it." *FTC v. AbbVie Inc*, 976 F.3d 327, 356 (3d Cir. 2020) (emphasis added), *cert. denied*, No. 20-1293, 2021 WL 2519407 (U.S. June 21, 2021). The Third Circuit has found, for instance, that non-cash payments are plausibly "large" and "unjustified" based on relatively general allegations. *Id.* at 357. Payments may be sufficiently "large" because they allegedly are "extremely valuable" and exceed litigation costs saved through settlement. *Id.* Similarly, reverse payments may be plausibly "unjustified" also because they exceed alleged litigation costs. *Lipitor*, 868 F.3d at 261; *accord AbbVie*, 76 F.3d at 355–56 (summarizing *Lipitor*'s holdings).

Here too, Plaintiffs allege non-cash payments that are both extremely valuable and exceed alleged litigation costs. *E.g.*, CAC ¶ 269. Specifically, Plaintiffs plausibly estimate that *each percent* of market share allocated to the Generic Defendants represents about $13.5 million per year: a calculation based on Xyrem's annual sales discounted by 10% for price competition even in an allegedly collusive market. CAC ¶ 270. Jazz allegedly allocated several percentage points of market share to each Later Generic Defendant. *See, e.g.*, Lupin AG Agreement § 1.27, 5; CAC ¶ 264 (alleging same). The resulting estimate of value is $13.5 million multiplied by each percent of market share—*i.e.*, "tens of millions of dollars" to each Later Generic Defendant. *E.g.*, CAC

¶ 269. At this early stage in the litigation, this estimate is sufficient. Again, as the Third Circuit has warned, Plaintiffs need not "calculat[e] reliably the payment's exact size." *AbbVie Inc*, 976 F.3d at 356.

**B. Plaintiffs adequately plead an overarching antitrust conspiracy (CAC Counts 5 and 11; UHS Counts 5, 7, and 8) that unlawfully allocates the Xyrem market (CAC Counts 8–10; UHS Counts 5, 7, and 8).**

Defendants' second ground for dismissal is that Plaintiffs fail to plead either (1) an overarching antitrust conspiracy; or (2) an unlawful horizontal market allocation. The Court agrees that the alleged market allocation is not per se unlawful, but otherwise disagrees with Defendants here. Below, the Court analyzes Plaintiffs' allegations of conspiracy followed by market allocation.

**1. Plaintiffs adequately allege an overarching conspiracy among all Defendants.**

Defendants argue that "Plaintiffs' allegations of bilateral litigation settlements between Jazz and each individual Generic Defendants do not plausibly allege an overarching conspiracy." Mot. at 23. For support, Defendants cite the rule that "mere allegations of parallel conduct—even consciously parallel conduct—are insufficient to state a claim under § 1 [of the Sherman Act]." *Id.* (quoting *In re Musical Instruments & Equip. Antitrust Litig.*, 798 F.3d 1186, 1193 (9th Cir. 2015)). "Plaintiffs must plead 'something more,' 'some further factual enhancement,' a 'further circumstance pointing toward a meeting of the minds' of the alleged conspirators." *Musical Instruments*, 798 F.3d at 1193 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557, 560 (2007)). Applying this rule to reverse payment cases, Defendants concede that Plaintiffs plead an overarching conspiracy if Plaintiffs plausibly show that "each generic had an understanding about the nature of the conspiracy and its scope—which would include that there was more than just a bilateral conspiracy between each generic and the brand." Mot. at 23 (alterations omitted) (quoting *Staley v. Gilead Scis., Inc.* ("*Gilead II*"), No. 19-CV-02573-EMC, 2020 WL 5507555, at *7 (N.D. Cal. July 29, 2020)).

Plaintiffs show what Defendants concede would constitute an overarching conspiracy. As the *Gilead II* Court explained, an overarching conspiracy plausibly exists where, as here, each

Defendant (1) "had reason to know" that other Defendants were involved in the same "broad project"; and (2) "had reason to believe that their own benefits derived from the operation were probably *dependent upon the success of the entire venture*." *Gilead II*, 2020 WL 5507555, at *8 (emphasis in original) (quoting *United States v. Briscoe*, 896 F.2d 1476, 1505 (7th Cir. 1990)). The Court addresses each element of the plausible conspiracy in turn.

**a. Each Defendant plausibly had reason to know that other Defendants were involved in the same "broad project" to allocate the market.**

As to shared knowledge of the same "broad project," each Defendant had reason to know—or actually knew—that Jazz was allegedly allocating the market for Xyrem and its generics. This knowledge stemmed from, at a minimum, public information on Jazz's response to generic manufacturers' public ANDAs. *See, e.g.*, CAC ¶¶ 149–151 (detailing Hikma ANDA and Jazz's lawsuits), 183 (detailing other generics' ANDAs for generic version of Xyrem). In quick succession, Jazz settled its long-running patent lawsuits with Hikma, Par, Lupin, and Amneal.

Starting with Hikma, Jazz's response was to publicly allocate "limited volume[s]" to ensure "relatively low incursion on Xyrem." UHS ¶ 209 (quoting Jazz healthcare conference call on Nov. 14, 2018 and Jazz's Dec. 4, 2019 presentation). This public allocation started with the Jazz-Hikma agreement. Jazz partially disclosed the agreement in an August 5, 2017 securities filing. CAC ¶ 213 (citing https://www.sec.gov/Archives/edgar/data/1232524/000123252417000134/jazzq22017ex101.htm). The next day, Jazz's stock trading volumes spiked about five times their rolling average, and Jazz's market capitalization increased about 9% ($785 million). *Id.* ¶¶ 241–43. The jump in trading volume and Jazz's equity value reflected the high public impact of the Jazz-Hikma settlement. *Id.* ¶¶ 243–46.

Then, "over the course of 2018, [] Jazz worked a series of anticompetitive reverse payment settlements with the three remaining serious challengers to the Xyrem patents [*i.e.*, the Later Generic Defendants]." *Id.* ¶ 248. Each settlement halted the potential manufacture, marketing, and sale of an AB-rated generic manufactured by each Later Generic Defendant. In exchange, the

settlements licensed each Later Generic Defendant the right to sell a limited quantity of authorized generic ("AG"). Each AG, like Hikma AG, would be simply brand name Xyrem manufactured by Jazz and then *relabeled* by each Later Generic Defendant.

The first such settlement was with Par in January 2018. *Id.* ¶ 249. Jazz allocated Par "'a low single digit percentage' of Xyrem sales volume during the calendar year preceding the entry date of the Par AG," and protected that allocation with an acceleration clause. *Id.* ¶¶ 250, 253; *accord, e.g.*, Par AG Agreement § 1.28, ECF No. 110-16 (sealed percentage); *see* Section III-A-2-b-iii (discussing acceleration clauses). Importantly, at the time Par entered this settlement, Par was plausibly aware of the Jazz-Hikma agreement that had recently increased Jazz's public equity value by 9%. *Id.* ¶ 250.

Next, in June 2018, Lupin settled with Jazz. Lupin's settlement paralleled Par's settlement. Jazz allocated Lupin "'a low single digit percentage' of Xyrem sales volume" and shielded that allocation with an acceleration clause. CAC ¶¶ 257, 260; *accord, e.g.*, Lupin AG Agreement § 1.27 (sealed percentage). Lupin was also allegedly aware of the Jazz-Hikma and Jazz-Par agreements. CAC ¶ 259; UHS ¶ 197.

Lastly, in October 2018, Amneal settled with Jazz. Amneal's settlement also mirrored the others in its market allocation and acceleration clause. CAC ¶¶ 264, 267; *accord, e.g.*, Amneal AG Agreement § 1.30, ECF No. 110-20 (Ex. 11) (sealed percentage). Likewise, Amneal was plausibly aware of Jazz's similar agreements with the other Generic Defendants that had occurred just months before. CAC ¶ 266. In fact, in patent litigation, a judge ordered Jazz to disclose Jazz's agreements with Hikma and two other generic manufacturers to Amneal. *See* Letter Order at 4, *Jazz Pharm., Inc. v. Amneal Pharm. LLC, et al.*, No. 13-CV-00391-ES-JAD (D.N.J. Dec. 6, 2017), ECF No. 411 (ordering disclosure of "settlement / license agreements").

Given Jazz's public and tightly sequenced settlements of longstanding patent cases, Defendants "had reason to know" that other Generic Defendants were involved in the same "broad project" of market allocation. *Gilead II*, 2020 WL 5507555, at *8 (quoting *Briscoe*, 896 F.2d at 1505). Indeed, by November 2018, a senior Jazz executive was publicly boasting of Jazz's limited

output allocations to Hikma and "3 of the second filers"—plausibly Par, Lupin, and Amneal. CAC ¶ 274 (quoting Nov. 14, 2018 conference call). In Jazz's telling, those three second filers "are limited to low single-digit volume of the previous year Xyrem sales" so that "again," like with the Hikma settlement, "relatively low incursion on Xyrem" would result. *Id.* (quoting same). Similarly, by December 2019, Jazz CEO Bruce Cozadd was publicly stating that "the other couple folks with authorized generics have very limited volumes. So in terms of dynamics on price, it's – this is not what you would think of as a generic free for all." *Id.* ¶ 273 (quoting Dec. 4, 2019 presentation); UHS ¶ 208. These public statements underscore the likelihood that Jazz and the Generic Defendants shared a common understanding.

Nonetheless, Defendants insist that Plaintiffs fail to plead sufficient knowledge because Plaintiffs fail to "explain[] how each Generic Defendant conceivably was made aware of the terms of its competitors' litigation settlements with Jazz." Mot. at 24; Reply at 14. This argument overstates Plaintiffs' burden at the motion to dismiss stage. A "conspiracy by its very nature is a secretive operation, and it is a rare case where all aspects of a conspiracy can be laid bare in court with the precision of a surgeon's scalpel." *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 183 (2d Cir. 2012) (altered to include full quotation) (quoting *United States v. Snow*, 462 F.3d 55, 68 (2d Cir. 2006)) (reversing dismissal of antitrust claims). Even if a conspirator lacks "awareness" of much of a conspiracy, that ignorance is "immaterial" where, as here, the conspirator's acts "were essential steps in a single scheme." *United States v. Downing*, 297 F.3d 52, 57 (2d Cir. 2002) (quoting *United States v. Benjamin*, 328 F.2d 854, 864 (2d Cir. 1964) (Friendly, J.)). Thus, an antitrust plaintiff may present "direct *or circumstantial* evidence" of a conspiracy. *Anderson News*, 680 F.3d at 183 (emphasis in original) (quoting *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 764 (1984)). Plaintiffs present such evidence here through (1) Jazz's public statements, Jazz's public conduct, and the stock market's response; and (2) the co-dependent economic incentives described next.

