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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE XYREM (SODIUM OXYBATE) ANTITRUST LITIGATION

This Document Relates to All Actions

No. 5:20-md-02966-LHK

CONSOLIDATED CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

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I. INTRODUCTION

1. This civil antitrust action seeks treble damages and injunctive relief to address Defendants' anticompetitive scheme to delay generic competition for Xyrem, a prescription sodium oxybate drug product sold by Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals Ireland Limited, and Jazz Pharmaceuticals Public Limited Company (collectively "Jazz") for the treatment of cataplexy and daytime sleepiness in patients with narcolepsy.

2. Plaintiffs seek overcharge damages arising from a series of anticompetitive acts Jazz has undertaken to restrain competition in the market for sodium oxybate in the United States,[1] including: (i) abusing the Food and Drug Administration's ("FDA's") system for monitoring of medications with a high potential for serious adverse effects, and frustrating efforts of would-be generic competitors to obtain FDA approval; (ii) obtaining and enforcing bogus patents, and improperly listing these patents in the FDA's Orange Book; and (iii) filing Citizen Petitions with the FDA in an effort to delay the review and approval of Abbreviated New Drug Applications ("ANDAs") for generic versions of Xyrem. Since 2017, Jazz has entered a series of market allocation and reverse payment agreements with its would-be generic competitors by way of settlements of patent lawsuits against Defendants Hikma (which was the first company to file for approval of generic Xyrem, and has now agreed to delay entry of its FDA-approved generic until at least 2023), Amneal, Lupin, and Par.[2]

3. Defendants' anticompetitive conduct has prevented, delayed, and/or restricted competition in the market for Xyrem and its AB-rated generic versions of Xyrem in the United

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[1] "United States" is defined herein to include the United States, its territories, possessions, and the Commonwealth of Puerto Rico.

[2] The defendant generic companies are 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"), which are all related companies, and Amneal Pharmaceuticals LLC ("Amneal"), Par Pharmaceuticals, Inc. ("Par"), and Lupin Ltd, Lupin Pharmaceuticals Inc., and Lupin, Inc. (collectively "Lupin").

States. As a direct and proximate result, no generic version of Xyrem has entered the market to date, and full generic competition will not occur until at least December 31, 2025.

4. Xyrem was launched by Orphan Medical, Inc. ("Orphan") in 2002. Jazz acquired Orphan in 2005, and Xyrem quickly became Jazz's singularly most important drug, accounting for approximately 72 percent of its revenues by 2007. Since 2007, Jazz has incrementally raised the price of Xyrem from $2.04 per milliliter to $31.21, an increase of over 1,430%. For a patient taking a dosage in the middle of the effective range, the monthly cost of Xyrem exceeds $14,000.[3] Net sales of Xyrem were $1.64 billion in 2019, representing 76% of Jazz's total revenue for that year.[4] Jazz has profited handsomely from its Orphan acquisition and now improperly seeks to insulate Xyrem from less expensive generic entry.

5. Hikma was the first generic manufacturer to file an ANDA with the FDA seeking approval to manufacture, market, and sell a generic version of Xyrem. Hikma's ANDA included a certification that Jazz's patents covering Xyrem were invalid, unenforceable, and/or would not be infringed by Hikma's less expensive generic version. As the first ANDA filer, Hikma was entitled to 180 days of market exclusivity under the Hatch-Waxman Act[5] during which time no other unlicensed generic company could enter the market. This exclusivity period was potentially worth hundreds of millions of dollars to Hikma,[6] giving the company a strong incentive to bring its generic to market as soon as possible. Jazz could create competition in the first 180 days of the generic market with

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[3] *See Xyrem Prices, Coupons and Patient Assistance Programs*, Drugs.com, https://www.drugs.com/price-guide/xyrem (last updated Feb. 2, 2021); *Xyrem Dosage*, Drugs.com, https://www.drugs.com/dosage/xyrem.html (last updated Feb. 2, 2021) (effective dose range is 6-9 grams of sodium oxybate nightly; Xyrem solution contains 0.5 grams of sodium oxybate per milliliter).

[4] Jazz Pharmaceuticals plc, Annual Report (Form 10-K) at 63 (Feb 25, 2020).

[5] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). *See infra* Section IV for a detailed explanation of the regulatory structure put in place by the Hatch-Waxman Act.

[6] *See FTC v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223, 2229 (2013) ("[The] 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars.").

Hikma by licensing its product to a company to sell an "authorized generic" (AG)[7] version of Xyrem (i.e., a generic that is manufactured and sold under the brand's New Drug Application).

6. Rather than compete against the generic entrants, Jazz decided it would collude with and incentivize them to delay market entry. To avoid competition and the catastrophic loss of Xyrem market exclusivity, Jazz decided to foreclose competition by paying Hikma, the first ANDA filer, to delay launching its generic until at least July 1, 2023. This essentially created a "bottleneck" preventing other generic competitors from more timely entering the market. The Jazz/Hikma patent infringement settlement agreement gave Hikma: (i) an exclusive license to sell an AG for six months beginning January 1, 2023 (during which time Jazz would not license a competing AG); (ii) a license to sell its own generic from July 1, 2023 until December 31, 2025; and (iii) protection against a potential product hop, which made Hikma more willing to accept a later entry date.

7. Jazz's settlements with Hikma and the other generic manufacturers effectively allocated the market for sodium oxybate in the United States according to the following schedule:

- *July 2017 through December 31, 2022*: Branded Xyrem maintains its monopoly.
- *January 1, 2023 through June 30, 2023*: Hikma sells an AG (without competition from any other AG). During this time, the only versions of sodium oxybate on the market would be the Jazz's branded product and Hikma's AG.
- *July 1, 2023 through December 30, 2025*: Hikma may sell its own ANDA generic product, while other generic manufacturers may sell AGs in very limited quantities—small enough that they cannot create meaningful price competition (thus ensuring that Jazz and Hikma maintain the lion's share of market sales).
- *December 31, 2025*: Other generic manufacturers may launch their own generics and full competition in the sodium oxybate market will begin.

[7] An authorized generic, or "AG," is the brand product sold as a generic version at a lower price. *See* FDA, *List of Authorized Generic Drugs* (Apr. 1, 2020), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs.

8. As a result of the settlement agreements, Jazz will maintain complete control of the sodium oxybate market in the United States until at least January 1, 2023, and full generic competition will not occur until at least December 31, 2025.

9. Through Jazz's overarching anticompetitive scheme and by the unlawful payoffs to its would-be competitors, generic competition in the market for sodium oxybate oral solution was impaired and delayed, perhaps as long as until the end of 2025. Defendants have subverted the purpose and intent of the Hatch-Waxman Act, which is designed to quickly get less expensive generic drugs into the hands of consumers. Absent Jazz's unlawful conduct, free and unrestrained competition in the Xyrem market would have begun as early as July 2017. As a direct and proximate result, Plaintiffs and all other Class members have paid, and continue to pay, significant overcharges for Xyrem. On behalf of themselves and all others similarly situated, Plaintiffs seek damages equal to the amount they have already overpaid, treble damages, and injunctive relief to put an end to the overcharges they will continue to pay.

II. PARTIES

A. Plaintiffs

1. A.F. of L. – A.G.C. Building Trades Welfare Plan

10. Plaintiff A.F. of L. – A.G.C. Building Trades Welfare Plan ("A.F.L. Plan") is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. A.F.L. Plan purchases, pays and/or provides reimbursement for some or all of the purchase price of prescription drugs dispensed to its plan participants. A.F.L. Plan represents participants who purchased and/or were provided reimbursement for some or all of the purchase price of Xyrem.

11. During the class period, A.F.L. Plan purchased, paid for, and/or provided reimbursement for some or all of the price of prescriptions of Xyrem, i.e., sodium oxybate oral solution approved under the Xyrem NDA, at supracompetitive prices in Alabama and therefore suffered antitrust injury and lost money or property as a result of the anticompetitive conduct alleged in this complaint. The Xyrem prescriptions that A.F.L. Plan purchased, paid for, or provided

reimbursement for were for its participants' personal use. A.F.L. Plan intends to continue purchasing, paying for, and/or providing reimbursement for Xyrem and will be injured in the future.

2. Blue Cross Blue Shield Association

12. Plaintiff Blue Cross Blue Shield Association ("BCBSA") is a national association of 35 independent and locally operated Blue Cross Blue Shield ("BCBS") companies providing health plans to over 107 million members nationwide. BCBSA's principal place of business is in Chicago, Illinois 60601. BCBSA brings this action in its capacity as the carrier of the Service Benefit Plan, one of the Federal Employee Health Benefits Plans ("FEHBP"). Beginning in 1960, the Office of Personnel Management ("OPM") contracted with BCBSA under the Federal Employees Health Benefits Act ("FEHBA") to establish the government-wide FEHBP known as the Service Benefit Plan, also commonly known as the Federal Employee Program ("FEP"). FEP has the largest enrollment of any FEHBP. Pursuant to plan participation agreements between BCBSA and BCBS companies, BCBSA contracts with OPM for BCBS companies to underwrite and administer FEP in their individual locales. However, BCBSA pays for drugs purchased by FEP enrollees, including the drugs at issue in this case. As the carrier under the contract with OPM and under the plan participation agreements, BCBSA has the sole authority to make decisions to bring actions on behalf of the FEP.

13. During the class period, FEP purchased, paid for, and/or provided reimbursement for some or all of the price of thousands of prescriptions of Xyrem, i.e., sodium oxybate oral solution approved under the Xyrem NDA, at supracompetitive prices in Alabama, Alaska, Arkansas, Arizona, California, Colorado, Connecticut, District of Columbia, Delaware, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, Nebraska, New Hampshire, New Jersey, New Mexico, New York, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, and West Virginia and therefore suffered antitrust injury and lost money or property as a result of the anticompetitive conduct alleged in this complaint. The Xyrem prescriptions that FEP purchased, paid for, or provided reimbursement

for were for its members' personal use. FEP intends to continue purchasing, paying for, and/or providing reimbursement for Xyrem and will be injured in the future.

3. City of Providence, Rhode Island

14. Plaintiff City of Providence, Rhode Island ("Providence") is a municipal corporation with its principal office in Providence, Rhode Island. Providence operates a self-insured health and welfare benefit plan and purchases, pays and/or provides reimbursement for some or all of the purchase price of prescription drugs for its employees, retirees, and/or plan beneficiaries, who reside in locations across the United States.

15. During the class period, Providence purchased, paid for, and/or provided reimbursement for some or all of the price of prescriptions of Xyrem, i.e., sodium oxybate oral solution approved under the Xyrem NDA, at supracompetitive prices in Rhode Island and, therefore, suffered antitrust injury and lost money or property as a result of the anticompetitive conduct alleged in this complaint. The Xyrem prescriptions that Providence purchased, paid for, or provided reimbursement for were for its members' personal use. Providence intends to continue purchasing, paying for, and/or providing reimbursement for Xyrem and will be injured in the future.

4. Government Employees Health Association, Inc.

16. Plaintiff Government Employees Health Association, Inc. ("GEHA") is a not-for-profit association with its principal place of business in Lee's Summit, Missouri. GEHA provides health and dental plans to federal employees and retirees and their families through the Federal Employees Health Benefits Plan ("FEHBP") and the Federal Employees Dental and Vision Insurance Program. GEHA provides health benefits to nearly 700,000 covered lives nationwide through the FEHBP.

17. During the class period, GEHA purchased, paid for, and/or provided reimbursement for some or all of the price of prescriptions of Xyrem, i.e., sodium oxybate oral solution approved under the Xyrem NDA, at supracompetitive prices in Alabama, Arkansas, California, Colorado, District of Columbia, Florida, Georgia, Iowa, Indiana, Kentucky, Louisiana, Massachusetts, Maryland, Missouri, Mississippi, Montana, North Carolina, New Jersey, New Mexico, New York,

Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and West Virginia and therefore suffered antitrust injury and lost money or property as a result of the anticompetitive conduct alleged in this complaint. The Xyrem prescriptions that GEHA purchased, paid for, or provided reimbursement for were for its members' personal use. GEHA intends to continue purchasing, paying for, and/or providing reimbursement for Xyrem and will be injured in the future.

5. New York State Teamsters Council Health and Hospital Fund

18. Plaintiff New York State Teamsters Council Health and Hospital Fund ("Teamsters") is a self-insured health plan with a principal place of business in Syracuse, New York.

19. During the class period, Teamsters purchased, paid for, and/or provided reimbursement for some or all of the price of prescriptions of Xyrem, i.e., sodium oxybate oral solution approved under the Xyrem NDA, at supracompetitive prices in Alabama and New York and therefore suffered antitrust injury and lost money or property as a result of the anticompetitive conduct alleged in this complaint. The Xyrem prescriptions that Teamsters purchased, paid for, or provided reimbursement for were for its members' personal use. Teamsters intends to continue purchasing, paying for, and/or providing reimbursement for Xyrem and will be injured in the future.

6. Self-Insured Schools of California

20. Plaintiff Self-Insured Schools of California ("SISC"), is a Joint Powers Authority under California law that serves the interests of California public school district members. It is headquartered in Bakersfield, California. SISC provides health benefit plans to approximately 300,000 members who reside in numerous locations in the United States.

21. During the class period, SISC purchased, paid for, and/or provided reimbursement for some or all of the price of prescriptions of Xyrem, i.e., sodium oxybate oral solution approved under the Xyrem NDA, at supracompetitive prices in California and therefore suffered antitrust injury and lost money or property as a result of the anticompetitive conduct alleged in this complaint. The Xyrem prescriptions that SISC purchased, paid for, or provided reimbursement for were for its members' personal use. SISC intends to continue purchasing, paying for, and/or providing reimbursement for Xyrem and will be injured in the future.

7. UFCW Local 1500 Welfare Fund

22. Plaintiff UFCW Local 1500 Welfare Fund ("Local 1500") is a multi-employer welfare benefits fund with its principal place of business in Westbury, New York. Local 1500 provides nearly 23,000 plan participants with health and welfare benefits and, with more than 17,000 members, is the largest grocery union in New York.

23. During the class period, Local 1500 purchased, paid for, or provided reimbursement for some or all of the price of prescriptions of Xyrem, i.e., sodium oxybate oral solution approved under the Xyrem NDA, at supracompetitive prices in New York and therefore suffered antitrust injury and lost money or property as a result of the anticompetitive conduct alleged in this complaint. The Xyrem prescriptions that Local 1500 purchased, paid for, or provided reimbursement for were for its members' personal use. Local 1500 intends to continue purchasing, paying for, and/or providing reimbursement for Xyrem and will be injured in the future.

8. Ruth Hollman

24. Plaintiff Ruth Hollman resides in Los Angeles, California. Hollman has used Xyrem since 2009 and continuously since 2015. She has purchased Xyrem using insurance provided Health Net. Her co-payment has been $35, which is higher than the co-payment she would have paid for generic Xyrem under the terms of her insurance coverage.

25. During the class period, Hollman purchased and paid for some or all of the price of prescriptions of Xyrem, i.e., sodium oxybate oral solution approved under the Xyrem NDA, at supracompetitive prices in California and therefore suffered antitrust injury and lost money or property as a result of the anticompetitive conduct alleged in this complaint. Hollman's Xyrem prescriptions were for her personal use. Hollman intends to continue purchasing and paying for Xyrem and will be injured in the future.

B. Defendants

26. Defendant Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin 4, Ireland. Its U.S. headquarters is located at 3170 Porter Drive, Palo Alto,

CA 94304, with offices in Philadelphia, Pennsylvania and Ewing, New Jersey. Jazz principally develops, manufactures and markets brand name drugs.

27. Defendant Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin 4, Ireland.

28. Defendant Jazz Pharmaceuticals Public Limited Company is an Ireland public limited biopharmaceutical company organized and existing under the laws of Ireland, with its principal place of business at Waterloo Exchange, Waterloo Road, Dublin 4, Ireland. Jazz Pharmaceuticals plc common stock is publicly traded in the United States on the NASDAQ stock exchange. Jazz Pharmaceuticals plc is the parent company of Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited.

29. Each of the three Jazz Defendants was directly and substantially involved in planning and undertaking the anticompetitive acts alleged in this complaint. Among other things, Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited were parties to the document styled as the "Settlement Agreement" in this complaint. Among other things, Jazz Pharmaceuticals plc was directly involved in the negotiation of the unlawful agreements described in this complaint.

30. The three Jazz entities are referred to collectively as "Jazz."

31. Jazz manufactures and sells Xyrem, the only product approved by the FDA to be marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in both adult and pediatric patients with narcolepsy.

32. Defendant Hikma Pharmaceuticals plc is a public limited company organized and existing under the laws of the United Kingdom, with its principal place of business at 1 New Burlington Place, London, W1S 2HR and its U.S. headquarters at 246 Industrial Way West, Eatontown, New Jersey, 07724.

33. Defendant Hikma Pharmaceuticals USA Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 246 Industrial Way West, Eatontown, New Jersey, 07724, and is a wholly-owned subsidiary of Hikma Pharmaceuticals

plc. Before June 20, 2018, Hikma Pharmaceuticals USA Inc. was organized under the name West-Ward Pharmaceuticals Corp., which had been acquired by Hikma Pharmaceuticals plc in 1998.

34. Defendant Hikma Labs, Inc. is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 1809 Wilson Road, Columbus, Ohio, 43328. Hikma Labs, Inc. was formerly known as Roxane Laboratories, Inc., which was purchased by West-Ward Pharmaceuticals Corp. in 2016 and is now a wholly-owned subsidiary of Hikma Pharmaceuticals plc. In June 2018, the company's name was changed from Roxane Laboratories, Inc. to Hikma Labs, Inc.

35. Defendant Eurohealth (USA), Inc. is a holding company for Hikma Pharmaceuticals USA Inc. and a wholly-owned subsidiary of Hikma Pharmaceuticals plc, organized and existing under the laws of the State of Delaware, with its principal place of business at 246 Industrial Way West, Eatontown, New Jersey, 07724.

36. Each of the Hikma-related Defendants was directly and substantially involved in planning, entering into, and performing under the agreements reached beginning in 2017, as alleged in this complaint. Among other things, Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., Eurohealth (USA), Inc., and Hikma Pharmaceuticals plc were parties to the document styled as the "Settlement Agreement" in this complaint.

37. Defendant Amneal Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Crossing Boulevard, Bridgewater, New Jersey, 08807.

38. Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Ram Ridge Rd., Chestnut Ridge, New York 10977. Par is a subsidiary of Endo International plc, an Irish public limited company with its U.S. headquarters located in Malvern, Pennsylvania. In September 2015, Endo completed an acquisition of Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par Pharmaceutical, Inc., and combined it with Endo's existing generics subsidiary, Qualitest Pharmaceuticals. As used in this complaint, "Par" encompasses relevant predecessors-and-successors-in-interest.

39. Defendant Lupin Ltd. is a public limited company organized and existing under the laws of India, with its principal place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India.

40. Defendant Lupin Pharmaceuticals Inc., a wholly-owned subsidiary of Lupin Ltd., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 111 South Calvert Street, Baltimore, Maryland, 21202.

41. Defendant Lupin Inc., a wholly-owned subsidiary of Lupin Ltd., is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 111 South Calvert Street, Baltimore, Maryland, 21202.

42. All of Defendants' wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

43. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the Defendants. The Court further has jurisdiction over this action pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 as this action also alleges violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, that are actionable under sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26. The Court also has jurisdiction over the claims under the various state laws under both 28 U.S.C. § 1332(d) and 28 U.S.C. § 1367(a).

44. This action seeks to recover treble damages, interest, costs of suit, and reasonable attorneys' fees for the injuries sustained by Plaintiffs and members of the Classes (as defined below) resulting from the Jazz Defendants' monopolization and from all Defendants' conspiracy to restrain

trade in the United States market for Xyrem and its generic equivalents. The action also seeks permanent injunctive relief against Defendants to undo and prevent the unlawful conduct alleged here.

45. Venue is appropriate within this district as Defendants transact business here, and under 15 U.S.C. § 15(a) (Clayton Act), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. § 1391(b) (general venue provision). Further, Defendants and/or their agents may be found in this district.

46. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY FRAMEWORK

A. The regulatory structure for approval and substitution of generic drugs.

47. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"),[8] manufacturers that create a new drug must obtain approval from the FDA to sell the product by filing a New Drug Application ("NDA").[9] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[10]

48. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") patents that claim the drug or a method of using the drug, and that could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before

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[8] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 et seq.).

[9] 21 U.S.C. §§ 301-392.

[10] 21 U.S.C. §§ 355(a), (b).

the expiration of the listed patents.[11] The manufacturer may list in the Orange Book within 30 days of issuance any patents issued after the FDA approved the NDA.[12]

49. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments.

50. The Hatch-Waxman Amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[13] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must further show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, i.e., absorbed at the same rate and to the same extent as the brand. The FDA assigns generics that meet these criteria relative to their brand counterparts an "AB" rating.

51. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another.

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[11] For example, patents covering processes for making drug products may not be listed in the Orange Book.

[12] 21 U.S.C. § 355(b)(1), (c)(2).

[13] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.[14]

52. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

53. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions.[15] Generics are dispensed about 95% of the time when a generic form is available.[16]

2. Regulatory exclusivities for new drugs.

54. In order to promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman Amendments also provided for exclusivities (or exclusive marketing rights) for new drugs. These exclusivities are granted by the FDA upon approval of a drug if statutory requirements are met. These exclusivities are listed in the Orange Book, along with any applicable patents, and can run concurrently with the listed patents.

55. One such exclusivity, New Chemical Entity (NCE) exclusivity, applies to products containing chemical entities never previously approved by FDA either alone or in combination. If a product receives NCE exclusivity, the FDA may not accept for review any ANDA for a drug

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[14] 21 U.S.C. § 355(j)(8)(B).

[15] *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* 30, 51 (2014), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/IMS-Medicine%20use%20and%20shifting%20cost%20of%20healthcare.pdf.

