Todd A. Seaver (SBN 271067)
Carl N. Hammarskjold (SBN 280961)
Colleen Cleary (SBN 306659)
BERMAN TABACCO
44 Montgomery Street, Suite 650
San Francisco, CA 94104
Tel: (415) 433-3200
Fax: (415) 433-6382
Email: tseaver@bermantabacco.com
chammarskjold@bermantabacco.com
ccleary@bermantabacco.com

Gregory S. Asciolla (*pro hac vice forthcoming*)
Jay L. Himes (*pro hac vice forthcoming*)
Karin E. Garvey (*pro hac vice forthcoming*)
Matthew J. Perez (*pro hac vice forthcoming*)
Domenico Minerva (*pro hac vice forthcoming*)
Jonathan S. Crevier (*pro hac vice forthcoming*)
LABATON SUCHAROW LLP
140 Broadway
New York, NY 10005
Tel: (212) 907-0700
Fax: (212) 818-0477
Email: gasciolla@labaton.com
jhimes@labaton.com
kgarvey@labaton.com
mperez@labaton.com
dminerva@labaton.com
jcrevier@labaton.com

[Additional Attorneys Listed on Signature Page]

Counsel for Plaintiff

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UFCW LOCAL 1500 WELFARE FUND, on behalf of itself and all others similarly situated,

Plaintiff,

vs.

BAUSCH HEALTH COMPANIES INC., SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., SANTARUS, INC., ASSERTIO THERAPEUTICS, INC., LUPIN PHARMACEUTICALS, INC., and LUPIN LTD.

Defendants.

Case No.:

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiff UFCW Local 1500 Welfare Fund ("Plaintiff") brings this class action, on behalf of itself and all others similarly situated, against Bausch Health Companies Inc. (formerly known as Valeant Pharmaceuticals International, Inc.), Salix Pharmaceuticals, Ltd., Salix Pharmaceuticals, Inc., Santarus, Inc., Assertio Therapeutics, Inc. (formerly known as Depomed, Inc.), Lupin Pharmaceuticals, Inc., and Lupin Ltd. (collectively, "Defendants") for violations of state antitrust, consumer protection, and common laws. Plaintiff's claims arise from Defendants' anticompetitive scheme to restrain competition in the market for the pharmaceutical Glumetza® and its AB-rated generic equivalents sold in the United States. Plaintiff's allegations are made on personal knowledge as to Plaintiff and Plaintiff's own acts and upon information and belief as to all other matters.

I. INTRODUCTION

1. Plaintiff seeks damages and equitable relief arising from Defendants' anticompetitive pay-for-delay agreement, which eliminated generic competition in the United States for branded and generic versions of Glumetza (extended release metformin). Glumetza is a drug used to treat Type 2 diabetes.

2. Prescription metformin has been available as a generic drug since 2002. Defendant Assertio developed an extended-release version of metformin that can alleviate some of the drug's common side effects, particularly gastrointestinal intolerance. Assertio obtained several patents on the extended-release technology and began selling extended-release metformin, marketed under the brand name Glumetza, in 2005. Extended-release mechanisms are very common, however, and Assertio's patents were weak and narrow and could not prevent competition from generic versions of the drug.

3. When Defendant Lupin developed a generic version of Glumetza, Assertio and its co-venturer, Defendant Santarus, sued Lupin for patent infringement. That lawsuit triggered an automatic stay, prohibiting Lupin from entering the market for 30 months. Just before the 30 months were over, and Lupin could enter the market with generic Glumetza, Assertio/Santarus and Lupin settled their lawsuit on or about February 22, 2012, with Assertio/Santarus paying Lupin to delay generic entry.

4. The settlement agreement was a pay-for-delay agreement whereby (1) Lupin agreed not to compete in the market for Glumetza until February 1, 2016, thereby allocating the entire Glumetza market to Assertio/Santarus until that date; and (2) Assertio/Santarus agreed not to compete in the generic Glumetza market from February 1, 2016 to at least August 1, 2016, allocating the entire market for generic versions of Glumetza to Lupin for that six-month period.

5. One possible wrinkle with this plan stemmed from the fact that the weakness of the Assertio patents created the risk that another manufacturer could avoid them and market a generic Glumetza before February 2016, thereby upending the Assertio/Santarus/Lupin anticompetitive scheme. To prevent that possibility, Assertio/Santarus and Lupin included in their agreement two deterrent provisions aimed at other competitors: (a) if another generic manufacturer succeeded in entering the market before February 2016, Lupin could also enter on that earlier date; and (b) Assertio/Santarus would not grant a license to any other manufacturer to enter the market sooner than 180 days after Lupin.

6. These deterrents ensured that, no matter how many resources another manufacturer might expend in overcoming Assertio's patents, they could not reap the financial reward of being the only generic manufacturer on the market. Even if another generic manufacturer won a patent lawsuit against Assertio/Santarus, the deterrent provision would allow Lupin to enter earlier. And even if another generic manufacturer sought to negotiate a license from Assertio/Santarus, the deterrent provision expressly prohibited any license that would deprive Lupin of its 180-day exclusivity period.

