UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SELF-INSURED SCHOOLS OF CALIFORNIA, on behalf of itself and all others similarly situated,

Individual and Representative Plaintiff,

v.

JAZZ PHARMACEUTICALS PLC; JAZZ PHARMACEUTICALS, INC.; JAZZ PHARMACEUTICALS IRELAND LIMITED; HIKMA PHARMACEUTICALS PLC; EUROHEALTH (USA), INC; HIKMA PHARMACEUTICALS USA, INC.; WEST-WARD PHARMACEUTICALS CORP.; ROXANE LABORATORIES, INC.; AMNEAL PHARMACEUTICALS LLC; ENDO INTERNATIONAL, PLC; ENDO PHARMACEUTICALS LLC; PAR PHARMACEUTICAL, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS INC; LUPIN INC.; SUN PHARMACEUTICAL INDUSTRIES LTD.; SUN PHARMACEUTICAL HOLDINGS USA, INC; SUN PHARMACEUTICAL INDUSTRIES, INC.; RANBAXY LABORATORIES LTD.; TEVA PHARMACEUTICAL INDUSTRIES LTD.; WATSON LABORATORIES, INC; WOCKHARDT LTD.; MORTON GROVE PHARMACEUTICALS, INC,; WOCKHARDT USA LLC; MALLINCKRODT PLC; MALLINCKRODT LLC,

Defendants.

Case No.

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Individual and Representative Plaintiff Self-Insured Schools of California ("SISC"), on behalf of itself and all others similarly situated, brings this Class Action Complaint against Defendants Jazz Pharmaceuticals PLC, Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals Ireland Limited, Hikma Pharmaceuticals PLC, Eurohealth (U.S.A.), Inc., Hikma Pharmaceuticals USA, Inc., West-Ward Pharmaceuticals Corp., Roxane Laboratories, Inc., Amneal Pharmaceuticals LLC, Endo International, PLC, Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., Lupin Inc., Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Holdings USA, Inc., Sun Pharmaceutical Industries, Inc., Ranbaxy Laboratories Ltd., Teva Pharmaceutical Industries, Ltd., Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Wockhardt Ltd., Morton Grove Pharmaceuticals Inc., Wockhardt USA LLC, Mallinckrodt PLC, Mallinckrodt LLC for Defendants' violations of state antitrust, consumer protection, and unjust enrichment laws concerning the narcolepsy drug Xyrem (sodium oxybate) and its A-B generic equivalent.

Based on personal knowledge, information and belief, and the investigation of counsel, Plaintiff alleges as follows:

I. NATURE OF THE ACTION

1. Defendant Jazz is the manufacturer of Xyrem (sodium oxybate), a blockbuster drug. Xyrem accounted for over a billion dollars annually that accounted for over 70% of the company's revenue. Loss of patent exclusivity would destroy its revenue. Price competition from generic competitors would bring competitive market forces to bear and would drive prices Xyrem prices down.

2. Facing a patent cliff, and the impact of competitive market forces, Jazz turned to an anticompetitive scheme to delay generic entry and maintain its monopoly. This scheme included, among other things, obtaining invalid and unenforceable patents and improperly listing these patents in the FDA's Orange Book, prosecuting sham litigation based on fraudulent, invalid, or unenforceable patents, abusing the REMS program, and filing sham citizen petitions. Jazz pursued that scheme.

3. In addition, Jazz entered into reverse settlement agreements (collectively the "Settlement Agreements") with Roxane, Amneal, Lupin, Par, Ranbaxy, Wockhardt, Watson, and Mallinckrodt (collectively, the "Generic Manufacturers"), agreeing to provide the Generic Manufacturers substantial compensation in exchange for the Generic Manufacturers' promise to delay entry into the market.

4. Through the Settlement Agreements, Jazz and the Generic Manufacturer effectively allocated the market for sodium oxybate in the United States according to the following schedule:

- Branded Xyrem will maintain its monopoly until December 31, 2022;
- On January 1, 2023, Jazz will introduce an Authorized Generic ("AG"), and profits from the AG will be shared with Roxane;
- On July 1, 2023, Jazz will introduce several more AGs, and profits from those AGs will be shared with other generic manufacturers in accordance their respective patent litigation settlement agreements;
- Roxane may also launch its own generic on July 1, 2023;

- On December 31, 2025, Amneal, Lupin, Par, Ranbaxy, Wockhardt, Watson, and Mallinckrodt may launch their own generics.

5. Jazz also raised prices to supracompetitive levels. Since 2007, Jazz has raised the price of Xyrem from approximately $2.04 per milliliter to approximately $29.69, an increase of over 1,350%.[1] For a patient taking a dosage in the middle of the effective range, the monthly cost of Xyrem exceeds $13,000.[2] One study showed that Jazz raised price more than any other pharmaceutical company for price increases on a single drug.[3]

6. In addition, Jazz pursued a plan to "product hop" to avoid generic substitution laws, thereby destroying any future generic's market share and forcing consumers to continue to pay supracompetitive prices for years in the future.

7. Defendants' anticompetitive behavior prevented, delayed, and restricted competition in the market for Xyrem and AB-rated generic versions in the United States and its territories. As a result, no generic version of Xyrem has entered the market and full generic competition will not occur until at least December 31, 2025.

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[1] *Compare Drug Prices Soar for Top-Selling Brands*, Bloomberg (May 1, 2014) https://www.bloomberg.com/graphics/infographics/drug-prices-soar-for-top-selling-brands.html#xyrem (noting that a 1-milliliter dose of Xyrem cost $2.04 in 2007) *with Xyrem Prices, Coupons and Patient Assistance Programs*, Drugs.com, https://www.drugs.com/price-guide/xyrem (noting that a 1-milliliter dose of Xyrem cost $29.69 in May of 2020).

[2] *See Xyrem Dosage,* Drugs.com, https://www.drugs.com/dosage/xyrem.html (accessed May 4, 2020) (effective dose range is 6-9 grams of sodium oxybate nightly; Xyrem solution contains 0.5 grams of sodium oxybate per milliliter).

[3] Sean Williams, *A company's 841% price increase on a sleep drug could attract attention from Capitol Hill*, Business Insider (Nov. 2, 2016), https://www.businessinsider.com/jazz-drug-price-increase-841-percent-drug-regulators-2016-11#:~:text=According%20to%20FiercePharma%2C%20between%202007,2014%2C%20an%20841%25%20increase.

8. Defendants' scheme caused consumers to pay supracompetitive prices for brand and generic Xyrem. Plaintiff seeks overcharge damages arising from Defendants' unlawful and anticompetitive tactics to maintain and allocate the monopoly in the market for indirect purchasers of sodium oxybate in the United States and its territories.

9. Plaintiff and the Class (defined below) have been injured by Jazz, Roxane, Amneal, Par, Lupin, Ranbaxy, Wockhardt, Watson, and Mallinckrodt's anticompetitive conduct in the form of overcharges for branded Xyrem. In the absence of such anticompetitive conduct, Class members would have been able to buy less-expensive generic sodium oxybate instead of branded Xyrem from as early as January 17, 2017.

II. JURISDICTION AND VENUE

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs, there are more than one hundred Class members, and at least one member of the putative Class is a citizen of a state different from that of one of the Defendants. This Court also has jurisdiction under Section 16 of the Clayton Act, 15 U.S.C. § 26.

11. Venue is appropriate within this district under 28 U.S.C. §1391 because, at all relevant times, Defendants transacted business within this district, and the interstate trade and commerce described hereinafter is carried out, in substantial part, in this district. Venue is also appropriate under Section 12 of the Clayton Act, 15 U.S.C. § 22, because Defendant Par maintains an office in this District. Further, Defendants and/or their agents may be found in this district.

12. 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.

III. INTRADISTRICT ASSIGNMENT

13. Assignment to the White Plains Courthouse is proper because a related case—*A.F. of L. – A.G.C. Building Trades Welfare Plan v. Jazz Pharmaceuticals PLC, et al.*, Case No. 7:20-cv-06003-NSR (S.D.N.Y.) is currently pending in that division.

IV. THE PARTIES

14. 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. During the Class Period, SISC indirectly purchased and paid for some or all the purchase price for Xyrem that was manufactured by Defendant Jazz. During the Class Period, SISC paid and reimbursed more for Xyrem than it would have absent Defendants' anticompetitive conduct. As a result of the wrongful conduct alleged herein, SISC was injured in its business or property by reason of the violations of law alleged herein. SISC intends to continue purchasing and/or reimbursing for brand and generic Xyrem and will continue to be injured unless the Defendants are enjoined from their unlawful conduct as alleged herein.

15. Defendant Jazz Pharmaceuticals PLC is an Ireland public limited 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. The contacts of Jazz Pharmaceuticals PLC with this District, and the United States, are regular, constant and pervasive. Jazz Pharmaceuticals PLC is the corporate parent of Defendants Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited.

16. 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 3170 Porter Drive, Palo Alto, CA 94304, and offices in Philadelphia, Pennsylvania and Ewing, New Jersey. Jazz Pharmaceuticals, Inc. is a wholly owned subsidiary of Jazz Pharmaceuticals PLC.

17. Defendant Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, with its principal place of business at Monksland, Co. Roscommon, Ireland. Jazz Pharmaceuticals Ireland Limited is a wholly owned subsidiary of Jazz Pharmaceuticals PLC.

18. As used in this complaint, "Jazz" encompasses all the entities paragraphs 15–17 and relevant predecessors-and successors-in-interest. At all times relevant to this complaint, Jazz manufactured and sold Xyrem (sodium oxybate) oral solution, the only product approved by the U.S. Food and Drug Administration (the "FDA") to be marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness ("EDS") in both adult and pediatric patients with narcolepsy.

19. Defendant Hikma Pharmaceuticals PLC is a public limited biopharmaceutical company organized and existing under the laws of the United Kingdom with its principal place of business at 1 New Burlington Place, London, United Kingdom. The contacts of Hikma Pharmaceuticals PLC with this District, and the United States, are regular, constant and pervasive Hikma Pharmaceuticals PLC is the corporate parent of Defendants Eurohealth (USA), Inc., Hikma Pharmaceuticals USA, Inc., West-Ward Pharmaceuticals Corp., and Roxane Laboratories, Inc.

20. Defendant Eurohealth (U.S.A.), 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. Eurohealth is a wholly owned subsidiary of Hikma Pharmaceuticals PLC, by and through Hikma Pharmaceuticals PLC's subsidiaries.

21. Defendant Hikma Pharmaceuticals USA, Inc. ("Hikma USA") 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. Hikma USA is the successor in interest to Defendant West-Ward Pharmaceutical Corp. and Roxane Laboratories, Inc., as discussed below. Hikma USA is a wholly owned subsidiary of Hikma Pharmaceuticals PLC, by and through Hikma Pharmaceuticals PLC's subsidiaries.

22. Defendant West-Ward Pharmaceuticals Corp. is a corporation organized and existing under the laws of the United States with its principal place of business at 246 Industrial Way West, Eatontown, New Jersey, 07724. In 2016, West-Ward Pharmaceuticals Corp. acquired Defendant Roxane Laboratories, Inc. Beginning in 2018, West-Ward Pharmaceuticals Corp. operated as Hikma Pharmaceuticals, USA, Inc. West-Ward Pharmaceuticals Corp. is a wholly

owned subsidiary of Hikma Pharmaceuticals PLC, by and through Hikma Pharmaceuticals PLC's subsidiaries.

23. Defendant Roxane Laboratories, Inc. is a corporation organized under the laws of the State of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio, 43228. In 2016, Roxane Laboratories, Inc. was acquired by West-Ward Pharmaceuticals Corp. and operated under that name until 2018. Since 2018, the company has operated under the name of Hikma Pharmaceuticals USA, Inc.

24. As used in this Complaint, "Roxane" encompasses all the entities in paragraphs 19–23 and relevant predecessors-and successors-in-interest. At all times relevant to this complaint, Roxane was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

25. Defendant Amneal Pharmaceuticals LLC ("Amneal") 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. At all times relevant to this complaint, Amneal was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

26. Defendant Endo International, PLC is a public limited biopharmaceutical company organized and existing under the laws of Ireland with its principal place of business at First Floor, Minerva House, Simmonscourt Road Ballsbridge, Dublin 4, Ireland. Endo International, PLC is the corporate parent of Defendants Endo Pharmaceuticals Inc. and Par Pharmaceutical, Inc. The contacts of Endo International PLC with this District, and the United States, are regular, constant and pervasive

27. Defendant Endo Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania, 19355. In September 2015, Endo Pharmaceuticals Inc. acquired Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par Pharmaceutical, Inc., and combined it with Endo Pharmaceuticals Inc.'s existing generics subsidiary, Qualitest Pharmaceuticals. Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo International, PLC, by and through Endo International, PLC's subsidiaries.

28. Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of New York, with its principal place of business at One Ram Ridge Rd., Chestnut Ridge, New York 10977. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Endo International, PLC, by and through Endo International, PLC's subsidiaries.

29. As used in this complaint, "Par" encompasses the entities described in paragraphs 26–28 and relevant predecessors-and successors-in-interest. At all times relevant to this complaint, Par was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

30. 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. Lupin Ltd. is the parent company of Defendants Lupin Pharmaceuticals, Inc. and Lupin Inc. The contacts of Lupin Ltd. with this District, and the United States, are regular, constant and pervasive

31. Defendant Lupin Pharmaceuticals, Inc., 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. Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Ltd., by and through Lupin Ltd.'s subsidiaries.

32. Defendant Lupin Inc. 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. Lupin Inc. is a wholly owned subsidiary of Lupin Ltd.

33. As used in this complaint, "Lupin" encompasses all the entities in paragraphs 30–32 and relevant predecessors-and successors-in-interest. At all times relevant to this complaint, Lupin was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

34. Defendant Sun Pharmaceutical Industries Ltd. is a public limited company organized and existing under the laws of India, with its principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400 063, Maharashtra. Sun Pharmaceutical Industries Ltd. is the parent company of Defendants Sun Pharmaceutical Holdings USA, Inc., Sun Pharmaceutical Industries, Inc. The contacts of Sun Pharmaceutical PLC with this District, and the United States, are regular, constant and pervasive

35. Defendant Sun Pharmaceutical Holdings USA, Inc., is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2 Independence Way, Princeton, New Jersey, 08540. Sun Pharmaceutical Holdings USA has no operating activities. Sun Pharmaceutical Holdings USA, Inc., is a wholly owned subsidiary Sun Pharmaceutical Industries Ltd.

36. Defendant Sun Pharmaceutical Industries, Inc., is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2

Independence Way, Princeton, New Jersey, 08540. Sun Pharmaceutical Industries, Inc conducts all operating activities of Sun Pharmaceutical Holdings USA, including developing, licensing, manufacturing, marketing and distributing generic and brand prescription pharmaceuticals to wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers throughout the United States, Canada and Puerto Rico. Sun Pharmaceutical Industries, Inc., is a wholly-owned subsidiary Sun Pharmaceutical Industries Ltd., by and through Sun Pharmaceutical Industries Ltd.'s subsidiaries.