[16] *Id.* at 51.

containing the same active moiety for five years from the date of the NDA's approval, unless the ANDA contains a certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.[17]

56. A drug product may also receive a three-year period of exclusivity if its sponsor submits a supplemental application that contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the supplemental application. If this exclusivity is granted, the FDA may not approve an ANDA for that drug for three years from the date on which the supplemental application is approved.[18]

57. Regulatory exclusivities are not always absolute bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons.[19]

3. Abbreviated New Drug Applications and paragraph IV certifications.

58. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a) That no patent for the brand has been filed with the FDA (a "paragraph I certification");

b) That the patent for the brand has expired (a "paragraph II certification");

c) That the patent for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a "paragraph III certification"); or

d) That the patent for the brand is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").[20]

59. If a generic manufacturer files a paragraph IV certification, a brand manufacturer has the ability to delay FDA approval of the ANDA simply by suing the ANDA applicant for patent

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[17] 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[18] 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

[19] *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7); 21 U.S.C. § 355a(o).

[20] 21 U.S.C. § 355(j)(2)(A)(vii).

infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (i) the passage of two-and-a-half years, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.[21] Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA is ready for final approval but for the 30-month stay.

4. The first-filer's 180-day exclusivity period.

60. Generics may be classified as: (i) first-filer generics; (ii) later generic filers; or (iii) authorized generics.

61. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer ("first-filer") a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.[22] That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first generic has been on the market for 180 days.[23]

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[21] 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a "30-month Hatch-Waxman stay" or "30-month stay." The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

[22] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

[23] Or, until its first-filer exclusivity has been forfeited. A first-filer can forfeit its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA. There is no forfeiture here.

62. The 180-day window is often referred to as the first-filer's six-month or 180-day "exclusivity"; this is a bit of a misnomer because a brand manufacturer (such as Jazz) can launch an AG at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling through a third party at a lower price point. Brand manufacturers frequently launch AGs in response to generic entry in order to recoup some of the sales they would otherwise lose.

63. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first-filer.[24]

64. A first-filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

5. Patents are subject to judicial and administrative scrutiny.

65. A patent may be valid or invalid, infringed or not infringed, and enforceable or unenforceable. Simply owning a patent does not entitle the patent owner to exclude others. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the PTO, by court decision, or by jury verdict.

66. A patent holder at all times bears the burden of proving infringement. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

67. A patent is invalid or unenforceable when, among other things: (i) the disclosed invention is obvious in light of earlier prior art; (ii) when an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material or submits materially false

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[24] *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 144 (2013) (quoting C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

information to the PTO during prosecution; and/or (iii) when a later acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

68. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of: (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent; and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

69. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002.[25] An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.[26]

6. FDA regulations encourage drug manufacturers to work cooperatively to establish single, shared REMS programs.

70. "A Risk Evaluation and Mitigation Strategy ("REMS") is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks."[27]

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[25] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* vi-vii (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

[26] John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

[27] https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems#:~:text=A%20Risk%20Evaluation%20and%20Mitigation,the%20medication%20outweigh%20its%20risks.

71. In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA").[28] Section 505-1(a)(1) of the FDAAA authorizes the FDA to require sponsors of drug applications to submit a proposed REMS program if the agency determines that such is needed to ensure that a drug's benefits outweigh its safety risks. A REMS program can include a medication guide, patient package inserts, a plan for communicating with health care providers about risks, and/or restrictions on the distribution of the drug (*e.g.*, by requiring practitioners, pharmacies, or healthcare settings to obtain special certifications before dispensing the drug). As examples, the FDA notes that: if a drug carries a risk of serious infection, a REMS program action might be to require patient education about the initial warning signs of infection prior to prescribing; if a drug is known to bear a risk of liver damage, a REMS program might require liver function monitoring while the patient is taking the drug; for drugs that can cause a severe allergic reaction, a REMS might require that only a certified healthcare professional can administer the product; for drugs that can cause severe birth defects, a REMS could require a negative pregnancy test before each prescription can be dispensed.[29]

72. The FDA can require a REMS before a drug enters the market, based on known risks, or after a drug has been approved, based on new evidence of risk. In determining whether a REMS will be required for a particular drug, the FDA considers factors including (i) the size of the population likely to use the drug; (ii) the seriousness of the disease; (iii) the drug's expected benefit; (iv) the expected duration of treatment; (v) the seriousness of adverse effects; and (vi) the drug's novelty.

73. Generally, single, shared REMS systems—i.e., jointly administered REMS programs—which may include more than one sponsor, or multiple NDAs and other ANDAs, are required for innovator and generic manufacturers in order to reduce the burden to the healthcare system, including regulatory oversight, of having multiple REMS programs for drugs in the same

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[28] Pub. L. No. 110-85, 121 Stat. 823 (codified as amended at 21 U.S.C. § 301 et seq.).

[29] Presentation by Elaine Lippmann, Office of Regulatory Policy, CDER, FDA, Risk Evaluation and Mitigation Strategies (REMS), https://www.fda.gov/media/105565/download.

class. Single, shared REMS systems allow for cost sharing among sponsors, provide for single portal access to materials and other documentary information about the program, and allow prescribers and pharmacies to complete certification and other administrative requirements just once, rather than multiple times for each manufacturer.

74. The FDA may waive the single, shared system REMS requirement and permit the generic company to use a "different, comparable" aspect of the ETASU—Elements To Assure Safe Use, which are designed to "provid[e] safe access for patients to drugs with known serious risks that would otherwise be unavailable," including requiring the drug's sponsor to monitor and evaluate the implementation of the ETASU, if the agency finds that: (i) the burden of forming a single shared system outweighs the benefits of having one; or (ii) an aspect of the REMS is covered by a patent or is a trade secret and the generic applicant certifies that it sought a license for use of that aspect and was unable to obtain one.[30]

75. According to guidance issued by the FDA, FDA policy "makes clear that while the FDA encourages companies to work together to form a single, shared system, the agency will consider a waiver at any time (either upon request of the applicant, or on the agency's own initiative)."[31] The FDA has no power to force such cooperation under the FD&C Act.

76. One policy issue Congress and the FDA faced when establishing the REMS system was the potential for abuse of the system by brand companies seeking to make it more difficult for generic competitors to enter the market. Such abuse can be tempting given the economic realities. Competition from generics that are AB-rated to the brand usually decimate the brand drug company's profits from the product. Within the first year of availability, generics typically capture all but a small percentage of the brand's market share.

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[30] 21 U.S.C. § 355-1.

[31] Statement from FDA Commissioner Scott Gottlieb, M.D., on New Policies to Reduce the Ability of Brand Drug Makers to Use REMS Programs as a Way to Block Timely Generic Drug Entry, Helping Promote Competition and Access (May 31, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-policies-reduce-ability-brand-drug-makers-use-rems.

77. As the FDA has explained: "One of the primary ways that FDA facilitates a competitive marketplace is through the efficient approval of generic drugs, which are often lower cost than brand drugs. Unfortunately, the process established by Congress may not always function as intended. At times, certain 'gaming' tactics have been used by brand drug companies to delay generic competition."[32]

78. The FDA has recognized that one gaming tactic involved shared REMS requirements. In 2017, then-Commissioner of the FDA, Scott Gottlieb, outlined the problem:

> Current law requires that branded and generic companies try to reach agreement on the implementation of a single, shared system REMS rather than maintaining separate REMS for the branded drug and its generic competitor. Any generic drug application referencing a branded drug with a REMS with ETASU must use a single, shared system REMS with the innovator, unless the FDA waives that requirement and permits the generic drug to use a separate, comparable REMS program. But we know that negotiations to reach agreement on shared system REMS can take extended periods of time. This can block the timely entry of a generic competitor. I believe branded firms sometimes use these negotiations strategically, as a way to slow generic competitors.[33]

7. Citizen Petitions.

79. Citizen Petitions are a means by which any interested person can request that the FDA issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action.

80. All Citizen Petitions must specify the action requested and include a statement of the factual and legal grounds supporting the petition.

81. In practice, the Citizen Petition process is often abused through the filing of petitions by brand drug manufacturers requesting that the FDA deny (or make more difficult, expensive, and time-consuming) the approval process of their would-be generic competitors. The factual and legal

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[32] RLD Access Inquiries.

[33] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Improve FDA Review of Shared Risk Evaluation and Mitigation Strategies to Improve Generic Drug Access* (Nov. 8, 2017), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-improve-fda-review-shared-risk-evaluation-and.

bases for these requests often purport to concern the safety and efficacy of the generic drugs seeking approval, or their bioequivalence to the brand. These arguments are typically lengthy and raise complex scientific issues.

82. Even when the arguments raised in these Citizen Petitions are meritless or request something the FDA was already doing or planning to do—something that happens all too often—the FDA is legally required to nonetheless thoroughly analyze and respond to them, diverting resources and delaying generic approvals.

B. The competitive effects of AB-rated generic and authorized generic competition.

83. Generic versions of brand name pharmaceutical drugs contain the same active ingredient(s) as the brand name drug and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand versions is the price. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or between generic versions, is price. Typically, generics are 50% to 80% (or more) less expensive than their brand counterparts when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers, especially direct purchasers.

84. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market, within the first six months after entry. According to the IQVIA Institute—the leading provider of data in the healthcare sector—since 2013, for drugs where a generic is available, consumers purchase

the generic 97% of the time.[34] The Federal Trade Commission ("FTC") has found that on average, within a year of generic entry, prices had dropped 85%.[35] As a result, competition from generics is viewed by brand manufacturers as a serious threat to their bottom line.

85. Generic competition enables purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price.

86. Until a generic version of the brand drugs enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand, and the brand manufacturer can, therefore, continue to profitably charge supracompetitive prices. Brand manufacturers are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means—to delay or prevent generic competition.

1. The first AB-rated generic is priced below the brand.

87. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[36] Every state either requires or permits that a prescription written for the brand be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and AB-rated generic combined).

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[34] IQVIA Institute, *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022* at 14 (2018), *available at* https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

[35] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ("FTC Pay-for-Delay Study").

[36] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study"); FTC Pay-for-Delay Study at 1.

88. During the 180-day exclusivity period, the first-filer is the only ANDA-approved generic manufacturer on the market (though the brand's AG can be, and often is, on the market during the 180-day exclusivity period). In the absence of competition from other generics, during the 180-day exclusivity period, a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

2. Later generics drive prices down further.

89. Once generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[37]

90. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price.

91. In a report by the FTC issued at the request of Congress in 2011, the FTC found that generics captured 80% or more of sales in the first six months (this percentage erosion of brand sales holds regardless of the number of generic entrants.).[38] In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[39]

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[37] *See*, e.g., Tracy Regan, Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market, 26 INT'L J. INDUS. ORG. 930 (2008); Richard G. Frank, The Ongoing Regulation of Generic Drugs, 357 NEW ENG. J. MED. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, Does Regulation Drive Out Competition in Pharmaceutical Markets?, 43 J.L. & ECON. 311 (2000).

[38] FTC 2011 AG Study at 66-67.

[39] *See* FDA, *What Are Generic Drugs?*, https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs (last updated Aug. 24, 2017).

3. Authorized generics, like other generics, compete on price.

92. An "authorized generic"—frequently referred to as an "AG"—is a product sold under the authority of the brand's approved NDA. An AG, then, is chemically identical to the brand drug but is sold as a generic, typically through either the brand manufacturer's subsidiary (if it has one) or through a third-party distributor.

93. If the 180-day exclusivity period applies to a first-filer ANDA, the exclusivity exists only to bar the FDA from approving another ANDA during that time period. The exclusivity does not apply to products sold under the authority of the original NDA. As a result, the 180-day exclusivity does not bar the entry of authorized generics; the statutory scheme does not prevent a brand manufacturer from marketing and selling (directly or indirectly) an AG at any time or from licensing another company to do so.

94. The FDA has found that allowing brand manufacturers to introduce AGs during the 180-day exclusivity period is consistent with the "fundamental objective of the Hatch-Waxman [A]mendments" to encourage competition and, as a result, "lower prices in the pharmaceutical market."[40] The FDA reasoned that if a brand releases an AG at a reduced price during the 180-day exclusivity period, "this might reasonably be expected to diminish the economic benefit" to the generic first-filer by increasing competition and causing the generic to "reduc[e] the substantial 'mark-up' [generics] can often apply during the [180-day] period."[41] Such competition, and the resulting price decreases, work to benefit drug purchasers.

95. Brand manufacturers recognize the significant economic advantages of releasing their AGs to compete with the first-filer generic during the 180-day exclusivity period. One study noted

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[40] FDA Response to Mylan and Teva Citizen Petitions at 11-12, Docket Nos. FDA-2004-P-0400 (formerly 2004P-0075) and FDA-2004-P-0146 (formerly 2004P-0261) (July 2, 2004).

[41] *Id.* at 12.

that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[42]

96. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period).

97. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[43]

98. The FTC similarly found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by about 50% on average.[44] The first-filer generic makes much less money when it faces competition from an AG because: (i) the AG takes a large share of unit sales away from the first-filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

99. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic manufacturer's 180-day exclusivity period. All drug industry participants recognize this. In 2006, the branded pharmaceuticals industry group known as PhRMA sponsored a study that concludes that the presence of an authorized generic causes generic wholesale prices to be more than 15% lower as

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[42] Kevin A. Hassett & Robert J. Shapiro, Sonecon, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3 (2007), http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

[43] Ernst R. Berndt et al., Authorized Generic Drugs, Price Competition, and Consumers' Welfare, 26 Health Affairs 790, 796 (2007).

[44] FTC 2011 AG Study at 139.

compared to when there is no authorized generic.[45] Generic companies recognize it.[46] Brand companies recognize it.[47]

C. Manipulation of the regulatory structure to impair competition.

100. The brand manufacturer of a pharmaceutical product that has no generic competition in the marketplace gets all of the profits on all of the unit sales. In this circumstance, brand manufacturers can usually sell their drug for far more than the marginal cost of production, generating profit margins in excess of 70% or more, while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call market power.

101. When a generic equivalent enters the market, however, it quickly captures 80% or more of the unit sales from the brand drug. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturer sells almost all of the units but at drastically reduced prices—delivering enormous savings to drug purchasers. And when multiple generics compete in the market, that competition drives prices down to near the marginal cost of production. This

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[45] IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf.

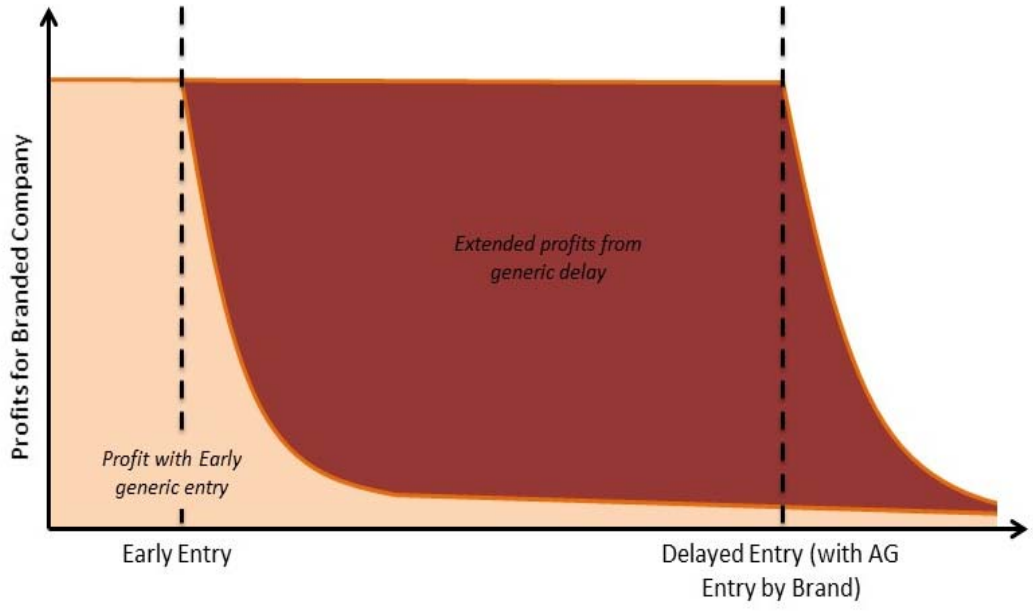
[46] One generic stated that "[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario." *See* FTC 2011 AG Study at 81. Another generic manufacturer quantified the fiscal consequences of competing with an authorized generic and determined that the authorized generic reduced its first generic's revenues by *two-thirds*, or by approximately *$400 million*. Comment of Apotex Corp. in Support of Mylan Citizen Petition at 4, Docket No. 2004P-0075 (Mar. 24, 2004), https://web.archive.org/web/20041216115511/http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf.

[47] Commenting on an FDA Citizen Petition by drug manufacturer Teva Pharmaceuticals, Pfizer stated: "Teva's petition [to prevent the launch of an authorized generic] is a *flagrant effort to stifle price competition* – to Teva's benefit and the public's detriment." Comment of Pfizer at 6-7, Docket No. 2004P-0261 (June 23, 2004), https://web.archive.org/web/20050601041653/http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/04p-0261-cr00001-01-vol2.pdf; Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), https://web.archive.org/web/20041227172543/http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf.

competition ends the brand manufacturer's market power and delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings.

102. While brand manufacturers and first-filer generic manufacturers are typically marketplace competitors, they have a collective interest in preventing robust competition from other generic manufacturers—competition that severely depresses prices—from breaking out. If the brand and first-filer generic work together to prevent or delay such competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. In other words, by stifling competition, the brand manufacturer and first-filer generic manufacturer can maintain high prices, protect their profits, and split between themselves the enormous savings that increased generic competition would have delivered to drug purchasers.

103. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where it settles a patent lawsuit on the merits (i.e., with only an agreed entry date and without a pay-off to the generic company); and (ii) a situation where it settles the lawsuit with a large, unjustified payment to the generic manufacturer. In the former situation, the agreed entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly.



104. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide between them the ill-gotten gains—the increased profit to the detriment of drug purchasers—that delayed competition makes possible. After all, the generic manufacturer will not refrain from competing if it does not share in the profit gains through some means. The means usually takes the form of pay-offs from the brand manufacturer, deals that are often referred to as "pay-for-delay," "exclusion payment," or "reverse payment" agreements.

105. The brand manufacturer may choose to—unlawfully—pay off only the first-filer, even if other generic manufacturers are also lined up to challenge the patents. The first-filer's agreement to delay marketing its generic drug also prevents other generic manufacturers from marketing their products: none of the later filers can enter until the first-filer's 180-day exclusivity period has run.

106. Later ANDA filers have more modest financial expectations because they may have little or no expectation of any form of market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized. As a result, later-filing generics can be motivated away from competitively driven modest sales results and toward anticompetitive payoffs by brand companies. Under these unlawful arrangements, the brand shares some of its supracompetitive profits with the later-filing generics, and in exchange the later-filing generics agree to drop their patent challenges and accept a late agreed entry date.

107. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. They extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

1. No-AG agreements provide a means for brand and generic manufacturers to share the gains from conspiring.

108. In the 1990s, pay-offs from brand manufacturers often took the form of cash payments to would-be generic competitors. Since the 2000s—as a result of regulatory scrutiny, congressional investigations, and class action lawsuits—brand and generic manufacturers have entered into increasingly more elaborate agreements in an attempt to hide payoffs.

109. One form of payoff is a "no-authorized generic" or "no-AG" agreement. With a no-AG agreement, the brand manufacturer agrees not to market an AG version of the brand drug for some period of time after the first generic enters the market in exchange for the first generic agreeing to a delayed entry date..

110. No-AG agreements between a brand manufacturer and would-be generic competitors are sometimes explicit. Other times, such agreements may be structured in a way that ostensibly reserves some right in the brand manufacturer to sell a generic version of its branded product, but that still functionally acts as a no-AG agreement, resulting in the same impact on competition as an explicit no-AG agreement. The FTC recognizes the existence and impact of such functional no-AG agreements. In a study by the FTC of the settlement agreements, the FTC explained that:

> The most common form of possible compensation—appearing in 9 final settlements—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. This type of commitment could have the same effect as an explicit no-AG commitment, for example, if the brand company does not market generics in the United States.[48]

111. That same FTC report explained that an agreement that includes a "declining royalty structure, in which the generic's obligation to pay royalties is reduced or eliminated if a brand launches an authorized generic product" can have "the same effect as an explicit no-AG commitment."[49]

112. Absent a no-AG promise, it often makes economic sense for the brand manufacturer to begin marketing an AG through a third party as soon as (or sometimes weeks or months before) the first-filer generic enters the marketplace. The AG entry affords the brand company a price strategy (competing with a low-priced generic), and this competition takes sales from what would otherwise be sold by the first-filer generic. Competition from an AG typically cuts the first-filer's

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[48] FTC, *Overview of Agreements Filed in FY 2016: A Report by the Bureau of Competition* (2017), https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf. *See also* FTC, *MMA Reports: No tricks or treats – just facts*, October 27, 2020, https://www.ftc.gov/news-events/blogs/competition-matters/2020/10/mma-reports-no-tricks-or-treats-just-facts.

[49] *Id.*

revenues approximately in half, and by having two generics in the market (the first-filer generic and the AG), the two generics compete on price. This lowers prices, delivering savings to drug purchasers.

113. To prevent an AG from causing this substantial loss of revenues and profits, a first-filer generic may be willing to delay its entry into the marketplace in return for the brand manufacturer's agreement to forgo competing with an AG during the exclusivity period. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than makes up for the profits it forgoes by temporarily not competing with its AG. The brand manufacturer gains from the delayed onset of generic competition; the first-filer gains from the absence of generic competition for the first 180 days of marketing.

114. Drug purchasers lose. The brand and first-filer's reciprocal pledges not to compete harm purchasers thrice over. First, the pact delays the first-filer's generic entry into the marketplace and thereby extends the time during which the more expensive brand is the only product on the market. Second, by delaying the first-filer's entry, the pact also delays the time when other, later, generics enter. Third, the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing price competition during that period, particularly price competition that would otherwise occur between the first-filer's generic and the brand's AG.