**b. Defendants plausibly had reason to know that other Defendants were involved in the same "broad project" to allocate the market.**

The other element of an overarching conspiracy is that Defendants "had reason to believe that their own benefits derived from the operation were probably *dependent upon the success of the entire venture*." *Gilead II*, 2020 WL 5507555, at *8 (emphasis in original) (quoting *Briscoe*, 896 F.2d at 1505). Evidence of this shared belief includes "economic actions and outcomes that are largely inconsistent with unilateral conduct but largely consistent with explicitly coordinated action." *Musical Instruments*, 798 F.3d at 1194. When firms act unilaterally in non-collusive markets, "the goal of any profit-maximizing firm is to obtain a monopoly by *capturing an ever increasing share* of the market." *State of Ill., ex rel. Burris v. Panhandle E. Pipe Line Co.*, 935 F.2d 1469, 1481 (7th Cir. 1991) (emphasis added). Analogously, "[i]n a competitive market, attempts to grow the pie by charging supracompetitive prices will be tempered by *price competition* as individual firms attempt to capture greater market share." *Musical Instruments*, 798 F.3d at 1195 (emphasis added). By contrast, "[w]hen firms in a market are able to coordinate their pricing and production activities, they can increase their collective profits and reduce consumer welfare by raising price and reducing output." *Costco Wholesale Corp. v. Maleng*, 522 F.3d 874, 896 (9th Cir. 2008) (citing John E. Lopatka & William H. Page, *State Action and the Meaning of Agreement Under the Sherman Act: An Approach to Hybrid Restraints*, 20 Yale J. on Reg.. 269, 311 (2003)).

Jazz's agreements with each Generic Defendant incentivized lower output and higher prices—the opposite of competitive behavior. The Jazz-Hikma agreement did so in two ways. To start, the Jazz-Hikma agreement plausibly delayed any Jazz AG for at least six months, thereby delaying any price competition between Jazz AG, Hikma AG, and Xyrem. Next, the agreement created a royalty structure that will charge Hikma a royalty rate that increases with Hikma's market share. This escalating royalty structure (1) disincentivizes output because "market share" is defined in terms of unit volume (*e.g.*, number of bottles); and (2) incentivizes higher prices because Jazz and Hikma can boost revenue while keeping volume low by raising prices. *See* Section III-A-2, *supra* (analyzing Jazz-Hikma agreement); *see generally, e.g.*, *Crystal*

*Semiconductor Corp. v. TriTech Microelectronics Intern., Inc.*, 246 F.3d 1336, 1359 (Fed. Cir. 2001) ("[C]onsumers will almost always purchase fewer units of a product at a higher price than at a lower price . . . ."). Supra-competitive prices are the result. *See, e.g.*, *Actavis*, 570 U.S. at 157 (discussing pharmaceutical collusion "to maintain supracompetitive prices").

Similarly, the Later Generic Defendants' agreements also limited each Later Generic Defendant to a low single-digit market share as defined by total units sold—again incentivizing higher prices because volumes were capped. *See* Sections III-A-3 and III-B-2, *supra* (analyzing agreements with Later Generic Defendants). The Later Generic Defendants' Agreements also immediately paid each Later Generic Defendant millions in cash to cease potentially meritorious patent challenges. These payments of "many millions of dollars" to a generic manufacturer are paradigmatic reverse payments. *Actavis*, 570 U.S. at 140.

Furthermore, *all* the agreements contained an acceleration clause. *See* CAC ¶¶ 225, 232, 253, 260, 267; UHS ¶¶ 177, 188, 191, 196, 203 (describing acceleration clauses). The acceleration clauses plausibly function as a cartel enforcement mechanism. *See* Section III-A-1-a, *supra* (detailing acceleration clauses). They do so by threatening a "reversion to competitive behavior"—*i.e.*, immediate entry by Hikma, Amneal, Par, and Lupin—if certain market events were to occur. Specifically, the acceleration clauses allow every Generic Defendant to immediately market their AG if (1) a generic version of Xyrem were to market itself without Jazz's permission; or (2) anyone were to successfully invalidate or render unenforceable Xyrem's unexpired patent claims. CAC ¶ 225; UHS ¶¶ 191, 196, 203; *accord, e.g.*, Hikma AG Agreement §§ 1.5.5, 2.8 (acceleration clause); Lupin AG Agreement § 1.4 (same). Thus, if any Generic Defendant were to try to seize more profit than its agreement with Jazz provides, that Generic Defendant would immediately face profit-crushing competition from the other Generic Defendants.

Such "penalt[ies]" for "firms exceeding their agreed upon shares" are cartel mechanisms that "give the firms a disincentive to steal sales from one another." Areeda & Hovenkamp, *supra*, ¶ 2006 & n.5. In other words, the Generic Defendants are bound together through mutually assured competition, if not mutually assured destruction. Thus, "[e]ven at the summary judgment

stage," courts have "found it significant for inferring the existence of a conspiracy that each generic competitor" agreed to an acceleration clause. *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc*, No. 15-CIV-6549-CM, 2018 WL 7197233, at *31 (S.D.N.Y. Dec. 26, 2018) (citing *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 254 (D. Mass. 2014), *aff'd*, 842 F.3d 34 (1st Cir. 2016)). It follows that acceleration clauses are even more "potent" evidence of a "conspiracy to monopolize" at the motion to dismiss stage. *Id.* (denying motion to dismiss).

In sum, Jazz's agreements with each Generic Defendant included "economic actions and outcomes that are largely inconsistent with unilateral conduct." *Musical Instruments*, 798 F.3d at 1194. It is thus plausible that Defendants "had reason to believe that their own benefits derived from the operation were probably *dependent upon the success of the entire venture*." *Gilead II*, 2020 WL 5507555, at *8 (emphasis in original) (quoting *Briscoe*, 896 F.2d at 1505). Accordingly, Plaintiffs have plausibly pled an overarching conspiracy to allocate the Xyrem market. In fact, if Jazz's agreements had not settled patent lawsuits, they would be "condemned as per se unlawful." *O'Bannon v. Nat'l Collegiate Athletic Ass'n*, 802 F.3d 1049, 1063 (9th Cir. 2015).

**2. Plaintiffs adequately allege that Jazz's settlements with the Later Generic Defendants are market allocation agreements (CAC Counts 8–10; UHS Counts 5, 7, and 8) under the rule of reason.**

Despite the plausible overarching conspiracy just described, Defendants also argue that Plaintiffs "fail to state a claim for unlawful horizontal market allocation." Mot. at 20. Specifically, Defendants argue that Jazz's volume-limited licenses are "generally exempt from antitrust scrutiny" because they merely exercise Jazz's patent rights. *Id.*

The Court disagrees. Granting Defendants a "general[] exempt[ion]" from antitrust scrutiny would contravene binding precedent. In *Actavis*, the Supreme Court squarely held that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Actavis*, 570 U.S. at 148. In fact, even before *Actavis*, "the [Supreme] Court ha[d] struck down overly restrictive patent licensing agreements—irrespective of whether those agreements produced supra-

patent-permitted revenues." *Id.* at 150. Thus, "[w]hether a particular restraint lies 'beyond the limits of the patent monopoly' is a *conclusion* that flows from [an] analysis" under the rule of reason, "not [the analysis's] starting point." *Id.* at 149 (emphasis in original).

Ninth Circuit precedent emphasizes the light burden Plaintiffs bear at the motion to dismiss stage. The Ninth Circuit has instructed that, when analyzing the effect of agreements under the rule of reason, "we must give plaintiffs 'the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each.'" *In re Nat'l Football League's Sunday Ticket Antitrust Litig.* ("*NFL Sunday Ticket*"), 933 F.3d 1136, 1152 (9th Cir. 2019) (quoting *City of Long Beach v. Standard Oil Co.*, 872 F.2d 1401, 1404–05 (9th Cir. 1989), *opinion amended on denial of reh'g*, 886 F.2d 246 (9th Cir. 1989)), *cert. denied sub nom. Nat'l Football League v. Ninth Inning, Inc.*, 141 S. Ct. 56 (2020). Applying this standard in *NFL Sunday Ticket*, the Ninth Circuit reversed the dismissal of claims that "defendants' interlocking agreements reduce[d] [] output" and raised prices. *Id.* at 1155, 1158.

Here too, Jazz's volume-limited licenses are plausibly anticompetitive market allocations that reduced output and raised prices. These licenses, as detailed in Section III-A-2 above, gave each Later Generic Defendant a limited right to sell a constrained supply of AG. Specifically, each license (1) began only after the expiration of Hikma's 180-day exclusivity period in July 2023; (2) was capped at a low-single-digit market share; and (3) required a royalty payment, as a percentage of sales, that increased over time. *See, e.g.*, Lupin AG Agreement § 1.27, 5, ECF No. 110-18 (Exh. 8). These licenses were also paired with acceleration clauses that plausibly deterred generic entry. *See* Section III-A-2-b-iii, *supra* (analyzing Jazz-Hikma acceleration clause and acceleration clauses generally). Giving Plaintiffs "the full benefit of their proof," the effect of this licensing scheme was anticompetitive. *NFL Sunday Ticket*, 933 F.3d at 1152 (quoting *City of Long Beach*, 872 F.2d at 1404–05). Indeed, in December 2019, Jazz's CEO boasted that "in terms of dynamics on price, it's – th[e] [market] is not what you would think of as a generic free for all" because of the "very limited volumes" for Par, Lupin, and Amneal. CAC ¶ 273 (emphasis omitted).

Furthermore, the authorities Defendants cite largely support *Plaintiffs*' position. Mot. at 20. Defendants cite three cases to argue that Jazz's licensing agreements are "generally exempt from antitrust scrutiny." Yet those cases subjected licensing agreements to rule of reason antitrust scrutiny. *See In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 838 (N.D. Ill. 2020) (applying the rule of reason); *In re Zetia (Ezetimibe) Antitrust Litig.*, No. CV 2:18-MD-2836, 2019 WL 1397228, at *20 (E.D. Va. Feb. 6, 2019) (same), *report and recommendation adopted as modified*, 400 F. Supp. 3d 418 (E.D. Va. 2019); *In re Novartis & Par Antitrust Litig.*, No. 18-CV-11835-AKH, 2019 WL 3841711, at *4 (S.D.N.Y. Aug. 15, 2019) ("[C]ase law uniformly supports the application of *Actavis* and the rule of reason approach to" market allocation claims). Defendants also cite the treatise *IP and Antitrust* to further argue against antitrust scrutiny of Jazz's licensing agreements with Generic Defendants. Yet that same treatise warns that "fears of competitive harm grow" where, as here, "the licensor [*i.e.*, Jazz] is itself a manufacturer" and licenses to other manufacturers. Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, Christopher R. Leslie, and Michael A. Carrier, *IP and Antitrust* § 32.01 (updated Nov. 2020).