37. Defendant Ranbaxy Laboratories Ltd. is a public limited company organized and existing under the laws of India, with its principal place in Gurugram, India. In 2014, Ranbaxy Laboratories Ltd. was acquired by Sun Pharmaceutical Industries Ltd.

38. As used in this complaint, "Ranbaxy" encompasses all the entities in paragraphs 34–37 and relevant predecessors-and successors-in-interest. At all times relevant to this complaint, Ranbaxy was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

39. Defendant Teva Pharmaceutical Industries, Ltd. is a publicly traded pharmaceutical company organized and existing under the laws of Israel with its principal place of business at 5 Basel Street, Petach Tikva, Israel, 491033. Teva Pharmaceutical Industries, Ltd. is the parent company of Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc. The contacts of Teva Pharmaceutical Industries, Ltd. with this District, and the United States, are regular, constant and pervasive

40. Defendant Teva Pharmaceuticals USA, Inc., is a pharmaceutical company incorporated under the laws of Delaware with its principal place of business at 1090 Horsham

Road North Wales, Pennsylvania, 19454. Teva Pharmaceuticals USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd.

41. Defendant Watson Laboratories, Inc., is incorporated under the laws of Delaware with its principal place of business at 1090 Horsham Road North Wales. Watson Laboratories, Inc. is a wholly owned subsidiary of Teva Pharmaceuticals Ltd. following Teva Pharmaceuticals Ltd acquisition of Allergan, PLC's generic division, which in turn acquired Watson Laboratories, Inc. through a complicated series of acquisitions and name changes.

42. As used in this complaint, "Watson" encompasses all the entities in paragraphs 39–41 and relevant predecessors-and successors-in-interest. At all times relevant to this complaint, Watson was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

43. Defendant Wockhardt Ltd. is a company organized and existing under the laws of India with its principal place of business at Wockhardt Towers, Bandra Kurla Complex Bandra (East), Mumbai-400051 Maharashtra, India. Wockhardt Ltd. is the parent corporation of Morton Grove Pharmaceuticals Inc. and Wockhardt USA LLC.

44. Defendant Morton Grove Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 6451 W. Main Street, Morton Grove, Illinois, 60053. Morton Grove Pharmaceuticals Inc. is a wholly owned subsidiary of Wockhardt Ltd., by and through Wockhardt Ltd.'s subsidiaries.

45. Defendant Wockhardt USA LLC is a limited liability company organized and existing under the laws of Delaware with its principal place of business at 20 Waterview Blvd Ste

315, Parsippany, New Jersey, 07054-1271. Wockhardt USA LLC is a wholly owned subsidiary of Wockhardt Ltd., by and through Wockhardt Ltd.'s subsidiaries.

46. As used in this complaint, "Wockhardt" encompasses all the entities in paragraphs 43–45 and relevant predecessors-and successors-in-interest. At all times relevant to this complaint, Wockhardt was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

47. Defendant Mallinckrodt PLC, a public limited company organized and existing under the laws of Ireland with its principal place of business at 3 Lotus Park, The Causeway, Staine-Upon-Thames, Surrey TW18 3AG, United Kingdom. Mallinckrodt PLC is the parent company of Mallinckrodt LLC. The contacts of Mallinckrodt PLC with this District, and the United States, are regular, constant and pervasive

48. Defendant Mallinckrodt LLC is a limited liability company organized and existing under the laws of Delaware with its principal place of business at 675 McDonnell Blvd., Saint Louis, Missouri, 63042, United States. Mallinckrodt LLC is a wholly owned subsidiary of Mallinckrodt PLC.

49. As used in this complaint, "Mallinckrodt" encompasses all the entities in paragraphs 47–48 and relevant predecessors-and successors-in-interest. At all times relevant to this complaint, Mallinckrodt was engaged in the development, manufacture, and sale of generic pharmaceutical products in the United States.

50. Collectively, the Defendants named in paragraphs 15–49 are referred to herein as "Defendants."

V. AGENTS AND CO-CONSPIRATORS

51. The anticompetitive and unlawful acts alleged against the Defendants in this class action complaint were authorized, ordered or performed by Defendants' respective officers, agents, employees, or representatives, while actively engaged in the management, direction, or control of Defendants' businesses or affairs. Each Defendant associated with a corporate family held itself out as, and in fact acted as a single economic unit. Each Defendant acted under the actual and apparent authority of its principals, including but not limited to its respective corporate parents.

52. Various persons and/or firms not named as Defendants herein may have participated as co-conspirators in the violations alleged herein and may have performed acts and made statements in furtherance thereof.

53. Each Defendant acted as the principal, agent or joint venture of, or for other Defendants with respect to the acts, violations, and common course of conduct alleged herein. In particular, each Defendant headquartered outside the United States relied on their agents in the United States to implement, enforce and conceal the anticompetitive and unlawful acts alleged against the Defendants in this class action complaint.

VI. REGULATORY FRAMEWORK AND THE MARKETPLACE

A. Unique Characteristics of the Pharmaceutical Marketplace in the United States

54. There are several unique characteristics of the pharmaceutical market that make violations of antitrust laws especially attractive and lucrative.

55. Healthcare in the United States is by far the most expensive in the world, in part due to the high cost of pharmaceutical products. Americans spent roughly $485 billion on pharmaceuticals in 2018, and that number is expected to rise to $625–655 billion by 2023.[4]

56. The market for pharmaceuticals is susceptible to anticompetitive activity because of the relationship between the payment obligation and the purchase decision. In most industries, the person responsible for paying for a product is also the person who chooses which product to purchase. When the person who pays also chooses the product, the price of the product plays a predominant role in the person's choice of product. Based on ordinary economic principles of supply and demand, manufacturers have a strong incentive to lower the price of their products to maintain profitability. In the pharmaceutical industry, state laws prohibit pharmacists from dispensing many pharmaceutical products—including Xyrem—to patients without a prescription written by the patient's physician. Since the patient's physician chooses which product the patient will buy, and the patient—and in most cases his or her insurer—has the obligation to pay, there is a strong incentive for anticompetitive behavior by drug companies.

57. So-called "brand manufacturers" (i.e., the manufacturers of branded, as opposed to generic, pharmaceuticals) employ large forces of sales representatives, known as "detailers," who visit physicians' offices to persuade physicians to prescribe the manufacturer's products.[5] Importantly, these detailers do not advise the physicians of the cost of the branded products.

[4] *Global pharma spending will hit $1.5 trillion in 2023, says IQVIA*, Pharmaceutical Commerce (Jan. 29, 2019), https://pharmaceuticalcommerce.com/business-and-finance/global-pharma-spending-will-hit-1-5-trillion-in-2023-says-iqvia/.

[5] Troy Brennan, *Drug Detailing Works, But for Whom?*, CVS Health (May 3, 2017), https://payorsoluti
ons.cvshealth.com/insights/drug-detailing-works-but-for-whom.

Studies show that physicians typically are not aware of the relative costs of branded pharmaceutical products and that, even when physicians are aware of the relative cost, they are insensitive to price differences, because they do not pay for the products themselves.[6] The result is a marketplace in which price plays a relatively unimportant role in product selection.

58. Brand manufacturers spend huge sums of money to influence physician prescribing habits and create name recognition for their drugs. In 2016 alone, pharmaceutical companies spent roughly $29.9 billion on marketing, including about $20 billion to persuade doctors and other medical professionals about the benefits of a drug.[7] This spending shows results, as doctors who receive money from pharmaceutical companies—even just a meal—prescribed a higher percentage of brand-name drugs overall than doctors who don't.[8]

59. When the relative importance of the price between two branded pharmaceuticals—or pharmaceuticals that otherwise are not AB-rated to one another—is low, the price elasticity of demand (i.e., the extent to which sales go down when price goes up) is by definition also low, which in turn gives brand manufacturers the ability to raise or maintain price substantially above competitive levels without losing sales. The ability to raise price above competitive levels without losing sales is referred to by economists and antitrust courts

[6] *See e.g.*, Michael Allan, et al., *Physician Awareness of Drug Cost: A Systemic Review*, PLoS Med 4(9): e283 (Sep. 25, 2007), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1989748/.

[7] Beth Mole, *Big Pharma shells out $20B each year to schmooze docs, $6B on drug ads*, ARS Technica (Jan. 11, 2019), https://arstechnica.com/science/2019/01/healthcare-industry-spends-30b-on-marketing-most-of-it-goes-to-doctors/.

[8] Charles Ornstein, et al., *How Money From Pharmaceutical Companies Sways Doctors' Prescriptions*, the Atlantic (Mar. 21, 2016), https://www.theatlantic.com/health/archive/2016/03/how-money-from-pharmaceutical-companies-influences-doctors-prescriptions/474399/.

as market power or monopoly power. Thus, the net result of the pharmaceutical industry features and marketing practices described above often is to allow brand manufacturers to gain and maintain monopoly power.

B. Regulatory Structure in the Pharmaceutical Market

i) Patent Application

60. To receive a patent on a new drug, a company must file a patent application with the U.S. Patent and Trademark Office ("PTO").[9] A patent applicant has a "duty of candor and good faith in dealing with the [PTO]"[10] and must "disclose all information known to that individual to be material to patentability",[11] including prior art, information on enablement, possible prior public uses, sales, offers to sell, derived knowledge, prior invention by another, inventorship conflicts, and litigation statements.[12] A PTO patent examiner evaluates the patent application to ensure it meets all the applicable legal requirements to merit the grant of a patent. For a patent to be a valid, the claimed invention must be (1) new, (2) useful, (3) nonobvious, and (4) directed to patentable subject matter.[13]

61. A patent applicant may file one or more continuation applications, which allows a patent applicant to "re-file" the application, extending the period of examination at the PTO in

[9] Kevin T. Richards, et al., *Drug Pricing and Pharmaceutical Patenting Practices*, Congressional Research Services (Feb. 11, 2020), at 7, https://fas.org/sgp/crs/misc/R46221.pdf.

[10] 37 CFR 1.56.

[11] *Id.*

[12] *Id.*

[13] 35 U.S.C. §§ 101–03; *see also* Kevin J. Hickey, et al., *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress*, Congressional Research Services (Apr. 4, 2019), at 6–9, https://crsreports.congress.gov/product/pdf/R/R45666.

order to amend existing claims or submit new ones.[14] If the continuation application is granted, it will gain the benefit of the filing date of the prior application for determining patentability and priority.[15] If a patent applicant's original application is "finally rejected," it can file a continuation application, which results in effectively getting another chance to argue in favor of the patentability of his or her invention to the PTO.[16]

62. A patent applicant can also file a divisional patent, which "can result in multiple patents, with overlapping claims and different expiration dates, ultimately issuing out of the filing of a single initial patent application."[17]

63. If the PTO issues a patent, its term typically expires twenty years from the patent application's filing date.[18] This twenty-year term may be extended in certain circumstances. For example, "patents claiming a drug product or medical device (or a method of using or manufacturing the same) may be extended for up to five years to account for delays in obtaining regulatory approval from FDA."[19]

[14] *Patent "Evergreening": Issues in Innovation and Competition*, Congressional Research Services (Nov. 13, 2009), at 5, https://www.everycrsreport.com/files/20091113_R40917_9536d486c1db2b54f1f4621cef2e664d693472f2.pdf.

[15] Christopher M. Holman, *Biotechnology's Prescription for Patent Reform*, 5 J. Marshall Rev. Intell, Prop. L. 318 (2006), at 331, https://repository.jmls.edu/cgi/viewcontent.cgi?article=1098&context=ripl.

[16] *Id.*

[17] *Id.*

[18] 35 U.S.C. § 154(a)(2).

[19] Richard, *supra* note 9, at 7.

64. The fact that the PTO issues a patent does not mean that the patent is valid and enforceable. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the PTO, by court decision, or by jury verdict.

65. A patent holder at all times bears the burden of proving infringement. One way that a patent challenger can prevail in patent infringement litigation is to show that its product does not infringe the patent or that the patent holder cannot meet its burden to prove infringement. A patent challenger may also show that the patent is invalid or unenforceable.

66. Under settled law, a patent is invalid or unenforceable when: (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 information to the PTO during prosecution; 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).

67. 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.

68. Patent rights are generally independent and distinct from the regulatory exclusivities administered by FDA. Patent rights granted by the PTO are based primarily on the

technological novelty of the claimed invention, while regulatory exclusivities granted by FDA result from the completion of FDA's regulatory process.[20]

ii) New Drug Applications

69. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new branded drug product must obtain FDA approval to sell it by filing a New Drug Application ("NDA") with the agency.[21] An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on patents applicable to that drug.[22]

70. When the FDA approves a brand manufacturer's NDA, the brand manufacturer may list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") any patent that it certifies (1) claims either the approved drug product or approved methods of using the drug product, and (2) could reasonably be asserted against a generic manufacturer who makes, uses, or sells the drug product without authorization prior to the expiration of the listed patent(s).[23] Relevant patents issued after NDA approval must be listed in the Orange Book within 30 days of issuance.[24]

71. The FDA relies completely on the brand manufacturer's certification about its patents, as the FDA does not have the resources or authority to verify for accuracy or

[20] *Id.*

[21] 21 U.S.C. §§ 301–392.

[22] 21 U.S.C. § 355(a),(b).

[23] 21 U.S.C. § 355(b)(1).

[24] 21 U.S.C. §§ 355(b)(1), (c)(2).

trustworthiness whether those patents are valid and enforceable and cover the drug product or its use. In listing patents in the Orange Book, the FDA performs a ministerial act.

iii) Hatch-Waxman Amendments

72. In 1984, Congress enacted the Hatch-Waxman Amendments ("HWA") to the FDCA, simplifying the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). Using an ANDA, the generic manufacturer relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. The generic manufacturer must also show that the generic drug 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 premise is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, absorbed into the blood stream at a similar rate over a similar period of time, are expected to be equally safe and effective. The FDA assigns generics that meet these criteria an "AB" rating, meaning the generics are therapeutically equivalent to and may be substituted for the brand (as well as other AB-rated generics of the brand).[25]

73. Through this shortcut, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress

[25] *See FDA List of Authorized Generic Drugs*, FDA (current as of July 1, 2020), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs

also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

74. Congress achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historic high profit margins for brand pharmaceutical manufacturers. In 1983, before the HWA, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did.[26] In 1985, prescription drug revenues for brands and generics totaled approximately $21.6 billion;[27] by 2018, total prescription drug revenues had climbed to more than $335 billion.[28] Prescriptions for generic drugs accounted for just 19% percent of all prescriptions dispensed in the U.S. in 1984[29] and approximately 90 percent in 2019.[30] Generic drugs saved the U.S. health care system $1.67 trillion from 2007 to 2016.[31]

iv) ANDA Certifications

75. Through the HWA, Congress created a procedural mechanism to resolve patent disputes between brand and generic manufacturers before generic products are marketed, in the

[26] Anna Cook, et al., *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Market*, the Congressional Budget Office (July 1998), at xiii, https://www.cbo.gov/sites /default/files/105th-congress-1997-1998/reports/pharm.pdf.