115. For the first-filer generic, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-AG pledge thus has the same economic effect as a pay-off made in cash. As explained by the then-Chairman of the FTC:

> Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to

> the generic, "if I launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG."[50]

Courts agree that no-AG agreements are a form of payment actionable under *Actavis* and are anticompetitive.[51]

116. For a first-filer generic (like Hikma) in a situation involving a brand drug with more than a billion dollars in annual sales (like Xyrem), the difference between selling a generic without having to compete against another generic, whether AG or otherwise, amounts to tens, and in some instances, hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. No-AG agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

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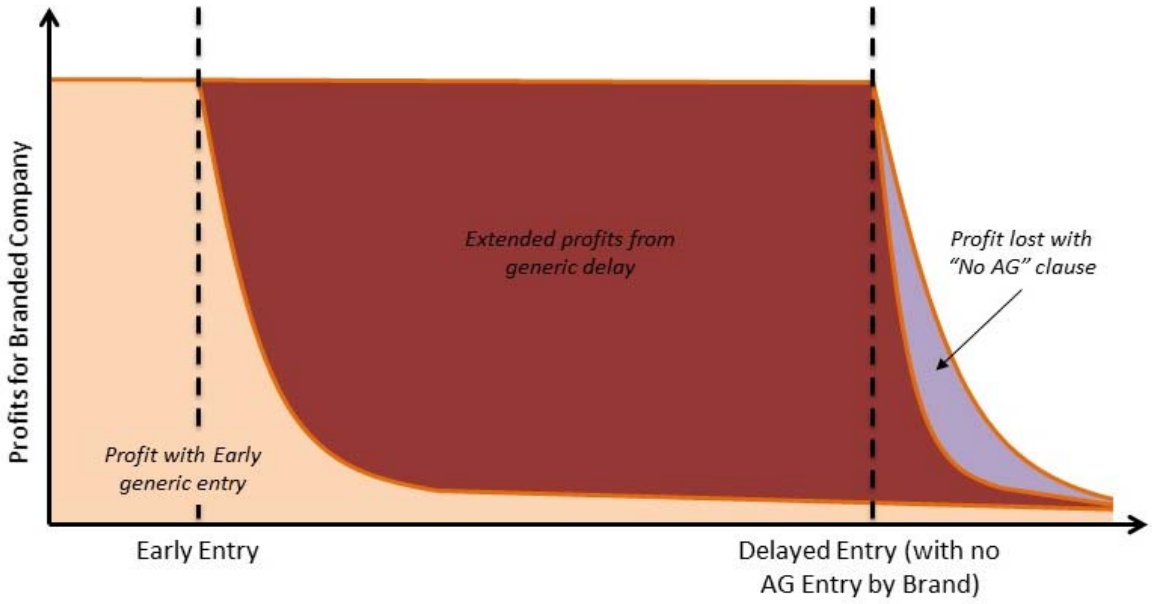
[50] "Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics," FTC (June 24, 2009), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authgenstatementleibowitz.pdf.

[51] *See In re Loestrin 24 Fe Antitrust Litig.*, Nos. 14-2071, 15-1250, 2016 U.S. App. LEXIS 3049, at *25-26 (1st Cir. Feb. 22, 2016); *In re Opana ER Antitrust Litig.*, No. 14 C 10150, 2016 U.S. Dist. LEXIS 16700, at *23-25 (N.D. Ill. Feb. 10, 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, 2014 U.S. Dist. LEXIS 142206, at *62 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. AstraZeneca AB*, 52 F. Supp. 3d 705, 709-10 (E.D. Pa. 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

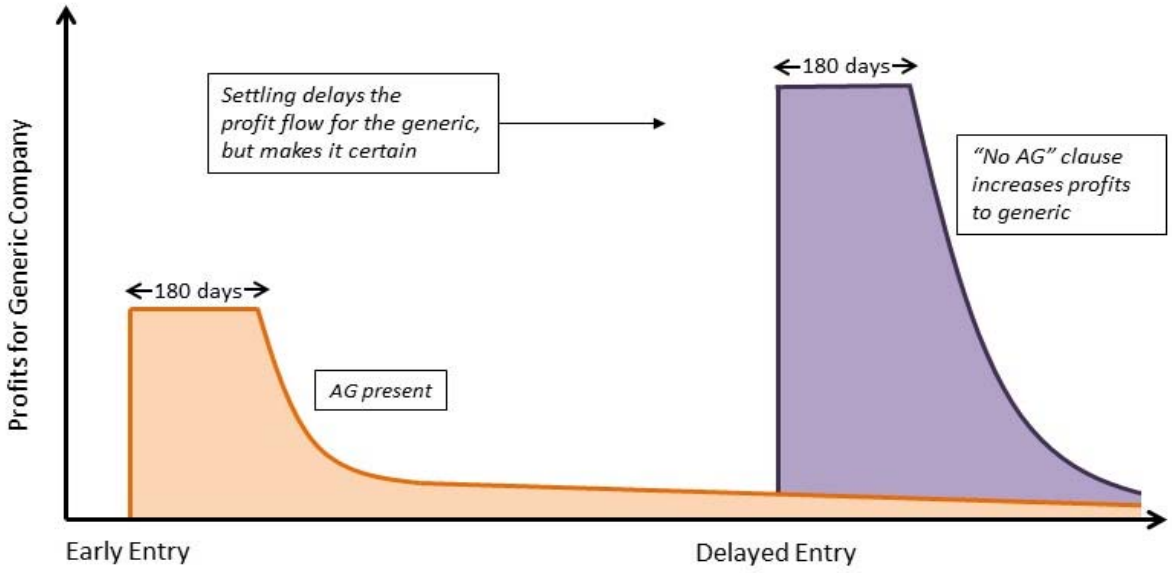
117. Figure 2 depicts what happens when a settlement agreement includes a no-AG promise. The red area shows the brand manufacturer's additional monopoly profits earned during the period of delay. The purple area shows the amount of monopoly profit the brand manufacturer gives up (i.e., shares with the generic) by not selling its own AG.

Figure 2. Impact of No-AG Clause on Brand Profits



118. Figure 3 depicts the generic manufacturer's principal considerations in deciding whether to accept a settlement that includes a no-AG agreement. Without a settlement, the generic could enter earlier—either when the 30-month stay expires ("at risk") or when it wins the litigation. The generic manufacturer's profits (gross margins) would be high during the 180-day exclusivity period and then fall rapidly as additional generics enter. This profit flow is somewhat uncertain because (i) if the generic launches at risk, it could (theoretically) later be found to infringe a valid patent, and (ii) it is expected that the brand manufacturer will launch an authorized generic and capture approximately 50% of the generic's sales. With a no-AG promise, the profit flow occurs later but is more certain and is larger—roughly twice the size—because the generic manufacturer does not lose half of the market to the brand manufacturer's authorized generic and can charge a higher price.

Figure 3. Impact of No-AG Promise on Generic's Profits



119. Pay-offs by means of no-AG clauses usually exceed the value that the first-filer generic could have obtained *even if it had won* the patent infringement litigation. By settling the patent case in exchange for a no-AG payoff, the first-filer converts that critical six months into a period of *total* generic exclusivity that it was not otherwise entitled to, thus doubling its unit sales and making those sales at a higher price.

2. Manufacturers also use anticompetitive "acceleration" clauses to delay competition.

120. Another tool used by pharmaceutical monopolists is "acceleration" clauses, also referred to as "poison pills," which, when used in settling Hatch-Waxman litigation, disincentivize generic filers from entering the market by eliminating the possibility of any one generic obtaining *de facto* exclusivity (aside from the first-filing generic).

121. Brand manufacturers can induce generics to enter settlements by including these clauses in their agreements. In practice, such "acceleration" clauses do not accelerate generic entry—they delay it.

122. The purpose and effect of an "acceleration" clause is to dramatically reduce any other generic manufacturer's incentive to try to enter the market as quickly as they can. Absent the "acceleration" clause, other generic manufacturers would have an incentive to enter the market as soon as they were able, thereby enjoying a substantial period as the only ANDA-based generic product on the market. By eliminating this possibility, an "acceleration" clause results in delayed generic entry by, among other things, disincentivizing generics that would otherwise be willing and able to come to market from doing so because of the knowledge that other generics would immediately flood the market.

123. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—twice testified to Congress that "acceleration" clauses represent "the primary anticompetitive aspects of settlements" because they "eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry."[52] The clauses both induce prospective generic competitors to accept later entry dates and deter others from challenging weak patents:

> [N]o 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. If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase.[53]

124. Scholars agree. A recently published study analyzing empirical pharmaceutical settlement data concluded that "[a]n acceleration clause paired with the 180-day exclusivity period

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[52] Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 110th Cong., at 65, 67 (2007) (statement of Bernard Sherman, CEO, Apotex, Inc.), http://www.gpo.gov/fdsys/pkg/CHRG- 110hhrg38992/pdf/CHRG-110hhrg38992.pdf.

[53] 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 218 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.) (hereinafter "Apotex 2009 Statement"), http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf. Apotex addressed acceleration clauses in the context in which, as here, the first-filing generic retained the 180-day exclusivity.

appears to effectively deter other generics and, at least in the instances we observed, never to have resulted in an actual 'accelerated' entry." Indeed, the study found that in cases like this one where the first-filer retained its 180-day exclusivity, the use of "acceleration" clauses had not once promoted earlier generic entry. "Among 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."[54]

V. FACTS

A. The development and approval of Xyrem.

125. In the late 1990s and into 2000, Orphan, of Minnetonka, Minnesota, developed the use of sodium oxybate as a central nervous system depressant providing anti-cataplectic activity in patients with narcolepsy.

126. In September 2000, Orphan submitted a New Drug Application ("NDA") seeking FDA approval to manufacture, market and sell sodium oxybate oral solution, 500 mg/ml in the United States to treat cataplexy associated with narcolepsy. The product was brand named Xyrem.

127. In July 2002, the FDA approved the Xyrem NDA (sodium oxybate oral solution) for the treatment of cataplexy (i.e., a sudden and transient episode of muscle weakness accompanied by full conscious awareness, typically triggered by emotions such as laughing, crying, or terror) in patients with narcolepsy. Later in 2005, the FDA also approved the Xyrem NDA for the treatment of excessive daytime sleepiness in patients with narcolepsy.

128. Sodium oxybate is the sodium salt of gamma-hydroxybutyrate, commonly known as GHB, the active ingredient in Xyrem. GHB is a chemical that has been abused (and misused). Abuse can cause serious medical problems, including trouble breathing, seizures (convulsions), loss of

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[54] Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, Journal of Competition Law & Economics, 00(00), 1–32 at 1, 7.

consciousness, coma, and death. Abuse of Xyrem could also lead to dependence, craving for the medicine, and severe withdrawal symptoms.

129. At the time of the development of Xyrem, abuse of GHB was also designated by the Drug Enforcement Agency as a "date-rape drug." GHB is designated by the DEA as a Schedule I controlled substance under the Controlled Substances Act. Xyrem itself is a Schedule III drug under the CSA, i.e., it has a medium potential for abuse and abuse can cause severe mental addiction, or moderate physical addiction.

130. Xyrem is an oral solution that is recommended to be taken two times each night, the first dose right at bedtime and the second dose two-and-a-half to four hours later.

131. The original FDA approval of the Xyrem NDA was conditioned on implementation of a risk management program (or, "RiskMAP"). Components of the original plan included: (a) implementation of a restricted distribution program for Xyrem; (b) implementation of a program to educate physicians and patients about the risks and benefits of Xyrem; (c) filling of the initial prescription only after the prescriber and patient have received and read the educational materials; and (d) maintenance of a registry of all patients and a record of all prescribers. In addition, at the time of the original approval, Orphan agreed with the FDA: (i) that each of the bulk drug and drug product would be manufactured at a single site; (ii) that the drug product would be stored at a facility compliant with Schedule III regulations, where a consignment inventory will be maintained; (iii) that the inventory would be owned by Orphan; (iv) that the facility would be managed by a central pharmacy which would maintain the consignment inventory; and (v) that other than in the single central pharmacy, Xyrem would not be stocked in retail pharmacy outlets.

132. Since the original approval and under requirements requested by Orphan, Xyrem has been dispensed through a single central pharmacy directly to patients under the RiskMAP (and later, a REMS program).

133. After approval, the FDA granted Xyrem a New Chemical Entity ("NCE") exclusivity of five years from the NDA approval date, expiring on July 17, 2007, and orphan drug exclusivity of seven years from the NDA approval date, expiring on July 17, 2009. These government grants of exclusivity assured the lack of competition by generic versions of Xyrem through mid-2009.

134. In June 2005, Jazz Pharmaceuticals, acquired Orphan (and thereby all rights to Xyrem).

135. By 2007, Jazz reported net sales of $39 million for Xyrem, which made up about three-quarters of the company's net sales of all products for the year. Over the years, Xyrem has continued to be Jazz's major product. In 2019, Jazz reported total revenue from Xyrem of about $1.6 billion, which again accounted for about three-quarters of the company's net product sales.

B. The patents ostensibly covering aspects of Xyrem or its use.

136. Over time, at first Orphan and later Jazz filed for and obtained approximately 21 patents ostensibly claiming aspects of Xyrem and its use.

137. Jazz's patents are grouped into three patent families: the '431 family, the '730 family, and the '302 family. Because the active pharmaceutical ingredient in Xyrem, gamma-hydroxybutyrate, has long been known, none of the patents in these families claim the active pharmaceutical compound.

1. The '431 family of patents claim processes for making Xyrem, formulations of Xyrem, and methods of using Xyrem.

138. The '431 family of patents all claim priority to U.S. Patent Application No. 09/470,570, which Orphan filed on December 22, 1999. The patents in the '431 family include the following patents that Jazz and/or Orphan requested be listed in the Orange Book as covering Xyrem:

'431 PATENT FAMILY: LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
6,780,889	June 11, 2002	Aug. 24, 2004	July 4, 2020
7,262,219	July 7, 2004	Aug. 28, 2007	July 4, 2020
7,851,506	July 13, 2007	Dec. 14, 2010	Dec. 22, 2019
8,263,650	Apr. 13, 2012	Sept. 11, 2012	Dec. 22, 2019

'431 PATENT FAMILY: LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
8,324,275	Apr. 13, 2012	Dec. 4, 2012	Dec. 22, 2019
8,859,619	Nov. 26, 2012	Oct. 14, 2014	Dec. 22, 2019
8,952,062	March 6, 2013	Feb. 10, 2015	Dec. 22, 2019
9,539,330	Nov. 9, 2015	Nov. 8, 2016	Dec. 22, 2019

The '431 family of patents includes Orange Book-listed patents that claim pharmaceutical formulations of sodium oxybate or other salts of GHB (the '889, '219, '650, '619, and '330 patents) and/or methods of treating sleep-related conditions with sodium oxybate or other salts of GHB (the '506, '650, '275, and '062 patents).

139. The patents in the '431 family also include two patents that claim specific processes for manufacturing Xyrem. As process patents, they are not eligible for Orange Book listing.

'431 PATENT FAMILY: PROCESS PATENTS NOT LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry
6,472,431	Dec. 22, 1999	Oct. 22, 2002	Dec. 22, 2019
8,461,203	July 13, 2011	June 11, 2013	Dec. 22, 2019

140. The patents in the '431 family were set to expire on December 22, 2019, with the exception of the '889 and '219 patents, which received patent term adjustments under 35 U.S.C. § 154(b). In 2018, the FDA granted pediatric exclusivity to the Orange Book-listed patents, and that six-month exclusivity will expire on June 22, 2020 (for the '506,' 650, '275, '619, '062 and '330 patents) or January 4, 2021 (for the '889 and '219 patents). The process patents were not eligible to be listed in the Orange Book and were not entitled to pediatric exclusivity and so have expired.

2. The '730 family of patents claim methods of tracking prescriptions of a sensitive drug through a computer database.

141. The '730 family of patents all claim priority to U.S. Patent Application No. 10/322,348, which Orphan filed on December 17, 2002. The '730 family of patents are all entitled "Sensitive Drug Distribution System and Method."

142. The patents in the '730 family include the following patents that Jazz and/or Orphan requested be listed in the Orange Book as covering Xyrem:[55]

'730 PATENT FAMILY: LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
7,668,730	Dec. 17, 2002	Feb. 23, 2010	June 16, 2024
7,765,106	Nov. 2, 2004	July 27, 2010	June 16, 2024
7,765,107	Apr. 1, 2005	July 27, 2010	June 16, 2024
7,895,059	Feb. 11, 2010	Feb. 22, 2011	Dec. 17, 2022
8,457,988	Aug. 27, 2012	June 4, 2013	Dec. 17, 2022
8,589,182	Aug. 27, 2012	Nov. 19, 2013	Dec. 17, 2022
8,731,963	Aug. 22, 2012	May 20, 2014	Dec. 17, 2022

The patents in the '730 family "relat[e] to a drug distribution system for tracking prescriptions of a 'sensitive drug,'" which is "one which can be abused, or has addiction properties or other properties that render the drug sensitive."[56]

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[55] The '730 family also includes United States Patent No. 7,797,171, which issued on September 14, 2010. The '171 patent claims *methods of obtaining FDA approval* for a prescription drug that uses a controlled distribution method involving an exclusive central computer database. Jazz did not list the '171 patent in the Orange Book and has not asserted this patent against any ANDA applicant for generic Xyrem.

[56] *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 895 F.3d 1347, 1350 (Fed. Cir. 2018).

143. Despite the fact that these patents were not eligible for Orange Book listing because they do not claim a drug substance (active ingredient), drug product, or method of use, Jazz nevertheless requested that the FDA list the '730 family of patents in the Orange Book.

144. In 2018, the FDA granted pediatric exclusivity to the Orange Book-listed patents for Xyrem. The expiration of that six-month exclusivity was listed in the Orange Book as December 16, 2024 for the '730, '106 and '107 patents and as June 17, 2023 for the '059, '988, '182, and '963 patents.

3. The '302 family of patents claims methods of treating sleep disorders with sodium oxybate in patients who are also taking divalproex sodium.

145. The '302 family of patents all claim priority to United States Patent Application No. 13/837,714, which Jazz filed on March 15, 2013. The '302 family of patents are all entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters."

146. The patents in the '302 family include the following patents that Jazz requested be listed in the Orange Book as covering Xyrem:

'302 PATENT FAMILY: LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
9,050,302	Mar. 15, 2013	June 9, 2015	Mar. 15, 2033
8,772,306	Apr. 29, 2013	July 8, 2014	Mar. 15, 2033
9,486,426	May 8, 2015	Nov. 8, 2016	Mar. 15, 2033
10,213,400	Jan. 12, 2018	Feb. 26, 2019	Mar. 15, 2033
10,864,181	Jan. 19, 2019	Dec. 15, 2020	Mar. 15, 2033

The patents in the '302 family claim methods of treating sleeping disorders by decreasing the amount of sodium oxybate or other salt of GHB administered to the patient if the patient is also taking valproate or divalproex sodium, medications used to treat seizures.

147. In 2018, the FDA granted pediatric exclusivity to the Orange Book-listed patents for Xyrem. The expiration of that six-month exclusivity is listed in the Orange Book as September 15, 2033 for the patents in the '302 family with the exception of the '400 patent, which did not issue and was not listed in the Orange Book until 2019 and is not currently listed in the Orange Book with pediatric exclusivity, and the '181 patent, which did not issue until 2020, was not listed in the Orange Book until 2021 and is not currently listed in the Orange Book with pediatric exclusivity.

C. The Jazz lawsuits against Roxane/Hikma.

148. On July 8, 2010, Roxane submitted ANDA 202090, seeking FDA approval to manufacture, market and sell an AB-rated generic version of Xyrem in the 500 mg/ml strength. Roxane was the first generic to file, making it potentially eligible for 180-day exclusivity when its ANDA received approval. Roxane's ANDA proposed use of its own pharmacy dispensing program to meet risk requirements.

149. Roxane's ANDA included Paragraph IV certifications to the five patents that, at that time, were listed in the Orange Book for Xyrem: the '889 patent, the '219 patent, the '730 patent, the '106 patent, and the '107 patent.

150. On October 14, 2010, Roxane notified Jazz of its ANDA filing and provided a detailed account of why the '889, '219, '730, '106 and '107 patents were invalid, unenforceable, and/or not infringed by Roxane's ANDA product ("Paragraph IV notice letter"). On November 22, 2010, Jazz filed suit against Roxane alleging infringement of these patents.

151. Over time, and as Jazz obtained additional patents and listed them in the Orange Book, Roxane would, in turn, send additional Paragraph IV notice letters to Jazz, each certifying the new patent was invalid, unenforceable, and/or not infringed by Roxane's product. And Jazz responded by filing additional complaints alleging infringement. Those were:

COMPLAINTS FILED BY JAZZ AGAINST ROXANE

Complaint Date	Docket No. (D.N.J.)	Date Paragraph IV Notice Letter Received	Patent(s) in Suit
Nov. 22, 2010	2:10-cv-06108	Oct. 14, 2010	'889, '219, '730, '106,'107

COMPLAINTS FILED BY JAZZ AGAINST ROXANE

Complaint Date	Docket No. (D.N.J.)	Date Paragraph IV Notice Letter Received	Patent(s) in Suit
Feb. 4, 2011	2:11-cv-00660	Jan. 10, 2011	'431, '506
May 2, 2011	2:11-cv-02523	Mar. 22, 2011	'059
Oct. 26, 2012	2:12-cv-06761	Oct. 5, 2012	'650
Dec. 5, 2012	2:12-cv-07459	unknown	'275
Feb. 20, 2015	2:15-cv-01360	Jan. 15, 2015	'203, '306, '619
June 1, 2015	2:15-cv-03684	Apr. 16, 2015	'062
Jan. 27, 2016	2:16-cv-00469	Dec. 14, 2015	'302
Aug. 12, 2016	2:16-cv-04971	Jan. 9, 2015	'963

152. By the time of the last complaint, Hikma (through its subsidiary, West-Ward Pharmaceuticals Corp.) had an agreement in principle to acquire Roxane. As a result, the last complaint listed as named defendants not only Roxane but also Hikma Pharmaceuticals plc and Hikma subsidiaries West-Ward Pharmaceuticals Corp. and Eurohealth (USA), Inc.

153. In February of 2016, Hikma completed its acquisition of Roxane. Actions attributable to Roxane, West-Ward, and Hikma are, from this point forward, referred to just as "Hikma."

154. Over a period of about seven years—from when the first lawsuit was filed in 2010 through to an eventual settlement in 2017—the contentious litigation between Jazz and Roxane/Hikma included repeated acts by Jazz that unlawfully abused its patent positions. And often Jazz sought to enforce its patents without any realistic likelihood of prevailing, knowing that its lawsuits would tie Hikma up in the judicial processes, thus facilitating Jazz's overall goal of delaying or impeding generic entry.