Defendants are correct as to one point they make for the first time on reply, however. Reply at 11. Nothing supports United's allegations that Jazz's licensing agreements are per se violations of the Sherman Act. Sherman Act claims are examined "under one of two distinct tests: per se violation or rule of reason. Under the per se test, 'agreements whose nature and necessary effect are so plainly anti-competitive that no elaborate study of the industry is needed to establish their illegality' are found to be antitrust violations. For those activities not within the per se invalidity category, courts employ the rule of reason test." *Eichorn v. AT & T Corp.*, 248 F.3d 131, 138 (3d Cir. 2001), as amended (June 12, 2001) (quoting *Nat'l Soc'y of Prof. Eng'rs v. United States*, 435 U.S. 679, 692 (1978)). Here, as to allegations that Defendants have allocated a patented drug market, "case law uniformly supports the application of *Actavis* and the rule of reason approach." *In re Novartis & Par Antitrust Litig.*, 2019 WL 3841711, at *4 (collecting cases). Plaintiffs' per se allegations are few but do exist in United's complaint. *See* UHS ¶¶ 263, 292 (alleging "per se violations" of the Sherman Act and Minnesota Antitrust Law). Because the inapplicability of the

per se rule is clear here, the Court considers the argument that Defendants raise on reply and dismisses United's per se allegations against Defendants' market allocation scheme. Class Plaintiffs do not appear to make per se claims.

In sum, Defendants are wrong that Jazz's volume-limited licenses are "generally exempt from antitrust scrutiny." Mot. at 20. Those licenses receive antitrust scrutiny under the rule of reason. Accordingly, the Court grants in part and denies in part Defendants' motion to dismiss Plaintiffs' market allocation claims. Specifically, the Court only dismisses United's market allocation claims to the extent they allege that Jazz's licenses are antitrust violations per se. Lastly, because such per se allegations are legally futile, the Court dismisses them with prejudice. *See Leadsinger*, 512 F.3d at 532.

**3. Count 5 of the CAC and the UHS Complaint adequately notify Defendants of the challenged misconduct.**

Next, Defendants briefly argue that Count 5 of both the CAC and UHS complaint "fail to articulate the conduct they challenge" in three ways. Mot. at 22. First, Count 5 of the CAC—which is pleaded "against all Defendants," CAC ¶ 380—supposedly confuses Defendants because it "simply refer[s] to the individual patent litigation settlements entered into by each Defendant." Mot. at 22. Second, Count 5 of the UHS complaint supposedly confuses Defendants because it pleads not only an overarching conspiracy, but also four bilateral conspiracies "in the alternative." *Id.* (citing UHS ¶¶ 262–64). Third, Defendants argue that UHS Count 5 impermissibly "bring[s] [UHS] Counts 2, 3, and 4 back into the litigation" in violation of the Court's order limiting the number of claims to be initially litigated. *Id.* n.13 (citing Case Management Order, ECF No. 66 filed on March 19, 2021).

None of these arguments has merit. The Court addresses each in turn. To start, as summarized above, the complaints detail Defendants' alleged agreements and their alleged anticompetitive effects. *See, e.g.*, Section III-B-1, *supra* (summarizing alleged conspiracy); CAC ¶¶ 209–76; UHS ¶¶ 161–223 (alleging same). It thus strains credulity for Defendants to argue that they lack "'an idea of where to begin' in defending themselves." Mot. at 22 (quoting *Kendall v.*

*Visa USA, Inc.*, 518 F.3d 1042, 1047 (9th Cir. 2008)). Second, Federal Rule of Civil Procedure 8(d) expressly allows "alternative statements of a claim or defense"—"regardless of consistency." *Accord, e.g.*, *Molsbergen v. United States*, 757 F.2d 1016, 1018 (9th Cir. 1985) (holding same).

Lastly, Plaintiffs did not violate the Court's March 19, 2021 Case Management Order ("CMO") or any other order. That CMO ordered the Class Plaintiffs and Defendants to select 10 claims to initially litigate through resolution. ECF No. 66 at 2. Then, on March 24, 2021, United informed the Court that United's individual action against the same Defendants would soon be transferred to the instant multidistrict litigation. ECF No. 78. In response on March 30, 2021, the Court ordered the parties to address the overlap between (1) United's claims and (2) the Selected Claims. ECF No. 82.

On April 2, 2021, United represented that its claims "largely overlap with the class action claims and advance materially the same theories of liability." ECF No. 84 at 1. United thus agreed to initially litigate through resolution only the claims that overlap with the Selected Claims. *Id.* at 2. One of the claims that United publicly noticed was "Count 5" of its complaint, which had been filed on March 18, 2021 in Case No. 21-CV-02710-LHK, ECF No. 1. On April 7, 2021, the Court adopted United's proposal on which of United's claims should be first litigated through resolution. ECF No. 85. That adopted proposal included UHS Count 5. All told, Defendants have received fair notice of Plaintiffs' conspiracy claims.

**C. Plaintiffs adequately plead antitrust injury (CAC Counts 1, 5, 6, and 12; UHS Counts 1, 5, 6, and 11).**

Defendants' third ground for dismissal is that Plaintiffs inadequately plead antitrust injury. For context, to bring a federal antitrust claim, a private plaintiff must allege "antitrust injury." 15 U.S.C. §§ 15, 26 (Clayton Act §§ 4, 16); *see* Areeda & Hovenkamp, *supra*, ¶ 335 (summarizing antitrust injury requirement). Antitrust injury is "loss or damage 'of the type the antitrust laws were designed to prevent and that flows from that which makes defendants' acts unlawful.'" *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 113 (1986) (quoting *Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc.*, 429 U.S. 477, 489 (1977)). In turn, whether Plaintiffs' injury "flows

from" Defendants' anticompetitive acts depends on "common law principles of causation." *Pac. Shores Properties, LLC v. City of Newport Beach*, 730 F.3d 1142, 1169 (9th Cir. 2013) (quoting *Mead v. Retail Clerks Int'l Assoc., Local Union No. 839*, 523 F.2d 1371, 1376 (9th Cir. 1975)). "Causation is an intensely factual question that should typically be resolved by a jury." *Id.* at 1168. Thus, "once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand *summary judgment*"—let alone a motion to dismiss—"on the ground of absence of causation." *Id.* (emphasis added) (quoting *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 758 (7th Cir. 2011)).

Despite the lenient standard set forth above, Defendants make two arguments why "the complained-of-settlement agreements" did not cause Plaintiffs antitrust injury. Mot. at 10. Defendants first argue that "Plaintiffs fail to allege the Generic Defendants would have surmounted Jazz's patent portfolio." *Id.* at 10. Defendants next argue that, because the Later Generic Defendants may start to sell AGs in July 2023, the Jazz's settlements with the Later Generic Defendants will not prolong the period of supra-competitive prices. *Id.* at 12. As explained below, neither argument is persuasive.

**1. Plaintiffs need not allege how the Generic Defendants would have prevailed in the patent litigations.**

Defendants first argue that because Jazz's patents are allegedly valid, no injury stems from the challenged settlement agreements. Mot. at 10. Specifically, Defendants argue that Plaintiffs have inadequately pled that "'the outcome of the patent litigation [between the Generic Defendants and Jazz] was reasonably certain to favor' the Generic Defendants." Mot. at 11 (quoting *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.* ("*Lidoderm*"), 74 F. Supp. 3d 1052, 1072 & n.25 (N.D. Cal. 2014)). Defendants thus argue that regardless of the settlement agreements, Jazz's patents block the Generic Defendants from selling generic Xyrem. In short, the strength of Jazz's patents supposedly "act as an independent bar to Plaintiffs' claims of antitrust injury." *Id.*

The Court disagrees. As the United States Supreme Court has held—and the Fifth Circuit and unanimous California Supreme Court have confirmed—"it is normally not necessary to litigate patent validity to answer the antitrust question." *Impax Lab'ys, Inc. v. FTC*, 994 F.3d 484, 495 (5th Cir. 2021) (quoting *Actavis*, 570 U.S. at 157); *accord, e.g.*, *In re Cipro Cases I & II*, 348 P.3d 845, 870–71 & n.19 (Cal. 2015) (quoting and holding same); Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, Christopher R. Leslie, and Michael A. Carrier, *IP and Antitrust* § 16.01 & nn.276.44–49 (updated Nov. 2020) (collecting cases). Indeed, the case Defendants quote, *Lidoderm*, only reiterates this holding. In *denying* a motion to dismiss, *Lidoderm* held that a court "do[es] not need analyze the validity of the patents in the settled litigation in order to find the allegations adequate to meet the rule of reason." *Lidoderm*, 74 F. Supp. 3d at 1072.

*Actavis* explained why. There, the Supreme Court reasoned that "even a *small* risk of [patent] invalidity" often results in a reverse payment that "likely seeks to prevent the risk of competition"—a "consequence constitut[ing] the relevant anticompetitive harm." *Actavis*, 570 U.S. at 157 (emphasis added). Thus, "a court, by examining the size of the [challenged] payment, may well be able to assess its likely anticompetitive effects along with its potential justifications *without litigating the validity of the patent*." *Id.* at 158 (emphasis added). "In a word, 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." *Id.* (emphasis added).

Here, the alleged reverse payments are plausibly large and unexplained. The Court analyzes the reverse payment to Hikma first, followed by the reverse payments to the Later Generic Defendants.

Plaintiffs estimate that the value to Hikma from the Jazz-Hikma agreement is over $480 million just in the first 180 days after Hikma launches its AG (which is relabeled Jazz Xyrem). CAC ¶ 237 (estimating $480 million to $540 million); UHS ¶ 181 (estimating $705 million). During at least those 180 days, Hikma AG will be the only generic version of Xyrem on the market. Furthermore, in addition to being manufactured by Jazz, Hikma AG will be distributed by

Jazz's pharmacy, Express Scripts. Hikma and Jazz will thus share a "horizontal market division"—*i.e.*, an agreement among direct competitors to split the market—while Hikma AG is the only generic. Areeda & Hovenkamp, *supra*, ¶ 2045; *see generally, e.g.*, *California ex rel. Harris v. Safeway, Inc.*, 651 F.3d 1118, 1137 (9th Cir. 2011) (defining horizontal market division). In fact, because Jazz is the only manufacturer under the Jazz-Hikma agreement, Hikma and Jazz's market division is worse than a duopoly. "*Monopoly* exists when one firm controls all or the bulk of a product's output, and no other firm can enter the market, or expand output, at comparable costs." Areeda & Hovenkamp, *supra*, ¶ 403 (footnote omitted). Hikma and Jazz simply share Jazz's monopoly for at least 180 days.