[27] *Id.*, at 4.

[28] Matej Mikulic, *Prescription drug expenditures in the United States from 1960 to 2020*, Statista (Apr. 2020), https://www.statista.com/statistics/184914/prescription-drug-expenditures-in-the-us-since-1960/.

[29] Ann M. Thayer, *30 Years of Generics*, Chemical Engineering News, https://cen.acs.org/articles/ 92/i39/30-Years-Generics.html.

[30] *Generic Drugs*, FDA (current as of Nov. 21, 2019), https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs.

[31] *Generic Drug Facts*, FDA (current as of June 1, 2018), https://www.fda.gov/drugs/generic-drugs/generic-drug-facts.

hopes that resolving patent challenges in advance of generic marketing would prevent unnecessary delay. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. There are four certifications a generic manufacturer can choose from:

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

(ii) the patent has expired (a "paragraph II certification");

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

(iv) the patent is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").

76. Under the HWA, if a generic manufacturer files a paragraph IV certification, a brand manufacturer can sue the ANDA applicant for patent 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 (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA cannot authorize the generic manufacturer to begin marketing its product. The FDA may grant a "tentative approval" when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

77. The brand manufacturer can file patent infringement claims more than 45 days after receiving the paragraph IV certification, but doing so would not trigger the automatic 30-month stay of FDA approval.

v) ANDA 180-day Exclusivity

78. Under the HWA, Congress created an incentive for generics to challenge patents, providing a 180-day exclusivity period to the first manufacturer to file an ANDA that contains a paragraph IV certification (the "first-filer"). This period of protection from competition is extremely valuable: a generic manufacturer that enters the market with only the brand to compete with can keep its prices high and still attract market share.[32] Once the period is over, more generics can enter the market and price competition flourishes.

79. The 180-day exclusivity period was meant to encourage generic manufacturers to challenge the validity of weak pharmaceutical patents or invent around them. Congress believed that bona fide litigation would result in determinations that either confirmed legitimate patent protection or exposed invalid or unenforceable drug patents, thus allowing market forces to operate and, among other things, reduce prices.

80. More often than not, generics are able to identify invalid and unenforceable patents and succeed in patent litigation. Between 1992 and 2002, "generics prevailed in 73% of the patent litigation ultimately resolved by a court decision."[33] And between 2000 and 2010, generic manufacturers had an overall success rate of 76% when taking into account cases won at trial, cases that were settled, and cases that were dropped by the brand manufacturer.[34]

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[32] *See FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013) (noting the "180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars").

[33] *Pay-for Delay: How Drug Company Pay-Offs Cost Consumers Billions*, Federal Trade Commission (Jan. 2010), at 3, 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.

[34] Adam Greene, et al., *Pharmaceuticals, Analyzing Litigation Success Rates*, RBC Capital Markets (Jan. 15, 2010), https://amlawdaily.typepad.com/pharmareport.pdf.

vi) REMS Program

81. In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA").[35] Under the FDAAA, the FDA has the authority to require sponsors of drug applications to submit a Risk Evaluation and Mitigation Strategy (REMS) program for medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are not designed to mitigate all the negative effects of a medication, but instead focus on preventing, monitoring and/or managing a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency or severity of the event.[36] One such risk is the abuse of prescription drugs.[37]

82. The FDA can require a REMS "[b]efore approval if the FDA determines a REMS is necessary to ensure the benefits of the drug outweigh the risks," or "[p]ost-approval if FDA becomes aware of new safety information and determines that a REMS is necessary to ensure the benefits of the drug outweigh the risks." [38]

[35] *Food and Drug Administration Amendments Act (FDAAA) of 2007*, FDA (current as of Mar. 29, 2018), https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007.

[36] *Risk Evaluation and Mitigation Strategies*, FDA (current as of Aug. 8, 2019), https://www.fda.gov /drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems.

[37] *See Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, FDA (current as of Sept. 27, 2018), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems.

[38] Elaine Lippmann, *Risk Evaluation and Mitigation Strategies (REMS)*, FDA, at 5, https://www.fda.gov/ media/105565/download.

83. A REMS can include one or more of the following: medication guide ("MG") or patient package insert; communication plan (CP) for healthcare providers; elements to assure safe use ("ETASU"); implementation system.[39]

84. ETASU provides rules governing prescribing or dispensing the drug. These rules may include "Certification or specialized training of HCPs who prescribe the drug; Certification of pharmacies or other dispensers of the drug; Dispensing/administration of drug in limited settings e.g., hospitals; Dispensing/administration of drug only with evidence of safe-use conditions; Each patient using the drug is subject to certain monitoring; [and/or] Enrollment of treated patients in registries."[40]

85. If a generic manufacture submits an ANDA for a drug that has a REMS, the ANDA "must use a single, shared system ['SSS'] with the innovator for any ETASU," unless the FDA waves this requirement.[41] Use of an SSS has the potential for increased efficiencies.[42]

86. The FDA can waive the SSS requirement under two circumstances: "if FDA finds that (1) the burden of creating a [SSS] outweighs the benefit of a single, shared system, taking into consideration the impact on health care providers, patients, the applicant for the [ANDA], and the holder of the reference drug product" or (2) an aspect of the ETASU for the applicable listed drug is claimed by an unexpired patent or is a method or process that, as a trade secret, is

[39] *Id.*

[40] *Id.* at 14.

[41] *Id.* at 23.

[42] *Waivers of the Single, Shared System REMS Requirement, Guidance for Industry*, FDA (June 2018), at 4, https://www.fda.gov/files/drugs/published/Waivers-of-the-Single--Shared-System-REMS--Requirement--Draft-Guidance-for-Industry.pdf.

entitled to protection, and the ANDA applicant certifies that it sought a license for use of the aspect, but was unable to obtain one."[43]

vii) Citizen Petitions

87. Under the Administrative Procedures Act ("APA"), government agencies must provide the public with "the right to petition for issuance, amendment, or appeal of a rule."[44] To comply with this rule, the FDA allows individuals to express safety, scientific, or legal issues concerning a product in what is known as a citizen petition.[45] Using a citizen petition, 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."[46] All citizen petitions must include the "action requested," particularly the "rule, order, or other administrative action" that the petitioner seeks to "issue, amend or revoke."[47] Citizen petitions also must disclose a "[s]tatement of grounds," including "the factual and legal grounds for the petition."[48]

88. In 2007, Congress enacted Section 914 of Title IX of the FDAAA, [49] which added a new rule, known as section 505(q), to citizen petitions.[50] Section 505(q) was enacted to ensure

[43] *Development of a Single, Shared System (SSS) Risk Evaluation and Mitigation Strategy (REMS) or a Separate REMS with Elements to Assure Safe Use (ETASU)*, Office of Surveillance and Epidemiology (Feb. 7, 2019), https://www.fda.gov/media/123900/download.

[44] 5 U.S.C.A. § 553.

[45] 21 C.F.R. §10.30(a) (2012); *see also* Michael A. Carrier, et al., *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. 249 (2012).

[46] 21 C.F.R. §§10.25, 10.30.

[47] 21 C.F.R. §10.30(b)(A).

[48] 21 C.F.R. §10.30(b)(B).

[49] 21 U.S.C. §355(q) (2006).

[50] Carrier, *supra* note 46, at 263.

that the FDA did not delay approval of drug applications unless a petition was "necessary to protect the public health."[51]

89. Section 505(q) applies to "certain petitions that request that FDA take any form of action related to a pending ANDA."[52] Under Section 505(q), petitioners must (i) ensure that they have not delayed filing the petition,[53] and (ii) certify that their allegations are true to the best of their knowledge and that they are not withholding unfavorable information.[54] Section 505(q) allows the Secretary of Health and Human Services to deny a petition if she "determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues."[55]

90. Section 505(q) requires that the FDA act quickly in addressing petitions. As originally drafted, the FDA was required to take final action no later than 180 days after the petition's filing date. In 2012, this requirement was shortened to 150 days by The Food and Drug Administration Safety and Innovation Act (FDASIA).[56]

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[51] *Id.*; *see also* 153 Cong. Rec. 25,047 (2007) (Senator Edward Kennedy explaining that "[t]he citizen petition provision is designed to address attempts to derail generic drug approvals. Those attempts, when successful, hurt consumers and the public health").

[52] Ctr. for Drug Evaluation and Research, *U.S. Dept. of Health and Human Servs., Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act 1*, FDA (2019), at 2, https://www.fda.gov/media/130878/download (hereinafter Guidance for Industry).

[53] *See* 153 Cong. Rec. 25,047 (2007).

[54] FFDCA §505(q)(1)(H).

[55] FFDCA §505(q)(1)(E).

[56] Guidance for Industry at 2.

91. In September of 2019, the Food & Drug Administration released additional guidance titled Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[57] The Guidance was issued to "deter 'gaming' of the generic drug approval process by the use of citizen petitions."[58]

C. Generic Entry Benefits Consumers

92. Brand drugs with an AB-rated generic are fungible products. Because AB-rated generics contain the same active ingredient(s) 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 price.

93. Therefore, when AB-rated generics enter the market, prices drop due to competition. Typically, generics are at least 31% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 44% to 95% when there are multiple generic competitors on the market for a given brand.[59] Consequently, the launch of a generic drug usually results in significant cost savings to all drug purchasers.

[57] Guidance for Industry at 2.

[58] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency actions to further deter 'gaming' of the generic drug approval process by the use of citizen petitions*, FDA (Oct. 2, 2018), https://www.fda.gov /news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-agency-actions-further-deter-gaming-generic-drug.

[59] *See Generic Competition and Drug Prices*, FDA (content current as of 12/13/2019), https://www.fda. gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices.

94. Recognizing the impact of market forces to reduce prices, the U.S. healthcare system has developed institutional structures to drive generic penetration. Every state except Oklahoma has laws in place permitting or requiring pharmacists to substitute an AB-rated generic for its brand counterpart.[60]

95. Furthermore, Pharmacy Benefit Managers (PBMs) ordinarily list generics at a preferred tier on formularies to increase savings for their clients—the Third-Party Payors ("TPPs") that insure individuals.[61] Listing a generic on a preferred tier encourages consumers to purchase the generic, otherwise they would be required to pay out of pocket for the difference between the brand price and the generic.

96. As a result of generic substitution laws and other institutional features of the pharmaceutical marketplace, brand manufacturers rapidly lose market share after generic entry. Between 2013 and 2017, average generic efficiency (the overall rate of generic dispensing for all molecule-forms) was 97%.[62] A key consequence of generic entry is the reduction of prices by the operation of market forces, in particular price competition.

[60] *National Association of Boards of Pharmacy, Survey of Pharmacy Law, 2019 News*, Oklahoma State Board of Pharmacy, (July 2013) at 3, https://nabp.pharmacy/wp-content/uploads/2016/06/OK072013.pdf.

[61] Nicole Kruczek, *Navigating Drug Formularies in Pharmacy Benefit Management*, Pharmacy Times (Jan. 8, 2020) https://www.pharmacytimes.com/news/navigating-drug-formularies-in-pharmacy-benefit-management.

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

D. Brand Companies use Multiple Tools to Delay Generic Entry

97. Recognizing that generic entry leads to rapid loss in market share, brand manufacturers have developed a variety of tools to delay generic entry, including "Evergreening," abusing the REMS program, filing sham citizen petitions, filing sham patent litigation, and "product hopping."

i) "Evergreening"

98. Evergreening, also known as secondary patents, patent "layering" or "life-cycle management," is a practice by which drug innovators seek "to prolong their effective periods of patent protection [through] strategies that add new patents to their quivers as old ones expire."[63] In 2018, an empirical analysis of the twelve best selling drugs in the United States revealed that on average, these drugs brand manufacturers filed 125 patent applications, and received 71 granted patents per drug.[64] The authors noted that "Today, drug makers have transformed the patent system in to a defensive business strategy to avoid competition in order to earn outsized profits on medicines for many years beyond what was intended."[65]

99. Empirical study of all drugs on the market between 2005 and 2015 shows that 78% of the drugs associated with new patents were not new drugs, but existing ones, leading the

[63] Richards, *supra* note 9.

[64] *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices*, I-MAK (Aug. 2018), at 2, https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-OverpatentedOverpriced-Report.pdf.

[65] *Id.*

authors to conclude that "Rather than creating new medicines, pharmaceutical companies are largely recycling and repurposing old ones."[66]

100. Evergreening includes the use of continuation patents, which delay and create uncertainties in the patent prosecution process, wear down patent prosecutors, and create "submarine patent[s]" that are intentionally delayed until a company invents a product that might infringe upon the patent.[67]

ii) Abuse of the REMS Program

101. Brand manufacturers attempt to delay generic entry and prevent competition by abusing REMS program.

102. Brand manufacturers refuse to sell or provide samples of their drugs to generic competitors, citing REMS restrictions on distribution of drugs.[68] This is especially harmful where, as here, a single pharmacy dispenses all the brand product. Generic manufactures need these samples to perform tests to establish bioequivalence.

103. Brand manufacturers use the requirement to institute a single, shared REMS plan to delay generic entry by prolonging these negotiations indefinitely.[69] As the FTC has noted: "If

[66] Robin Feldman, *May Your Drug Price be Evergreen*, 5 J.L. & Biosciences 590 (Dec. 7, 2018), https://doi.org/10.1093/jlb/lsy022.

[67] Holman, *supra* note 15, at 332.

[68] David Balto, *Abuse of the FDA Regulatory Process and Possible Solutions*, Coalition to Protect Patent Choice, https://www.fda.gov/files/drugs/published/Presentation--Abuse-of-the-FDA-Regulatory-Process-And-Possible-Solutions--Hatch-Waxman-Meeting-July-2017.pdf

[69] *REMS Abuse Impeding Patient Access to Generic Drugs – Myths and Facts*, Association for Accessible Medicine, https://accessiblemeds.org/resources/blog/rems-abuse-impeding-patient-access-generic-drugs-myths-and-facts#:~:text=According%20to%20a%20July%202014,billion%20to%20the%20federal%20government.

the branded and generic firms cannot reach agreement over the terms of a shared REMS, the generic will not be approved unless the FDA grants a waiver for the generic to establish its own REMS distribution system. In practice, the FDA has rarely granted a waiver of the shared REMS requirement, which can create a strategic incentive for the branded firm to refuse to cooperate with the generic entrant, since lack of cooperation can delay generic entry."[70]

104. The FDA has concluded that this conduct delays generic entry and, therefore, price competition. In 2014, FDA Office of New Drugs Director Dr. John Jenkins called the abuse a "growing major problem" for FDA. He went on to say, "I think companies have really gone to the extent of kind of abusing the system, because the system was designed to try to ensure the safe use of the drug and now it's become an evergreening system for avoiding generic competition." He added, "the problem is use of REMS to block generic competition and the innovators have really become very aggressive in using that strategy and hiring the best lawyers to back up that strategy."[71]

105. The director of FDA's Center for Drug Evaluation and Research—Dr. Janet Woodcock, M.D.—testified before Congress that these abuses are "a problem we struggle with a lot" and went on to note that they have "delayed [the] availability of generics."[72]

[70] Federal Trade Commission, *Antitrust Concerns and the FDA Approval Process*, testimony before the House Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law (July 27, 2017), www.ftc.gov/system/files/documents/public_statements/1234663/p859900 _commission_ testimony_re_at_concerns_and_the_fda_approval_process_ house_7-27-17.pdf.