155. During the litigation between Jazz and Hikma, Hikma asserted affirmative defenses based on Jazz's misuse of its patents. Specifically, Hikma argued that Jazz had engaged in "an abusive scheme to unfairly multiply [the patent] litigation" by:

> holding patent applications pending, gleaning [Hikma]'s noninfringement defenses from [Hikma]'s notice letters or from litigation, and then many

> years after issuance of the parent patents, filing continuation applications for new patent claims in an effort to forestall [Hikma]'s noninfringement defenses, more closely capture [Hikma]'s product, or delay the litigation. Then, upon obtaining its new patent claims, Jazz turns around and asserts those new patents in infringement claims against [Hikma]. Thus, the litigation never ends and [Hikma] is continually fighting a moving target.[57]

156. For example, in response to Jazz's original complaint alleging infringement of the '506 patent, Hikma asserted that it would not infringe the '506 patent because "all of the claims in the '506 patent required that the sodium oxybate solution be administered using a concentrated medium of 500 mg/ml of sodium oxybate," and the "administration of [Hikma]'s sodium oxybate solution required dilution of the concentrated medium prior to patient administration."[58]

157. Hikma disclosed this defense as part of the invalidity and non-infringement contentions it provided to Jazz in April and August 2011.[59]

158. Jazz then filed the patent applications that issued as the '650 patent and the '275 patent. Jazz filed these applications on April 12, 2012, 14 years after their parent application was filed.[60] These patents issued in September 2012 and December 2012, respectively. Both the '650 and '275 patents contain claims calling for dilution of the sodium oxybate solution prior to patient administration. Jazz then sued Hikma in October 2012 and December 2012, alleging infringement of the '650 and '275 patents.

159. Hikma contended that it did not infringe the '219 or '889 patents because the claims of those patents require the inclusion of "a pH adjusting agent" and Hikma's product did not contain a pH adjusting agent. Jazz then filed the application for the '650 patent, which included claims to

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[57] Memorandum in Support of Roxane's Motion for Leave to Amend Its Answers, ECF No. 221, *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 2:10-cv-06108 (D.N.J. May 3, 2013)

[58] Roxane Laboratories, Inc.'s Amended Answer, Affirmative Defenses and Counterclaims to Plaintiff's Complaint Regarding U.S. Patent No. 8,263,650, ECF No, 218-3, *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 2:10-cv-06108 (D.N.J. Apr. 26, 2013), Affirmative Defenses ¶¶ 17-18.

[59] *Id.*, Affirmative Defenses ¶ 14.

[60] *Id.*, Affirmative Defenses ¶¶ 19, 27.

compositions that do not require "a pH adjusting agent," and then asserted the '650 patent against Hikma after the patent issued.

160. Hikma contended that it did not infringe the '431 patent because "[a]ll of the claims of the '431 patent require that sodium oxybate be 'added' to an aqueous medium" and "[Hikma] makes its sodium oxybate solution without 'adding' sodium oxybate to an aqueous medium." After learning of this defense, Jazz filed the patent application that issued as the '203 patent. Jazz filed this application on July 13, 2011. The claims of the '203 patent, which issued on June 11, 2013, include claims for "admixing" sodium oxybate with an aqueous medium rather than "adding" sodium oxybate to an aqueous medium, claims to a method that "contacts" a salt of GHB with an aqueous medium, and claims that do not specify how sodium oxybate is combined with the aqueous medium to prepare the composition. Jazz then asserted the '203 patent against Hikma after the patent issued.

161. In response, Hikma asserted that because "Jazz continues to seek and obtain new patents, add patents to the Orange Book, bring patent infringement suits against [Hikma], including to seek consolidation of all suits relating to [Hikma]'s sodium oxybate ANDA product," Hikma had suffered and would "continue to suffer material prejudice by being forced to indefinitely defend itself against patents that were not invented by the named inventors but are based on information gleaned by patent attorneys during a litigation, causing [Hikma] to face an 'at-risk' launch of its sodium oxybate product due to delayed resolution of this litigation."

162. It was still early in Jazz's scheme that culminated in the reverse payment agreements, but with Hikma already discussing launch "at risk" of Jazz's patent thicket, Jazz knew it needed to fortify its barriers.

D. The Jazz "single pharmacy" REMS program for Xyrem.

163. In 2007, Congress passed the Food and Drug Administration Amendments Act (the "FDAAA") that set forth a comprehensive statutory framework for a Risk Evaluation and Mitigation Strategies ("REMS") program that, for particular drug products, requires a careful balance between, on the one hand, the need to evaluate and mitigate risk of a drug to ensure that its benefits outweigh its risks, and, on the other, the potential burdens of REMS elements on patient access and the health

care delivery system. The FDA then formalized the REMS regulatory program for the monitoring of medications with a high potential for serious adverse effect. A REMS program applies only to specific prescription drugs, but can apply to brand name or generic drugs.

164. When creating the REMS program, Congress was particularly concerned that restrictions placed on access to a particular medication through a REMS program not become an artifice through which brand companies impaired the ability of companies to develop similar and generically equivalent drug products. Congress expressly prohibited the use of restrictions on use to "block or delay approval" of applications under sections 505(b)(2) and 505(j) of the FD&C Act.

165. Because at the time some products already had a form of a risk management program in place—like the RiskMAP covering Xyrem—there was a process by which the earlier approved risk program could be deemed a REMS program. Xyrem's RiskMAP had been instituted as part of the original approval in February 2002, with a modified version of that plan being approved in November 2005. In March of 2008, the FDA deemed that plan to be a REMS program; however, Jazz was required to formally submit to the FDA a proposed REMS for review within 180 days of that notice.

166. In late August 2008, Jazz requested of the FDA that the existing risk management plan simply be approved as the new REMS approach for Xyrem under the FDAAA. That began a *seven-year* negotiation between Jazz and the FDA over the appropriate terms for the Xyrem REMS.

167. For example, when the FDA initially approved the RiskMAP in 2002 with the limitation that Xyrem be dispensed only from a single central pharmacy, the FDA had been led to believe that to be a good way to effectuate the overall restrictions on distribution necessary for safe use of the drug.

168. But in August 2009, as part of its transition from a RiskMAP to a REMS, Jazz submitted a proposal to, among other things, remove the single pharmacy restriction and instead allow certification of multiple pharmacies. Its rationale for this proposed change was that it would "increase patient access without compromising patient safety." Jazz also stated that the single pharmacy program in existence at that time "imposes numerous impediments to patient access to

Xyrem, possibly depriving narcolepsy patients of an important medication to control their EDS and cataplexy and potentially affect their lives dramatically."

169. By 2011—years into the discussion—Jazz had realized it could use the ongoing negotiations to delay generic entry. At that time, Jazz's 2002 RiskMAP was still under discussion with FDA to convert it to the REMS program. Xyrem was still not included on FDA's list of current REMS. And an industry commentator stated that "[a]t this point, it's hard to say which will happen first: Jazz fixing its RiskMAP/REMS, or the generic appearing on the market."

170. In February 2014, Jazz completed the flip-flop, filing a formal dispute resolution request, appealing an FDA notification and claiming that the agency's "assertion that the closed-loop distribution system for Xyrem is no longer necessary is not only unsupported, it puts patients and others at risk." Jazz also argued that the FDA "lacked statutory authority to modify a REMS 'deemed' to be in effect by operation of FDAAA, and alternatively, even if FDA did have such authority, it could only be exercised to add restrictions to a REMS, not to modify or remove elements." But even at that time, the Jazz CEO acknowledged that the single pharmacy REMS was "a piece of Xyrem exclusivity." And at an August 2014 meeting to discuss the ongoing dispute, a Jazz representative acknowledged that it might be possible for a distribution system that involves two, and perhaps more, specialty pharmacies to effectively prevent the abuse, misuse, and diversion of sodium oxybate.

171. During the process, the FDA expressed two primary public health goals: (i) to have a REMS that ensures safe use of the drug; and (ii) to ensure that the REMS does not stand in the way of generic approval. But eventually, the FDA folded to Jazz's litigiousness.

172. Eventually granting the single pharmacy approach for the REMS, the FDA wrote that "[i]n light of the significant drain on Agency resources posed by the dispute, and the fact that the outcome of Jazz's challenge to the Agency's legal authority to require a modification to a 'deemed REMS' had the potential to affect only a small number of drug products, the Agency decided to approve the REMS Jazz had proposed (i.e., with the single, central pharmacy limitation), and deny the dispute as moot." The FDA's disapproval of Jazz's anticompetitive acts was clear:

> FDA is mindful of the statutory requirement under the FD&C Act that [terms of use] be 'commensurate with the specific serious risk[s] listed in the labeling' of the drug, that [terms of use] 'not be unduly burdensome on patient access to the drug,' and 'to the extent practicable,' that [terms of use] be structured 'so as to minimize their burden on the health care delivery system.' We also note that it is part of FDA's statutory mandate to approve generic drugs that meet the standard for approval.
>
> Pursuant to these statutory provisions, FDA has sought to finalize and approve the REMS for Xyrem since 2008. In doing so, we have faced repeated, lengthy delays. The REMS you submitted on November 7, 2014, which we are now approving, contains a requirement that Xyrem be distributed only by a single pharmacy. Jazz's position that a single pharmacy is critical to the safe use of Xyrem has not been a consistent one. In 2009, Jazz submitted a supplemental NDA for a new indication for Xyrem for treatment of fibromyalgia in which it proposed to include multiple certified pharmacies.
>
> However, by early 2011, after FDA declined to approve the fibromyalgia indication, Jazz changed its position. By that time, Jazz had been granted several patents related to its single pharmacy distribution system. In its 2013 SEC filings, Jazz noted that it expected FDA modifications to the Xyrem REMS and stated that, 'depending on the extent to which certain provisions of our Xyrem deemed REMS which are currently protected by our method of use patents covering the distribution of Xyrem are changed as part of updating our REMS documents, the ability of our existing patents to protect our Xyrem distribution system from generic competitors may be reduced.' This statement, in conjunction with Jazz's change in position regarding the necessity of the single pharmacy requirement, suggests Jazz's awareness that the Xyrem REMS could have the effect of blocking or delaying approval of generic versions of Xyrem. Such an outcome would reflect the use of REMS to block or delay generic competition in a manner inconsistent with section 505-1(f)(8). It would also place an unjustified burden on patient access and on the healthcare delivery system.
>
> FDA is approving the REMS Jazz submitted on November 7, 2014, closing a chapter on a REMS that has been pending for 7 years -- far longer than could have been reasonably anticipated when FDAAA was enacted. 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.

173. The industry's Pink Sheet newsletter subsequently reported that "the FDA's tone of disapproval is bound to be cited in the context of any antitrust cases that ensue."

E. The Jazz 2012 Citizen Petitions to the FDA.

174. In addition to filing patent infringement lawsuits against Hikma seeking to block Hikma's launch in court and abusing the REMS system, Jazz filed Citizen Petitions with the FDA to delay the ANDA review and approval process.

175. On May 18, 2012, Jazz submitted to FDA a baseless Citizen Petition, Docket No. FDA-2012-P-0499, asking FDA to: (i) immediately publish whether generic Xyrem ANDAs were required to prove bioequivalence to the brand using *in vitro* testing, *in vivo* testing or both; (ii) not accept, review, or approve any ANDAs until after this information had been published; and (iii) require *in vivo* bioequivalence testing, including both fed and fasting conditions, "and a demonstration of onset of drug action similar to Xyrem," for any proposed ANDA product that differs from the brand in manufacturing process, pH, excipients, impurities, degradants or contaminants.

176. Jazz attached forty-nine exhibits to its May 2012 Citizen Petition, including numerous scientific studies spanning many hundreds of pages and, at footnote 2, an implicit threat to sue if FDA's review and response was not sufficiently thorough: "it would . . . be arbitrary and capricious for FDA to deny [the requests] without a substantive response."

177. On July 10, 2012, before FDA had responded to Jazz's May 2012 Citizen Petition, Jazz submitted to FDA a second Citizen Petition concerning the requirements for submission of ANDAs referencing Xyrem, Docket No. FDA-2012-P-0733 and asked the FDA to rescind the acceptance of any previously-accepted ANDA (including the ANDA submitted by Hikma) that did not include a proposed risk management system at the time that FDA accepted it for review, arguing that such ANDAs would not contain the same labeling and conditions as Xyrem, as required by law.

178. The July 2012 Citizen Petition further requested that the FDA: (i) not accept for review any ANDA referencing Xyrem that did not contain, at the time of its submission, a proposed risk management system sufficient to demonstrate that the new generic drug product has the same

labeling and conditions of use as Xyrem; and (ii) subject any revised ANDA or later-submitted proposed risk management system to a renewed automatic 30-month stay of approval in the event Jazz timely opted to initiate patent litigation based on such notice.

179. On November 13, 2012, the FDA denied Jazz's May 18, 2012 Citizen Petition, dutifully outlining its bases in 20 pages of single-spaced text and eighty-six footnotes.

180. The FDA found that, contrary to Jazz's contentions, it is not required to publish bioequivalence guidance prior to accepting ANDAs, nor is it required to reject ANDAs submitted prior to such publication.

181. In denying Jazz's May 2012 Citizen Petition, FDA noted that publication of bioequivalence guidance is intended to benefit ANDA applicants, whereas the only beneficiary of Jazz's baseless interpretation is brand manufacturers like Jazz, "who will benefit from a delay in generic competition in the marketplace."

182. On December 13, 2012, the FDA denied in its entirety Jazz's July 2012 Citizen Petition finding, as with Jazz's May 2012 Citizen Petition, that none of the requests had merit.

F. The Jazz lawsuits against at least eight other generic companies.

183. After the first-to-file ANDA by Roxane, at least eight other generic manufacturers submitted ANDAs for approval of AB-rated generic versions of Xyrem:

OTHER ANDA SUBMISSIONS

ANDA Applicant	ANDA No.	Date of Initial Paragraph IV Notice Letter to Jazz
Amneal Pharmaceuticals, LLC	203631	Dec. 10, 2012
Par Pharmaceutical, Inc.	205403	Nov. 20, 2013
Ranbaxy Laboratories Limited and Ranbaxy Inc.	203351	June 3, 2014
Watson Laboratories, Inc.	204952	Oct. 29, 2014
Wockhardt Bio AG	207526	June 8, 2015
Lupin Ltd. and Lupin Pharmaceuticals Inc.	207415	July 23, 2015

OTHER ANDA SUBMISSIONS

ANDA Applicant	ANDA No.	Date of Initial Paragraph IV Notice Letter to Jazz
Ascent Pharmaceuticals, Inc.	210523	June 14, 2017
Mallinckrodt plc, Mallinckrodt Inc., and Mallinckrodt LLC	210936	Nov. 21, 2017

184. After each ANDA applicant sent its initial Paragraph IV notice letter to Jazz, Jazz filed patent infringement actions against each applicant. And as Jazz acquired more and more patents, Jazz brought additional suits against these other would-be Xyrem generic drug makers.

185. Under the Hatch-Waxman Act, Jazz's filing of these 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. These stays prevented the FDA from granting final approval of these ANDAs until the earlier of: (i) the expiration of the thirty-month stay; or (ii) entry of a final judgment that the patents at issue were invalid, unenforceable, and/or not infringed.

G. The notorious Jazz price increases for Xyrem.

186. Jazz was a small, relatively unsuccessful biotech firm before it leveraged the company to buy the Xyrem franchise. And in 2005 when Jazz first acquired Orphan, a one-year supply of Xyrem cost about $5,000 to $10,000.

187. After a series of shockingly large price increases by Jazz for each of seven successive years, by 2014 a one-year supply cost approximately $62,000 to $124,000. Specifically, the recommended dose of Xyrem ranges from 4.5 to 9 grams, which converts to a monthly dosage range of 270 to 540. In 2007, the yearly cost of Xyrem ranged from $6,610 to $13,219. But by 2014, the yearly cost for the drug had ballooned to a range from $62,208 to $124,416.

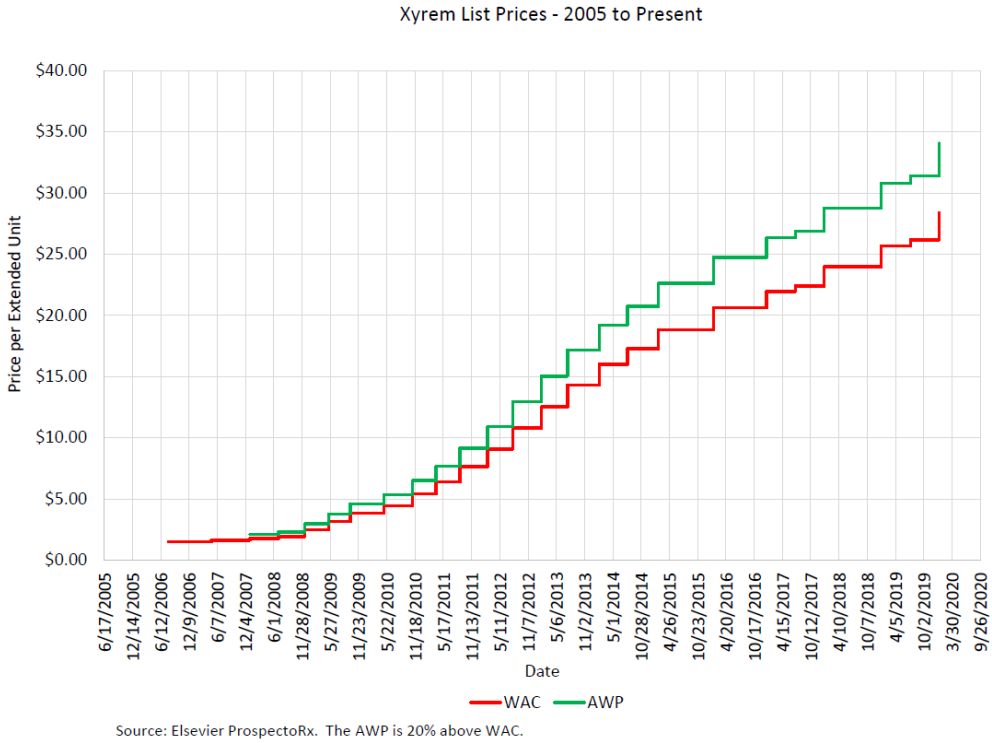
188. In 2014, Jazz came under heavy scrutiny for alleged pricing abuse on Xyrem. For example, in May of 2014, Bloomberg published a ranking of drug price increases from 2007 to 2014. Xyrem ranked *first* with an overall increase of 841% from 2007 to 2014. Bloomberg's data indicated the following percentage price increases:

Year	Price Per mL	% Change from Previous Year
2007	$2.04	-
2008	$3.09	51%
2009	$4.60	49%
2010	$6.50	41%
2011	$9.17	41%
2012	$12.97	41%
2013	$17.15	32%
2014	$19.20	12%

189. Since 2007, Jazz has incrementally raised the price of Xyrem from $2.04 per milliliter to $31.21, an increase of over 1,430% to date. For a patient taking a dosage in the middle of the effective range, the monthly cost of Xyrem now exceeds $14,000 ($168,000 annually).[61]

[61] *See Xyrem Prices, Coupons and Patient Assistance Programs*, Drugs.com, https://www.drugs.com/price-guide/xyrem (last updated Feb. 2, 2021); *Xyrem Dosage*, Drugs.com, https://www.drugs.com/dosage/xyrem.html (last updated Feb. 2, 2021) (effective dose range is 6-9 grams of sodium oxybate nightly; Xyrem solution contains 0.5 grams of sodium oxybate per milliliter).

190. The following chart details Jazz's dramatic pricing increases by tracking the list prices for Xyrem over the life of Jazz's monopoly on the drug:



191. The pricing history of Xyrem stands in stark contrast to that of other branded drugs. From 2009 to 2018, Xyrem's WAC price increased a staggering 525%, as compared to an average of just over 100% for all other brand drugs for which data is available.

H. The patents in the '730 family are found invalid.

192. Beginning in January 2015, would-be generics for Xyrem filed a series of petitions with the PTAB for *inter partes* review of the '730 family of patents relating to the distribution system for sensitive drugs. Claims in all of the '730 family of patents were challenged in the proceedings.

193. Collectively, and as consolidated, Par and Amneal challenged claims in the '730, '106, '107, '059, '988, '182, and '936 patents.

194. Each of the challenged patents derive from the same original application: U.S. Patent Application No. 10/322,348, filed December 17, 2002 by Orphan, and each contains, as noted above,

claims relating to a drug distribution system and method that utilizes a central pharmacy and database to track prescription.

195. On April 28, 2016, Jazz settled with Wockhardt (one of the generics that was pressing IPR review), resolving not only the IPR proceedings but also the patent infringement litigation Jazz had filed against Wockhardt. That settlement agreement, according to Jazz's public filings, granted Wockhardt a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or ostensibly "earlier depending on the occurrence of certain events" (the import of which is discussed later). The specific terms of the settlement agreements are confidential. Jazz and Wockhardt then sought, and were granted, termination of the IPR proceedings as to Wockhardt.

196. Days later, on May 9, 2016, Jazz settled with Ranbaxy. Ranbaxy was also granted a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or ostensibly "earlier depending on the occurrence of certain events" (again to be discussed later). That settlement also is confidential. With its settlement, Ranbaxy's IPRs and civil counterclaims in the Hatch-Waxman litigation pending against it were terminated.

197. From July 2016 to March 2017, with just Amneal and Par remaining as petitioners, the PTAB issued a series of six decisions finding that "by a preponderance of the evidence" all claims of the '730, '106, '107, '059, '182, '988 patents, and claims 24, 26, and 27 of the '963 patent, were unpatentable as obvious.

198. The board found that these claims, which related to Jazz's REMS program and described a centralized database containing patient, physician and prescription information, were obvious because Orphan had disclosed the program long before it filed the first patent application, i.e., Orphan's disclosure at a publicly-held FDA Advisory Committee meeting on June 6, 2001, and such information was posted to the FDA's website.

199. Jazz appealed the ruling to the Federal Circuit. In July 2018, that court affirmed the PTAB invalidity rulings, eviscerating Jazz's REMS patent portfolio for Xyrem.

I. Hikma obtains final ANDA approval for generic Xyrem.

200. On January 17, 2017, with its infringement trial with Jazz just six months away, Hikma obtained final approval from FDA for its generic Xyrem ANDA.

201. In its approval of Hikma's ANDA, the FDA also issued a decision to waive the requirements for a single, shared system ("SSS") REMS for Xyrem. This meant that Hikma was no longer required, under FDA regulations, to seek a license to rely on Jazz's Xyrem REMS protocol. The decision referenced the ANDAs of Hikma, Ohm, and Amneal, among other applicants whose names were redacted, and provided that they or any other generic sodium oxybate oral solution manufacturer could also rely on Hikma's REMS program (and not be required to use Jazz's).