Plaintiffs value Hikma's share of this monopoly at over $480 million based on the typical market share and price of generic drugs. As to market share, Plaintiffs allege that the Hikma AG—as the only generic—will capture approximately 80% to 90% of Xyrem sales. CAC ¶ 91, 237 (citing FTC 2011 AG Study); UHS ¶ 181. That is a plausible market share for a sole generic. *See, e.g.*, *Lidoderm*, 74 F. Supp. 3d at 1071 (holding same and citing FDA study); Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 Fordham L. Rev. 1835, 1848 (2013) ("[T]he generic version of a drug, on average, seizes 80 percent of brand-name drug sales within six months of the loss of patent protection."). As for price, Plaintiffs allege that "Hikma can price its generic product at a smaller discount (20%) to the branded price." UHS ¶ 181. This price difference is also plausible. "The first generic to enter the market typically costs 10 to 25 percent less than the branded drug; those discounts grow to between 50 and 80 percent once other generics enter." *Impax*, 994 F.3d at 488. Together, these market share and pricing assumptions value Hikma's settlement between $480 million and $540 million—even if Xyrem sales stay flat at approximately $1.5 billion and fail to grow through 2023. CAC ¶ 237. If, by contrast, "one conservatively assumes 8% annual increases" in Xyrem sales, Hikma's settlement is worth about $705 million. UHS ¶ 181; *see also* Jazz Form 10-K for 2020, at 76 (reporting 6% annual growth in Xyrem net sales); Jazz Form 10-K for 2019, at 63 (reporting 17% annual growth in Xyrem net

sales).

Yet it is immaterial whether the $480 million or $705 million estimate is more accurate. Even the lower estimate is more than enough to suggest that Jazz and Hikma "likely s[ought] to prevent the risk of competition" by shielding potentially invalid patents. *Actavis*, 570 U.S. at 157. The reason, as the *Actavis* Court explained, is that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Id.* Applying this analysis, both the *Actavis* Court and other courts have found that reverse payments in the tens of millions state an antitrust injury. *See, e.g.*, *Actavis*, 570 U.S. at 145 (payments of $12 million, $60 million, and $171–270 million); *Impax*, 994 F.3d at 494 (payment of $24.5 million). Accordingly, the Jazz-Hikma payment of over $480 million more than suffices.

Jazz's payments to the Later Generic Defendants are similarly suspect. The payments included (1) millions in cash; (2) a license to sell AG at a supra-competitive price; and (3) and acceleration clauses that enforce supra-competitive pricing. *See* Section III-A-2 (detailing reverse payments to Later Generic Defendants). The valuation of the license component alone is in the tens of millions. Specifically, Plaintiffs estimate that "every one percent of brand sales allocated in 2023"—the start of the licensing period—represents between $13.5 million to $19.8 million in sales. CAC ¶ 270 (estimating $13.5 million); UHS ¶ 206 (estimating $19.8 million). The range of the estimate depends on whether Xyrem sales stay flat or grow through 2023—the same plausible assumption from the Hikma settlement. *Id.* In any event, Jazz allocated each Later Generic Defendant several percentage points of the Xyrem market. *See, e.g.*, Lupin AG Agreement § 1.27, 5 (sealed low-single-digit percentage). Thus, the resulting value of each Later Generic Defendant's settlement is "at least [] tens of millions of dollars." CAC ¶¶ 255, 262, 269-70; UHS ¶¶ 193, 198, 205, 206. Again, these are "large and unexplain[ed] payment[s] exceeding any reasonable estimate of saved litigation costs." UHS ¶¶ 193, 198, 205, 206; *accord, e.g.*, *Actavis*, 570 U.S. at 145 (reversing dismissal of alleged $12 million reverse payment); *Impax*, 994 F.3d at 494 (estimating

average litigation costs to be "in the $5–$10 million range").

In sum, Plaintiffs have plausibly alleged reverse payments that, under *Actavis*, "suggest that [Jazz] has serious doubts about the patent[s]' survival." *Actavis*, 570 U.S. at 157. Accordingly, Plaintiffs need not detail how the Generic Defendants would have prevailed in the patent litigations. Rather, Plaintiffs' reverse payment allegations are enough to plead an antitrust injury. In short, "it is normally not necessary to litigate patent validity to answer the antitrust question." *Impax*, 994 F.3d at 495.

To argue otherwise, Defendants rely on two inapposite court of appeals cases. Mot. at 11. In *In re Wellbutrin XL Antitrust Litigation*, the Third Circuit relied on two factual findings at *summary judgment*. 868 F.3d 132, 169 (3d. Cir. 2017). First, the record at summary judgment showed that "assignor estoppel would have prevented [the generic] from arguing that the [] patent was invalid or that the patent was unenforceable because of inequitable conduct." *Id.* Second, an expert witness's "*unrebutted analysis*" showed that the generic "would only have a 20% chance of winning [its infringement] suit." *Id.* (emphasis added). The instant case is different. Here, Plaintiffs' detailed allegations at the motion to dismiss stage do not face an undisputed factual record of assignor estoppel or a mere 20% chance of prevailing in a patent infringement suit. *Wellbutrin* is thus inapposite. *See also, e.g.*, *In re Effexor Antitrust Litig.*, 337 F. Supp. 3d 435, 452 (D.N.J. 2018) (denying judgment on the pleadings and distinguishing *Wellbutrin* on similar grounds).

Defendants' other case, *In re Nexium (Esomeprazole) Antitrust Litigation*, 842 F.3d 34 (1st Cir. 2016), is even less apt. There, "upon the conclusion of plaintiffs' case in chief" at a *jury trial*, the district court saw "no evidence" that the brand manufacturer's patents were invalid. *Id.* at 63. The district court thus "requir[ed] some evidence of the patents' invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory." *Id.* The First Circuit affirmed this trial requirement. *Id.* In affirming, the First Circuit expressly distinguished "allegations of antitrust injury at the Rule 12(b)(6) stage." *Id.* at 62–63. The First Circuit further cited two other cases where courts of appeals rejected arguments like Defendants' arguments here. *See In re Cardizem*

*CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003) (holding that patent validity "merely raises a disputed issue of fact that cannot be resolved on a motion to dismiss"); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (rejecting argument that pending patent infringement suit blocks claim of anticompetitive delay).

Accordingly, at the motion to dismiss stage, Plaintiffs need not allege how the Generic Defendants would have prevailed in the patent lawsuits against Jazz.

**2. Plaintiffs adequately plead that the Later Generic Defendants caused antitrust injury.**

Defendants' other argument against antitrust injury also lacks merit. This argument, which spans only one paragraph in Defendants' 35-page motion, is that Jazz's settlements with the Later Generic Defendants will not prolong the period of supra-competitive prices allegedly caused by the Jazz-Hikma agreement. Mot. at 12. Defendants reason that the period of higher prices "is alleged to exist only between January 1, 2023 and July 1, 2023"—the 180 days during which Jazz has explicitly agreed that Hikma AG will be the sole third-party AG. *Id.* After July 1, 2023, Jazz will have the option to license an AG to other third parties, and Hikma will have the option to manufacture, market, and independently distribute an AB-rated generic. *Id.* (citing CAC ¶ 218; UHS ¶¶ 165–69). Defendants thus argue that, by the time the Later Generic Defendants begin to sell AGs in July 2023, the Jazz and Hikma generics will have reduced prices to competitive levels. *Id.*

Defendants' argument fails for two reasons. First, it ignores another competitive harm: if the Later Generic Defendants had not settled, they could have launched an AG or AB-rated generic *before* July 2023. Specifically, the Later Generic Defendants could have launched earlier in at least three ways. First, the Later Generic Defendants could have reached an alternative settlement with an earlier entry date and no reverse payments. *See, e.g.*, *Actavis*, 570 U.S. at 158 (describing such settlements). Second, the Later Generic Defendants could have pursued—and prevailed in—their patent litigation. *See id.* at 154–55 (describing same). Third, the Later Generic Defendants could have launched their AB-rated generics at risk while simultaneously pursuing patent litigation. *See,*

*e.g.*, *In re Glumetza Antitrust Litig.*, No. 19-CV-05822-WHA, 2021 WL 1817092, at *3 (N.D. Cal. May 6, 2021) (describing same).

The other reason Defendants' argument fails is that Plaintiffs plausibly allege that all Defendants were engaged in an overarching conspiracy to allocate the market for Xyrem and its generics. *See* Section III-B-2, *supra* (detailing alleged conspiracy). In this conspiracy, Defendants "ha[ve] reason to believe that their own benefits derived from the operation [are] *probably dependent upon the success of the entire venture*." *Gilead II*, 2020 WL 5507555, at *8 (emphasis in original) (quoting *Briscoe*, 896 F.2d at 1505). Price competition and increased output would plausibly doom the venture. *See* Section III-B-2, *supra* (analyzing, *e.g.*, single-digit market share allocations and acceleration clauses as cartel enforcement mechanisms). Thus, Jazz and Hikma lack an incentive to engage in the price competition that Defendants posit.

In short, Plaintiffs plausibly allege how Jazz's reverse payment settlements with the Later Generic Defendants delayed generic competition that otherwise would have occurred, thereby injuring consumers and entities, such as Plaintiffs, who pay for Xyrem. *See* Section III-A-2 and 3, *supra* (detailing reverse payments and market allocations); Section III-B, *supra* (detailing conspiracy). "Remove the pay, remove the delay." *Glumetza*, 2021 WL 1817092, at *14. Accordingly, Plaintiffs have adequately pled that Jazz's settlements caused antitrust injury.

**D. *Noerr-Pennington* doctrine does not require dismissal of Plaintiffs' monopolization claims under Sherman Act § 2 (CAC Count 6 and UHS Count 6).**

As their fourth ground for dismissal, Defendants contend the *Noerr-Pennington* doctrine requires dismissal of Plaintiffs' monopolization claims under Sherman Act § 2. The Court first summarizes the *Noerr-Pennington* doctrine and its exception for sham litigation. The Court then analyzes Defendants' *Noerr-Pennington* argument.

"Under the *Noerr-Pennington* doctrine, 'those who petition the government for redress are generally immune from antitrust liability.'" *AbbVie*, 976 F.3d at 359–60 (quoting *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.* ("*PRE*"), 508 U.S. 49, 56 (1993)). This "'right to petition extends to all departments of the Government,' including the courts." *Id.* (quoting *Cal.*

*Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972)). However, *Noerr-Pennington* immunity does not apply if a governmental petition is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Id.* (quoting *E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961)). This sham exception has two elements. First, the petition at issue "must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id.* (quoting *PRE*, 508 U.S. at 60–61). Second, the petitioner's "subjective motivation" must have been "to thwart competition." *Id.* (quoting *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 556 (2014)).