[71] *REMS Abuse Impeding Patient Access to Generic Drugs*, *supra* note 70.

[72] *Id.*

106. The FDA has also published a list of companies that "have potentially been blocking access to the samples of their branded products" in the hopes that "increased transparency will help reduce unnecessary hurdles to generic drug development and approval."[73]

107. According to a September 2018 study conducted by Matrix Global Advisory, the ongoing abuse of REMS and other forms of restricted access costs the U.S. health system $13.4 billion in generic savings annually.[74]

iii) Sham Citizen Petitions

108. Citizen petitions can delay generic entry. As the Director of the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research (CDER) noted, "it is very rare that petitions present new issues that CDER has not fully considered" and "very few of these petitions on generic drug matters have presented data or analyses that significantly altered FDA's policies."[75] Despite this, "the agency must nevertheless assure itself of the fact by carefully reviewing these citizen petitions."[76] This requirement to carefully review citizen petitions, "add to the resource burdens on the generic drug review process and the FDA's regulatory decision making."[77]

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[73] *Statement from FDA Commissioner Scott Gottlieb*, *supra* note 59.

[74] Alex Brill, *Unrealized Savings from the Misuse of REMS and Non-REMS Barriers*, Matrix Global Advisors (Sep. 2018), http://getmga.com/wp-content/uploads/2018/09/REMS_WhitePaper_September2018.pdf.

[75] *The Generic Drug Maze: Speeding Access to Affordable Life-Saving Drugs*, Senate Hearing 109-685 (July 20, 2006), https://www.govinfo.gov/content/pkg/CHRG-109shrg30710/html/CHRG-109shrg30710.htm.

[76] *Id.*

[77] *Statement from FDA Commissioner Scott Gottlieb*, *supra* note 59.

109. Similarly, FDA Chief Counsel Sheldon Bradshaw commented that citizen petitions "appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application, but rather to delay approval by compelling the agency to examine arguments that could have been made previously."[78]

110. In 2011, an empirical study was done of citizen petitions submitted to the FDA.[79] It found that between 2001 and 2010, the FDA granted 19% of petitions and denied 81%[80] The study also found that the FDA denied 80% of citizen petitions filed by brands against generics during that time.[81]

111. Despite their low success rate, citizen petitions are an effective tool to delay generic competition. Citizen petitions cost little for the companies that file them, consisting of boilerplate arguments, generally involving scientific data regarding a drug's manufacturing process.[82] Also, if a petitioner filed "within six months of patent expiration…they force the FDA to take the time and resources to evaluate the merits of each filing, delaying generic approval."[83] And citizen petitions can be used in combination with other delay tactics like evergreening, product hopping, and abuse of a REMS program.

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[78] Marc Kaufman, *Petitions to FDA Sometimes Delay Generic Drugs*, Wash. Post. (July 3, 2006) (quoting Sheldon Bradshaw, Chief Counsel, U.S. Food & Drug Admin.), https://www.washingtonpost.com/archive/politics/2006/07/03/petitions-to-fda-sometimes-delay-generic-drugs-span-classbankheadcritics-say-companies-misusing-processspan/5460e43a-72de-454b-ab21-b9a022094531/.

[79] Carrier, *supra* note 46, at 274.

[80] *Id.*

[81] *Id.* at 278.

[82] *Id.* at 279.

[83] *Id.*

iv) Sham Patent Litigation

112. The filing by a generic manufacturer of a paragraph IV notice constitutes infringement of the brand manufacturer's patents. Therefore, filing of a paragraph IV notice routinely results in patent litigation by the brand manufacturer suing the generic manufacturer for patent infringement.

113. Under the law, when a brand manufacturer initiates patent litigation against a generic manufacturer that filed a paragraph IV notice, FDA approval of that generic company's ANDA is automatically delayed thirty-months or until the patent is held to be invalid or not infringed.[84]

114. In contrast, if the brand manufacturer does not file suit within 45 days, FDA may approve the ANDA immediately, provided that all other conditions for approval have been met.[85]

115. This delay—whether 30 months or 45 days—incentivizes brand manufacturers to file patent litigation regardless of the strength of their patents.

v) Pay-for-Delay Settlements

116. Another way that brand manufacturers game the system to anticompetitive effect is by paying generic manufacturers to delay entering the market. These agreements not to compete are sometimes referred to as "pay-for-delay agreements." Brand and generic manufacturers execute pay-for-delay agreements to take advantage of the regulatory consequences associated with the generic manufacturers' Paragraph IV certifications.

[84] Saami Zain, *Antitrust Liability for Maintaining Baseless Litigation*, 54 Santa Clara L. Rev. 729 (2014), 738–39, http://digitalcommons.law.scu.edu/lawreview/vol54/iss3/5

[85] *Id.*, at 739.

117. In a typical pay-for-delay agreement, the brand manufacturer pays or provides substantial consideration to a generic manufacturer to delay or abandon market entry. For this reason, these agreements are also called "reverse payment agreement," because the plaintiff pays the defendant to end the suit—the opposite of what normally happens in a civil settlement. The brand manufacturer preserves its monopoly by effectively paying some of its monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product. Because of the sharp price drop that would result from generic competition, both the brand and the generic manufacturer can make more money from this arrangement than from competing against each other for increasingly smaller margins.

118. Pay-for-delay agreements often take the form of settlement agreements to end patent infringement suits filed by brand manufacturers when they get notice of an ANDA with a Paragraph IV certification concerning one or more of their patents. Instead of defending their patents in court, as the Hatch-Waxman Act's drafters intended, the brand company pays the generic manufacturer to stay off the market, allowing both companies to benefit from monopoly profits.

119. An anticompetitive agreement entered between the brand and the first-filer generic often creates a bottleneck preventing the later ANDA filers from launching, since the later ANDA filers cannot launch earlier than 180 days after the first-filer's launch.

120. Later ANDA filers have more modest financial prospects than the first-filer generic because the later filers have no expectation of any form of market exclusivity, such as the first-filer's 180-day exclusivity. By the time the later ANDA filers enter the market, they typically must compete with the brand, the first-filer, an authorized generic, and other later filers.

121. Nevertheless, in the absence of an anticompetitive agreement between the brand company and the first-filer, the later ANDA filers have procompetitive incentives. They are motivated to enter the market as early as possible because the sooner they enter, the sooner they can earn profits by competing for sales in the market, which results in lower prices.

122. However, later ANDA filers cannot obtain final FDA approval to enter the market until the first-filer's 180-day exclusivity has run or been forfeited. An agreement between the brand and the first-filer that delays the first-filer's entry thus creates a bottleneck that, by delaying the first filer's 180-day exclusivity, consequently delays the later ANDA filers' entry as well.

123. Agreements causing such bottlenecks are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking and delaying access to more affordable generic drugs, forcing purchasers to buy the more expensive brand drug instead.

vi) Product Hopping

124. Another anticompetitive tool in brand manufacturers kit is called "product hopping." Product hopping goes hand in glove with evergreening. As a brand manufacturer reaches loss of exclusivity of a patent, it uses its dominant market position to switch doctors, pharmacists, and consumers to a newer version of the same (or similar) drug with later-expiring patents. The switch to the new version may be accompanied by a marketing campaign or discounts and rebates to encourage doctors, insurers, and patients to switch to the new version; in some cases, production of the older version may even be discontinued.[86]

[86] Richards, *supra* note 9, at 20.

125. Product hopping can be either a "hard switch," where the brand removes the original product from the market, or a "soft switch," where the brand leaves the original product on the market.[87]

126. Product hopping works because it thwarts state substitution laws. Once a doctor switches a patient to the new drug, a generic can't be substituted at the pharmacy because the generic drug is not therapeutically equivalent to the new branded drug.[88] Thus, just as generic drugs enter the market, the market dies—replaced by a slightly different, but non-substitutable alternative.

VII. FACTUAL ALLEGATIONS

E. The History of GHB, the Active Ingredient in Xyrem

127. GHB, the active ingredient in Xyrem, was discovered in 1960 by Henri Laborit, a French surgeon and neurobiologist, while he was searching for therapeutically useful analogues of gamma aminobutyric acid (GABA), a naturally occurring inhibitory neurotransmitter. It was later discovered that GHB is itself a naturally occurring substance found in brain and other tissues in the human body.

128. After his discovery, Laborit outlined the potential merits of GHB as an anesthetic agent. He further suggested GHB could have beneficial effects in obstetrics, psychiatry, alcohol and opiate withdrawal symptoms, and lipid metabolism.[89] Although GHB has been used as a

[87] *Id.*

[88] Arti K. Rai & Barak D. Richman, *A Preferable Path for Thwarting Pharaceutical Product Hopping*, Health Affairs (May 22, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180522.408497/full/

[89] *See* Henri Laborit *Sodium 4-hydroxybutyrate*, 3 Int'l J. Neuropharmacology 433 (1964).

surgical anesthetic in Europe, due to certain drawbacks it never gained wide acceptance as a general anesthetic.

129. After further investigations, researchers found that GHB did not significantly change the normal sleep cycle, and scientists recognized its potential to treat disorders that cause disruption in nocturnal sleep, such as narcolepsy. Initial clinical studies yielded promising results, demonstrating prompt improvements in the quality of nocturnal sleep in narcoleptic patients, and gradual abatement of the daytime symptoms of narcolepsy.[90]

130. During the 1980's, GHB was marketed in the U.S as an unregulated dietary supplement. Often used by body builders, it was thought to cause anabolic benefits by stimulating growth hormone release. It was also promoted as a 'natural' treatment for insomnia.[91]

131. Following reports of several fatal overdoses among body builders, the FDA banned all GHB sales in 1990.[92] After the FDA ban, GHB synthesis went underground but the drug was still widely available on the black market.

132. By the mid-1990's, illicit GHB was gaining notoriety as a popular club drug, with users reporting feelings of euphoria, disinhibition, and sexual arousal, similar to those caused by alcohol but without the unpleasant hangovers. Like many CNS depressants, GHB can also cause anterograde amnesia, especially when combined with alcohol, which led in part to its increasing

[90] *See, e.g.*, Roger Broughton & Mortimer Mamelak, *The Treatment of Narcolepsy-Cataplexy with Nocturnal Gamma-Hydroxybutyrate*, 6 Can. J. of Neurological Sci. 1 (1979).

[91] *See* Gregory Wedin et al., *The Clinical Development of γ-Hydroxybutyrate (GHB)*, 1 Current Drug Safety 99 (2006).

[92] *Id.* at 100.

use as a date-rape drug. GHB is still widely available on the black market and remains a popular club drug. Its use as a date-rape drug also continues.

F. Orphan Develops Xyrem

133. Based on the promising results of the initial investigations into GHB as treatment for narcolepsy, Orphan began formal clinical development of the drug (now known by its formal generic name: sodium oxybate) in 1994.

134. On December 22, 1999, Orphan filed its first patent related to Xyrem.[93] As discussed below, Orphan and its predecessors in interest Jazz, would later file for and obtain about 21 patents ostensibly claiming aspects of Xyrem and its use. Because the active pharmaceutical ingredient in Xyrem—GHB—has long been known, none of the patents claim the active pharmaceutical compound.

135. In 2000, Congress enacted the J. Farias and Samantha Reid Date-Rape Drug Prohibition Act.[94] The law proscribed a novel bifurcated scheduling of GHB under the Controlled Substances Act,[95] whereby GHB was listed as a Schedule I drug but with an exception that any FDA-approved formulations of the drug would be listed as Schedule III, thereby allowing Orphan to continue its clinical development.[96]

[93] U.S. Patent Application No. 09/470,570

[94] Public Law 106-172, 114 Stat. 7 (2000) (codified at 21 U.S.C. §§ 801, 802, 827, 841, 960).

[95] *Id.* at 8–9.

[96] *See* Wedin, *supra* note 92, at 101.

136. Orphan conducted a series of three clinical studies to establish the safety and efficacy of sodium oxybate as a treatment for narcolepsy,[97] the results of which reinforced the promise demonstrated in the earlier studies.

137. Orphan submitted an NDA for sodium oxybate under the brand name Xyrem in October 2000 and was granted approval on July 17, 2002 to market the drug for treatment of cataplexy associated with narcolepsy.

138. The FDA approval of Xyrem was conditioned on Orphan implementing 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 Medical, Inc., (iv) that the facility would be managed by a central pharmacy which would maintain the

[97] *See* The U.S. Xyrem® Multicenter Study Group, *A Randomized, Double Blind, Placebo-Controlled Multicenter Trial Comparing the Effects of Three Doses of Orally Administered Sodium Oxybate with Placebo for the Treatment of Narcolepsy*, 25 Sleep 42 (2002); U.S. Xyrem® Multicenter Study Group, *A 12-Month, Open-Label, Multicenter Extension Trial of Orally Administered Sodium Oxybate for the Treatment of Narcolepsy*, 1 Sleep 31 (2003); Xyrem® Multicenter Study Group, *Sodium Oxybate Demonstrates Long-Term Efficacy for The Treatment of Cataplexy in Patients with Narcolepsy*. 5 Sleep Med. 119 (2004).

consignment inventory, and (v) that other than in the single central pharmacy, Xyrem would not be stocked in retail pharmacy outlets.

139. Since the original approval and under requirements requested by Orphan, Xyrem has been dispensed w2 Orphan 2005, and quickly made Xyrem its signature drug, recognizing its potential as a blockbuster.

140. Since 2007, Jazz has incrementally raised the price of Xyrem from $2.04 per milliliter[98] to $29.69,[99] an increase of over 1,355%. For a patient taking a dosage in the middle of the effective range, the monthly cost of Xyrem is approximately $13,360.25[100] Jazz's price increase for Xyrem ranked first in a list of pharmaceutical drug price increases according to Fierce Pharma.[101]

141. Net sales of Xyrem were $1.64 billion in 2019, representing 76% of Jazz's total revenue for that year.[102] The company's gross margin as a percent of net product sales was 94% in 2019.[103]

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[98] *See* Sean Williams, *A company's 841% price increase on a sleep drug could attract attention from Capitol Hill,* Business Insider (Nov. 2, 2016), https://www.businessinsider.com/jazz-drug-price-increase-841-percent-drug-regulators-2016-11.