202. In issuing its decision, the FDA detailed the history of the parties' negotiations regarding an SSS REMS. According to the FDA, Roxane first contacted Jazz regarding the development of an SSS REMS on October 12, 2012. Other ANDA filers joined the negotiations over time.

203. On January 23, 2014, FDA hosted a meeting between Jazz and the ANDA filers to facilitate the development of an SSS REMS for sodium oxybate. At this meeting, the ANDA filers provided a proposed timeline to the meeting attendees with 30, 60, and 90 day milestones with deliverables, including a 30-day timeline for execution of a confidentiality and disclosure agreement (CDA)—a basic prerequisite for negotiations. On January 28, 2014, the ANDA filers provided a draft CDA to Jazz, but Jazz insisted on substantially different terms, and negotiations dragged on for seven months. The CDA was not signed until the end of August 2014.

204. But Jazz's efforts to delay were not finished. The parties continued not to reach agreement on threshold issues, such as voting rights for the negotiations, through summer 2015. Jazz insisted on voting by consensus until after approval and implementation of the REMS, while the ANDA filers preferred to use the more standard "one company, one vote" system used in other SSS REMS. On August 19, 2015, the ANDA filers email the FDA, reporting a lack of progress with Jazz, and stated their intent to develop a proposal for a separate REMS. On October 13, 2015, the FDA hosted a teleconference with Jazz and the ANDA filers, where the ANDA filers reported that Jazz's

positions "put them in an untenable position" and "essentially would have required [them] to forfeit their right to obtain a waiver" of the SSS requirement.

205. On December 4, 2015, Jazz submitted a letter to the FDA expressing its opposition to a potential waiver of the SSS requirement for sodium oxybate. Jazz argued, among other things, that the FDA cannot grant a waiver and approve a separate REMS for generics that utilizes multiple pharmacies, instead of a single, central pharmacy.

206. On March 23, 2016, the FDA hosted another joint teleconference, but the parties were not any further along in resolving their disagreements than they had been in October 2015. Finally, later in 2016, the ANDA applicants submitted requests for waivers of the SSS requirement.

207. In its decision on January 17, 2017, the FDA rejected Jazz's argument that the agency could not grant a waiver and noted that "the parties have been attempting to negotiate an SSS REMS for sodium oxybate for a substantially longer period of time than the applicants for alosetron or buprenorphine, the other drug products for which an SSS waiver has been granted"—for which waiver was granted after one to three years of negotiation. The FDA reiterated the ANDA filers' 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."[62] The FDA "recognize[d] that there are financial incentives and considerations . . . that can hinder [redacted] efforts to establish an SSS REMS" and that "[c]ertain statements by Jazz, including the concerns expressed in its SEC filings and its change in position regarding the necessity of the single pharmacy requirement (from urging FDA to remove the restriction to a single pharmacy in 2009 to insisting it is critical to safe use in 2011), suggest Jazz's awareness that the Xyrem REMS could have the effect of blocking or delaying approval of generic versions of Xyrem."

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[62] *See* FDA Memorandum, Decision to waive the requirement for a single, shared system REMS for sodium oxybate oral solution, January 17, 2017, at 11, https://www.fda.gov/media/102913/download.

208. Ultimately, the FDA determined that "[i]n the absence of a waiver of the SSS requirement, the ANDA [redacted] and Jazz's failure to agree to SSS terms is likely to further delay the approval of a generic version of sodium oxybate" and accordingly waived the SSS requirement for Xyrem.[63]

J. The Jazz-Hikma reverse payment agreement.

209. By the spring of 2017, Hikma had received final FDA approval for its generic product, and no statutory exclusivities stood in the way for its market entry. Hikma's challenge to Jazz's remaining Xyrem patents was set for trial only a few weeks away. Under its approved application, there was no legal obstruction to Hikma entering the U.S. market with its own approved product, its own pharmacy arrangements, and its own approved REMS program.

210. Such a full market entry by Hikma would likely cause Jazz to immediately launch its own AG to compete with Hikma's ANDA product. Given tentative approvals already granted to other generic companies, Hikma's entry into the market would likely be followed, six months later, by other generic entries, thereby fully "genericizing" the U.S. market for sodium oxybate oral solution.

211. However, in early April 2017 Jazz and Hikma settled the lawsuit by means of an unlawful reverse payment agreement, under which generic entry in the market for sodium oxybate oral solution was delayed and impaired for years.

212. The April 2017 Jazz-Hikma agreement was, in part, memorialized in three documents, a "Settlement Agreement," a "License Agreement," and an "AG Agreement," each of which was executed at the same time and effective upon dismissal of the last of the infringement lawsuits between Jazz and Hikma. Although these documents evince some of the agreements between Jazz and Hikma, other tacit agreements were also reached between Jazz and Hikma at the time.

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[63] *Id*. at 12-13.

213. The document styled as a "Settlement Agreement" between Jazz and Hikma was partially disclosed in the public securities filings for Jazz.[64] Jazz and Hikma agreed to conceal from the public the other two documents as well as the tacit agreements between them. All the written and tacit arrangements between Jazz and Hikma in April of 2017 were negotiated simultaneously, are interdependent, and are collectively referred to in this complaint as the "Jazz-Hikma agreement."

214. The Jazz-Hikma agreement included: (a) an explicit promise from Hikma not to enter the market with its ANDA-approved generic version of Xyrem until July 1, 2023; and (b) a *de facto* promise from Hikma not to enter the market its ANDA-approved generic version of Xyrem for a further extended period of time (which was later pegged by Jazz to the end of 2025).

215. In consideration for its promise to delay launching its ANDA-approved product, Hikma received, among other things: (i) a *de jure* and *de facto* exclusive right to sell an AG of unlimited quantities between January 1, 2023, and July 1, 2023, at supra-competitive prices; (ii) a *de jure* and *de facto* right to continue to sell an AG of unlimited quantities for extended periods of time under circumstances where such sales would continue to command supra-competitive prices, and (iii) a *de facto* right to share supra-competitively priced sales with Jazz for however long Jazz could defer market entry by other generic companies (which later Jazz arrangements pegged to the end of 2025). The result was to give Hikma a *de facto* AG exclusivity period of six months during which it would be Jazz's only competitor on price, and a period of about two and one-half years during which Hikma's AG sales would occur while sharing supra-competitive sales with others. Other consideration included earlier entry protection in the "event of substantial reduction in Xyrem net sales over specified periods of time[,]"[65] that would occur with Jazz's successful introduction of a Xyrem line extension, i.e. product hop.

216. While other generic manufacturers will be authorized to sell a limited amount of Xyrem AG between July 1, 2023, and December 31, 2025, they would be incentivized to sell their

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[64] *See* Settlement Agreement between Jazz and Roxane dated April 5, 2017, *available at* https://www.sec.gov/Archives/edgar/data/1232524/000123252417000134/jazzq22017ex101.htm.

[65] Jazz Pharmaceuticals plc, Form 8-K at 2 (Apr. 5, 2017).

limited supply for as high a price as possible, thus ensuring that Jazz and Hikma can keep their prices high as well.

217. The April 2017 Jazz-Hikma agreement has a series of anticompetitive provisions that, taken together against the realities of pharmaceutical regulation and industry economics, were designed to have, have had, and continue to have, substantial anticompetitive consequences.

218. *First*, the Jazz-Hikma agreement was designed to have, and has had, the effect of delaying the entry into the market of Hikma's first-to-file ANDA generic until at least July 2023, but likely until the end of 2025. Absent the unlawful payments to Hikma, a rational economic actor in the position of Hikma, who expended considerable time and resources to first-file an ANDA seeking entry into the Xyrem market, would likely have entered the market as early as July 2017. That entry was delayed until at least July 2023, i.e., the date that technically, under the agreement, Hikma could decide to stop selling the Hikma AG and instead launch the Hikma FDA-approved generic.

219. *Second*, the Jazz-Hikma agreement was designed to have, and may well have, the effect of delaying the entry into the market of Hikma's first-to-file ANDA generic well past July 2023 and until the end of December 2025. If Hikma elected to launch its own generic product, Hikma would no longer have the right to sell the Hikma authorized generic product.[66] Thus, while Hikma may launch its FDA-approved generic by July 2023 under the technical terms of the agreement, doing so would: (i) forfeit its Hikma AG rights; (ii) void any incentives Jazz otherwise may have to withhold launch of its own AG product (e.g., the Hikma AG "royalties" back to Jazz); and (iii) trigger the rights of some other would-be generics to enter the market. As a result, Hikma would have significant incentives not to launch its own ANDA product. In short, the economics behind the agreements were designed to, and may well have, the likely impact of delaying entry of Hikma's generic product until the end of 2025, i.e., when the agreed entry date arrives for all would-be makers. The Jazz-Hikma agreement was designed to, and does have, the effect of prolonging as

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[66] In a later earnings call, Jazz Chairman and CEO Bruce Cozadd acknowledged that "Hikma has a license to launch its generic product as of July 1, 2023, but it will no longer have the right to sell an AG product through the Xyrem REMS if it elects to do so."

long as feasible the period of duopoly supracompetitive prices for Xyrem and the Hikma AG product.

220. The consequence has been, and will be, that supracompetitive prices for Xyrem are unnecessarily charged for sodium oxybate oral solution while only NDA-approved versions of the product are on the market, and those supracompetitive prices will remain until there is full and fair generic competition. Hikma's agreement to delay entry was induced by the market allocation payments in the agreement.

221. *Third,* the Jazz-Hikma agreement was designed to, and does have, an explicit or *de facto* commitment on the part of Jazz not to launch its own authorized generic of Xyrem through a third-party during at least the first six months that Hikma is eventually on the market (the "Jazz no-AG commitment").[67] Among other things, Jazz would have no incentive to also launch an AG of its own to challenge the Hikma AG sales if: (i) the first-to-file ANDA generic—Hikma—would be the company that would enter as an authorized generic; and (ii) Hikma provided "meaningful" payments back to Jazz during the time it was on the market with the Hikma AG. Instead, the agreement was designed to, and does 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), the Hikma AG would be the only authorized generic.

222. The consequence is that at least during the initial six-month period after the Hikma AG is eventually launched on January 1, 2023, the only two sodium oxybate oral solution products on the market will likely be branded Xyrem and the Hikma AG, with each able to command highly supracompetitive prices for sodium oxybate oral solution. And because Hikma could not sell its own

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[67] Jazz's business custom and practice, as well as its manufacturing capabilities, suggest that it would not have launched a generic version of Xyrem without a third-party distributor. Jazz currently only sells branded (commercialized) products in the United States. *See* Jazz Pharmaceuticals plc, Annual Report (Form 10-K) at 6-11 (Feb 23, 2021) (detailing commercialized products). Jazz also has limited manufacturing capacity and only manufactures its Xyrem and Xywav products. *Id.* at 16 ("our 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 API, other raw materials, packaging materials and finished products.").

generic while it was selling the Hikma AG, the agreement ensured that there was only one generic—of any kind—on the market.

223. *Fourth*, the Jazz-Hikma agreement was designed to, and does have, the effect of significantly limiting both the extent to which Hikma AG sales would cut into Xyrem sales, and the extent to which Hikma AG sales would be discounted to Xyrem sales. Under the agreement, Hikma was required to use the Xyrem REMS for its Hikma AG product. As a result, all Hikma AG product will be required to be delivered by Jazz directly to the same, single central pharmacy used by Jazz for Xyrem—it appears that Hikma would never take delivery of any AG product, nor have the ability to introduce competition into the market by increasing the number of companies dispensing to patients.

224. *Fifth,* the Jazz-Hikma agreement was designed to hinder, and has had the effect of hindering, other generic companies from coming into the marketplace. It does so by delaying the availability of a second REMS program, with additional dispensaries, for use by later generic entrants. The requirement in the agreement that Hikma use the Xyrem REMS for the Hikma AG product reduced the availability for other generics to gain market entry by use of the Hikma ANDA approved REMS, delaying later generic market entry.

225. *Sixth,* the Jazz-Hikma agreement was designed to hinder, and has had the effect of hindering, later generic entry by providing a form of a most favored entry clause (sometimes dubiously termed an "acceleration clause") that would provide disincentives to later generics to continue challenges to the Xyrem patents. By allowing Hikma to enter with the Hikma AG product on the "earlier events" of either "market entry of other generic versions of Xyrem" or "a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable," the most favored entry provisions reduced incentives for other generics to seek earlier generic entry.

226. *Seventh,* the fact that the Jazz-Hikma agreement effectuated delayed market entry by Hikma is shown by the entry term enabling earlier Hikma AG entry in the event of "a substantial reduction in Xyrem net sales over specified periods of time." Jazz did not have any arguable patent rights to exclude entry dependent on the extent of its Xyrem sales, nor did Hikma have any argument that it would not infringe a valid Xyrem patent claim based on the extent of Xyrem sales. Instead, the provision was added to the overall agreement because Hikma was delaying its market entry, and in

return it needed a commitment that the size of that market would remain at specified levels; if not, it no longer needed to delay its entry.

227. *Finally*, the fact that the Jazz-Hikma agreement is anticompetitive by design and execution is shown by the terms that provide the agreement "permits [Hikma] to develop and implement the separate REMS approved with its ANDA, and permits Jazz to challenge the FDA's waiver decision and the separate REMS approved in connection with [Hikma's] ANDA, and to raise any other safety issues pertaining to Xyrem." At the time of the settlement, Hikma *already had FDA approval* for its separate REMS program, a process that Jazz had fought tooth and nail. With the parties now settling outstanding issues, yet preserving the ability of Jazz to challenge the FDA's approval of the Hikma REMS program, the parties were now working towards the same, anticompetitive goal of seeking to limit the ability of other generics to gain market access.

228. The Jazz-Hikma agreement contains an unlawful reverse payment forbidden by the Supreme Court in *FTC v. Actavis*. Unlike a typical, lawful patent settlement (where the parties agree to an entry date based on the relative merits of their legal positions), the Jazz-Hikma agreement includes a large and unlawful reverse payment from Jazz to Hikma in exchange for Hikma's agreement to delay generic competition until later than the date Hikma would otherwise have been willing to accept. The payment takes several forms.

229. *First*, and most significantly, the Jazz-Hikma reverse payment agreement functions to incentivize both Jazz and Hikma to benefit by delaying other generics from entering the market for years (which delay period was later pegged at the end of 2025), during which Hikma would be the only AG on the market with unlimited quantities of the product for about three years. Given Xyrem's astronomically high price, this *de facto* exclusivity period could be worth hundreds of millions of dollars to Hikma.

230. *Second*, the large reverse payment to Hikma takes the form of the Jazz no-AG commitment, i.e., the promise by Jazz (either express, or implied by operation of the other terms of the settlement) not to launch its own AG product in competition with the Hikma AG during the first six months after Hikma launches on January 1, 2023. The valuable absence of a competitive AG

(licensed by Jazz to another company) on the market is not value that Hikma could have gained in the litigation nor procured if it had launched its own, ANDA-approved product.

231. *Third*, the large reverse payment to Hikma takes the form of *de facto* limitations on price competition that enable both Jazz and Hikma to make more money than they would under competitive conditions. The deal is structured to provide a royalty from Hikma to Jazz during the Hikma AG term, with the royalty rate increasing based on increased net sales of the Hikma AG. In effect, while Hikma sells some of the Hikma AG, the payback to Jazz is relatively small, but the payback increases when Hikma's net sales increase too much (making, of course, Hikma's ability to price against Jazz's product less likely). In effect, Hikma and Jazz allocate the market and keep prices high. This enables Hikma to earn far more through a collusive scheme than it would if it entered lawfully with its own ANDA-approved product.

232. *Fourth*, the acceleration clause that granted Hikma an earlier entry in the event of substantial reduction in Xyrem net sales over specified periods of time is also valuable to Hikma. It protects Hikma from entering a substantially reduced market that a successful Xyrem line extension product would create. With earlier entry triggered by reduced Xyrem sales, Hikma would still reap the rewards of selling its generic Xyrem before the vast majority of Xyrem patients migrated to Jazz's line extension product.

233. *Fifth*, the provision that permits Hikma to use the Xyrem REMS program is also a large reverse payment. By using the Xyrem REMS program rather than its own, FDA-approved Hikma REMS, Hikma can distribute product to patients without providing other generics a pathway to the market. Because Hikma has not operationalized its separate REMS program (agreeing instead to delay launching its ANDA product and sell an allocation of AG provided by the brand and sold under the brand's REMS program), subsequent generics faced yet another hurdle on their path to market: They would need to establish their own REMS program from the ground up before selling their generic versions of Xyrem. This is value that Hikma could not have gained in the litigation nor procured if it had launched its own, ANDA-approved product.

234. The combined reverse payments from Jazz to Hikma—in the forms of the no-AG commitment, the price support arrangement, the earlier entry triggered by a Jazz product hop, and the use of the Xyrem REMS—is large under any view of the facts and within the meaning of *Actavis*.

235. Under the Jazz-Hikma agreement, Jazz is also required to pay to Hikma a sum of money that approximates the avoided litigation costs of Jazz by settling the patent infringement litigations. As a result, *any* further payment of value from Jazz to Hikma is likely a large reverse payment, i.e., it will exceed avoided litigation costs.

236. The Xyrem market at the time of projected *bona fide* generic entry would have been about $1.5 billion per year. Under competitive conditions, a first-to-file generic company entering that market might expect about 40-45% market penetration, with the other 40-45% penetration going to an authorized generic licensed by Jazz. Facing competition from both the brand and two generics in the market, generic prices would fall at least 40%. So, during the first six months, the first-to-file generic might likely estimate sales of about $150 million to $202.5 million.

237. Under the anticompetitive conditions created by the Jazz-Hikma agreement, Hikma stands to make markedly more. Under typical industry assumptions, without competition from an authorized generic from Jazz, the Hikma AG will gain 80-90% of sales and will be priced higher than it would under competitive conditions. The resultant sales to the Hikma AG under this parameter would be between $480 million to $540 million (if the Hikma AG sells for 80% of the brand price).

238. Under these parameters—shown simply to illustrate that a first-to-file generic can make huge sums more if it cuts an anticompetitive no-AG deal with the brand—Hikma would stand to make a very significant amount of money more if it did not share some of that money back with Jazz. (Under these parameters, in the vicinity of about $225 million to $360 million more.)

239. In this case, the variable "royalties" in the Jazz-Hikma agreement are intended to (a) kick back to Jazz some of that windfall to make up for the large amount Hikma gains by being the only generic on the market and (b) maintain a higher than usual level of pricing by Hikma. But in all events Hikma receives a payment to limit and delay full generic competition.

240. This calculation only accounts for the revenues to Hikma during the first six months after launch. But the agreement permits Hikma's AG sales to be extended for up to five years, meaning that the size of the payment will increase due to the likely longer term of the Hikma AG.

241. There are other indicia suggesting a large reverse payment from Hikma to Jazz. On April 6, the day following the announcement of the Jazz-Hikma agreement, Jazz's stock rose sharply, from $140.65 at the close of markets on April 5, to $153.88 per share at the close on April 6, representing over 9% increase in value on septuple the normal trading volume. These price and volume changes are shown in the charts below:

242. This change represents an increase in Jazz's adjusted market capitalization of $785 million, as shown in the right-hand column of Table 1, below.

243. When analyzed using established methods of econometric modeling (reflected in Tables 1 and 2, below) the probability that the April 6, 2017 increase in Jazz's share price and trading volume occurred by chance is approximately zero, as shown in the "p-value" columns, below. Rather, it was a reaction to the Jazz-Hikma agreement.

TABLE 1: STOCK PRICE MOVEMENTS AROUND THE JAZZ-HIKMA AGREEMENT

Date	Days From Event	Actual Return	Predicted Return	Abnormal Return	Standard p-value	SQ Test p-value	Adjusted Market Cap Change ($M)
4/3/2017	-3	-1.53%	-0.28%	-1.25%	0.56	0.39	-$87
4/4/2017	-2	0.21%	0.06%	0.15%	0.94	0.89	$13
4/5/2017	-1	-1.79%	-0.50%	-1.29%	0.55	0.37	-$111
4/6/2017	0	9.41%	0.27%	9.13%	0.00	0.01	$785
4/7/2017	1	-0.06%	-0.16%	0.09%	0.97	0.93	$8
4/10/2017	2	-0.59%	0.08%	-0.66%	0.75	0.62	-$57
4/11/2017	3	0.07%	-0.25%	0.31%	0.88	0.83	$27

TABLE 2: ABNORMAL VOLUME OF TRADING IN JAZZ SHARES AROUND THE JAZZ-HIKMA AGREEMENT

Date	Days From Settlement	Trading Volume	Abnormal Volume	t-Statistic	p-Value
3/30/2017	-5	-52%	-41%	-0.715	0.476
3/31/2017	-4	-19%	0	-0.218	0.828
4/3/2017	-3	-12%	-7%	-0.116	0.908
4/4/2017	-2	-50%	-39%	-0.690	0.492
4/5/2017	-1	6%	4%	0.070	0.944
4/6/2017	0	332%	343%	5.995	0.000
4/7/2017	1	2%	15%	0.266	0.791
4/10/2017	2	-29%	-10%	-0.178	0.859
4/11/2017	3	3%	15%	0.254	0.800
4/12/2017	4	-34%	-23%	-0.410	0.683
4/13/2017	5	-48%	-36%	-0.637	0.525

244. Stock prices reflect investors' expectations about a company's ability to continue generating cash flows and value for shareholders. Changes in the stock price reflect changes in these expectations.

245. The spike in Jazz's stock price implies that, prior to the settlement, the company's shareholders were expecting generic competition to occur on a date earlier than permitted under the terms of the Jazz-Hikma agreement. There was also no corresponding drop in the price of Hikma's stock price.

246. The magnitude of the increase in Jazz's stock cannot be explained by factors such as increased certainty or other business arrangements. Rather, the jump in Jazz's stock price suggests the settlement included a payment to extend the agreed upon entry date later than was otherwise expected to occur and is thus evidence of the anticompetitive effects of the settlement.