The sham exception is further strengthened by Ninth Circuit precedent. "The Ninth Circuit has held that 'whether something is a genuine effort to influence government action, or a mere sham for *Noerr-Pennington* purposes, is a question of fact." *Sonus Networks, Inc. v. Inventergy, Inc.*, No. 15-CV-0322-EMC, 2015 WL 4539814, at *2 (N.D. Cal. July 27, 2015) (original alterations omitted) (quoting *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1253 (9th Cir. 1982)). Thus, "courts rarely award *Noerr-Pennington* immunity at the motion to dismiss stage." *AbCellera Biologics Inc. v. Berkeley Lights, Inc.*, No. 20-CV-08624-LHK, 2021 WL 2719264, at *6 (N.D. Cal. July 1, 2021) (quoting *Sonus Networks*, 2015 WL 4539814, at *2).

With this framework in mind, the Court analyzes Defendants' *Noerr-Pennington* arguments below. Defendants' three arguments are that *Noerr-Pennington* immunizes (1) Jazz's REMS-related petitioning to the FDA; (2) Jazz's allegedly sham citizen petitions to the FDA; and (3) Jazz's allegedly sham litigation against generic manufacturers. The Court finds that *Noerr-Pennington* does not immunize Jazz's REMS-related petitioning or Jazz's allegedly sham litigation. As for Plaintiffs claims against Jazz's allegedly citizen petitions to the FDA, however, the Court finds those claims time-barred.

The Court notes that Defendants also moved to dismiss Plaintiffs' "product hop" allegations as not actionable under Sherman Act § 2. Mot. at 29–30. The product hop allegations,

in brief, are that Jazz has launched a new product (called Xywav) that extends Xyrem's patents and further deters the entry of any AB-rated generic. *See, e.g.*, UHS ¶¶ 2, 210, 230, 236. In their opposition, Plaintiffs clarified that the product hop allegations do not constitute a "viable stand-alone" claim. Thus, on reply, Defendants no longer sought to dismiss the product hop allegations after. Opp'n at 29 n.11 (clarifying product hop); *see* Reply (no longer mentioning product hop). Accordingly, the Court need not address the product hop allegations. *See, e.g.*, *Maciel v. Cate*, 731 F.3d 928, 932 n.4 (9th Cir. 2013) (holding that "failing to address [an argument] in [ ] reply brief" forfeits the argument).

**1. Jazz's REMS-related petitioning is not entitled to *Noerr-Pennington* immunity at the motion to dismiss stage.**

Defendants first argue that "Jazz's REMS-related petitioning to the FDA" is immune because Jazz prevailed before the FDA. Mot. at 28. Specifically, Defendants note that the FDA approved Jazz's petition for a single-pharmacy REMS, under which only Express Scripts may dispense Xyrem. *Id.* Defendants therefore assert that their REMS petitions were not "objectively baseless" under the first element of the sham exception to *Noerr-Pennington*.

The Court disagrees. Although Defendants are correct that "a *successful* action self-proves its [objective] reasonableness," Defendants' REMS petitions are not "successful" on the allegations here. *U.S. Futures Exch., L.L.C. v. Bd. of Trade of the City of Chicago, Inc.*, 953 F.3d 955, 963 (7th Cir. 2020) (emphasis in original). The FDA expressly held that its approval of Jazz's REMS "should not be construed or understood as agreement with Jazz." Memorandum from Trueman Sharp, Deputy Director for the Office of Generic Drugs, to ANDAs for sodium oxybate oral solution products, *et seq.* ("Sharp Memo") (Jan. 17, 2017) (UHS, Ex. B). Rather, the FDA approved Jazz's REMS to halt the "significant drain on [FDA] resources posed by the dispute, and the fact that the outcome of Jazz's challenge to the [FDA]'s legal authority to require a modification to a 'deemed REMS' had the potential to affect only a small number of drug products." Sharp Memo at 7–8. Such "[p]assive government approval is insufficient" for *Noerr-Pennington* immunity. *A.D. Bedell Wholesale Co. v. Philip Morris Inc.*, 263 F.3d 239, 251 (3d Cir.

2001).

Moreover, as Plaintiffs note, the FDA expressly doubted both (1) the objective merits of Jazz's REMS; and (2) Jazz's subjective motivations in proposing a single-pharmacy REMS. As to the objective merits, the FDA reiterated concerns by Dr. John K. Jenkins, Director of the Office of New Drugs. Specifically, Dr. Jenkins noted the uniquely exclusionary nature of Xyrem REMS and its "burdens on patient access and the healthcare delivery system":

> Our action approving the REMS submitted by Jazz *should not be construed or understood as agreement* with Jazz that limiting dispensing to a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh the risks under section 505-1 of the FD&C Act. We continue to be concerned that limiting the distribution of Xyrem to one pharmacy *imposes burdens on patient access and the healthcare delivery system*. *No other currently approved REMS* requires a sponsor to limit dispensing to a single pharmacy.

Sharp Memo at 8 (emphasis added). As for subjective motivations, the FDA expressly "note[d] the inconsistent position Jazz has taken on [REMS safety]"—an inconsistency which "suggest[ed] [Jazz's] *knowledge* that this aspect of its REMS *could have the effect of preventing generic competition*." *Id.* at 26 (emphasis added). The FDA reiterated this antitrust concern elsewhere in the Sharp Memo by again noting "Jazz's awareness that Xyrem REMS could have the effect of blocking or delaying approval of generic version of Xyrem." *Id.* at 12; UHS ¶ 136 (quoting same). Accordingly, Plaintiffs plausibly allege that Jazz's REMS-related petitioning to the FDA meets the sham exception to *Noerr-Pennington* immunity.

**2. Plaintiffs' sham citizen petition allegations are time-barred.**

Defendants next challenge Plaintiffs' allegations that Jazz filed "'baseless' citizen petitions with the FDA in an effort to slow down the ANDA review and approval process." Mot. at 29 (citing CAC ¶¶ 175–178; UHS ¶¶ 114–117). In Defendants' view, these allegations should be dismissed on two independent grounds. The first ground is *Noerr-Pennington* immunity. *Id.* The second ground is that Plaintiffs' claims are time-barred. *Id.*

The Court need not reach *Noerr-Pennington* immunity because the Court agrees—and Plaintiffs implicitly concede—that Plaintiffs' citizen petition allegations are time-barred. The

challenged citizen petitions were filed and addressed by the FDA in 2012. *See, e.g.*, CAC ¶¶ 175–81 (detailing timeline). As Defendants note, "[t]he longest conceivable limitations period for Plaintiffs' claims is six years (*see* Me. Rev. Stat. tit. 14, § 752; Wis. Stat. § 133.18(2)), meaning that the time for Plaintiffs to file any such claim ran in 2018." Mot. at 29. Plaintiffs fail to respond to this argument. *See* Opp'n 28–29 (failing to mention statute of limitations); Reply at 16–17 (noting failure to respond). Nor do Plaintiffs argue that equitable tolling may apply. Plaintiffs "ha[ve] forfeited this argument by failing to address it in [their] reply brief." *Maciel*, 731 F.3d at 932 n.4; *see also, e.g.*, *Stichting Pensioenfonds ABP v. Countrywide Fin. Corp.*, 802 F. Supp. 2d 1125, 1132 (C.D. Cal. 2011) (collecting cases holding same). Plaintiffs have thus conceded that their citizen petition allegations are time-barred.

Accordingly, the Court grants Defendants' motion to dismiss Plaintiffs' citizen petition allegations. "Because th[ese] [allegations] [are] time-barred, leave to amend [] would be futile." *Mark Castillo v. Countrywide Home Loans, Inc.*, No. 10-CV-03538-LHK, 2010 WL 4704429, at *4 (N.D. Cal. Nov. 12, 2010); *accord Del Toro v. Centene Corp.*, No. 19-CV-05163-LHK, 2020 WL 6081738, at *5 (N.D. Cal. Oct. 14, 2020) (collecting cases holding same). The Court thus dismisses with prejudice Plaintiffs' citizen petition allegations.

**3. Plaintiffs adequately plead the sham litigation exception to *Noerr-Pennington* immunity.**

Defendants again invoke *Noerr-Pennington* immunity against allegations that Jazz's serial patent infringement lawsuits abused the court system. Mot. at 30–31; *see also* Section I-A-2, *supra* (detailing sham litigation allegations). Specifically, Defendants argue that Plaintiffs' allegations "fail on the first prong" of the sham litigation exception: objective baselessness. Mot at 31. For support, Defendants rely on *International Longshore & Warehouse Union v. ICTSI Oregon, Inc.*, 863 F.3d 1178, 1188–89 (9th Cir. 2017), and *Kaiser Foundation Health Plan, Inc. v. Abbott Laboratories, Inc.*, 552 F.3d 1033, 1044, 1046 (9th Cir. 2009). Reply at 16.

The Court disagrees with Defendants. In fact, both of Defendants' cited cases show that Plaintiffs have adequately pleaded the sham litigation exception to *Noerr-Pennington* immunity.

The Court addresses each case in turn. In *International Longshore*, 863 F.3d at 1187, the Ninth Circuit gave nuance to the usual rule for objective baselessness. Specifically, the Ninth Circuit explained that "[i]n the context of a *series of alleged sham proceedings*, [] 'the question is *not whether any one suit has merit*[,] but whether they are *brought pursuant to a policy* of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.' In such a context, the legal success of an occasional sham suit is irrelevant." *Id.* (emphasis added) (quoting *PRE*, 508 U.S. at 60–61).

Here, Plaintiffs allege "a series of alleged sham proceedings" against generic manufacturers to delay generic entry. *Id.* Specifically, Jazz allegedly brought cyclical litigation in which Jazz would "assert a patent position, glean defenses to that position in the litigation, file new 'follow-on' patents, and then file a new lawsuit asserting those patents." Opp'n at 5 (citing CAC ¶¶ 155–61; UHS ¶¶ 104–09). For instance, Jazz sued Hikma for patent infringement *nine* times. CAC ¶¶ 151–62 (detailing suits). Jazz also brought at least eight other suits against Later Generic Defendants and five other later generics. CAC ¶¶ 183–85 (listing suits). Yet by March 2017, the Patent Trial Appeal Board ("PTAB") had invalidated as obvious one of Jazz's three asserted families of patents relating to REMS.[5] UHS ¶¶ 151–57.

Moreover, Jazz's lawsuits were plausibly "brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival." *Int'l Longshore*, 863 F.3d at 1187 (quoting *PRE*, 508 U.S. at 60–61). This type of anticompetitive policy is incentivized by "the ANDA context," as the Third Circuit recently explained. *AbbVie*, 976 F.3d at 361. Under the Hatch-Waxman Act, the filing of a lawsuit triggers an "automatic, 30-month stay" of any FDA approval of an ANDA—regardless of a suit's outcome. *Id.* at 340, 361; *accord Actavis*, 570 U.S. at 143 (explaining same). Thus, "[t]he automatic, 30-month stay is a collateral injury the defendant's mere use of legal process invariably inflicts." *AbbVie*, 976 F.3d at

[5] The invalidated REMS patents claimed methods of tracking drug prescriptions in a computer database. CAC ¶¶ 141–44.