[99] *See Xyrem Prices, Coupons and Patient Assistance Programs*, Drugs.com, https://www.drugs.com/price-guide/xyrem.

[100] *Xyrem Dosage,* Drugs.com, https://www.drugs.com/dosage/xyrem.html (last updated May 4, 2020) (effective dose range is 6-9 grams of sodium oxybate nightly; Xyrem solution contains 0.5 grams of sodium oxybate per milliliter).

[101] Tracy Staton, *10 big brands keep pumping out big bucks, with a little help from price hikes*, Fierce Pharma (May 7, 2014), https://www.fiercepharma.com/sales-and-marketing/10-big-brands-keep-pumping-out-big-bucks-a-little-help-from-price-hikes.

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

[103] *Id.*, at 64.

G. Orphan and Jazz's Patents Thicket

142. Between 2004 and 2018, Orphan and later Jazz, filed for and obtained about 20 patents ostensibly claiming aspects of Xyrem and its use. These patents are grouped into three patent families: the '431 family, the '730 family, and the '302 family.

143. The '431 family of patents claim processes for making Xyrem, formulations of Xyrem, and methods of using Xyrem. The '431 family of patents all claim priority to U.S. Patent Application No. 09/470,570, which Orphan Medical filed on December 22, 1999. The '730 family also includes United States Patent No. 7,797,171, which issued on September 14, 2010.

144. The '730 family of patents claim methods of tracking prescriptions of a sensitive drug (i.e., "one which can be abused, or has addiction properties or other properties that render the drug sensitive"[104]) through a computer database. 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 '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.

145. The '302 family of patents claim methods of treating sleep disorders with sodium oxybate in patients who are also taking divalproex sodium. The '302 family of patents all claim priority to United States Patent Application No. 13/837,714, which Jazz filed on March 15, 2013.

146. Jazz's Xyrem patents and the anticipated expiration dates for each are represented in Table 1, below:

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

Table 1

Patent	Type	Issue Date	Expiration Date[105]	Family
6,472,431 (the '431	Original	10/22/2002	12/22/2019	431
6,780,889 (the '889	Divisional	8/24/2004	7/4/2020	431
7,262,219 (the '219	Divisional	8/28/2007	4/5/2021	431
7,851,506 (the '506	Divisional	12/14/2010	12/22/2019	431
8,263,650 (the '650	Continuation	9/11/2012	12/22/2019	431
8,324,275 (the '275	Continuation	12/4/2012	12/22/2019	431
8,461,203 (the '203	Process	6/11/2013	12/22/2019	431
8,859,619 (the '619	Continuation	10/14/2014	12/22/2019	431
8,952,062 (the '062	Continuation	2/10/2015	12/22/2019	431
9,539,330 (the '330	Continuation	11/8/2016	12/22/2019	431
7,668,730 (the '730	Original	2/23/2010	6/16/2024	730
7,765,106 (the '106	Divisional	7/27/2010	6/19/2027	730
7,765,107 (the '107	Divisional	7/27/2010	9/19/2026	730
7,895,059 (the '059	Continuation	2/22/2011	12/17/2022	730
8,457,988 (the '988	Divisional	6/4/2013	12/17/2022	730
8,589,182 (the '182	Continuation	11/19/2013	12/17/2022	730
8,731,963 (the '963	Continuation	11/19/2013	12/17/2022	730
9,050,302 (the '302	Original	6/9/2015	3/15/2033	306
8,772,306 (the '306	Continuation	7/8/2014	3/15/2033	306
9,486,426 (the '426	Continuation	11/8/2016	3/15/2033	306
10,213,400 (the '400	Continuation	2/26/2019	3/15/2033	306

H. Jazz's Anticompetitive Conduct

147. Over almost a decade, Jazz engaged in a multi-faceted scheme to delay generic entry. This scheme included "evergreening" patents coupled with sham patent litigation, abusing the REMS process, filing sham citizens petitions, and attempt to "product hop," and ultimately

[105] Expiration date does not include the FDA's grant of pediatric exclusivity for certain patents, which extends patent exclusivity for six months: June 22, 2020 for the '506,' 650, '275, '619, '062 and '330 patents; January 4, 2021 (for the '889 and '219 patents; December 16, 2024 for the '730, '106 and '107 patents; June 17, 2023 for the '059, '988, '182, and '963 patents; September 15, 2033 for the '302, '306, and '426 patents.

[106] The '431 patent is a process patent, and therefore is not listable in the Orange Book. Process patents concern the process for manufacturing Xyrem and are not listable in the Orange Book

pay-for-delay settlements. Some of this scheme proceeded chronologically, but various portions overlap temporally. Therefore, Jazz's anticompetitive conduct is grouped by device, rather than strictly flowing in chronological order.

i) Jazz uses Evergreening and Sham Patent Litigation to delay generic entry

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

Table 2

Complaint Date	Docket No.	Date ¶ IV Notice	Patent(s) in Suit
Nov. 22, 2010	2:10-cv-06108	Oct. 14, 2010	'889, '219, '730,

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
June 1, 2015	2:15-cv-03684	Apr. 16, 2015	'062
Jan. 27, 2016[107]	2:16-cv-00469	Dec. 14, 2015	'302
Aug. 12, 2016	2:16-cv-04971	Jan. 9, 2015	'963

152. Jazz used "evergreening" together with an aggressive patent litigation campaign to delay generic entry, often seeking to enforce patents without any realistic likelihood of prevailing but knowing the prosecution would tie up the judicial and regulatory process. As Roxane noted, Jazz engaged in "an abusive scheme to unfairly multiply [the patent] litigation" by:

> holding patent applications pending, gleaning [Roxanne]'s noninfringement defenses from [Roxanne]'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 [Roxanne]'s noninfringement defenses, more closely capture [Roxanne]'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 [Roxanne]. Thus, the litigation never ends and [Roxanne] is continually fighting a moving target.[108]

153. For example, in response to Jazz's original complaint alleging infringement of the '506 patent, Roxanne asserted that it would not infringe the '506 patent because "all of the claims

[107] By the time of this complaint, Hikma (through its subsidiary, West-Ward Pharmaceuticals Corp.) had an agreement in principal to acquire Roxane. As a result, the last complaint listed named as defendants not only Roxane but also Hikma Pharmaceuticals plc and Hikma subsidiaries West-Ward Pharmaceuticals Corp. and Eurohealth (USA), Inc. In February of 2016, Hikma completed its acquisition of Roxane. For ease of reference, actions attributable to Roxane, Westward, and Hikma after February of 2016 are referred to just as "Hikma."

[108] 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)

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 [Roxanne]'s sodium oxybate solution required dilution of the concentrated medium prior to patient administration."[109] Roxanne disclosed this defense as part of the invalidity and non-infringement contentions it provided to Jazz in April and August 2011.[110]

154. 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.[111] 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 Roxane in October 2012 and December 2012, alleging infringement of the '650 and '275 patents.

155. Roxane 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 Roxane's product did not contain a pH adjusting agent. Jazz then filed the application for the '650 patent, which included claims to compositions that do not require "a pH adjusting agent," and then asserted the '650 patent against Roxane after the patent issued.

156. Roxane 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

[109] 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.

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

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

"[Roxanne] 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 Roxane after the patent issued

157. In response, Roxane asserted that because "Jazz continues to seek and obtain new patents, add patents to the Orange Book, bring patent infringement suits against [Roxanne], including to seek consolidation of all suits relating to [Roxane]'s sodium oxybate ANDA product," Roxane 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 [Roxane] to face an 'at-risk' launch of its sodium oxybate product due to delayed resolution of this litigation."

158. It was still early in Jazz's scheme that culminated in the reverse payment agreements, but with Roxane already discussing launch "at risk" of Jazz's patent thicket, Jazz knew it ran a real risk of a generic entering the market.

ii) Jazz abuses REMS program to delay generic entry

159. As discussed in Section V.B.vi, in 2007 Congress passed FDAAA, setting for a drug safety program (REMS) that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

160. At the time Congress passed FDAAA, some products already had a form of a risk management program in place. Therefore, Congress designed a process by which the earlier approved risk program could be deemed a REMS program. For Xyrem, a risk management plan 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.

161. 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 seven-years of negotiations between Jazz and the FDA, delay tactics designed by Jazz to keep a generic off the market.

162. For example, when the FDA initially approved the REMS-like program ("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.

163. But in August 2009, as part of its transition from RiskMAP to REMS, Jazz submitted a proposal to, among other things, remove the restriction to a single pharmacy and instead allow certification of multiple pharmacies. Its rationale for this proposed change was that it would "increase patient access without compromising patient safety."[112] Jazz also stated that the single pharmacy program in existence at that time "imposes numerous impediments to

[112] Trueman W. Sharp, *Decision to waive the requirement for a single, shared system REMS for sodium oxybate oral solution*, FDA (Jan. 17, 2017), at 6, https://www.fda.gov/media/102913/download

patient access to Xyrem, possibly depriving narcolepsy patients of an important medication to control their EDS and cataplexy and potentially affect their lives dramatically."[113]

164. By 2011—years into the discussion—Jazz had realized it could use the ongoing negotiations to delay generic entry. Jazz changed its position and abruptly dropped its proposal for certification of multiple pharmacies.[114] By that time, Jazz had listed several patents related to its REMS in the Orange Book.[115] Commenting on these negotiations, 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."[116]

165. On July 8, 2010, Roxane submitted an ANDA to FDA, seeking approval of a generic version of Xyrem.

166. In August 2012, FDA provided interim comments on the proposed REMS which stated that, consistent with Jazz's earlier request, the final REMS should not contain the single pharmacy limitation. FDA was concerned that the restriction to a single pharmacy in the REMS could unduly burden patient access and the health care delivery system.[117]

167. On October 12, 2012, Roxane first contacted Jazz regarding the development of an SSS REMS[118] to facilitate the efficient approval of generic Xyrem.

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[113] *Id.*

[114] *Id.*

[115] *Id.*

[116] *Jazz Pharmaceutical's Xyrem drug has adverse-events, REMS problems*, Pharmaceutical Commerce (Oct. 27, 2011) https://pharmaceuticalcommerce.com/cold-chain-focus/jazz-pharmaceuticals-xyrem-drug-has-adverse-events-rems-problems/.

[117] *Sharp*, *supra* note 113, at 6.

[118] *Id.*, at 8.

168. 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."[119]

169. On January 23, 2014, FDA hosted a meeting between Jazz and Roxane to facilitate the development of an SSS REMS for sodium oxybate. At this meeting, Roxane provided a proposed timeline to the meeting attendees with 30, 60, and 90-day milestones with deliverables. Also at this meeting, FDA requested that the parties submit bi-weekly updates to the Agency on the status of negotiations.[120]

170. In February 2014, Jazz filed a formal dispute resolution request, appealing the 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."[121] 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."[122]

[119] *Id.*, at 7 (citing Jazz Form 10-Q (Sep. 30, 2013) at 54).

[120] *Id.*, at 8.

[121] *Id.*, at 7.

[122] *Id.*, at n.19.

171. In March 2014, Roxane, having learned of the dispute resolution request, expressed concern that "any dispute resolution process will be a protected matter which will further delay the implementation of a REMS."[123]

172. At an August 2014 meeting to discuss the ongoing dispute, the FDA expressed two primary public health goals: (i) to have a REMS that assures safe use of the drug, and (ii) to ensure that the REMS does not stand in the way of generic approval. At the same meeting, 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.[124]

173. On February 27, 2015, the FDA folded to Jazz's delay tactics, noting 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."[125]

[123] *Id.* at 9.

[124] *Id.*, at 7.

[125] *Id.*, at 7–8.

174. The FDA's disapproval of Jazz's anticompetitive acts was clear:

> 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.[126]

175. Succeeding in its fight against the FDA, Jazz proceeded to use its newly acquired weapon.

176. On August 19, 2015, Roxane emailed the FDA to report a "lack of progress on key terms for an operating agreement." In light of this lack of progress, Roxane intended to go through the expensive and time-consuming process of developing a separate REMS.[127]

177. On January 17, 2017—over six years after Roxane filed its ANDA—the FDA granted a waiver of the SSS, allowing Roxane to develop a separate REMS. In granting the waiver, the FDA noted that "[c]ertain statements by Jazz, including the concerns expressed it its SEC filings and its change in position regarding the necessity of the single pharmacy requirement…suggest Jazz's awareness that the Xyrem REMS could have the effect of blocking or delaying approval of generic versions of Xyrem.[128]

[126] *Id.* at 8.

[127] *Id.*, at 9.

[128] *Id.*, at 11–12.

iii) Jazz files sham citizen petitions to delay generic entry

178. In addition to filing patent infringement lawsuits against Roxane and abusing the REMS program, Jazz filed citizen petitions with the FDA to slow down the ANDA review and approval process.

179. On May 18, 2012, Jazz submitted to FDA a baseless citizen petition, 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 approval 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.[129]

180. 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."[130]

181. 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 and asked the FDA to rescind the acceptance of any previously-accepted ANDA (including the ANDA submitted by Roxane) that did not include a proposed risk

[129] *Jazz Pharmaceuticals, Inc., Citizen Petition*, Docket No. FDA-2012-P-0499-0001 (May 18, 2012), https://beta.regulations.gov/document/FDA-2012-P-0499-0001.

[130] *Id.*

management system when accepted for FDA review, arguing that such ANDAs would not contain the same labeling and conditions as Xyrem, as required by law.[131]

182. 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) determine that if any sponsor, including Roxane, submitted an ANDA referencing Xyrem that did not contain a proposed risk management system at the time it was accepted for review, or later submits or resubmits an ANDA that contains an adequate proposed risk management system, then such ANDA should be subject to a renewed automatic 30-month stay of approval in the event Jazz timely opted to initiate patent litigation based on such notice.[132]

183. 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.[133]

184. The FDA found that, contrary to Jazz's contention, it is not required to publish bioequivalence guidance prior to accepting ANDAs, nor is it required to reject ANDAs submitted prior to such publication. The FDA noted that publication of bioequivalence guidance is intended to benefit ANDA applicants, whereas the only beneficiary of Jazz's baseless interpretation is

[131] *Jazz Pharmaceuticals, Inc., Citizen Petition*, Docket No. FDA-2012-P-0733-0001 (July 10, 2012), https://beta.regulations.gov/document/FDA-2012-P-0733-0001.