K. Jazz enters into unlawful reverse payment agreements with additional generic manufacturers.

247. By 2018, Jazz had effectively forestalled generic entry for sodium oxybate oral solution. But while Hikma (the first-to-file ANDA applicant) and several other generics had abandoned their challenges to the Xyrem patents, other generic companies continued to press

forward.[68] And if any of these later challengers succeeded, the entire market for sodium oxybate would become genericized, and along with that, almost all of Jazz's Xyrem sales. But settling these remaining patent challenges in a lawful manner based on the merits (or lack thereof) of Jazz's patent position would likely mean having to concede to an agreed entry date markedly earlier than had been the case for others. Competitive conduct would result in earlier generic entry for sodium oxybate.

248. Over the course of 2018, then, Jazz worked a series of anticompetitive reverse payment settlements with the three remaining serious challengers to the Xyrem patents.

249. In January 2018, Jazz and generic maker Par entered into an anticompetitive reverse payment agreement (the "Jazz-Par agreement").

250. Under the agreement, Jazz granted Par a right to sell a limited volume of an authorized generic version of Xyrem (the "Par AG") for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. The volume of AG that Par was permitted to sell was limited to "a low single digit percentage" of Xyrem sales volume during the calendar year preceding the entry date of the Par AG. In effect, Jazz simply agreed to pay to Par a share of the supra-competitive profits it was gaining through the anticompetitive conditions it had created.

251. In exchange for this share of Jazz's brand Xyrem revenue (via volume-limited AG supply), Par agreed to abandon its challenge to Jazz's patents and delay launch of its own ANDA-based generic until December 31, 2025.

252. At the time it entered into the Jazz-Par agreement, Par was aware of the arrangements between Jazz and Hikma. Although unlawful, Par's acceptance of the terms of the Jazz-Par agreement only made sense if Par knew that the Jazz-Hikma agreement operated to have Jazz, Hikma, and Par sharing supra-competitive pricing of Xyrem products.

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[68] At the time of the Jazz-Hikma agreement, Jazz had already settled similar patent litigations against Wockhardt and Ranbaxy. As part of these settlements, Wockhardt and Ranbaxy each agreed not to launch their own generics until December 31, 2025. In exchange, Jazz promised to market limited supplies of two separate AGs, in partnership with each of the companies, and to share profits from these AGs with Wockhardt and Ranbaxy, respectively.

253. By entering into the Jazz-Par agreement, Par also agreed to become part of the anticompetitive agreement to allocate the market for sodium oxybate oral solution. Along with the explicit market allocation arrangements, the Jazz-Par agreement also included a so-called "acceleration clause," which facilitated the horizontal market share by ensuring that no participant to the market share would be able to jump the line to early generic entry.

254. Because Par was agreeing to delay its market entry, the Jazz-Par agreement also contained a provision under which the agreed entry date would be accelerated in the event of a substantial reduction in Xyrem net sales over specified periods of time.

255. The reverse payment from Jazz to Par is objectively valued in at least the tens of millions of dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

256. In June 2018, Jazz and generic maker Lupin entered into an anticompetitive reverse payment agreement (the "Jazz-Lupin agreement").

257. Under the agreement and as it had done with Par, Jazz granted Lupin a right to sell a limited volume of an authorized generic version of Xyrem (the "Lupin AG") for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. The volume of AG that Lupin was permitted to sell was limited to "a low single digit percentage" of Xyrem sales volume. In effect, Jazz simply agreed to pay to Lupin a share of the supra-competitive profits Jazz was gaining through the anticompetitive conditions it had created.

258. In exchange for this share of Jazz's brand Xyrem revenue (via volume-limited AG supply), Lupin agreed to abandon its challenge to Jazz's patents and delay launch of its own ANDA generic until December 31, 2025.

259. At the time of entering into the Jazz-Lupin agreement, Lupin was aware of the arrangements between Jazz, Hikma, and Par. Although unlawful, Lupin's acceptance of the terms of the Jazz-Lupin agreement only made sense if Lupin knew that the Jazz-Hikma-Par agreements operated, as a practical matter, to have Jazz, Hikma, and Par sharing supra-competitive pricing of Xyrem products.

260. By entering into the Jazz-Lupin agreement, Lupin agreed to become part of the overall anticompetitive agreement to allocate the market for sodium oxybate oral solution. Along with the explicit market allocation arrangements, the Jazz-Lupin agreement also provided a so-called "acceleration clause," which facilitated the horizontal market share by assuring that no participant to the market share would be able to jump the line to early generic entry.

261. Because Lupin was agreeing to delay its market entry, the Jazz-Lupin agreement also contained a provision under which the agreed entry date would be accelerated in the event of a substantial reduction in Xyrem net sales over specified periods of time.

262. The reverse payment from Jazz to Lupin is objectively valued in the tens of millions of dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

263. In October 2018, Jazz and generic maker Amneal entered into an anticompetitive reverse payment agreement (the "Jazz-Amneal agreement").

264. Under the agreement and as it had done with Par and Lupin, Jazz granted Amneal a right to sell a limited volume of an authorized generic version of Xyrem (the "Amneal AG") for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. The volume of AG that Amneal was permitted to sell was limited to "a low single digit percentage" of Xyrem sales volume. In effect, Jazz simply agreed to pay to Amneal a share of the supra-competitive profits Jazz was gaining through the anticompetitive conditions it had created.

265. In exchange for this share of Jazz's brand Xyrem revenue (via volume-limited AG supply), Amneal agreed to abandon its challenge to Jazz's patents and delay launch of its own ANDA generic until December 31, 2025.

266. At the time of entering into the Jazz-Amneal agreement, Amneal was aware of the arrangements between Jazz, Hikma, Lupin, and Par. Although unlawful, Amneal's acceptance of the terms of the Jazz-Amneal agreement only made sense if Amneal knew that the Jazz-Hikma-Par-Lupin agreements operated, as a practical matter to have Jazz, Hikma, Par, and Lupin sharing supra-competitive pricing of Xyrem products.

267. By entering into the Jazz-Amneal agreement, Amneal was also agreed to become part of the anticompetitive agreement to allocate the market for sodium oxybate oral solution. Along with the explicit market allocation arrangements, the Jazz-Amneal agreement also provided a so-called "acceleration clause," which facilitated the horizontal market share by assuring that no participant to the market share would be able to jump the line to early generic entry.

268. Because Amneal was agreeing to delay its market entry, the Jazz-Amneal agreement also contained a provision under which the agreed entry date would be accelerated in the event of a substantial reduction in Xyrem net sales over specified periods of time.

269. The reverse payment from Jazz to Amneal is objectively valued in the tens of millions of dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

270. Although the precise percentage of the brand Xyrem market allocated to Jazz's would-be generic competitors under each of the agreements is not publicly known, the value of these allocations can be estimated by observing that every 1 percent of brand sales allocated represents a value of approximately $13.5 million per year, assuming $1.5 billion annual brand sales in the year preceding their entry and a discount of 10% off of brand pricing ($1.5B x 0.01 x 0.90 = $13.5 million).

271. As with the Jazz-Hikma agreement, Jazz's agreements with other generic manufacturers will not increase overall output, nor significantly reduce price, nor increase consumer choice; it will merely substitute the generic manufacturers as the sellers of millions of dollars' worth of branded Xyrem for the sole purpose of paying them to delay market entry of less-expensive generic Xyrem, preserving Jazz's massive monopoly profits in exchange for doling out a small slice of them to generic manufacturers. Individually and collectively, these agreements are classic market allocation. Had any one of the generic Defendants with output capacity defected from the conspiracy and refused to restrict output, Xyrem and its generic equivalents would be available to Plaintiffs and the Classes at lower prices, sooner.

272. Jazz has admitted that its series of reverse payment settlements with Hikma, Amneal, Lupin, and Par were designed to effectively allocate the Xyrem market.

273. In December 2019, the Jazz CEO noted that the settlements were structured in a way to specifically prevent full genericization and, therefore, any real pricing competition:

> So again, in the period starting in '23, and I would say, really '23 through '26, we're expecting authorized generic competition other than Hikma, the first to file, 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*. So I'd point that out from '23 to '26. In terms of what payers will do [with respect to Jazz's product hop], I think, if payers see a therapeutic equivalent, equal safety and efficacy, I have a pretty good idea, they're going to pick the cheapest product. But the question is, particularly, if there isn't a huge price differential, whether they will force patients onto a less healthy product. And I think that's a little different from the dynamics you usually see, including some of the ones you've referenced.

274. Similarly, during a healthcare conference call on November 14, 2018, a senior official described the agreements and their ends as follows:

> And now I want to sort of lay out for you where we are with the generic landscape for Xyrem. Now our first-filer, Hikma, settled with the agreement for them to launch an authorized generic on the 1st of January 2023. And what was said about that authorized generic, that authorized generic would provide Jazz with meaningful royalties and would provide Hikma with meaningful economics during that first year. And that authorized generic can last for up to 5 years. Post that first year, the royalties become even more meaningful for Jazz.
>
> Then 6 months later, after that 6-month exclusivity period for the first-filer, 3 of the second filers 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. And they get to have that for up until the end of 2025 when all 8 of the second filers have the opportunity to bring a generic product forth.

275. With the vast majority of Jazz's revenue on the line, it becomes clear why Jazz decided to maximize the delay of competition from ANDA-based generics (as opposed to those selling an AG made by Jazz) and its accompanying revenue cliff by entering into its series of reverse payment agreements. All of these settlements shared a common, unlawful element; a payment from Jazz in the form of a limited volume of product made under the brand's NDA to be sold by the would-be generic competitor at supracompetitive prices as a *quid pro quo* for the generics' agreement to delay launch of their own ANDA-based generic version of Xyrem. In every one of

these settlements, the amount of the payment was large, unexplained, and far in excess of any reasonable estimate of the parties' saved litigation costs.

276. By structuring the deals in this manner, Jazz was able to achieve several anticompetitive ends. First, the generic was assured a fixed amount of sales at only a very modest discount off of the brand's price; the generic manufacturer will easily sell its full allotment at supracompetitive prices, as there is no incentive for price competition of the sort that occurs when a company is able to sell an unlimited amount of its own generic product, effectively conveying a sizeable payment to each settling generic. Second, this deal structure implicitly (if not explicitly) assured the generics that, prior to an actual generic launch, an AG would not be launched in competition; each would-be generic can sell its full (limited volume) allotment of AG with or without competition from another AG, so Jazz would only be taking sales away from its own brand sales (unlike when an AG is launched in response to a competitor selling a generic under its own ANDA). And third, by permitting the settling generics' limited allotments of NDA product to be sold under the brand's REMS program, Jazz effectively prevented the launch of any separate REMS program for use by ANDA generics, thereby increasing the burden and expense for subsequent generics to bring their competing products to market.

L. Jazz develops a line extension for Xyrem.

277. Because the vast majority of Jazz's overall revenues come from Xyrem sales, in addition to its scheme to delay Xyrem's loss of exclusivity, Jazz has for years been keenly focused on developing or acquiring new products to extend its revenue streams beyond it. Chief among them is Jazz's plan to develop a line extension for Xyrem: a product with a renewed term of patent protection, approved pursuant to a separate NDA (so generics would have to go back to the drawing board), but using the same active ingredient and indicated to treat the same conditions. The benefit of this strategy is that, instead of developing or acquiring a product that treats a new condition or patient population, the brand manufacturer simply cannibalizes its own existing patient population from the legacy product (that is nearing the end of patent protection) to the successor product and then enjoys a new 20-year patent term.

278. By early 2017, Jazz was developing line extension products for Xyrem. One product, code-named JZP-258, is a low-sodium reformulation of Xyrem. But Xyrem's first generic applicant, Hikma, had just overcome the last of Jazz's hurdles and, on January 17, 2017, obtained final approval of its ANDA and separate REMS program. Jazz knew that Hikma could launch its generic "at risk" at any time. And even if Hikma opted not to launch at risk, there was a May 2017 patent trial, which brought with it the very real likelihood that Jazz's Xyrem patent portfolio would be found invalid or unenforceable, opening the floodgates not just for Hikma but for all generic Xyrem competition, years before Jazz's successor product would be ready for market.

279. On an August 8, 2017 earnings call, Jazz reported that the NDA for Xyrem's low-sodium successor product would be ready for filing as early as 2019. When asked whether the settlement with Hikma had any "guarantees in place on how much share they can have out of that low-sodium version as well", Mr. Cozadd, Jazz's CEO, replied that, other than a "fairly typical" market decline provision, "[u]nder that settlement, Hikma does not have any particular participation in or -- well, our low-sodium programs, of which there are several, remain completely ours."

280. When asked later on the same earnings call whether Jazz planned to "effectuate a hard switch and stop supplying Xyrem to the market," following launch of its low-sodium product, Mr. Cozadd did not rule out the strategy but advised it was "too early to start commenting on commercial strategy."

281. On a May 8, 2018 earning call, Mr. Cozadd was asked, "how you think JZP-258 will be received in the market when Xyrem generics are available," particularly among those patients "without ongoing sodium-sensitive comorbidities." Mr. Cozadd reminded that, "under our current time lines, our hope is the 258 would be available before generics were available," and implied he did not foresee patients migrating back to the legacy generic once the hop to the low sodium product had been effectuated.

282. Jazz completed clinical trials and submitted NDA 212690 for the JZP-258 product, brand named Xywav, which the FDA approved for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy on July 21, 2020. On the same day, the FDA approved a

modified version of the Xyrem REMS to include Xywav, and renamed the REMS program the Xyrem and Xywav REMS.

283. Jazz also submitted a supplemental NDA requesting that Xywav be approved for the treatment of idiopathic hypersomnia as well as narcolepsy. As of the filing of this complaint, the FDA has not granted approval for the additional indication.

284. Jazz launched Xywav in the U.S. on November 2, 2020. During an earnings call that same day, Daniel Swisher, Jazz President and COO, outline a strategy of gradual switching Xyrem patients to Xywav with goal of having "the majority of [sodium] oxybate patients on Xywav by 2023."

M. Since its launch in 2002, Xyrem has been dispensed through a single specialty pharmacy operated by Express Scripts, to which title passes only momentarily.

285. Xyrem is a prescription drug product which is subject to the FDA's RiskMAP/REMS program. One of the goals of the RiskMAP/REMS program with respect to Xyrem is to mitigate the risk of potential abuse, misuse, and/or diversion of the product. Toward that end, Xyrem is a tightly controlled substance which is sold through a unique, exclusive distribution system. Under RiskMAP/REMS, Orphan/Jazz were required to maintain ownership of Xyrem product, provide it on a consignment basis to a single distributor and ensure that such product would not be stocked in traditional retail pharmacies.

286. The distribution of Xyrem is unlike other traditional prescription drug products, which are typically sold directly to multiple independent wholesalers and/or large chain store pharmacies for resale to consumers.

287. Consistent with RiskMAP/REMS and since Xyrem's launch in October 2002, Xyrem has been dispensed directly through a specialty central pharmacy arrangement established and controlled by Jazz. Jazz and Express Scripts Specialty Distribution Services, Inc. ("ESSDS"), a subsidiary of Express Scripts, entered into a Pharmacy Master Services Agreement ("MSA").

288. Under this agreement, ESSDS is the central "certified pharmacy" to exclusively sell Xyrem in the United States. MSA ¶ 2.1. Under the MSA, Jazz expressly authorizes ESSDS to

exclusively provide "pharmacy and REMS services" to U.S. consumers, including warehousing and pharmacy dispensing services. *Id.* ¶¶ 2.1, 2.5.

289. The MSA also exclusively authorizes ESSDS to ship Xyrem directly to each U.S. patient or a patient-authorized adult designee, and track and verify receipt of each shipment of Xyrem.

290. As Jazz's exclusive provider of "pharmacy and REMS services," ESSDS performs and serves as Jazz's controlled REMS Xyrem fulfillment agent. The degree to which ESSDS is authorized to exercise its discretion concerning price and terms is expressly limited by the MSA. *Id.* ¶ 6.2. The MSA establishes pricing parameters which ESSDS may not exceed with respect to the sale of Xyrem. *Id.* ("the price at which ESSDS sells Product shall not exceed [***]") (redaction in original).

291. Xyrem is held by ESSDS on a consignment basis. MSA ¶ 4.1. Title remains with Jazz during the time that ESSDS holds Xyrem in its facilities until it is removed from the ESSDS's product storage area just before it is shipped to a patient. *Id.* In exchange for these fulfillment or dispensing services ESSDS receives a fee from Jazz. *Id.* ¶ 3.1 (describing service fees to be received by Jazz). The provisions of the MSA taken together suggest that the monies ESSDS receives from the sale of Xyrem constitute the service fee paid by Jazz to compensate ESSDS for its fulfillment and reporting services. Unlike traditional wholesalers which take title and sell prescription drugs, ESSDS is required to "confirm all such purchases and shipments of Product in writing to Jazz Pharmaceuticals on a weekly basis." *Id.*

292. Under these circumstances, it is clear the distribution and sale of Xyrem is vastly distinguishable from traditional prescription drug products. The RiskMAP/REMS program and the MSA establish a central method for the distribution of Xyrem which is dominated and controlled by Jazz, though its warehousing and fulfillment agent ESSDS.

VI. MARKET POWER AND DEFINITION

293. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many

pharmaceutical products, including Xyrem, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy while the patient (and in most cases, his or her insurer) has the obligation to pay for the product.

294. Brand manufacturers, including Jazz, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

295. The relative unimportance of price to the prescriber reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Xyrem.

296. Through at least January 1, 2023, Jazz has had, and will continue have, monopoly power in the market for Xyrem. Jazz has had, and will continue to have, the power to exclude competition and/or raise or maintain the price of sodium oxybate at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable. When Hikma does come to market with an AG of Xyrem, Hikma, and Jazz will have substantial market power in the market for Xyrem and its AB-rated generic equivalents because they will have the power to exclude competition and/or raise or maintain the price of sodium oxybate at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

297. Before January 1, 2023, a small but significant, non-transitory increase to the price of brand Xyrem would not have caused a significant loss of sales. From January 1, 2023 forward until at least December 31, 2025, a small but significant, non-transitory increase in the price of generic Xyrem would not have caused a significant loss of sales.

298. Brand Xyrem does not exhibit significant, positive cross-elasticity of demand with respect to price with any other sodium oxybate product or treatment for narcolepsy other than AB-rated generic versions of Xyrem.

299. Brand Xyrem is differentiated from all other sodium oxybate products, and all other narcolepsy treatments, other than the AB-rated generic versions of Xyrem.

300. Jazz needs to control only brand Xyrem and its AB-rated generic equivalents, and no other products, in order to maintain the price of sodium oxybate profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions would render Defendants unable to profitably maintain their prices for Xyrem without losing substantial sales.

301. During the 180-day exclusion period starting in January 1, 2023, Jazz, with Hikma's conspiratorial aid, will sell brand Xyrem at prices well in excess of marginal costs and in excess of the competitive price, and, therefore, Jazz will enjoy high profit margins.

302. Defendants have, and have exercised, the power to exclude generic competition to brand Xyrem.

303. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected and continue to protect branded Xyrem from the forces of price competition.

304. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Defendants' ability to control the price of Xyrem, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of the following facts, among others: (i) generic Xyrem would have entered the market at a much earlier date, at a substantial discount to brand Xyrem, but for Defendants' anticompetitive conduct; and (ii) Jazz's gross margin on Xyrem (including the costs of ongoing research/development and marketing) at all relevant times was very high.

305. To the extent proof of monopoly power by defining a relevant product market is required, Plaintiffs allege that the relevant antitrust market is the market for Xyrem and its AB-rated generic equivalents.

306. The United States, including the District of Columbia and the U.S. territories, constitutes the relevant geographic market.

307. Jazz's market share in the relevant market has been and will continue to be 100% until January 1, 2023, when Hikma enters the market at throttled capacity per its anticompetitive, reverse payment settlement agreement with Jazz.

VII. MARKET EFFECTS

308. Defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. Defendants designed a scheme to delay competition on the products' merits to further Jazz's anticompetitive purpose of forestalling generic competition against Xyrem, in which Hikma cooperated in order to increase its own profits. Defendants carried out the scheme with the anticompetitive intent and effect of maintaining supracompetitive prices for sodium oxybate tablets.

309. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Xyrem from competition. These actions allowed Jazz to maintain a monopoly and exclude competition in the market for Xyrem and its AB-rated generic equivalents to the detriment of Plaintiffs and all other Class members, as defined below.

310. Defendants' exclusionary conduct delayed and continues to delay generic competition and unlawfully enabled Jazz to sell Xyrem without further generic competition. Were it not for Defendants' illegal conduct, one or more additional generic versions of Xyrem would have entered the market sooner, and Hikma's generic product would face competition during its 180-day exclusivity period from a Jazz authorized generic product.

311. Defendants' illegal acts and conspiracy to delay generic competition for Xyrem caused Plaintiffs and all members of the Classes to pay more than they would have paid for sodium oxybate absent this illegal conduct.

312. General economic theory recognizes that any overcharge at a higher level of distribution in the chain of distribution for Xyrem results in higher prices at every level below.[69]

313. The institutional structure of pricing and regulation in the pharmaceutical industry assures that overcharges at the higher level of distribution are passed on to End-Payors.

314. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant market, Plaintiffs and members of the Classes would have paid less for sodium oxybate by: (i) paying lower prices on their remaining brand purchases of Xyrem; (ii) substituting purchases of less expensive generic Xyrem for their purchases of more expensive brand Xyrem when market entry occurs (or should have occurred); and/or (iii) purchasing generic Xyrem at lower prices sooner.

315. Thus, Defendants' unlawful conduct deprived Plaintiffs and Class members of the benefits from the competition that the antitrust laws are designed to ensure.

VIII. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

316. During the relevant time period, Defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. Defendants designed a scheme to delay competition on the products' merits, to further Jazz's anticompetitive purpose of forestalling generic competition against Xyrem, in which Hikma cooperated in order to increase its own profits. Defendants carried out the scheme, and continue to do so, with the anticompetitive intent and effect of maintaining supracompetitive prices for sodium oxybate.

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[69] Herbert Hovenkamp, Federal Antitrust Policy, The Law of Competition and its Practice 624 (1994). Professor Herbert Hovenkamp states that "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." He also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level." *Id*

317. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Xyrem, and later the generic Defendants' sodium oxybate products, from competition. These actions allowed Defendants to maintain a monopoly and to exclude competition in the market for Xyrem and its AB-rated generic equivalents, to the detriment of Plaintiffs and all other members of the Classes.