361. From this "collateral injury," a district court may conclude that "in filing an objectively baseless lawsuit against [the generic manufacturer], the [brand name manufacturer] w[as] motivated not to assert a patent in good faith, but to impose expense and delay on [the generic manufacturer] to delay its entry into the [drug] market." *Id.* at 371.

Plaintiffs allege that Jazz exploited this 30-month stay to delay generic entry. Namely, Plaintiffs allege that each of Jazz's lawsuits—"irrespective of their prospects of success—triggered automatic 30-month stays, running from the date Jazz received the generic manufacturer's paragraph IV notice letter." CAC ¶ 185. These lawsuits began in November 2010 with Hikma's ANDA, CAC ¶ 151, and continued at least through November 2017 with a later generic manufacturer's ANDA. CAC ¶ 183. Jazz's lawsuits thus imposed a stay on ANDA approvals through at least mid-2020 (*i.e.*, 30 months from November 2017). Indeed, as of today, more than a decade later, there is no generic version of Xyrem. *E.g.*, UHS ¶ 5 (alleging monopoly through "at least 2023"). All told, Plaintiffs' allegations show that under *International Longshore*, it is plausible that Jazz brought lawsuits pursuant to an anticompetitive policy. *See Int'l Longshore*, 863 F.3d at 1187.

Defendants' other main case is *Kaiser Foundation*, 552 F.3d 1033. There, the Ninth Circuit rejected the sham litigation exception as to 17 infringement suits. *Id.* at 1046. Yet those 17 suits were, on their face, much more meritorious than Jazz's lawsuits here. Of the 17 suits in *Kaiser Foundation*, the patent holder "won seven." *Id.* Of the remaining ten suits, six were resolved in a published opinion by the Federal Circuit in light of intervening Supreme Court precedent. *Id.* at 1047. The last four suits either involved "a question of first impression" or a treaty provision that "had not been the subject of prior interpretation." *Id.* at 1046–47 (quoting *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1359 (S.D. Fla. 2004)).

Here, by contrast, Jazz did not prevail in any of its patent suits. To the contrary, the PTAB invalidated as obvious one of Jazz's three asserted families of patents relating to REMS. UHS ¶¶ 151–57. Nor is there any indication that Jazz's suits involved legal issues of first impression or issues subject to intervening Supreme Court precedent. On the pleadings and briefing here, Jazz's

suits plausibly involved one overarching purpose: imposing the "crushing burden" of litigation and the 30-month automatic stay to delay generic entry into the Xyrem market. *Kaiser Found.*, 552 F.3d at 1046 (quoting *USS-POSCO Industries v. Contra Costa County Building & Construction Trades Council*, 31 F.3d 800, 810–11 (9th Cir. 1994)). This is a harm that the sham litigation exception to *Noerr-Pennington* aims to prevent. *See, e.g.*, *AbbVie*, 976 F.3d at 371 (affirming that lawsuits were "an anticompetitive weapon" under the sham exception). Plaintiffs thus adequately plead the sham litigation exception to *Noerr-Pennington* immunity.

In sum, *Noerr-Pennington* doctrine does not require dismissal of Plaintiffs' monopolization claims under Sherman Act § 2. The Court therefore denies Defendants' motion to dismiss CAC Count 6 and UHS Count 6 on this ground.

**E. Plaintiffs inadequately plead federal antitrust standing for damages (CAC Counts 5, 6, and 12; UHS Counts 1, 5, 6, and 11).**

As noted in background Section I-B, Plaintiffs purchase or provide reimbursement for Xyrem nationwide. However, according to Defendants, Plaintiffs' federal antitrust claims for damages fail because "Plaintiffs are *indirect* purchasers who lack [antitrust] standing." Mot. at 31 (emphasis added). For support, Defendants rely on *Apple Inc. v. Pepper*, 139 S. Ct. 1514 (2019). In *Pepper*, the United States Supreme Court held that "[its] decision in *Illinois Brick* established a *bright-line rule* that authorizes suits by direct purchasers but *bars suits by indirect purchasers*." 139 S. Ct. at 1520 (emphasis added) (citing *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 746 (1977)). Defendants note that "Plaintiffs do not allege—nor can they—that they purchased Xyrem from any named Defendant and therefore cannot claim to be direct purchasers. Rather, Plaintiffs purchased Xyrem from a non-party, Express Scripts." Mot. at 32. Express Scripts is the exclusive pharmacy for Xyrem. *See* Section I-A-3-a (summarizing Jazz REMS). Thus, in Defendants' view, *Illinois Brick* and *Pepper* bar Plaintiffs' federal antitrust claims for damages.[6]

[6] The Ninth Circuit has held, and Defendants do not dispute, that "*Illinois Brick* doesn't apply to equitable relief." *Freeman v. San Diego Ass'n of Realtors*, 322 F.3d 1133, 1145 (9th Cir. 2003); *accord* Reply at 17 (not disputing same).

The Court agrees with Defendants. *Illinois Brick* "constrain[s] the class of parties that have statutory standing to recover damages through antitrust suits." *Del. Valley Surgical Supply Inc. v. Johnson & Johnson*, 523 F.3d 1116, 1120 (9th Cir. 2008). *Pepper* constrains that class of plaintiffs further by holding that *Illinois Brick* set forth a "bright-line rule," which "means that there is no reason to ask whether the rationales of *Illinois Brick* 'apply with equal force' in every individual case." *Pepper*, 139 S. Ct. at 1524 (quoting *Kansas v. UtiliCorp United, Inc.*, 497 U.S. 199, 216 (1990)).

Plaintiffs offer three arguments in response, but none is persuasive on the pleadings here. The first argument is that Plaintiffs' federal damages claims must survive because "[t]he rationale underlying *Illinois Brick* was to promote private antitrust claims, not discourage them." Opp'n at 33. The Supreme Court rejected a purposivist argument just like this in *Pepper*. Again, the *Pepper* Court held that "there is no reason to ask whether the rationales of *Illinois Brick* 'apply with equal force' in every individual case." *Pepper*, 139 S. Ct. at 1524 (quoting *UtiliCorp*, 497 U.S. at 216). The *Pepper* Court further stressed that "[w]e should not engage in 'an unwarranted and counterproductive exercise to litigate a series of exceptions.'" *Id.* (quoting *UtiliCorp*, 497 U.S. at 216). Following *Pepper*, this Court cannot explore whether Plaintiffs' "individual case" might qualify for some novel exception to *Illinois Brick*'s direct purchaser rule. *Id.*

Plaintiffs' second argument relies on *In re National Football League's Sunday Ticket Antitrust Litigation* ("*NFL Sunday Ticket*"), 933 F.3d 1136 (9th Cir. 2019), *cert. denied sub nom. Nat'l Football League v. Ninth Inning, Inc.*, 141 S. Ct. 56 (2020). According to Plaintiffs, *NFL Sunday Ticket* allows antitrust damages claims to proceed whenever Plaintiffs allege an antitrust conspiracy. Opp'n at 33 (citing *NFL Sunday Ticket*, 933 F.3d at 1156–58). Plaintiffs overread *NFL Sunday Ticket*. That case merely applied the settled co-conspirator exception to *Illinois Brick*. "[W]hen co-conspirators have jointly committed the antitrust violation, a plaintiff who is the immediate purchaser from any of the conspirators is directly injured by the violation." *NFL Sunday Ticket*, 933 F.3d at 1157.

Here, there is no allegation that any Plaintiff directly bought Xyrem from any Defendant.

Instead, Plaintiffs allege that they buy Xyrem through Express Scripts—"the sole specialty central pharmacy through which Xyrem is distributed." Opp'n at 32 (CAC ¶¶ 288–291; UHS ¶¶ 211–212). Express Scripts is not a Defendant, let alone an alleged co-conspirator in the conspiracy detailed in Section III-B-2, *supra*. *NFL Sunday Ticket* is thus inapposite.

Third and most significantly, Plaintiffs argue that Express Scripts is "owned or controlled" by Jazz. Opp'n at 29 (quoting *Illinois Brick*, 431 U.S. at 736 n.16). Such "owne[rship] or control[]" would allow Plaintiffs to sue Jazz (and its co-conspirators) for damages. *Illinois Brick*, 431 U.S. at 736 n.16. Yet Plaintiffs fail to show ownership and control here. Plaintiffs instead rely on distinguishable cases which, if applied here, would violate the Supreme Court's rule that "[w]e should not engage in 'an unwarranted and counterproductive exercise to litigate a series of exceptions.'" *Pepper*, 139 S. Ct. at 1524 (quoting *UtiliCorp*, 497 U.S. at 216); *accord UtiliCorp*, 497 U.S. at 216 ("The possibility of allowing an exception, even in rather meritorious circumstances, would undermine the [*Illinois Brick*] rule."). Neither Plaintiffs' in-circuit authority or out-of-circuit authority is availing. The Court addresses each set of authority in turn.

Plaintiffs cite two Ninth Circuit cases finding ownership or control. In those cases, the alleged antitrust violator actually owned the direct purchaser at issue. Specifically, in *Royal Printing Co. v. Kimberly Clark Corp.*, the Ninth Circuit held that "*Illinois Brick* does not bar an indirect purchaser's suit where the direct purchaser is a *division* or *subsidiary*." 621 F.2d 323, 326 (9th Cir. 1980) (emphasis added); *see* Opp'n at 30 (citing same). *Freeman v. San Diego Ass'n of Realtors* accordingly held that "*Royal Printing* applies because the associations [(*i.e.*, the antitrust defendants] own [the direct purchaser]." 322 F.3d 1133, 1146 & n.12 (9th Cir. 2003); *see* Opp'n at 29–30 (citing same). Here, by contrast, there is no allegation that Express Scripts is a division or subsidiary of any Defendant.

Plaintiffs' three out-of-circuit cases—which are district court cases predating *Pepper*—are also inapposite. *See* Opp'n at 30 (citing cases). In *Kentucky v. Marathon Petroleum Co.*, plaintiffs' sufficient allegations included that (1) the direct purchaser was in "economic unity" with defendant; and that (2) defendant, as a petroleum refiner, "control[ed] certain of its direct-

purchaser retailers through contractual provisions that waive the ability of those retailers to bring antitrust suits on their own." 2018 WL 4620621, at *10–11 (W.D. Ky. Sept. 26, 2018). Similarly, in *In re Mercedes-Benz Antitrust Litigation*, the leasing agent that stood between plaintiffs and defendants was "said to be a subsidiary" of a defendant. 157 F. Supp. 2d 355, 366 (D.N.J. 2001).