[132] *Id.*

[133] *FDA CDER to Jazz Pharmaceuticals, Inc., Petition Denial*, Docket No. FDA-2012-P-0499-0005 (Nov. 13, 2012), https://beta.regulations.gov/document/FDA-2012-P-0499-0005.

brand manufacturers like Jazz, "who will benefit from a delay in generic competition in the marketplace."[134]

185. 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.[135] The FDA's response was thirteen pages and contained sixty-six footnotes.[136]

186. On September 2, 2016, Jazz filed a third citizen petition concerning the requirements for submission of ANDAs referencing Xyrem and asked the FDA to "[r]efuse to approve any sodium oxybate ANDA that [did] not include in its proposed labeling the portions of the Xyrem package insert related to divalproex" and did not include portions of the Xyrem REMS related to divalproex.[137] Jazz's third citizen petition was eighteen pages long, contained sixty-seven footnotes, and included thirteen attachments.[138] Jazz's third petition also contained 21 C.F.R. § 10.30(b) and 21 U.S.C. § 355(q)(1)(H) certifications, certifying under penalty of perjury that, *inter alia*, "(a) this petition includes all information and views upon which the petition relies, and (b) this petition includes representative data and/or information known to petitioner which are unfavorable to the petition."[139]

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[134] *Id.*

[135] *FDA CDER to Jazz Pharmaceuticals, Inc., Petition Denial*, Docket No. FDA-2012-P-0733-0004 (Dec. 13, 2012), https://beta.regulations.gov/document/FDA-2012-P-0733-0004.

[136] *Id.*

[137] *Citizen Petition from Jazz Pharmaceuticals, Inc.* Docket No. FDA-2016-P-2672-0001 (Sep. 2, 2016) https://beta.regulations.gov/document/FDA-2016-P-2672-0001.

[138] *Index of Exhibits re Citizen Petition from Jaxx Pharmaceuticals*, Docket No. FDA-2016-P-2672-0003 (Sep. 2, 2016), https://beta.regulations.gov/document/FDA-2016-P-2672-0003.

[139] *Id.* at 15.

187. On November 15, 2016, Par (a sodium oxybate ANDA applicant) responded to Jazz's third citizen petition, arguing that "[t]he Citizen Petition is the result of a patent-driven effort to prevent consumer access to lower cost generic drugs" and that "Jazz cites safety issues in an effort to conceal its true anti-competitive motive."[140] Par also noted that Jazz's "Citizen Petition represents a quintessential example of a life-cycle management strategy employed with increasing frequency by NDA holders to avoid generic competition."[141] Par's argument is bolstered by Jazz's statement to investors that the divalproex sodium labeling change is part of its "life cycle management of Xyrem" to "enhance and enforce [its] intellectual property rights."[142]

iv) Jazz misled the PTO and the PTAB regarding the '306 family of patents

188. On or about March 1, 2013, Jazz filed a provisional application (No. 61/771,557) seeking patent protection for inventing a method of co-administering Xyrem in patients also taking valproate—another CNS depressant used to treat epilepsy, bipolar disorder, and migraine headaches—by administering a lower dose of Xyrem. Provisional Application No. 61/771,557 resulted in three patents: 8,772,306 (the '306 patent); 9,050,302 (the '302 patent); and 9,486,426 (the '426 patent) (collectively, "the '306 family"). The earliest effective filing date for each patent in the '306 family is March 1, 2013.

189. In or around December 2012, Jazz published a revised version of its Xyrem label, updating the language regarding coadministration of Xyrem with other CNS depressants as reflected in table below:

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[140] *Comment from Par Pharmaceutical, Inc., Latham and Watkins LLP*, FDA-2016-P-2672-0017 (Nov. 15, 2016) https://beta.regulations.gov/document/FDA-2016-P-2672-0017.

[141] *Id.*, at 2.

[142] Jazz Pharmaceuticals plc, Form 10-Q (May 8, 2014), at 28.

Table 3

Jazz's 2002 and 2005 Xyrem Labels	Jazz's 2012 Xyrem Label
"Sodium oxybate should not be used in combination with . . . other CNS depressants."[143]	"The concurrent use of Xyrem with other CNS depressants . . . may increase [certain risks]. If use of these CNS depressants in combination with Xyrem is required, dose reduction or discontinuation of one or more CNS depressants (including Xyrem) should be considered."[144]

190. During the prosecution of the '306 patents, Jazz disclosed to the PTO only its 2002 and 2005 labels but withheld its 2012 revision.

191. Jazz's omissions persisted for over three-and-a-half years—over two years for the '302 patent (filed March 15, 2013, and issued June 9, 2015); over a year for the '306 patent (filed April 29, 2013, and issued July 8, 2014); and another year-plus for the '426 patent (filed May 8, 2015, and issued November 8, 2016).

192. When the '306 patents were challenged under *inter partes* review, Jazz affirmatively misled the PTAB. Jazz argued in response to IPR petitions that its label advised against, or "taught away," from co-administering sodium oxybate with any other CNS depressant (including valproate), at any dose.[145] Jazz relied on only the 2005 label for its "teaching away" argument to the PTAB, even while its 2012 label clarifications had retracted the very "should not be used" language on which Jazz relied. Jazz's own 2012 revision squarely contradicted its argument that the Xyrem label would have taught away from the claimed co-administration.

[143] 2002 Xyrem, at 11; 2005 Xyrem label, at 8.

[144] 2012 Xyrem Label, at 2.

[145] *See Amneal Pharms. LLC v. Jazz Pharms., Inc.*, IPR2016-00546, Paper 10 at 23–26 (PTAB May 6, 2016); *Par Pharm., Inc. et al. v. Jazz Pharms., Inc.*, IPR2016-0002, Paper 10 at 2, 29–30 (PTAB Jan. 15, 2016).

193. Jazz's actions before the PTAB were not just misleading, they violated the explicit disclosure requirements of IPR proceedings. Under 37 C.F.R. 42.51, "a party must serve relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contains the inconsistency." Instead of revealing the disclosure of the 2012 label pursuant to 37 C.F.R. 42.51, Jazz withheld it. Denying IPR institution, the PTAB relied first and foremost on Jazz's "teaching away" argument; an argument that was contradicted directly by the withheld 2012 label revision.[146]

v) Jazz files sham patent infringement lawsuits against later-filing generics

194. 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:

Table 4

ANDA Applicant	ANDA No.	Date of Initial ¶ 4 Notice
Amneal Pharmaceuticals, LLC	203631	Dec. 10, 2012
Par Pharmaceutical, Inc.	205403	Nov. 20, 2013
Ranbaxy Laboratories Limited	203351	June 3, 2014
Watson Laboratories, Inc.	204952	Oct. 30, 2014
Wockhardt Bio AG	207526	June 8, 2015
Lupin Ltd. and Lupin	207415	July 23, 2015
Ascent Pharmaceuticals, Inc.	210523	June 14, 2017
Mallinckrodt plc,	210936	Nov. 21, 2017

195. 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.

[146] *See Amneal Pharms. LLC v. Jazz Pharms., Inc.*, IPR2016-00546, Paper 12 at 11–12 (PTAB July 28, 2016); *Par Pharm., Inc. et al. v. Jazz Pharms., Inc.*, IPR2016-0002, Paper 12 at 12. (PTAB Apr. 12, 2016).

196. 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.

vi) Jazz's '730 family of patents are invalidated by the PTAB

197. On or about January 8, 2015, Amneal and Par jointly filed a series of petitions before the Patent Trial and Appeal Board (PTAB) requesting institution of *inter partes* review (IPR) of the patents in the '730 family including the '730 patent (IPR2015-00554); the '106 patent (IPR2015-00546); the '107 patent (IPR2015-00547); the '059 patent (IPR2015-00548); the '988 patent (IPR2015-00551); and the '182 patent (IPR2015-00545). On or about September 14, 2015, Amneal and Par jointly filed a petition for inter partes review of the '963 Patent (IPR2015-01903).

198. The PTAB instituted *inter partes* review of the '182 patent (IPR2015-00545), the '106 patent (IPR2015-00546), '107 patent (IPR2015-00547), the '059 patent (IPR2015-00548), the '988 patent (IPR2015-00551), and the '730 patent (IPR2015-00554) on or about July 28, 2015, and did the same for the '963 patent (IPR2015-01903) on or about March 25, 2016.

199. On July 27, 2016, the PTAB issued final decisions as to the '182 patent (IPR2015-00545), the '106 patent (IPR2015-00546), '107 patent (IPR2015-00547), the '059 patent (IPR2015-00548), the '988 patent (IPR2015-00551), and the '730 patent (IPR2015-00554), finding certain claims contained in each to be obvious and therefore unpatentable in light of prior

art that was publicly available more than one year before patents' respective earliest priority filing dates.

200. On March 22, 2017, the PTAB issued a final decision as to the '963 patent (IPR2015-01903) finding certain claims to be obvious and therefore unpatentable in light of prior art that was publicly available more than one year before patent's earliest priority filing date.

201. The prior art came in the form of published and publicly available background materials to an FDA advisory committee meeting in June 2001, which describe in detail the REMS system that Jazz later patented under the '730 family. The earliest effective date for the '730 family patents is December 17, 2002, more than a year after the date the prior art became available publicly.

202. After Jazz appealed all seven decisions, the U.S. Court of Appeals for the Federal Circuit affirmed the PTAB in all instances.[147]

203. The result of *inter partes* review, as affirmed by the Federal Circuit, was the invalidation of all the patents in the '730 family.

vii) The Unlawful and Anticompetitive Pay-for-Delay Settlement

204. Jazz settled its litigation with Hikma[148] in April 2017. Contemporaneously with the execution of the Settlement Agreement,[149] Jazz and Hikma entered into a license agreement (the "License Agreement") and an authorized generic agreement (the "AG Agreement"), which are not available publicly. In consideration for its promise to delay launching its generic product,

[147] *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1363 (Fed. Cir. 2018).

[148] Note that Hikma acquired Roxane in February of 2016.

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

Hikma received, *inter alia*, (i) the exclusive right to sell an authorized generic (AG) between January 1, 2023 and July 1, 2023; (ii) a license to sell its own generic as of July 1, 2023; and (iii) a promise from Jazz not to grant additional licenses for other generic manufacturers to market their own generic products until December 31, 2025.

205. The Jazz-Hikma agreement also contained a most favored entry clause (sometimes given the dubious term "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.

206. Upon information and belief, the value of the consideration Hikma received from Jazz as part of the Settlement was more than ten million dollars.

207. Jazz subsequently settled its litigation with other Generic Manufacturers, agreeing to allow these other Generic Manufacturers the right to manufacture, market, and sell a generic after Hikma entered the market. The timeline of these settlements and the generic entry dates are listed in table 5 below:

Table 5

Generic	Settlement Date	AG Entry Date	Generic Entry Date
Wockhardt	4/18/2016	N/A	12/31/2025
Ranbaxy	5/9/2016	N/A	12/31/2025
Hikma	4/5/2017	1/1/2023	7/1/2023
Par	1/9/2018	7/1/2023	12/31/2025
Watson	3/30/2018	N/A	12/31/2025
Mallinckrodt	6/4/2018	N/A	12/31/2025
Lupin	6/12/2018	7/1/2023	12/31/2025
Amneal	10/15/2018	7/1/2023	12/31/2025

208. These settlements and any contemporaneous agreements are referred to collectively as the "Settlement Agreements."

209. By means of the Settlement Agreements, Jazz allocated the market for sodium oxybate in the United States according to the following schedule:

- Branded Xyrem will maintain its monopoly until December 31, 2022;
- On January 1, 2023, Jazz will introduce an AG, and profits from the AG will be shared with Hikma;
- On July 1, 2023, Jazz will introduce several more AGs, and profits from those AGs will be shared with Amneal, Lupin, Par, Ranbaxy, Wockhardt, Watson, and Mallinckrodt, respectively;
- Hikma may also launch its own generic on July 1, 2023;
- Finally, on December 31, 2025, Amneal, Lupin, Par, Ranbaxy, Wockhardt, Watson, and Mallinckrodt may launch their own generics.

210. Jazz has admitted that its series of reverse payment settlements were designed to effectively allocate the Xyrem market.

211. 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.

212. 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.

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

viii) Jazz plans to "product hop" to prevent generics from obtaining market share.

214. Not content with delaying generics through its anticompetitive settlement agreements, Jazz seeks to prevent generics from ever making a dent in its vast profits.

215. Jazz sought to develop 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.

216. As described in Section V.D.vi., this strategy is known as "product hopping," and it works because it circumvents state substation laws. Jazz can then rely on massive marketing budget to push its new product and destroy the market share of the generic competitors.

217. In early 2017, Jazz was progressing on its hop strategy. It had multiple line extension prospects in development and one, a low-sodium reformulation of Xyrem code-named JZP-258, had shown promising early results and was preparing to enter phase III clinical trials. But there was one huge problem: 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 of its patents, there was a May 2017 patent trial, which brought with it the very real likelihood that Jazz's Xyrem patent portfolio would be tanked, opening the floodgates not just for Hikma, but for all generic Xyrem competition, years before Jazz's successor product would be ready for market. Jazz knew it had to act fast to prevent that; its very life as a company depended on it.

218. So, as detailed above, in April 2017, on the eve of trial, Jazz and Hikma finalized a settlement that included a payoff to induce Hikma to shelf its approved generic version of Xyrem. Jazz stock jumped as investors realized the unexpected windfall. Not long thereafter, Jazz's executives ramped up public discussion about their promising hop strategy.

219. On an August 8, 2017 earnings call, Jazz's CEO 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" (apparently meaning in addition to the agreed market allocation on legacy Xyrem), Mr. Cozadd 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."

220. 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, Jazz's CEO did not rule out the strategy, but advised it was "too early to start commenting on commercial strategy."

221. 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.

222. As of the filing of this complaint, it appears Jazz is on track to effectuate its planned product hop. Jazz's NDA seeking approval of JZP-258 was submitted to FDA on January 21, 2020. On July 21, 2020, the FDA approved of JZP-258 (commercial name Xywav). Jazz plans to launch Xywav by the end of the year.

VIII. ANTICOMPETITIVE EFFECTS

223. The anticompetitive scheme described above enabled Defendants to: (i) delay until January 1, 2023, the entry of any less-expensive generic versions of sodium oxybate products in the United States; (ii) restrict the market for sodium oxybate to branded Xyrem, Authorized Generics, and Roxane's generic until December 25, 2025; (iii) fix, raise, maintain, and/or stabilize the price of Xyrem and its generic equivalents.

224. But for the anticompetitive scheme, Roxane would have launched its generic as early as 2017; Amneal, Lupin, Par, Wockhardt, Ranbaxy, Watson, and Mallinckrodt would have followed after Roxane's 180-day exclusivity period; and full generic competition would have been achieved as early as 2018. As a result of Defendants' anticompetitive scheme, full generic competition will not be achieved until at least December 31, 2025.

225. Defendants' unlawful concerted action has: (i) delayed and prevented the sale of generic sodium oxybate in the United States and its territories; (ii) enabled Jazz to sell Xyrem at artificially inflated, supracompetitive prices; and (iii) caused Plaintiff and the Class to pay supracompetitive prices for Xyrem.

226. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT

227. During the relevant period, Plaintiff and Class members purchased substantial amounts of Xyrem indirectly from Defendants at supracompetitive prices. As a result of Defendants' illegal conduct, Plaintiff and Class members were compelled to pay, and did pay, artificially inflated prices for Xyrem. Those prices were substantially greater than the prices that

Plaintiff and Class members would have paid absent the illegal conduct alleged herein, because: (i) the price of Xyrem was artificially inflated by Defendants' illegal conduct, and (ii) Plaintiff and Class members were deprived of the opportunity to purchase lower-priced generic versions of Xyrem, which they would have done had they had the opportunity.

228. As a consequence, Plaintiff and Class members have sustained substantial losses and damage to their business and/or property in the form of overcharges. The full amount 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 charges passed through the chain of distribution to end-payors such as Plaintiff and Class members.

229. 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.[150]

230. 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. Wholesalers and retailers passed on the inflated prices of Xyrem to Plaintiff and Class members. Further, the delayed entry of generic competition at the direct purchaser level similarly injured End-Payors who were equally denied the opportunity to purchase less expensive generic sodium oxybate.

[150] 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.*

231. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

232. Defendants' unlawful anticompetitive conduct alleged herein enabled them to indirectly charge End-Payors prices in excess of what they otherwise would have been able to charge absent their unlawful actions.

233. Prices of Xyrem were artificially inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

234. The supracompetitive prices Plaintiff and Class members paid are traceable to, and are the direct, proximate, and foreseeable result of, Defendants' anticompetitive conduct.

235. The overcharges Plaintiff and Class members paid are traceable to, and are the direct, proximate, and foreseeable result of, Defendants' supracompetitive pricing.

X. EFFECT ON INTERSTATE COMMERCE

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

237. During the relevant time period, Plaintiff and members of the Classes purchased, paid, and/or reimbursed some or all the purchase price of Xyrem or its AB-rated generic equivalents from Defendants. As a result of Defendants' illegal conduct, Plaintiff and members of the Classes did so at artificially inflated prices for Xyrem and generic Xyrem.

238. 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 herein, within the flow of, and substantially affecting, interstate commerce, including within this District.

XI. MONOPOLY POWER AND MARKET DEFINITION

239. At all relevant times, Jazz had and maintained monopoly power in the market for Xyrem and its generic equivalents because it had the power to maintain the price of Xyrem at supracompetitive levels without losing sales so as to make the supracompetitive price unprofitable.

240. Direct proof exists that Jazz had monopoly power over the price of Xyrem. Such direct evidence includes, among other things, the abnormally high price-cost margins enjoyed by Jazz and Jazz's ability to profitably raise and maintain the price of Xyrem well above competitive levels.

241. Manufacturers attempt to differentiate brand name drugs like Xyrem based on features and benefits (including safety and efficacy), not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Xyrem. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. That different patients may respond differently to different drugs and even drugs within its same therapeutic class does not constrain the price of Xyrem.

242. Other drugs that are not AB-rated to Xyrem cannot be substituted automatically for Xyrem by pharmacists, do not exhibit substantial cross-price elasticity of demand with Xyrem, and thus are not economic substitutes for, nor reasonably interchangeable with, Xyrem.

243. Other products are not substitutes for Xyrem or its generic equivalents, and the existence of other products designed to treat narcolepsy have not significantly constrained Jazz's pricing of Xyrem. On information and belief, Jazz has never lowered the price of Xyrem in response to the pricing of other branded or generic drugs. In fact, Jazz has continuously raised the price of Xyrem.

244. Jazz needed to control only the sales of Xyrem, and no other products, in order to maintain the price of Xyrem profitably at supracompetitive prices. Only the market entry of a competing, generic version of Xyrem would render Jazz unable to profitably maintain its prices of Xyrem without losing substantial sales.

245. To the extent Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, the relevant market is Xyrem and generic equivalents (in all forms and dosage strengths). The relevant geographic market is the United States.

246. Jazz's anticompetitive reverse payments to the Generic Manufacturers demonstrate that Jazz enjoyed market and/or monopoly power with respect to sodium oxybate.

247. A small but significant non-transitory increase in price (SSNIP) above the competitive level for Xyrem by Jazz would not cause a loss of sales sufficient to make the price increase unprofitable. In fact, Jazz has increased the price of Xyrem in increments greater than the SSNIP level several times and has not suffered a corresponding decrease in sales.

248. At competitive price levels, Xyrem does not exhibit significant positive cross price elasticity of demand with any product other than generic Xyrem.

249. Jazz, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections, and high costs of entry and expansion.

250. During the relevant period, Defendants' anticompetitive conduct has significantly damaged competition and consumers through a reduction of output and higher prices caused by an elimination of lower cost generic Xyrem throughout the United States.

251. Jazz has maintained and exercised the power to exclude and restrict competition to Xyrem and its AB-rated generics.

252. At all relevant times, Jazz's market share in the relevant market was 100%, implying substantial monopoly power.

XII. CLASS ACTION ALLEGATIONS

253. Plaintiff brings this action on behalf of itself and, under Federal Rule of Civil Procedure 23(a), (b)(2) and (b)(3), as a representative of a class of End-Payor Purchasers (the "Class") defined as follows:

> All persons and entities in the United States and its territories that indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Xyrem in any form, other than for resale, from June 17, 2017 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period").

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

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

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

c. All persons or entities who purchased Xyrem purposes of resale or directly from Defendants or their affiliates;

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 regardless of the retail purchase price;

f. Pharmacy benefit managers; and

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

255. The Class is so numerous and widely geographically dispersed throughout the United States that joinder of all members is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The identities of Class members will be readily ascertainable through business records kept in regular order. Plaintiff's claims are typical of Class members. Plaintiff and all Class members were damaged by the same wrongful conduct by Defendants. Defendants' anticompetitive conduct deprived the Class members of the benefits of competition from less-expensive generic sodium oxybate, causing them to pay artificially inflated, supracompetitive prices for the drug.

256. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiff are aligned with, and not antagonistic to, those of the other Class members.

257. Questions of law and fact common to Class members predominate over questions, if any, that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants' wrongful conduct.

258. Questions of law and fact common to the Class include:

a. Whether the conduct alleged herein constitutes a violation of the antitrust laws;

b. Whether Defendants conspired to suppress generic competition to Xyrem;

c. Whether Defendants' challenged conduct suppressed generic competition to Xyrem;

d. Whether a relevant antitrust market needs to be defined in this case in light of the existence of direct proof of Jazz's power to exclude generic competition and charge supracompetitive prices for Xyrem and/or the per se illegal nature of the challenged conduct;

e. If a relevant antitrust market needs to be defined, what the definition of the relevant antitrust market for analyzing Jazz's monopoly power is, and whether Jazz had monopoly power in the relevant antitrust market;

f. Whether Jazz illegally obtained or maintained monopoly power in the relevant market;

g. Whether Defendants' actions were, on balance, unreasonable restraints of trade;

h. Whether Jazz's listings of certain Xyrem patents in the Orange Book was fraudulent;

i. Whether Jazz abused the REMS program to delay generic entry;

j. Whether Jazz filed sham citizen petitions;

k. Whether the Settlements included large and unjustified payments in exchange for promises from the Generic Manufacturers to delay generic entry;

l. Whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

m. Whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiff and the Purchaser Class; and

n. The quantum of overcharge damages paid by the Class in the aggregate.

259. 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

260. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
(Conspiracy and Combination in Restraint of Trade Under State Law)
(Against All Defendants)

261. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

262. 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.

263. During the Class Period, Defendants entered into an unlawful reverse payment agreement that restrained competition in the market for Xyrem and its generic equivalents.

264. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Xyrem and its generic equivalents.

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

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

a. Delayed entry of generic sodium oxybate;

b. Extended Jazz's monopoly over the market for sodium oxybate;

c. Caused Jazz to make supracompetitive profits;

d. Raised and maintained the prices that Plaintiff and other Class members paid and are paying for Xyrem at supracompetitive levels.

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

268. There was no legitimate, non-pretextual, procompetitive business justification for this reverse payment agreement that outweighs its harmful effect on End-Payors and on 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).

269. 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. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Xyrem in Arizona by Class members and/or purchases by Arizona residents.

b. Cal. Bus. and Prof. Code §§ 16720, *et seq.*, with respect to purchases of Xyrem in California by Class members and/or purchases by California residents.

c. Conn. Gen. Stat. § 35-26, *et seq.*, with respect to purchases of Xyrem in Connecticut by Class members and/or purchases by Connecticut residents.

d. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of Xyrem in the District of Columbia by Class members and/or purchases by D.C. residents.

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

f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Xyrem in Illinois by Class members and/or purchases by Illinois residents.

g. Iowa Code §§ 553.4, *et seq.*, with respect to purchases of Xyrem in Iowa by Class members and/or purchases by Iowa residents.

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

i. Md. Code, Com Law, Section 11-204, *et seq.*, with respect to purchases in Maryland by Class members and/or purchases by Maryland residents.

j. Me. Stat. tit. 10 § 1101, *et seq.*, with respect to purchases of Xyrem in Maine by Class members and/or purchases by Maine residents.

k. Mich. Comp. Laws §§ 445.772, *et seq.*, with respect to purchases of Xyrem in Michigan by Class members and/or purchases by Michigan residents.

l. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of Xyrem in Minnesota by Class members and/or purchases by Minnesota residents.

m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Xyrem in Mississippi by Class members and/or purchases by Mississippi residents.

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

o. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of Xyrem in Nevada by Class members and/or purchases by Nevada residents.

p. N.H. Rev. Stat. Ann. §§ 356:2, *et. seq.*, with respect to purchases of Xyrem in New Hampshire by Class members and/or purchases by New Hampshire residents.

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

r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Xyrem in New York by Class members and/or purchases by New York residents.

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

t. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Xyrem in North Dakota by Class members and/or purchases by North Dakota residents.

u. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of Xyrem in Oregon by Class members and/or purchases by Oregon residents.

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

w. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of Xyrem in Rhode Island by Class members and/or purchases by Rhode Island residents.

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

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

z. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of Xyrem in Utah by Class members and/or purchases by Utah residents.

aa. W.Va. Code §§ 47-18-43, *et seq.*, with respect to purchases of Xyrem in West Virginia by Class members and/or purchases by West Virginia residents.

bb. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Xyrem in Wisconsin by Class members and/or purchases by Wisconsin residents.

SECOND CLAIM FOR RELIEF
Unfair Methods of Competition, and Unfair and Deceptive Acts,
In Violation of State Consumer Protection Laws
(Against All Defendants)

270. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

271. Defendants engaged in unfair methods of competition and unfair, unconscionable, and/or deceptive acts or practices to wrongfully perpetuate their concerted conduct to restrain trade in the relevant market.

272. As a direct and proximate result of Defendants' unfair, unconscionable, and/or deceptive conduct, Plaintiff and Class members were: (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.

273. 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.

274. There was and is a gross disparity between the price that Plaintiff 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, unconscionable, and deceptive conduct.

275. As a direct and proximate result of Defendants' anticompetitive, unfair, unconscionable, and/or deceptive conduct, Plaintiff and Class members were denied the opportunity to purchase generic Xyrem and forced to pay higher prices for Xyrem.

276. By engaging in such conduct, Defendants violated the following consumer protection laws:

a. Ariz. Rev. Stat. Ann. §§ 44-1521, *et seq.*, with respect to purchases of Xyrem in Arizona by Class members and/or purchases by Arizona residents.

b. Ark. Code Ann. §§ 4-88-101, *et seq.*, with respect to purchases of Xyrem in Arkansas by Class members and/or purchases by Arkansas residents.

c. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases of Xyrem in California by Class members and/or purchases by California residents.

d. Conn. Gen. Stat. §§ 42-110b, *et seq.*, with respect to purchases of Xyrem in California by Class members and/or purchases by Connecticut residents.

e. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of Xyrem in D.C. by Class members and/or purchases by D.C. residents.

f. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Xyrem in Florida by Class members and/or purchases by Florida residents.

g. Haw. Rev. Stat. §§ 481-1, *et seq.*, with respect to purchases of Xyrem in Hawaii by Class members and/or purchases by Hawaii residents.

h. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of Xyrem in Idaho by Class members and/or purchases by Idaho residents.

i. 815 Ill. Comp. Stat. 505/1, *et seq.*, with respect to purchases of Xyrem in Illinois by Class members and/or purchases by Illinois residents.

j. Kan. Stat. Ann. §§ 50-623, *et seq.*, with respect to purchases of Xyrem in Kansas by Class members and/or purchases by Kansas residents.

k. Me. Stat. tit. 5, §§ 207, *et seq.*, with respect to purchases of Xyrem in Maine by Class members and/or purchases by Maine residents.

l. Mass. Gen. Laws ch. 93A, §§ 1, *et seq.*, with respect to purchases of Xyrem in Massachusetts by Class members and/or purchases by Massachusetts residents.

m. Mich. Comp. Laws §§ 445.901, *et seq.*, with respect to purchases of Xyrem in Michigan by Class members and/or purchases by Michigan residents.

n. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Xyrem in Minnesota by Class members and/or purchases by Minnesota residents.

o. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to purchases of Xyrem in Missouri by Class members and/or purchases by Missouri residents.

p. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Xyrem in Nebraska by Class members and/or purchases by Nebraska residents.

q. Nev. Rev. Stat. Ann. §§ 598.0903, *et seq.*, with respect to purchases of Xyrem in Nevada by Class members and/or purchases by Nevada residents.

r. N.H. Rev. Stat. Ann. §§ 358-A:1, *et seq.*, with respect to purchases of Xyrem in New Hampshire by Class members and/or purchases by New Hampshire residents.

s. N.M. Stat. Ann. §§ 57-12-1, *et seq.*, with respect to purchases of Xyrem in New Mexico by Class members and/or purchases by New Mexico residents.

t. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of Xyrem in New York by Class members and/or purchases by New York residents.

u. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of Xyrem in North Carolina by Class members and/or purchases by North Carolina residents.

v. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases of Xyrem in Oregon by Class members and/or purchases by Oregon residents.

w. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Xyrem in Rhode Island by Class members and/or purchases by Rhode Island residents.

x. S.D. Codified Laws §§ 37-24-6, *et seq.*, with respect to purchases of Xyrem in South Dakota by Class members and/or purchases by South Dakota residents.

y. Tenn. Code Ann. §§ 47-18-101, *et seq.*, with respect to purchases of Xyrem in Tennessee by Class members and/or purchases by Tennessee residents.

z. Utah Code Ann. §§ 13-11-1, *et seq.*, with respect to purchases of Xyrem in Utah by Class members and/or purchases by Utah residents.

aa. Vt. Stat Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of Xyrem in Vermont by Class members and/or purchases by Vermont residents.

bb. W. Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of Xyrem in West Virginia by Class members and/or purchases by West Virginia residents.

cc. Wis. Stat. § 100.20, *et seq.*, with respect to purchases of Xyrem in Wisconsin by Class members and/or purchases by Wisconsin residents.