318. Were it not for Defendants' illegal conduct, generic Xyrem would have been available in the United States as early as July 2017, and certainly earlier than January 2023. In addition, were it not for Defendants' illegal conduct, when generic Xyrem did become available earlier, there would have been full and fair competition between the available generics, thereby reducing price to a competitive level.

319. Plaintiffs have incurred significant injury and damage as a result of the unlawful conduct of Defendants. During the period from July 2017 to the present, Plaintiffs purchased, paid for, and/or reimbursed for Xyrem at supracompetitive levels and have done so in at least the following states: Alabama, Alaska, Arkansas, Arizona, California, Colorado, Connecticut, District of Columbia, Delaware, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, Nebraska, New Hampshire, New Jersey, New Mexico, New York, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Rhode Island, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, and West Virginia. If the conduct challenged in this complaint had not occurred, Plaintiffs would have paid for Xyrem under lawful competitive conditions, resulting in a substantial reduction in the amount it would have paid for Xyrem.

320. Plaintiffs and Class members have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charge passed through the chain of distribution to payors such as Plaintiffs and Class members.

321. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, Plaintiffs and Class members would have paid less for sodium oxybate by (a) paying lower prices on their remaining brand purchases of Xyrem, (b) substituting purchases of less-expensive generic Xyrem for their purchases of more-expensive brand Xyrem, and/or (c) purchasing generic Xyrem at lower prices sooner.

322. The supracompetitive prices Plaintiffs and Class members paid and continue to pay are traceable to, and the direct, proximate, and foreseeable result of Defendants' anticompetitive conduct.

IX. INTERSTATE AND INTRASTATE COMMERCE

323. During the relevant time period, Jazz manufactured, sold, and shipped Xyrem across state lines in an uninterrupted flow of interstate commerce.

324. During the relevant time period, Plaintiffs and Class members purchased substantial amounts of Xyrem from Jazz and/or its agents. As a result of Defendants' illegal conduct, Plaintiffs and Class members were compelled to pay, and did pay, artificially inflated prices for Xyrem, and should have already been paying far less for a generic version of the drug were it available and but for Defendants' conduct.

325. During the relevant time period, Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All Defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

326. Defendants' conduct was within the flow of and was intended to have and did have a substantial effect on, interstate commerce of the United States, including in this district.

327. During the Class period, each Defendant, or one or more of each Defendant's affiliates, used the instrumentalities of interstate commerce to join or effectuate the scheme. The scheme in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

328. Defendants' conduct has also had substantial intrastate effects in that, among other things, consumers and third-party payers have been prevented from purchasing more affordable generic versions of Xyrem in each state. Defendants' conduct materially deprived the consuming public—including hundreds, if not thousands, of purchasers in each state—of any choice to purchase more affordable versions of Xyrem. The absence of competition to Xyrem has, and continues to, directly and substantially affect and disrupt commerce within each state.

X. CLASS ACTION ALLEGATIONS

329. For counts 1 through 6, 13, 14, and 17, Plaintiffs bring this action on behalf of themselves and all others similarly situated as a class action under Rules 23(a), 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages and injunctive relief on behalf of the following Class.

> **Nationwide Class:** All persons and entities in the United States and its territories that purchased, paid for and/or provided reimbursement for some or all of the purchase price of Xyrem from Jazz or ESSDS, or any agents, predecessors, or successors of Jazz or ESSDS, other than for resale, during the time period from July 17, 2017, until the anticompetitive effects of the Defendants' unlawful conduct cease (the "Class Period").

330. The following persons and entities are excluded from the Nationwide Class:

a) Defendants and their counsel, officers, directors, management, employees, parents, subsidiaries, and affiliates;

b) ESSDS and any of its counsel, officers, directors, management, employees, parents, subsidiaries, and affiliates;

c) All federal and state governmental entities except for cities, towns, municipalities or counties with self-funded prescription drug plans;

d) Fully-insured health plans (i.e., health plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members);

e) Any "flat co-pay" consumers whose purchases of Xyrem were paid in part by a third-party payor and whose co-payment was the same and did not vary based on the drug's status as a brand or generic;

f) Pharmacy benefit managers; and

g) All judges assigned to this case and any members of their immediate families.

331. The Class seeks damages for at least the four years preceding the date the first complaint was filed, and permanent injunctive relief to prevent or remedy the unlawful conduct alleged herein.

332. As an alternative (*i.e.*, in the event of a determination that end-payers of Xyrem cannot assert damages claims under federal law), in connection with Counts 7 through 12 and 15, Plaintiffs bring this action on behalf of themselves and all others similarly situated as a Class action under Rules 23(a), 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure seeking damages and injunctive relief pursuant to the state antitrust, unfair competition, consumer protection and unjust enrichment laws of the states listed in Counts 7 through 12 and 15, on behalf of the following Class:.

> **State Law Damages Class:** All persons and entities in Alaska, Arizona, Arkansas, California, Connecticut, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin that, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries purchased, paid for and/or provided reimbursement, other than for resale, for some or all of the purchase price for Xyrem during the time period from July 17, 2017, through and until the anticompetitive effects of the Defendants' unlawful conduct cease.

333. The following persons and entities are excluded from the State Law Class:

a) Defendants and their counsel, officers, directors, management, employees, parents, subsidiaries, and affiliates;

b) ESSDS and any of its counsel, officers, directors, management, employees, parents, subsidiaries, and affiliates;

c) All federal and state governmental entities except for cities, towns, municipalities or counties with self-funded prescription drug plans;

d) Fully-insured health plans (i.e., health plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members);

e) Any "flat co-pay" consumers whose purchases of Xyrem were paid in part by a third-party payor and whose co-payment was the same and did not vary based on the drug's status as a brand or generic;

f) Pharmacy benefit managers; and

g) All judges assigned to this case and any members of their immediate families.

334. Members of the Classes are so numerous and geographically dispersed that joinder of all members is impracticable. Plaintiffs believe that members of each Class are numerous and widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many class members to bring individual claims and join them together. The Classes are readily identifiable from information and records in the possession of Defendants and third-parties.

335. Plaintiffs' claims are typical of the claims of the members of the Classes. Plaintiffs' claims arise out of the same course of anticompetitive conduct that gives rise to the claims of the other Class members. Plaintiffs and all members of the Classes were damaged by the same wrongful conduct of Defendants—they paid supracompetitive prices for Xyrem and were deprived of the benefits of earlier and more robust competition from less expensive generic Xyrem as a result of Defendants' unlawful conduct alleged herein.

336. Plaintiffs will fairly and adequately protect and represent the interests of the Classes. The interests of Plaintiffs are aligned with, and not antagonistic to, those of the other members of the Classes.

337. Plaintiff are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation involving pharmaceutical products.

338. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entirety of each Class, thereby making overcharge damages with respect to each Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct. Questions of law and fact common to the Classes include, but are not limited to:

a) Whether Defendants unlawfully maintained and continue to maintain monopoly power through all or part of their overall anticompetitive scheme;

b) To the extent procompetitive justifications exist, whether there were less restrictive means of achieving them;

c) Whether direct proof of Defendants' monopoly power is available and, if so, whether it is sufficient to prove Defendants' monopoly power without the need to define the relevant market;

d) Whether Defendants' scheme, in whole or in part, has substantially affected intrastate and/or interstate commerce;

e) Whether Defendants' unlawful agreements, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiff and the members of the Classes;

f) Whether Defendants conspired to delay generic competition for Xyrem;

g) Whether, pursuant to the reverse payment agreements, Jazz's promise not to compete against Hikma's generic product constituted a large and unexplained payment;

h) Whether Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Xyrem;

i) Determination of a reasonable estimate of the amount of delay Defendants' unlawful monopolistic conduct caused; and

j) The quantum of overcharges paid by the Classes in the aggregate.

339. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

340. Plaintiffs know of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

XI. APPLICATION OF CALIFORNIA LAW TO THE NATIONWIDE CLASS

341. Certification of the Nationwide Class, which seeks treble damages and injunctive and equitable relief under California's Cartwright Act and Unfair Competition Law (Counts 13 and 14), is proper.

342. Defendant Jazz's U.S. headquarters are located in Palo Alto California.

343. California has a strong interest in insuring the continued development of its economy by protecting against anticompetitive conduct, such as Defendants' conduct alleged herein.

344. California also has a strong government interest in protecting consumers and entities from unfair and unlawful business emanating from California and conducted by companies with their principal place of business in California.

345. California recently enacted Cal. Health & Safety Code § 134002, which deems the precise conduct alleged herein—reverse payment agreements between pharmaceutical manufacturers—unlawful.

346. Each Class member could bring an action in their individual capacity against Jazz in a California court (state or federal) for violations of California's Cartwright Act and Unfair Competition Law, based on the same operative facts alleged by Plaintiffs in this Complaint, regardless of where the Class member purchased Xyrem or suffered injury caused by Jazz.

347. The application of California law to claims against Jazz based on purchases that occurred outside of California would not violate the Due Process Clause of the United States Constitution. Jazz's anticompetitive and conspiratorial conduct occurred in California, and the connection between such conduct and California is not merely "slight and casual" or *de minimis*.

348. Jazz is a citizen of California, with its principal place of business in Palo Alto, California, subject to general jurisdiction in all courts located within the State of California. California was the nexus of Jazz's unlawful anticompetitive conduct alleged in this Complaint.

349. Jazz devised its anticompetitive scheme in California, negotiated and signed the anticompetitive reverse payment agreements in California, made pricing decisions regarding Xyrem in California, and made anticompetitive business decisions in California.

350. The State of California has a clear, substantial, legitimate, and compelling interest in protecting competition in California and entertaining claims by all victims of Jazz's unlawful and anticompetitive conduct that emanated from within California's borders, not only those by California residents, and not only those by persons who purchased Xyrem within the State.

351. In the alternative to certifying Counts 13 and 14 on behalf of the Nationwide Class, Plaintiffs seek certification of Counts 13 and 14 on behalf of the State Law Class.

XII. CLAIMS FOR RELIEF[70]

COUNT 1 – VIOLATION OF 15 U.S.C. § 1 (AGAINST JAZZ AND HIKMA)

352. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

353. Plaintiffs bring this Count on behalf of the Nationwide Class.

354. Jazz and Hikma violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

355. Plaintiffs and Class members have been injured in their business or property by the violation of 15 U.S.C. § 1. Their injury consists of having paid higher prices for their sodium oxybate requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Jazz and Hikma's conduct unlawful.

356. But for Hikma's reverse payment agreement delaying generic entry and its agreement to restrict output in the market for Xyrem and its generic equivalents, prices for Plaintiffs and Class members' sodium oxybate requirements would be lower, sooner.

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[70] One or more Plaintiffs previously delivered notice of this action and copies of this complaint to the attorneys general in Alabama, Alaska, Arizona, California, Connecticut, Hawaii, Illinois, Kansas, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nevada, New York, Oregon, Rhode Island, South Carolina, Utah, Vermont, West Virginia, and Wisconsin. Plaintiffs also provided a notice of the pendency of this action and demand for relief to Defendants.

357. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiffs, Class members, and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

358. As a direct and proximate result of Jazz and Hikma's anticompetitive conduct, Plaintiffs and Class members were harmed and continue to be harmed in the form of overcharges.

COUNT 2 – VIOLATION OF 15 U.S.C. § 1
(AGAINST JAZZ AND AMNEAL)

359. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

360. Plaintiffs bring this Count on behalf of the Nationwide Class.

361. Jazz and Amneal violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

362. Plaintiffs and Class members have been injured in their business or property by the violation of 15 U.S.C. § 1. Their injury consists of having paid higher prices for their sodium oxybate requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Jazz and Amneal's conduct unlawful.

363. But for Amneal's reverse payment agreement delaying generic entry and its agreement to restrict output in the market for Xyrem and its generic equivalents, prices for Plaintiffs and Class members' sodium oxybate requirements would be lower, sooner.

364. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiffs, Class members, and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

365. As a direct and proximate result of Jazz and Amneal's anticompetitive conduct, Plaintiffs and Class members were harmed and continue to be harmed in the form of overcharges.

COUNT 3 – VIOLATION OF 15 U.S.C. § 1
(AGAINST JAZZ AND LUPIN)

366. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

367. Plaintiffs bring this Count on behalf of the Nationwide Class.

368. Jazz and Lupin violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

369. Plaintiffs and Class members have been injured in their business or property by the violation of 15 U.S.C. § 1. Their injury consists of having paid higher prices for their sodium oxybate requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Jazz and Lupin's conduct unlawful.

370. But for Lupin's reverse payment agreement delaying generic entry and its agreement to restrict output in the market for Xyrem and its generic equivalents, prices for Plaintiffs and Class members' sodium oxybate requirements would be lower, sooner.

371. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiffs, Class members, and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

372. As a direct and proximate result of Jazz and Lupin's anticompetitive conduct, Plaintiffs and Class members were harmed and continue to be harmed in the form of overcharges.

COUNT 4 – VIOLATION OF 15 U.S.C. § 1
(AGAINST JAZZ AND PAR)

373. Plaintiff hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

374. Plaintiffs bring this Count on behalf of the Nationwide Class.

375. Jazz and Par violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

376. Plaintiffs and Class members have been injured in their business or property by the violation of 15 U.S.C. § 1. Their injury consists of having paid higher prices for their sodium oxybate requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Jazz and Par's conduct unlawful.

377. But for Par's reverse payment agreement delaying generic entry and its agreement to restrict output in the market for Xyrem and its generic equivalents, prices for Plaintiffs and Class members' sodium oxybate requirements would be lower, sooner.

378. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiffs, Class members, and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

379. As a direct and proximate result of Jazz and Par's anticompetitive conduct, Plaintiffs and Class members were harmed and continues to be harmed in the form of overcharges.

COUNT 5 – VIOLATION OF 15 U.S.C. § 1
(AGAINST ALL DEFENDANTS)

380. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

381. Plaintiffs bring this Count on behalf of the Nationwide Class.

382. Defendants violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

383. Plaintiffs and Class members have been injured in their business or property by the violation of 15 U.S.C. § 1. Their injury consists of having paid higher prices for their sodium oxybate requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Defendants' conduct unlawful.

384. From the launch of brand Xyrem in 2002 through present, Jazz possessed, and continues to possess, monopoly power in the relevant market—i.e., the market for sales of sodium

oxybate in the United States. But for Defendants' wrongful conduct, as alleged herein, Jazz would have lost its monopoly power in the relevant market as early as July 17, 2017 and in any event well before 2023.

385. Starting in January 2023, Jazz will share its monopoly power. First with Hikma, and then, six months later, with Amneal, Par, and Lupin, as a result of its anticompetitive reverse payment and market allocation agreements with each. These agreements individually and collectively will cover a sufficiently substantial percentage of the relevant market to harm competition.

386. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

387. As a direct and proximate result of Defendants' anticompetitive conduct, Plaintiffs and Class members were harmed and continues to be harmed in the form of overcharges.

COUNT 6 – VIOLATION OF 15 U.S.C. § 2
(AGAINST JAZZ)

388. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

389. Plaintiffs bring this Count on behalf of the Nationwide Class.

390. As described above, before January 2023, Jazz will maintain its monopoly power in the relevant market and, after that point, will share its, monopoly power with Hikma first, followed by Amneal, Lupin, and Par in an illegal monopoly.

391. Jazz willfully and unlawfully engaged in continuing illegal conduct to monopolize the relevant market through at least December 31, 2025 by engaging in an anticompetitive scheme to keep AB-rated generic equivalents of Xyrem from the market—not as a result of providing a superior product, business acumen, or historical accident.

392. Plaintiffs and Class members have been injured and continue to be injured in their business or property by Jazz's violation of 15 U.S.C. § 2. Such injury consists of having paid higher

prices for their sodium oxybate requirements than they would have paid in the absence of those violations. Such injury is of the type antitrust laws were designed to prevent, and it flows from that which makes Jazz's conduct unlawful.

COUNT 7 – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW
(AGAINST JAZZ AND HIKMA)

393. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

394. Plaintiffs bring this Count on behalf of the State Law Class.

395. During the Class Period, Jazz and Hikma engaged in a continuing contract, combination or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

396. During the Class Period, Jazz and Hikma entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

397. Jazz and Hikma's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

398. As a result of Jazz and Hikma's unlawful conduct, Plaintiffs and other similarly situated purchasers in the Class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supracompetitive prices for Xyrem.

399. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Jazz and Hikma did those things that they combined and conspired to do, including but not limited to the acts, practices and course of conduct set forth herein.

400. Jazz and Hikma's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Hikma delayed generic entry and its attendant lower prices for Plaintiff and Class members, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

401. Jazz and Hikma engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

402. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiff, Class members and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

403. By engaging the foregoing conduct, Jazz and Hikma intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.

d) D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.

e) Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.

g) Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.

k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.

l) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.

m) Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.

n) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.

o) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.

p) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.

q) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.

r) N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

s) N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.

t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.

u) Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.

v) P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases of Xyrem in Puerto Rico and/or purchases by Puerto Rico residents.

w) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.

x) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.

y) Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.

z) Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.

aa) W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.

bb) Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

404. Plaintiffs and Class members have been injured in their business or property by reason of Jazz and Hikma's violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Hikma's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Hikma's conduct unlawful.

405. Plaintiffs and Class members accordingly seek damages and multiple damages as permitted by law.

COUNT 8 – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW (AGAINST JAZZ AND AMNEAL)

406. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

407. Plaintiffs bring this Count on behalf of the State Law Class.

408. During the Class Period, Jazz and Amneal engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

409. During the Class Period, Jazz and Amneal entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

410. Jazz and Amneal's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

411. As a result of Jazz and Amneal's unlawful conduct, Plaintiffs and other similarly situated purchasers in the Class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supracompetitive prices for Xyrem.

412. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Jazz and Amneal did those things that they combined and conspired to do, including but not limited to the acts, practices and course of conduct set forth herein.

413. Jazz and Amneal's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Amneal delayed generic entry and its attendant lower prices for Plaintiffs and the class, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

414. Jazz and Amneal engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

415. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiffs, Class members, and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

416. By engaging the foregoing conduct, Jazz and Amneal intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.

d) D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.

e) Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.

g) Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.

k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.

l) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.

m) Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.

n) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.

o) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.

p) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.

q) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.

r) N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

s) N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.

t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.

u) Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.

v) P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases of Xyrem in Puerto Rico and/or purchases by Puerto Rico residents.

w) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.

x) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.

y) Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.

z) Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.

aa) W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.

bb) Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

417. Plaintiffs and Class members have been injured in their business or property by reason of Jazz and Amneal's violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Amneal's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Amneal's conduct unlawful.

418. Plaintiffs and Class members accordingly seek damages and multiple damages as permitted by law.

COUNT 9 – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW (AGAINST JAZZ AND LUPIN)

419. Plaintiffs hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

420. Plaintiffs bring this Count on behalf of the State Law Class.

421. During the Class Period, Jazz and Lupin engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

422. During the Class Period, Jazz and Lupin entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

423. Jazz and Lupin's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

424. As a result of Jazz and Lupin's unlawful conduct, Plaintiffs and other similarly situated purchasers in the Class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supracompetitive prices for Xyrem.

425. In formulating and carrying out the alleged agreement, understanding, contract, combination and conspiracy, Jazz and Lupin did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

426. Jazz and Lupin's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Lupin delayed generic entry and its attendant lower prices for Plaintiffs and the class, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

427. Jazz and Lupin engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

428. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiffs, Class members and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

429. By engaging the foregoing conduct, Jazz and Lupin intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.

d) D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.

e) Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.

g) Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.

k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.

l) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.

m) Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.

n) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.

o) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.

p) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.

q) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.

r) N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

s) N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.

t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.

u) Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.

v) P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases of Xyrem in Puerto Rico and/or purchases by Puerto Rico residents.

w) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.

x) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.

y) Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.

z) Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.

aa) W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.

bb) Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

430. Plaintiffs and Class members have been injured in their business or property by reason of Jazz and Lupin's violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Lupin's unlawful conduct. These injuries are of

the type that the above laws were designed to prevent and flow from that which makes Jazz and Lupin's conduct unlawful.

431. Plaintiffs and Class members accordingly seek damages and multiple damages as permitted by law.

COUNT 10 – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW (AGAINST JAZZ AND PAR)

432. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

433. Plaintiffs bring this Count on behalf of the State Law Class.

434. During the Class Period, Jazz and Par engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

435. During the Class Period, Jazz and Par entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

436. Jazz and Par's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

437. As a result of Jazz and Par's unlawful conduct, Plaintiffs and other similarly situated purchasers in the Class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supracompetitive prices for Xyrem.

438. In formulating and carrying out the alleged agreement, understanding, contract, combination and conspiracy, Jazz and Par did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

439. Jazz and Par's conspiracy had the following effects, among others: the reverse payment agreement between Jazz and Par delayed generic entry and its attendant lower prices for Plaintiff and the class, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

440. Jazz and Par engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

441. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiffs, Class members, and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

442. By engaging the foregoing conduct, Jazz and Par intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.

d) D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.

e) Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.

g) Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.

k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.

l) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.

m) Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.

n) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.

o) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.

p) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.

q) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.

r) N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiffs hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

s) N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.

t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.

u) Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.

v) P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases of Xyrem in Puerto Rico and/or purchases by Puerto Rico residents.

w) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.

x) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.

y) Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.

z) Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.

aa) W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.

bb) Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

443. Plaintiffs and Class members have been injured in their business or property by reason of Jazz and Par's violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz and Par's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz and Par's conduct unlawful.

444. Plaintiffs and Class members accordingly seek damages and multiple damages as permitted by law.

COUNT 11 – CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW (AGAINST ALL DEFENDANTS)

445. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

446. Plaintiffs bring this Count on behalf of the State Law Class.

447. During the Class Period, Defendants engaged in a continuing contract, combination, or conspiracy with respect to the sale of Xyrem in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

448. During the Class Period, Defendants entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Xyrem and/or its AB-rated generic equivalents.

449. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and/or its AB-rated generic equivalents.

450. As a result of Defendants' unlawful conduct, Plaintiffs and other similarly situated purchasers in the Class who purchased Xyrem have been harmed by being forced to pay artificially-inflated, supracompetitive prices for Xyrem.