Here, by contrast, Plaintiffs do not allege that Express Scripts is in "economic unity" with a Defendant, let alone a subsidiary of a Defendant. Nor do Plaintiffs allege that Jazz controls Express Scripts "through contractual provisions that waive the ability of [Express Scripts] to bring antitrust suits." *Id.* at *11. To the contrary, the Jazz-Express Scripts Master Services Agreement[7] provides that "[Express Scripts] shall have sole discretion over the management and oversight of its Personnel," and will "reasonably consult" with respect to Jazz's "personnel recommendations." Jazz-Express Scripts Pharmacy Master Services Agreement § 2.7 (July 1, 2017), https://www.sec.gov/Archives/edgar/data/1232524/000123252417000134/jazzq22017ex102.htm. This provision belies Plaintiffs' assertion that Jazz controls Express Scripts.

Plaintiffs' last out-of-circuit case is *In re Lorazepam & Clorazepate Antitrust Litigation*, 202 F.R.D. 12, 25 (D.D.C. 2001). There, the direct purchasers at issue were *plaintiffs*' agents. *Id.* Specifically, the *Lorazepam* plaintiffs had each "execute[d] a written agreement appointing [the direct purchaser] as its agent." *Id.* (emphasis omitted) (quoting plaintiffs' affidavit). Here, by contrast, the issue is whether Express Scripts is a *Defendant's* agent. Moreover, there is no allegation that Jazz executed a written agreement expressly appointing Express Scripts as its agent.

All told, none of Plaintiffs' cited authority is persuasive. The Court therefore must heed the Supreme Court's rule that "[w]e should not engage in 'an unwarranted and counterproductive exercise to litigate a series of exceptions'" to *Illinois Brick*. *Pepper*, 139 S. Ct. at 1524 (quoting *UtiliCorp*, 497 U.S. at 216). Accordingly, the Court grants Defendants' motion to dismiss Plaintiffs' federal antitrust claims for damages. However, because granting Plaintiffs leave to

[7] The Jazz-Express Scripts Master Services Agreement is incorporated by reference in UHS ¶ 213, which cites the agreement and links to it in full.

amend would not be futile, cause undue delay, or unduly prejudice Defendants, and Plaintiffs have not acted in bad faith, the Court dismisses with leave to amend Plaintiffs federal antitrust claims for damages. *See Leadsinger*, 512 F.3d at 532.

**F. Plaintiffs' state law claims survive Defendants' motion to dismiss (CAC Counts 7–12; UHS Counts 7–9).**

Lastly, Defendants briefly argue that Plaintiffs' state law claims fail on three grounds. Mot. at 34–35. First, Defendants argue that the state law claims fail on the merits for the same reason that the federal claims purportedly fail on the merits. Second, Defendants argue Illinois, New Hampshire, Connecticut, Puerto Rico, and Utah have adopted *Illinois Brick*'s bar against lawsuits by indirect purchasers. Third, Defendants argue that Plaintiffs lack Article III standing within Hawaii, North Dakota, Vermont, Wyoming, and Puerto Rico.

The Court addresses each asserted ground for dismissal in turn. Ultimately, the Court dismisses just a few of Plaintiffs' state law claims. Specifically, the Court dismisses (1) state law claims to the extent they rely on the already dismissed sham citizen petition allegations; (2) Class Plaintiffs' class claims under Illinois law; and (3) Class Plaintiffs' individual claims under Utah law.

**1. Plaintiffs' state law claims do not fail on the merits.**

First, Defendants argue that Plaintiffs' state law claims fail on the merits. For support, Defendants note that the merits of the state law claims rise and fall with the federal claims. Mot. at 34. Plaintiffs do not dispute this. Opp'n at 33. As detailed in this order, however, only one of Plaintiffs' federal antitrust claims fail on the merits: Plaintiffs' sham citizen petition allegations are time-barred. *See* Section III-D-2, *supra* (analyzing and dismissing with prejudice citizen petition allegations).

Accordingly, as to Defendants' motion to dismiss Plaintiffs' state law claims on the merits, the Court grants the motion just on the sham citizen petition allegations. Because those allegations are time-barred and dismissed with prejudice, they cannot support Plaintiffs' state law claims. Otherwise, the Court denies Defendants' motion to dismiss Plaintiffs' state law claims on the

merits.

Having addressed Defendants' argument against the merits of the state law claims, the Court now turns to Defendants' next argument: that indirect purchasers such as Plaintiffs cannot bring suit under some state laws.

**2. Plaintiffs can largely bring indirect purchaser claims under state law.**

Second, Defendants argue that because Plaintiffs lack direct purchaser standing under *Illinois Brick*, Plaintiffs cannot bring claims under state laws that bar indirect-purchaser suits. Mot. at 35; *see* Section III-E, *supra* (analyzing *Illinois Brick*). Those laws include the antitrust statutes of Illinois, New Hampshire, Connecticut, Puerto Rico, and Utah. *See* Reply at 19 (not disputing Plaintiffs' arguments for Florida and Massachusetts law). Given the parties' perfunctory briefing here, the Court briefly addresses each state's law in turn.

**a. Illinois: Class Plaintiffs cannot maintain class claims.**

The Illinois Antitrust Act provides that "[n]o provision of this Act shall deny any person who is an indirect purchaser the right to sue for damages." Opp'n at 43 (quoting 740 Ill. Comp. Stat. Ann. 10/7). At first glance, this provision seems to foreclose Defendants' argument that only direct purchasers may bring suit. However, Defendants cite a proviso immediately following the general statement that Plaintiffs cite. This proviso provides that "that *no person* shall be authorized to maintain a class action in any court of this State *for indirect purchasers* asserting claims under this Act, with the sole exception of this State's Attorney General." 740 Ill. Comp. Stat. Ann. 10/7.

On the cursory briefing here, the Court agrees with Defendants. In particular, the Court is persuaded by the detailed analysis of its sister court in *Lidoderm*, 74 F. Supp. 3d at 1083. There, United States District Judge William Orrick III explained why the class action limitation in the Illinois Antitrust Act is in fact "intertwined with Illinois substantive rights and remedies." *Id.* at 1084 (citing *In re Wellbutrin XL Antitrust Litig.*, 756 F. Supp. 2d 670, 677 (E.D. Pa. 2010). Because that class action limitation is substantive, it displaces Federal Rule of Civil Procedure 23's usual allowance of class actions in diversity actions. *Id.* (distinguishing *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393 (2010)). Judge Orrick therefore

dismissed the *Lidoderm* plaintiffs' Illinois Antitrust Act claims. *Id.*

Applying *Lidoderm*'s holding here, Class Plaintiffs cannot maintain their class claims against Defendants under Illinois law. By contrast, as an individual plaintiff, United may proceed with any indirect purchaser claim under Illinois law.

**b. New Hampshire: Plaintiffs' claims survive.**

Defendants' argument as to New Hampshire is meritless. Defendants argue that "[t]he New Hampshire Supreme Court expressly adopted the *Illinois Brick* rule against indirect purchaser suits in *Minuteman, LLC v. Microsoft Corp.*, 795 A.2d 833, 838 (N.H. 2002)," a case which construed N.H. Rev. Stat. § 356:11 (1995). Reply at 19. Yet Defendants fail to mention that effective January 1, 2008, New Hampshire superseded *Minuteman* by statute. The current version of N.H. Rev. Stat. § 356:11 provides that "any person" may bring suit "*regardless of whether that person dealt directly or indirectly with the defendant*." N.H. Rev. Stat. § 356:11(II) (adding emphasis on new statutory text). Defense counsel—who include at least 16 lawyers across six major law firms—should have brought this statutory revision to the Court's attention. In short, Plaintiffs' claims under New Hampshire law may proceed.

**c. Connecticut: Plaintiffs' claims survive.**

Defendants' argument as to Connecticut law also lacks merit. In their motion to dismiss, Defendants' only support for its conclusory argument against Connecticut (as well as Florida, Illinois, Massachusetts, and Puerto Rico) was one citation—in a footnote—to a 2015 case from this district. Mot. at 35 & n.20 (citing *In re Lidoderm Antitrust Litig.*, 103 F. Supp. 3d 1155, 1163–64 (N.D. Cal. 2015)). Yet as Plaintiffs correctly noted in their opposition, Connecticut passed a law abrogating any *Illinois Brick* requirement in October 2017. *See Health Care Providers—Pharmacists—Confidential or Privileged Information*, 2017 Conn. Legis. Serv. P.A. 17-241 (S.B. 445) (West) (providing that an antitrust defendant "[m]ay not assert as a defense that the defendant did not deal directly with the person on whose behalf the action is brought" (codified at Conn. Gen. Stat. Ann. § 35-46a(1))).

On reply, Defendants failed to acknowledge another misleading omission of an intervening

change in law. Instead, Defendants proffered a new argument: that Connecticut's statutory amendment is not retroactive. Reply at 20. Defendants cite only *Spinner Consulting LLC v. Stone Point Cap. LLC*, 623 B.R. 671, 678 (D. Conn. 2020), *aff'd on other grounds*, 843 F. App'x 411 (2d Cir. 2021), for this retroactivity point.

*Spinner* is unpersuasive. In *Spinner*, the challenged conduct ceased before 2018. *Spinner*, 623 B.R. at 675, 677. Here, by contrast, Plaintiffs allege that Jazz's anticompetitive agreements will maintain Jazz's unlawful monopoly "through at least January 1, 2023." CAC ¶ 296. Regardless, "[a]rguments raised for the first time in a reply brief are waived." *E.g.*, *McReynolds v. Merrill Lynch & Co.*, 694 F.3d 873, 889 n.9 (7th Cir. 2012). Thus, Plaintiffs' Connecticut law claims may proceed.

**d. Puerto Rico: Plaintiffs' claims survive.**

To argue that Plaintiffs' Puerto Rico law claims should be dismissed, Defendants cite one case: *Staley v. Gilead Sciences, Inc.* ("*Gilead I*"), 446 F. Supp. 3d 578, 626–68 (N.D. Cal. 2020). There, United States District Judge Edward Chen surveyed the conflicting district court authority on whether Puerto Rico allows indirect purchaser suits. Following several district courts and colleague Judge Orrick from this district, Judge Chen concluded that Puerto Rico has adopted the *Illinois Brick* rule. *Id.* at 628 (citing *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1086 (N.D. Cal. 2014)). Judge Chen thus held that Puerto Rico law bars indirect purchaser suits.