277. Plaintiff and Class members have been injured in their business and property by reason of Defendants' anticompetitive, unfair, unconscionable, and/or deceptive 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.

278. On behalf of itself and the Class, Plaintiff seeks all appropriate relief provided for under the foregoing statutes.

THIRD CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme Under State Law
(Against Jazz)

279. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

280. As described above, at all relevant times, Jazz had monopoly power in the relevant market.

281. Defendant Jazz willfully and unlawfully monopolized the relevant market by engaging in an anticompetitive scheme to keep AB-rated generic equivalents of Xyrem from the market—not by providing a superior product, business acumen, or historical accident.

282. Defendant's scheme is ongoing.

283. Defendant Jazz accomplished this scheme by, *inter alia*,

a. Delaying entry of generic sodium oxybate;

b. Filing sham citizen petitions;

c. Abusing the REMS program;

d. Filing sham patent infringement lawsuits;

e. Committing fraud on the U.S. Patent and Trademark Office;

f. Attempting to "product hop";

g. Extending Jazz's monopoly over the market for sodium oxybate;

h. Causing Jazz to make supracompetitive profits;

i. Raising and maintaining the price so that Plaintiff and other Class members would pay supracompetitive prices for Xyrem.

284. The goal, purpose, and effect of Defendant Jazz's scheme was also to maintain and extend Jazz's monopoly power with respect to Xyrem. Defendant's illegal scheme allowed

Jazz to continue charging supracompetitive prices for Xyrem, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

285. There was and is no legitimate, non-pretextual, procompetitive justification for Defendant 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.

286. As a result of Defendant Jazz's illegal conduct, Plaintiff and Class members were compelled to pay, and did pay, more than they would have paid for Xyrem absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Xyrem sooner than they did, and prices for Xyrem would have been and would be lower.

287. Had manufacturers of generic Xyrem entered the market and lawfully competed in a timely fashion, Plaintiff 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 purchases.

288. But for Defendant Jazz's illegal conduct, competitors would have begun marketing generic versions of Xyrem and they would have been able to market such versions successfully.

289. By engaging in the foregoing conduct, Defendants intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

a. Ariz. Rev. Stat. Ann. §§ 44-1403, *et seq.*, with respect to purchases of Xyrem in Arizona by Class members and/or purchases by Arizona residents.

b. Cal. Bus. & Prof. Code §§ 16720, *et seq.*, with respect to purchases of Xyrem in California by Class members and/or purchases by California residents.

c. Conn. Gen. Stat. §§ 35-27, *et seq.*, with respect to purchases of Xyrem in Connecticut by Class members and/or purchases by Connecticut residents.

d. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Xyrem in the District of Columbia by Class members and/or purchases by D.C. residents.

e. Haw. Rev. Stat. §§ 480-9, *et seq.*, with respect to purchases of Xyrem in Hawaii by Class members and/or purchases by Hawaii residents.

f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Xyrem in Illinois by Class members and/or purchases by Illinois residents.

g. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of Xyrem in Iowa by Class members and/or purchases by Iowa residents.

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

i. Me. Stat. tit. 10, § 1102, *et seq.*, with respect to purchases of Xyrem in Maine by Class members and/or purchases by Maine residents.

j. Md. Code, Com Law, Section 11-204, *et seq.*, with respect to purchases in Maryland by Class members and/or purchases by Maryland residents.

k. Mich. Comp. Laws §§ 445.773, *et seq.*, with respect to purchases of Xyrem in Michigan by Class members and/or purchases by Michigan residents.

l. Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Xyrem in Minnesota by Class members and/or purchases by Minnesota residents.

m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Xyrem in Mississippi by Class members and/or purchases by Mississippi residents.

n. Neb. Rev. Stat. §§ 59-802, *et seq.*, with respect to purchases of Xyrem in Nebraska by Class members and/or purchases by Nebraska residents.

o. N.H. Rev. Stat. Ann. §§ 356:3, *et. seq.*, with respect to purchases of Xyrem in New Hampshire by Class members and/or purchases by New Hampshire residents.

p. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of Xyrem in Nevada by Class members and/or purchases by Nevada residents.

q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Xyrem in New Mexico by Class members and/or purchases by New Mexico residents.

r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Xyrem in New York by Class members and/or purchases by New York residents.

s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Xyrem in North Carolina by Class members and/or purchases by North Carolina residents.

t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Xyrem in North Dakota by Class members and/or purchases by North Dakota residents.

u. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of Xyrem in Oregon by Class members and/or purchases by Oregon residents.

v. P.R. Laws Ann. tit. 10, §§ 260, *et seq.*, with respect to purchases of Xyrem in Puerto Rico by Class members and/or purchases by Puerto Rico residents.

w. R.I. Gen. Laws §§ 6-36-7, *et seq.*, with respect to purchases of Xyrem in Rhode Island by Class members and/or purchases by Rhode Island residents.

x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Xyrem in South Dakota by Class members and/or purchases by South Dakota residents.

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

z. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of Xyrem in Utah by Class members and/or purchases by Utah residents.

aa. W. Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Xyrem in West Virginia by Class members and/or purchases by West Virginia residents.

bb. Wis. Stat. § 133.03, *et seq.*, of Xyrem in Wisconsin by Class members and/or purchases by Wisconsin residents.

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

291. Plaintiff and Class members accordingly seek damages and multiple damages as permitted by law.

FOURTH CLAIM FOR RELIEF
Unfair Methods of Competition, and Unfair and Deceptive Acts,
In Violation of State Consumer Protection Laws
(Against Jazz)

292. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

293. Defendant Jazz engaged in unfair methods of competition and unfair, unconscionable, and/or deceptive acts or practices to wrongfully perpetuate its monopoly in the market for sodium oxybate.

294. Specifically, Defendant Jazz engaged in an anticompetitive scheme to delay generic entry by:

a. Delaying entry of generic sodium oxybate;

b. Filing sham citizen petitions;

c. Abusing the REMS program;

d. Filing sham patent infringement lawsuits;

e. Committing fraud on the U.S. Patent and Trademark Office;

f. Attempting to "product hop";

g. Extending Jazz's monopoly over the market for sodium oxybate;

h. Causing Jazz to make supracompetitive profits;

i. Raising and maintaining the price so that Plaintiff and other Class members would pay supracompetitive prices for Xyrem.

295. As a direct and proximate result of Defendant's unfair, unconscionable, and/or deceptive conduct, Plaintiff and Class members were: (i) denied the opportunity to purchase lower-priced generic Xyrem; and (ii) paid higher prices for Xyrem than they would have paid but for Defendant's unlawful conduct.

296. The gravity of harm from Defendant's wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and Class members could not reasonably have avoided injury from Defendant's wrongful conduct.

297. There was and is a gross disparity between the price that Plaintiff 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 Defendant's unfair, unconscionable, and deceptive conduct.

298. As a direct and proximate result of Defendant's anticompetitive, unfair, unconscionable, and/or deceptive conduct, Plaintiff and Class members were denied the opportunity to purchase generic Xyrem and forced to pay higher prices for Xyrem.

299. By engaging in such conduct, Defendants violated the following consumer protection laws:

a. Ariz. Rev. Stat. Ann. §§ 44-1521, *et seq.*, with respect to purchases of Xyrem in Arizona by Class members and/or purchases by Arizona residents.

b. Ark. Code Ann. §§ 4-88-101, *et seq.*, with respect to purchases of Xyrem in Arkansas by Class members and/or purchases by Arkansas residents.

c. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases of Xyrem in California by Class members and/or purchases by California residents.

d. Conn. Gen. Stat. §§ 42-110b, *et seq.*, with respect to purchases of Xyrem in California by Class members and/or purchases by Connecticut residents.

e. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of Xyrem in D.C. by Class members and/or purchases by D.C. residents.

f. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Xyrem in Florida by Class members and/or purchases by Florida residents.

g. Haw. Rev. Stat. §§ 481-1, *et seq.*, with respect to purchases of Xyrem in Hawaii by Class members and/or purchases by Hawaii residents.

h. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of Xyrem in Idaho by Class members and/or purchases by Idaho residents.

i. 815 Ill. Comp. Stat. 505/1, *et seq.*, with respect to purchases of Xyrem in Illinois by Class members and/or purchases by Illinois residents.

j. Kan. Stat. Ann. §§ 50-623, *et seq.*, with respect to purchases of Xyrem in Kansas by Class members and/or purchases by Kansas residents.

k. Me. Stat. tit. 5, §§ 207, *et seq.*, with respect to purchases of Xyrem in Maine by Class members and/or purchases by Maine residents.

l. Mass. Gen. Laws ch. 93A, §§ 1, *et seq.*, with respect to purchases of Xyrem in Massachusetts by Class members and/or purchases by Massachusetts residents.

m. Mich. Comp. Laws §§ 445.901, *et seq.*, with respect to purchases of Xyrem in Michigan by Class members and/or purchases by Michigan residents.

n. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Xyrem in Minnesota by Class members and/or purchases by Minnesota residents.

o. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to purchases of Xyrem in Missouri by Class members and/or purchases by Missouri residents.

p. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Xyrem in Nebraska by Class members and/or purchases by Nebraska residents.

q. Nev. Rev. Stat. Ann. §§ 598.0903, *et seq.*, with respect to purchases of Xyrem in Nevada by Class members and/or purchases by Nevada residents.

r. N.H. Rev. Stat. Ann. §§ 358-A:1, *et seq.*, with respect to purchases of Xyrem in New Hampshire by Class members and/or purchases by New Hampshire residents.

s. N.M. Stat. Ann. §§ 57-12-1, *et seq.*, with respect to purchases of Xyrem in New Mexico by Class members and/or purchases by New Mexico residents.

t. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of Xyrem in New York by Class members and/or purchases by New York residents.

u. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of Xyrem in North Carolina by Class members and/or purchases by North Carolina residents.

v. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases of Xyrem in Oregon by Class members and/or purchases by Oregon residents.

w. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Xyrem in Rhode Island by Class members and/or purchases by Rhode Island residents.

x. S.D. Codified Laws §§ 37-24-6, *et seq.*, with respect to purchases of Xyrem in South Dakota by Class members and/or purchases by South Dakota residents.

y. Tenn. Code Ann. §§ 47-18-101, *et seq.*, with respect to purchases of Xyrem in Tennessee by Class members and/or purchases by Tennessee residents.

z. Utah Code Ann. §§ 13-11-1, *et seq.*, with respect to purchases of Xyrem in Utah by Class members and/or purchases by Utah residents.

aa. Vt. Stat Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of Xyrem in Vermont by Class members and/or purchases by Vermont residents.

bb. W. Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of Xyrem in West Virginia by Class members and/or purchases by West Virginia residents.

cc. Wis. Stat. § 100.20, *et seq.*, with respect to purchases of Xyrem in Wisconsin by Class members and/or purchases by Wisconsin residents.

300. Plaintiff and Class members have been injured in their business and property by reason of Defendants' anticompetitive, unfair, unconscionable, and/or deceptive 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.

301. On behalf of itself and the Class, Plaintiff seeks all appropriate relief provided for under the foregoing statutes.

FIFTH CLAIM FOR RELIEF
Unjust Enrichment
(Against All Defendants)

302. Plaintiff incorporates the above paragraphs by reference.

303. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

304. Defendants have reaped and retained substantially higher profits due to their unlawful scheme.

305. Plaintiff 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 Plaintiff and Class members.

306. Defendants' financial gain from their unlawful conduct is traceable to overpayments for Xyrem by Plaintiff and Class members.

307. Plaintiff and Class members have no adequate remedy at law.

308. It would be futile for Plaintiff 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 Plaintiff and Class members for Defendants' unlawful conduct.

309. 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 Plaintiff and the Class members for Xyrem sold by Defendants during the Class Period.

310. The financial benefits Defendants derived from overcharging Plaintiff and Class members for Xyrem is a direct and proximate result of Defendants' unlawful practices described herein.

311. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiff and Class members, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

312. It would be wrong and inequitable, under unjust enrichment principles under the laws of each state in the United States as well as the District of Columbia, except for Delaware, Georgia, Indiana, Kentucky, Louisiana, New Jersey, Ohio, Oklahoma, Pennsylvania, Texas, Virginia, Washington, and Wyoming for Defendants to be permitted to retain any of the overcharges that Plaintiff and Class members paid for Xyrem that were derived from Defendants' unlawful practices described herein.

313. Defendants are aware of and appreciate the benefits that Plaintiff and Class members have bestowed upon them.

314. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and Class members.

315. Plaintiff 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 Plaintiff and Class members may make claims on a pro rata basis.

SIXTH CLAIM FOR RELIEF
Declaratory and Injunctive Relief Under Sections 1 and 2 of the Sherman Act and Section 16 of the Clayton Act (15 U.S.C. §§ 1–2, 26)

316. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

317. Plaintiff seeks declaratory and injunctive relief under the federal antitrust laws.

318. Plaintiffs' allegations described herein constitute violations of Sections 1 and 2 of the Sherman Act.

319. Defendant Jazz effectuated a scheme to restrain trade and monopolize the market for sodium oxybate.

320. Defendants effectuated a scheme to restrain trade and allocate the market for sodium oxybate.

321. There is and was no legitimate, non-pretextual, procompetitive business justification for Defendants' conduct that outweighs its harmful effect.

322. As a direct and proximate result of Defendants' anticompetitive conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

323. The goal, purpose and/or effect of Jazz's conduct was to prevent and/or delay competition, in order to continue charging supracompetitive prices for Xyrem without a substantial loss of sales.

324. The goal, purpose and/or effect of Defendants' conduct was to allocate the market for sodium oxybate to share in the monopoly profits.

325. Plaintiff and the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Count. 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.

326. 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 §§ 1 and 2 of the Sherman Act.

327. Plaintiff and the Class further seek equitable and injunctive relief pursuant to § 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct the anticompetitive effects caused by Defendants' unlawful conduct.

XIV. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, prays for judgment against all Defendants, jointly and severally, as follows:

A. Determining that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2) 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 Class, and appoint the Plaintiff as the named representative of the Class;

B. Granting injunctive relief that restores Defendants' incentives to compete in the relevant market;

C. Awarding Plaintiff and the Class damages (i.e., three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;

D. Entering joint and several judgments against Defendants and in favor of Plaintiff and the Class;

E. Granting Plaintiff and the Class equitable relief in the form of disgorgement or restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

F. Awarding Plaintiff and the Class their costs of suit, including reasonable attorneys' fees, as provided by law; and

G. Awarding such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XV. JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, Plaintiff, on behalf of itself and the proposed Classes, demands a trial by jury on all issues so triable.

Dated: August 14, 2020

JOSEPH SAVERI LAW FIRM, INC.

By: */s/ Steven N. Williams*
Steven N. Williams

Joseph R. Saveri (pro hac vice pending)
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