451. In formulating and carrying out the alleged agreement, understanding, contract, combination and conspiracy, Defendants did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

452. Defendants' conspiracy had the following effects, among others:

a) It delayed and continues to delay generic entry of Xyrem in order to lengthen the period in which Jazz's brand Xyrem could and can monopolize the market and make supracompetitive profits;

b) It will keep an authorized generic from Jazz off the market during Hikma's 180-day generic exclusivity period, thereby allowing Hikma to monopolize the generic market for Xyrem during the period, and allowing Hikma to make supracompetitive profits;

c) It will, after Hikma's exclusivity period ends, continue to keep an authorized product from Jazz off the market as Amneal, Lupin, and Par enter with "very limited" quantities (throttled by Jazz) of generic Xyrem; and

d) It raised and maintained the prices that the Plaintiffs and Class Members would and will pay for Xyrem at supracompetitive levels.

453. From January 2023 until at least December 31, 2025, Jazz will share its monopoly power with Hikma, Amneal, Lupin, and Par, and the companies will jointly maintain an illegal monopoly throughout that time.

454. Defendants engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Xyrem.

455. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiffs, Class members, and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

456. By engaging the foregoing conduct, Defendants intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.

b) Cal. Bus. & Prof. Code §§ 16700, et seq., with respect to Class members' purchases in California and/or purchases by California residents.

c) C.G.S.A. §§ 35-26 and 28, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.

d) D.C. Code §§ 28-4501, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by D.C. residents.

e) Haw. Rev. Stat. §§ 480-1, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.

f) 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.

g) Iowa Code § 553.1, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.

h) Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.

i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.

j) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.

k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.

l) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or by Minnesota residents.

m) Miss. Code Ann. §§ 75-21-1, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.

n) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.

o) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.

p) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.

q) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.

r) N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiff hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

s) N.C. Gen. Stat. §§ 75-1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.

t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.

u) Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.

v) P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to Class members' purchases of Xyrem in Puerto Rico and/or purchases by Puerto Rico residents.

w) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.

x) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.

y) Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.

z) Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by citizens or residents of Utah.

aa) W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.

bb) Wis. Stat. §§ 133.01, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

457. Plaintiffs and Class members have been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than

they would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

458. Plaintiffs and Class members accordingly seek damages and multiple damages as permitted by law.

COUNT 12 – MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW
(AGAINST JAZZ)

459. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

460. Plaintiffs bring this Count on behalf of the State Law Class.

461. As described above, before January 2023, Jazz has and will maintain its monopoly power in the relevant market and, after that point, will share its monopoly power with Hikma first, followed by Amneal, Lupin, and Par, in an illegal monopoly.

462. Jazz willfully and unlawfully engaged in continuing illegal conduct to monopolize the relevant market through at least December 31, 2025 by engaging in an anticompetitive scheme to keep AB-rated generic equivalents of Xyrem from the market—not as a result of providing a superior product, business acumen, or historical accident.

463. Jazz knowingly and intentionally maintained and enhanced its monopoly power in the relevant market, as described herein, injuring Plaintiffs and the Class. Jazz accomplished this scheme by:

a) Delaying generic entry of Xyrem in order to lengthen the period in which Jazz's brand Xyrem could monopolize the market and make supra- competitive profits;

b) Keeping an authorized generic off the market during Hikma's 180-day generic exclusivity period, and, subsequently when Amneal, Lupin, and Par are permitted to enter with only limited quantities of generic Xyrem, through at least December 31, 2025, thereby allowing Defendants to monopolize the generic market for Xyrem during the period, and allowing Defendants to make supracompetitive profits;

c) Raising and maintaining the prices so that Plaintiffs and Class members would pay supracompetitive prices for Xyrem; and

d) Otherwise conspiring with the other Defendants to unlawfully monopolize the relevant market, including through the use of anticompetitive "acceleration" clauses.

464. The goal, purpose, and effect of Jazz's scheme was also to maintain and extend its monopoly power with respect to Xyrem. Jazz's illegal scheme allowed it to continue charging supracompetitive prices for Xyrem, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Jazz's scheme will allow Hikma to reap the benefits of reduced generic competition in the United States.

465. There is and was no legitimate, non-pretextual, procompetitive justification for Jazz's conduct that outweighs its harmful effects. Even if there were some conceivable justification, the conduct is and was broader than necessary to achieve such a purpose.

466. As a result of Jazz's illegal conduct, Plaintiffs and Class members were compelled to pay (and did pay), and continue to be compelled to pay (and do pay), more than they would have paid for Xyrem and/or its generic Xyrem absent Defendants' unlawful conduct. But for Jazz's unlawful conduct, competitors would have begun selling generic Xyrem sooner, and prices paid for the drug or its generic equivalents, would therefore, be less.

467. Had manufacturers of generic Xyrem entered the market and lawfully competed with Jazz (and one another) in a timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic Xyrem for the higher-priced brand-name Xyrem for some or all of their Xyrem requirements, and/or would have paid lower net prices on their remaining Xyrem and generic Xyrem purchases.

468. But for Jazz's illegal conduct, competitors would have begun marketing generic versions of Xyrem well before January 2023, and they would be able to market such versions successfully.

469. By engaging in the foregoing conduct, Jazz intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

a) Arizona Rev. Stat. §§ 44-1403, et seq., with respect to Class members' purchases in Arizona and/or purchases by Arizona residents.

b) Cal. Bus. & Prof. Code §§ 16700, with respect to Class members' purchases in California and/or purchases by California residents.

c) C.G.S.A. §§ 35-27, et seq., with respect to Class members' purchases in Connecticut and/or purchases by Connecticut residents.

d) D.C. Code §§ 28-4503, et seq., with respect to Class members' purchases in the District of Columbia and/or purchases by District Columbia residents.

e) Fla. Stat. §§ 501.201, et seq., with respect to Class members' purchases in Florida and/or purchases by Florida residents, and such conduct constitutes a predicate act under the Florida Deceptive Practices Act.

f) Haw. Rev. Stat. §§ 480-2, 480-9, et seq., with respect to Class members' purchases in Hawaii and/or purchases by Hawaii residents.

g) 740 Ill. Comp. Stat. 10/1, et seq., with respect to Class members' purchases in Illinois and/or purchases by Illinois residents.

h) Iowa Code § 553.5, et seq., with respect to Class members' purchases in Iowa and/or purchases by Iowa residents.

i) Kan. Stat. Ann. § 50-101, et seq., with respect to Class members' purchases in Kansas and/or purchases by Kansas residents.

j) Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to Class members' purchases in Maine and/or purchases by Maine residents.

k) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to Class members' purchases in Maryland and/or purchases by Maryland residents.

l) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to Class members' purchases in Michigan and/or purchases by Michigan residents.

m) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to Class members' purchases in Minnesota and/or purchases by Minnesota residents.

n) Miss. Code Ann. §§ 75-21-3, et seq., with respect to Class members' purchases in Mississippi and/or purchases by Mississippi residents.

o) Mo. Rev. Stat. §§ 407.020, et seq., with respect to Class members' purchase in Missouri and/or purchases by Missouri residents.

p) Mont. Code Ann. §§ 30-14-101, et seq., with respect to Class members' purchases in Montana and/or purchases by Montana residents.

q) Neb. Rev. Stat. Ann. §§ 59-802, et seq., with respect to Class members' purchases in Nebraska and/or purchases by Nebraska residents.

r) Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to Class members' purchases in Nevada and/or purchases by Nevada residents.

s) N.H. Rev. Stat. Ann. §§ 356.1, et seq., with respect to Class members' purchases in New Hampshire and/or purchases by New Hampshire residents.

t) N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to Class members' purchases in New Mexico and/or purchases by New Mexico residents.

u) N.Y. Gen. Bus. Law § 340, et seq., with respect to Class members' purchases in New York and/or purchases by New York residents, and to the extent New York law so requires, Plaintiff hereby forgo any penalty or minimum recovery in order to preserve the right of New York class members to recover by way of a class action.

v) N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to Class members' purchases in North Carolina and/or purchases by North Carolina residents.

w) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to Class members' purchases in North Dakota and/or purchases by North Dakota residents.

x) Or. Rev. Stat. §§ 646.705, et seq., with respect to Class members' purchases in Oregon and/or purchases by Oregon residents.

y) P.R. Laws Ann. tit. 10, §§ 260, *et seq.*, with respect to Class members' purchases of Xyrem in Puerto Rico and/or purchases by Puerto Rico residents.

z) R.I. Gen. Laws §§ 6-36-5 et seq., with respect to Class members' purchases in Rhode Island and/or purchases by Rhode Island residents.

aa) S.D. Codified Laws §§ 37-1-3.2, et seq., with respect to Class members' purchases in South Dakota and/or purchases by South Dakota residents.

bb) Tenn. Code Ann §§ 47-25-101, et seq., with respect to Class members' purchases in Tennessee and/or purchases by Tennessee residents.

cc) Utah Code Ann. §§ 76-10-3101, et seq., with respect to Class members' purchases in Utah and/or purchases by Arizona residents.

dd) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to Class members' purchases in Vermont and/or purchases by Vermont residents.

ee) W.Va. Code §§ 47-18-1, et seq., with respect to Class members' purchases in West Virginia and/or purchases by West Virginia residents.

ff) Wis. Stat. §§ 133.03, et seq., with respect to Class members' purchases in Wisconsin and/or purchases by Wisconsin residents.

470. Plaintiffs and Class members have been injured in their business or property by reason of Jazz's violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Jazz's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Jazz's conduct unlawful.

471. Plaintiffs and Class members accordingly seek damages and multiple damages as permitted by law.

COUNT 13 – VIOLATION OF SECTION 16720 OF THE CALIFORNIA BUSINESS AND PROFESSIONS CODE ("THE CARTWRIGHT ACT")
(AGAINST ALL DEFENDANTS)

472. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

473. Plaintiffs bring this Count on behalf of the Nationwide Class, and in the alternative on behalf of the State Law Class.

474. The violations of federal antitrust law set forth above also constitute violations of section 16720 of California Business and Professions Code.

475. Defendants entered into an unlawful agreement in restraint of trade in violation of California Business and Professions Code § 16700 et seq.

476. During the Class Period, Defendants entered into and engaged in a continuing unlawful contract, combination or conspiracy in unreasonable restraint of the trade and commerce described above in violation of California Business and Professions Code § 16720.

477. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and Class members have been injured in their business and property in that they paid more for Xyrem than they otherwise would have paid in the absence of Defendants' unlawful conduct.

478. As a result of Defendants' violation of § 16720, Plaintiffs and members of the Nationwide Class seek treble damages and their cost of suit, including a reasonable attorney's fee, pursuant to California Business and Professions Code § 16750(a).

COUNT 14 – VIOLATION OF CALIFORNIA BUSINESS AND PROFESSIONS CODE SECTION 17200 (UNFAIR COMPETITION LAW)
(AGAINST ALL DEFENDANTS)

479. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

480. Plaintiffs bring this Count on behalf of the Nationwide Class, and in the alternative on behalf of the State Law Class.

481. The violations of federal antitrust law set forth above also constitute violations of section 17200, *et seq.* of California Business and Professions Code, also known as the Unfair Competition Law (the "UCL").

482. Defendants have engaged in unfair competition or unfair and/or, unconscionable acts or practices in violation of the UCL by engaging in the acts and practices specified above. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to Class members.

483. There are no countervailing benefits to class members and any utility of Defendants' conduct is outweighed by the consequences to class members.

484. Defendants' conduct also constitutes an unlawful business practice in that it violates the Sherman Act as set forth above and violates Cal. Health & Safety Code § 134002.

485. The effects of the illegal conduct alleged herein are continuing and while the conspiracy has ended, the effects of the conspiracy continue to harm Plaintiffs and members of the Nationwide California Class.

486. The unlawful and unfair business practices of Defendants, and each of them, as described above, have caused and continue to cause Plaintiffs and the members of the Nationwide Class to pay supra-competitive and artificially-inflated prices for Xyrem sold in the United States. Plaintiffs and the members of the Nationwide Class suffered injury in fact and lost money or property as a result of such unfair competition.

487. Defendants and their co-conspirators have been unjustly enriched as a result of their wrongful conduct and by Defendants' unfair competition. Plaintiffs and members of the Nationwide

Class are entitled to full restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by Defendants as a result of such business acts or practices pursuant to California Business and Professions Code sections 17203 and 17204.

COUNT 15 – UNFAIR METHODS OF COMPETITION AND UNFAIR AND/OR UNCONSCIONABLE CONDUCT IN VIOLATION OF STATE CONSUMER PROTECTION LAWS
(AGAINST ALL DEFENDANTS)

488. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

489. Defendants engaged in unfair methods of competition or unfair and/or unconscionable conduct in violation of the state consumer protection statues listed below.

490. There was and is a gross disparity between the price that Plaintiffs and the Class members paid for Xyrem and the value they received. Much more affordable generic Xyrem would have been and would be available, and prices for Xyrem would have been and would be far lower, but for Defendants' unfair competition or unfair and/or unconscionable conduct.

491. Jazz implemented shockingly large price increases, resulting in an over 1,430% increase in price for Xyrem since 2007.

492. Lower-priced generic Xyrem would have been and would be available, and prices for Xyrem would have been and would be far lower, but for Defendants' unfair competition or unfair and/or unconscionable conduct.

493. As a direct and proximate result of Defendants' unfair competition or unfair and/or unconscionable conduct, Plaintiffs and Class members were: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) forced to pay higher prices for Xyrem than they would have paid but for Defendants' unlawful conduct.

494. The gravity of harm from Defendants' wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and Class members could not reasonably have avoided injury from Defendants' wrongful conduct.

495. By engaging in such conduct, Defendants violated the following consumer protection laws:

a) Alaska Stat. Ann. §§ 45.50.471, et seq., with respect to Class members' purchases of Xyrem in Alaska and/or purchases by Alaska residents.

b) Ariz. Rev. Stat. Ann. §§ 44-1521, et seq., with respect to Class members' purchases of Xyrem in Arizona and/or purchases by Arizona residents.

c) Ark. Code Ann. §§ 4-88-101, et seq., with respect to Class members' purchases of Xyrem in Arkansas and/or purchases by Arkansas residents.

d) Cal. Bus. & Prof Code §§ 17200, et seq., with respect to Class members' purchases of Xyrem in California and/or purchases by California residents. Defendants engaged in business practices that are unfair in that they are immoral, unethical, oppressive, unscrupulous, and substantially injurious to class members. There are no countervailing benefits to class members and any utility of Defendants' conduct is outweighed by the consequences to class members. Defendants' conduct also constitutes an unlawful business practice in that it violates the Sherman Act as set forth above and violates Cal. Health & Safety Code § 134002.

e) D.C. Code §§ 28-3901, et seq., with respect to Class members' purchases of Xyrem in D.C. and/or purchases by D.C. residents.

f) Fla. Stat. §§ 501.201, et seq., with respect to Class members' purchases of Xyrem in Florida and/or purchases by Florida residents.

g) Haw. Rev. Stat. §§ 481-1, et seq., with respect to Class members' purchases of Xyrem in Hawaii and/or purchases by Hawaii residents.

h) 815 Ill. Comp. Stat. 505/1, et seq., with respect to Class members' purchases of Xyrem in Illinois and/or purchases by Illinois residents.

i) Mass. Gen. Laws ch. 93A, §§ 1 et seq., with respect to Class members' purchases of Xyrem in Massachusetts and/or purchases by Massachusetts residents.

j) Mich. Comp. Laws §§ 445.901, et seq., with respect to Class members' purchases of Xyrem in Michigan and/or purchases by Michigan residents.

k) Mo. Rev. Stat. §§ 407.010, et seq., with respect to Class members' purchases of Xyrem in Missouri and/or purchases by Missouri residents.

l) Mont. Code §§ 30-14-101, et seq., with respect to Class members' purchases of Xyrem in Montana and/or purchases by Montana residents.

m) Neb. Rev. Stat. §§ 59-1601, et seq., with respect to Class members' purchases of Xyrem in Nebraska and/or purchases by Nebraska residents.

n) Nev. Rev. Stat. Ann. §§ 598.0903, et seq., with respect to Class members' purchases of Xyrem in Nevada and/or purchases by Nevada residents.

o) N.H. Rev. Stat. Ann. §§ 358-A:1, et seq., with respect to Class members' purchases of Xyrem in New Hampshire and/or purchases by New Hampshire residents.

p) N.M. Stat. Ann. §§ 57-12-1, et seq., with respect to Class members' purchases of Xyrem in New Mexico and/or purchases by New Mexico residents.

q) N.C. Gen. Stat. §§ 75-1.1, et seq., with respect to Class members' purchases of Xyrem in North Carolina and/or purchases by North Carolina residents.

r) R.I. Gen. Laws §§ 6-13.1-1, et seq., with respect to Class members' purchases of Xyrem in Rhode Island and/or purchases by Rhode Island residents, for personal, family and/or household use.

s) S.C. Code Ann. §§ 39-5-20, et seq., with respect to Class members' purchases in South Carolina and/or purchases by South Carolina residents. Defendants engaged in unfair methods of competition and/or unfair practices in the conduct of trade and commerce. Defendants' conduct is offensive to public policy and immoral, unethical, and oppressive.

t) Utah Code Ann. §§ 13-11-1, et seq., with respect to Class members' purchases of Xyrem in Utah and/or purchases by Utah residents for personal, family, or household purposes.

u) Vt. Stat Ann. tit. 9, § 2453, et seq., with respect to Class members' purchases of Xyrem in Vermont and/or purchases by Vermont residents. Defendants engaged in unfair methods of competition, unfair practices, and/or deceptive practices in the conduct of trade and commerce.

v) W. Va. Code §§ 46A-6-101, et seq., with respect to Class members' purchases of Xyrem in West Virginia and/or purchases by West Virginia residents.

w) Wis. Stat. § 100.20, et seq., with respect to Class members' purchases of Xyrem in Wisconsin and/or purchases by Wisconsin residents.

496. Plaintiffs and Class members have been injured in their business and property by reason of Defendants' unfair competition or unfair and/or unconscionable conduct. Their injury consists of paying higher prices for Xyrem than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

497. On behalf of themselves and the Class, Plaintiffs seek all appropriate relief provided for under the foregoing statutes.

COUNT 16 – UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

498. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

499. Plaintiffs bring this Court on behalf of the Nationwide Class except for Delaware, Georgia, Indiana, Kentucky, Louisiana, New Jersey, Ohio, Oklahoma, Pennsylvania, Texas, Virginia, Washington, and Wyoming.

500. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

501. Defendants have reaped and retained substantially higher profits due to their unlawful scheme.

502. Plaintiffs and Class members have conferred and continue to confer an economic benefit upon Defendants in the form of profits resulting from the unlawful overcharges from Xyrem sales described herein, to the economic detriment of Plaintiffs and Class members.

503. Defendants' financial gain from their unlawful conduct is traceable to overpayments for Xyrem by Plaintiffs and Class members.

504. It would be futile for Plaintiffs and Class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Xyrem, as those intermediaries are not liable and would not compensate Plaintiffs and Class members for Defendants' unlawful conduct.

505. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiffs and Class members for Xyrem sold by Jazz during the Class Period.

506. The financial benefits the Defendants derived from overcharging Plaintiffs and Class members for Xyrem is a direct and proximate result of Defendants' unlawful practices described herein.

507. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiffs and Class members, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

508. It would be wrong and inequitable, under unjust enrichment principles under the laws of the relevant jurisdictions for Defendants to be permitted to retain any of the overcharges that Plaintiffs and Class members paid for Xyrem that were derived from Defendants' unlawful practices described herein.

509. Defendants are aware of and appreciate the benefits that Plaintiffs and Class members have bestowed upon them.

510. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of the Plaintiffs and Class members.

511. Plaintiffs and Class members are entitled to the amount of Defendants' ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct, and to the establishment of a constructive trust consisting of such amount, from which Plaintiffs and Class members may make claims on a pro rata basis.

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)

512. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

513. Plaintiffs bring this Count on behalf of the Nationwide Class.

514. Plaintiffs seek declaratory and injunctive relief under the federal antitrust laws.

515. As set forth in Count 1, 2, 3, 4, 5 and 11, Defendants have violated Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2.

516. Plaintiffs and Class members have been injured in their business or property by reason of Defendants' antitrust violations. Their injury consists of paying higher prices for Xyrem than they would have paid in the absence of those violations. These injuries will continue unless halted.

517. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct constitutes a violation of Sections 1 and 2 of the Sherman Act.

518. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct the anticompetitive effects caused by Defendants' unlawful conduct and to restore competition in the market for Xyrem.

ADEQUATE REMEDIES AT LAW

519. To the extent that equitable relief is sought under any of the above claims, Plaintiffs plead such claims in the alternative to any legal claims and further plead that their legal claims do not provide adequate remedies at law. Until discovery and other pretrial matters are complete, the extent to which the legal claims above may provide the same relief for the same harms as could be available under claims providing equitable relief is unknown. Restitution may, for example, be measured differently than legal damages and provide for a different amount of relief. The difference between the value of restitutionary and legal relief will therefore be unknown until, at the earliest, the completion of expert reports and discovery.

520. In states where only equitable remedies are available for claims of unfair, unlawful, or unconscionable conduct (such as claims under the California Unfair Competition Law), legal claims that prohibit fraudulent conduct or provide for implied warranties would not be adequate to provide relief for such unfair or unconscionable conduct. In other instances, equitable claims broadly prohibit fraudulent conduct whereas legal claims only prohibit specifically enumerated types of conduct. In addition, claims alleging unfair or unconscionable conduct or unjust enrichment are brought against numerous Defendants in addition to Jazz, and thus seek relief that is different and broader than the relief sought by way of Plaintiffs' legal claims. The legal claims thus do not inherently provide the same relief for the same harms as the equitable claims.

XIII. DEMAND FOR JUDGMENT

521. WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Classes, respectfully demand that this Court:

a) Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Classes, and appoint Plaintiffs as the named representatives of the Classes;

b) Award Plaintiffs and the Classes damages (i.e., three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

c) Enter joint and several judgments against Defendants and in favor of Plaintiffs and the Classes;

d) Permanently enjoin Defendants both from continuing the unlawful conduct alleged here, and from engaging in similar or related conduct in the future;

e) Grant Plaintiffs and the Classes equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy the Defendants' unjust enrichment;

f) Award Plaintiffs and the Classes their costs of suit, including reasonable attorneys' fees, as provided by law; and

g) Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIV. JURY DEMAND

522. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs, on behalf of themselves and the proposed Classes, demand a trial by jury on all issues so triable.

DATED: March 8, 2021

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