The Court respectfully disagrees with Judges Chen and Orrick on this question. As some district courts have recognized, both the Puerto Rico Supreme Court and the U.S. District Court for the District of Puerto Rico have not limited antitrust standing to direct purchasers. *See, e.g.*, *In re Zetia (Ezetimibe) Antitrust Litig.*, 400 F. Supp. 3d 418, 433 (E.D. Va. 2019) (holding same); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc*, No. 15-CV-06549-CM, 2018 WL 7197233, at *23 (S.D.N.Y. Dec. 26, 2018) (same). Rather, Puerto Rico's district court has expressly held that "it is immaterial whether Plaintiffs are direct or indirect purchasers." *Rivera-Muniz v. Horizon Lines Inc.*, 737 F. Supp. 2d 57, 61 (D.P.R. 2010) (citing *Pressure Vessels of P.R.,*

*Inc. v. Empire Gas de P.R.*, 137 D.P.R. 497, 509–18 (1994)). For support, the *Rivera-Muniz* Court cited the Puerto Rico Supreme Court's decision in *Pressure Vessels*. There, the Puerto Rico Supreme Court held, somewhat circumspectly, "that the plaintiff need not establish anything beyond a factual causal relation between the injury and the violation" to have antitrust standing under Puerto Rico law. *Pressure Vessels*, 137 P.R. Dec. 497 (English translation; no pincite).

Following Judge Orrick, Judge Chen found *Pressure Vessels* inapposite because it did not expressly discuss *Illinois Brick*. *Gilead I*, 446 F. Supp. 3d at 627. Judge Chen thus found *Rivera-Muniz* unpersuasive because it appeared to overread *Pressure Vessels*, a Puerto Rico Supreme Court case. *Id.*

By contrast, the Court finds that *Pressure Vessels* did address *Illinois Brick*. Even though the *Pressure Vessels* Court did not cite *Illinois Brick* itself, it did cite and criticize four United States Supreme Court cases that explicitly applied *Illinois Brick*. *See Pressure Vessels*, 137 P.R. Dec. 497 (citing *Kansas v. Utilicorp United, Inc.*, 497 U.S. 199 (1990); *Blue Shield of Virginia v. McCready*, 457 U.S. 465 (1982); *Associated General Contractors v. Carpenters*, 459 U.S. 519 (1983); and *Pfizer, Inc. v. Gov't of India*, 434 U.S. 308 (1978)). In *UtiliCorp*, for instance, the U.S. Supreme Court strictly barred indirect purchaser suits "even assuming that any economic assumptions underlying the *Illinois Brick* rule might be *disproved* in a specific case." *UtiliCorp*, 497 U.S. at 217 (emphasis added). Thus, the Puerto Rico Supreme Court was almost certainly aware of *Illinois Brick* when the Puerto Rico Supreme Court held—contrary to *Illinois Brick*—that an antitrust plaintiff "need not establish anything beyond a factual causal relation between the injury and the violation." 137 P.R. Dec. 497.

If the Court's reading of *Pressure Vessels* is correct, then the Court must also hold that indirect purchaser standing is allowed under Puerto Rico law. *See Vazquez-Filippetti v. Banco Popular de Puerto Rico*, 504 F.3d 43, 48 (1st Cir. 2007) (holding that the First Circuit is bound by the Puerto Rico Supreme Court in diversity cases). Yet even if the correct reading of *Pressure Vessels* is unclear, what is clear is that the Court owes "deference to the local district judges of Puerto Rico on matters of Puerto Rican law." *Rodriguez v. Escambron Dev. Corp.*, 740 F.2d 92, 96

(1st Cir. 1984) (collecting cases). In *Rivera-Muniz*, the Honorable Gustavo Gelpí—the Chief Judge of the U.S. District Court for the District of Puerto Rico and present nominee to the U.S. Court of Appeals for the First Circuit—held that indirect purchasers have standing under Puerto Rico law. *See Rivera-Muniz*, 737 F. Supp. 2d at 61 ("[I]t is immaterial whether Plaintiffs are direct or indirect purchasers.").

In sum, given the Court's own reading of *Pressure Vessels* and the deference owed to Judge Gelpí's *Rivera-Muniz* decision, the Court holds that indirect purchasers have antitrust standing under Puerto Rico law. Thus, Plaintiffs' Puerto Rico claims may also proceed.

**e. Utah: Class Plaintiffs can maintain class claims, but not individual claims.**

The Utah Antitrust Act allows "[a] person who is a *citizen of this state or a resident of this state*" to bring suit for antitrust injury. Utah Code Ann. § 76-10-3109(1)(a) (emphasis added). Defendants argue that because no Plaintiff is a citizen or resident of Utah, Plaintiffs' claims under Utah law must be dismissed. Mot. at 35.

The Court agrees in part as to Class Plaintiffs, but entirely disagrees as to United. Informing this conclusion is the Fourth Circuit's recent decision *Mayor of Baltimore v. Actelion Pharmaceuticals Ltd.*, 995 F.3d 123 (4th Cir. 2021). There, the Fourth Circuit synthesized a two-part approach for evaluating, at the motion to dismiss stage, the standing of class plaintiffs who cannot "satisfy the statutory requirements of the laws of the States they are invoking." *Id.* at 133–34. The Fourth Circuit explained that, on the one hand, these class plaintiffs "may not seek relief for their *own* injuries under those States' statutes." *Id.* (emphasis added). On other hand, these class plaintiffs have standing to assert "*class members*' claims" on behalf of class members who *can* satisfy states' statutory requirements. *Id.* (emphasis in original); *accord, e.g.*, *In re Asacol Antitrust Litig.*, 907 F.3d 42, 50 (1st Cir. 2018) (holding same and collecting court of appeals precedent); *Langan v. Johnson & Johnson Consumer Companies, Inc.*, 897 F.3d 88, 93 (2d Cir. 2018) (same). Thus, it was reversible error for the *Actelion* district court to dismiss the class plaintiffs' class claims. *Actelion Pharma.*, 995 F.3d at 134. The Fourth Circuit held that the district court should have delayed concerns about class treatment to the class certification stage. *Id.*

The Court follows the Fourth Circuit's approach here. Because Class Plaintiffs do not personally satisfy the citizenship or residency requirement of the Utah Antitrust Act, Class Plaintiffs "may not seek relief for their own injuries under" the Utah Antitrust Act. *Id.* Yet Class Plaintiffs' class claims on behalf of Utah citizens or residents "need not be stricken or disregarded." *Id.*

United, for its part, has asserted claims of its UnitedHealthcare Plans affiliate assignors, including "UnitedHealthcare of Utah, Inc." Opp'n at 34 (citing UHS ¶ 10, Ex. A). Defendants do not argue that this Utah assignor-plaintiff would be inadequate. Reply at 20. Thus, United's claim under Utah law may proceed.

In sum, the Court grants Defendants' motion to dismiss Class Plaintiffs' (1) class claims under Illinois law; and (2) individual claims only under Utah law. The Court otherwise denies Defendants' motion to dismiss Plaintiffs' other state law claims. Moreover, because granting Class Plaintiffs leave to amend would not be futile, cause undue delay, or unduly prejudice Defendants, and Class Plaintiffs have not acted in bad faith, the Court grants the Class Plaintiffs leave to amend the dismissed claims. *See Leadsinger*, 512 F.3d at 532.

**3. Plaintiffs have Article III standing.**

Finally, Defendants argue that Plaintiffs lack Article III standing to bring claims under the laws of five jurisdictions: Hawaii, North Dakota, Vermont, Wyoming, and Puerto Rico. Mot. at 35. Defendants reason that Plaintiffs have failed to allege that any Plaintiff "paid for and/or provided reimbursement for Xyrem in" those five jurisdictions. Mot. at 35.

The Court disagrees. Defendants have conflated Article III standing with so-called "statutory standing." As the Fourth Circuit explained in *Actelion Pharmaceutical*, "unlike Article III standing, statutory standing considers 'whether a cause of action exists under a particular statute.'" *Actelion Pharms.*, 995 F.3d at 134 (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 97 & n.2 (1998)). Thus, it is often immaterial to Article III standing that class plaintiffs "did not allege facts to show that they satisfied the statutory requirements of" some states' antitrust laws. *Id.* Those class plaintiffs may still have Article III standing to represent a class containing

members who *do* satisfy those statutory requirements. *Id.* Several other circuits have held the same. *See In re Asacol Antitrust Litig.*, 907 F.3d at 49–50 (holding same); *Langan*, 897 F.3d at 93 (same); *Morrison v. YTB Int'l, Inc.*, 649 F.3d 533, 536 (7th Cir. 2011) (same).

Here too, Class Plaintiffs have Article III standing to represent individuals affected by Xyrem overcharges in at least the five jurisdictions that Defendants challenge. Whether Class Plaintiffs are typical representatives of such individuals—or whether all these individuals together satisfy Rule 23(b)(3) predominance—is a question for class certification. *See Actelion Pharms.*, 995 F.3d at 134 (deferring same to class certification).

As to United, Defendants' standing argument is inapposite. United, as a third-party payor, paid for and/or provided reimbursement for United members "in all 50 states, the District of Columbia, and Puerto Rico." UHS ¶¶ 7–9. United therefore has Article III standing where its members transacted with a pharmacy to obtain Xyrem. *See In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 695 (E.D. Pa. 2014) (collecting cases). Defendants do not argue otherwise. In short, Plaintiffs have adequately pleaded Article III standing.

## IV. CONCLUSION

For the foregoing reasons, the Court GRANTS IN PART and DENIES IN PART Defendants' Motion to Dismiss Counts 1, 5–12, and 17 of the Consolidated Class Action Complaint and Counts 1, 5-9, and 11 of United Healthcare Services' Complaint. ECF No. 109. Specifically, the Court GRANTS the motion to dismiss the following with prejudice:

- In UHS Counts 5, 7, and 8: United's market allocation claims to the extent they allege that Jazz's licenses are antitrust violations per se.
- In CAC Count 6; UHS Count 6; and any related state law Counts (CAC Counts 7–12; UHS Counts 7–9): Plaintiffs' allegations against Jazz's citizen petitions to the FDA.

The Court GRANTS the motion to dismiss the following with leave to amend:

- In CAC Counts 5, 6, and 12; UHS Counts 1, 5, 6, and 11: Plaintiffs' federal antitrust claims for damages.
- In CAC Counts 7–12; UHS Counts 7–9: Class Plaintiffs' class claims under Illinois law

and individual claims under Utah law.

The Court DENIES the motion to dismiss as to all remaining claims.

Should Plaintiffs elect to file one consolidated amended complaint curing the deficiencies identified herein, Plaintiffs shall do so within 30 days of the date of this order. Failure to meet the 30-day deadline to file an amended complaint or failure to cure the deficiencies identified in this order or Defendants' motion to dismiss will result in dismissal of the deficient claims with prejudice. Plaintiffs may not add new causes of action or parties without leave of the Court or stipulation of the parties pursuant to Federal Rule of Civil Procedure 15. Plaintiffs are directed to file redlines comparing the CAC and UHS complaint to any amended complaint as an attachment to Plaintiffs' amended complaint.

**IT IS SO ORDERED.**

Dated: August 13, 2021

Lucy H. Koh

LUCY H. KOH
United States District Judge