7. The agreement between Assertio/Santarus and Lupin unlawfully closed every pathway to generic competition before February 2016 and extended the anticompetitive effect beyond February 2016 by agreeing that Lupin would be the only generic competitor from February 2016 until at least August 2016. In short, Assertio/Santarus and Lupin conjured a monopoly in the sale of Glumetza and its generic equivalents where a monopoly would not have existed under lawful, competitive practices.

8. In November 2013, Santarus, with Glumetza accounting for almost half its sales, announced that it was being acquired by Defendant Salix for $2.6 billion. Through its acquisition of Santarus, Salix acquired commercial rights to Glumetza and joined the Assertio-Santarus-Lupin unlawful patent settlement and reverse payment scheme and wasted no time in exploiting the monopoly that Assertio/Santarus had fashioned: from 2012 to 2015 Salix raised Glumetza prices.

9. In April 2015, when Glumetza accounted for more than 25% of its sales, Salix in turn sold the Glumetza monopoly to Valeant Pharmaceuticals, Inc. (now known as Bausch Health). Valeant paid $14.5 billion to acquire Salix. Through its acquisition of Salix, Valeant acquired commercial rights to Glumetza and joined the Assertio-Santarus-Lupin unlawful patent settlement and reverse payment scheme.

10. Valeant was known in the industry as an exploiter of drug-product monopolies. As Forbes magazine later characterized it, Valeant's business strategy "emphasized boosting drug prices, gutting research and development budgets, [and] firing employees . . . ."[1] "[S]cientists were seen as unnecessary costs to be cut," while Valeant's "drug-price increases became legendary."[2] Industry observers concluded that "Valeant was the pure expression of the view that companies are there to make money for shareholders, every other consideration be damned."[3]

11. Within four months of acquiring the Glumetza monopoly, Valeant *raised the price by approximately 800%*, with a monthly supply increasing for some patients from approximately $500 to $4,600. In the six months before the price hike, Salix made $145 million on Glumetza; in the six months after, Valeant made more than $800 million.

12. To make matters worse, not only did Valeant hike the price of branded Glumetza to exorbitant levels, that price hike led to the follow-on effect that Lupin's generic was also

[1] Nathan Vardi & Antoine Gara, *Valeant Pharmaceuticals' Prescription for Disaster*, Forbes, April 13, 2016, https://www.forbes.com/sites/nathanvardi/2016/04/13/valeant-pharmaceuticals-prescription-for-disaster/#6f4f657f206c.

[2] *Id.*

[3] Bethany McLean, *The Valeant Meltdown and Wall Street's Major Drug Problem*, Vanity Fair, Summer 2016, https://www.vanityfair.com/news/2016/06/the-valeant-meltdown-and-wall-streets-major-drug-problem.

priced at an exponentially high level when it finally entered the market in February 2016. In fact, Lupin's generic launched at a price significantly higher than the pre-Valeant price of branded Glumetza. Thus, the pay-for-delay agreement between Assertio/Santarus and Lupin enabled Lupin to sell its generic Glumetza product for substantially more than it would have absent the agreement. Indeed, following the launch of generic Glumetza, Lupin's profits soared.

13. Defendants' anticompetitive scheme has already caused indirect purchasers to overpay for branded and generic Glumetza by hundreds of millions of dollars per year.

14. Accordingly, to redress the economic injury that Defendants have caused, Plaintiff, on behalf of itself and all others similarly situated, seeks damages and other monetary relief under state antitrust, consumer protection, and common laws.

II. JURISDICTION AND VENUE

15. This Court has jurisdiction under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed Class exceeds $5,000,000, and at least one member of the Class is a citizen of a state different from that of one of Defendants. This Court also has supplemental jurisdiction over state law claims under 28 U.S.C. § 1367(a).

16. Venue is appropriate in this District under 28 U.S.C. §1391(b). Defendants reside, transact business, are found, or have agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District. Moreover, the effects of Defendants' conduct on interstate trade or commerce are ongoing.

17. This Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, 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.

18. ***Intradistrict Assignment***: Pursuant to Local Rule 3-2(c), this is an Antitrust Class Action to be assigned on a district-wide basis.

III. PARTIES

19. Plaintiff UFCW Local 1500 Welfare Fund ("Local 1500") is an employee welfare benefits fund with its principal place of business at 425 Merrick Avenue, Westbury, New York 11590. Local 1500 provides nearly 23,000 plan participants with health and welfare benefits and, with 15,000 members, is the largest grocery union in New York. During the Class Period (defined below), Local 1500 purchased and paid for some or all of the purchase price of Glumetza, thereby suffering injury to its business and property. Local 1500 paid and reimbursed more for these products than it would have absent Defendants' anticompetitive conduct.

20. Defendant Assertio Therapeutics, Inc. ("Assertio") is a corporation organized under the laws of Delaware with its principal place of business located at 100 South Saunders Road, Suite 300, Lake Forest, Illinois 60045. Until August 14, 2018, Assertio was named Depomed, Inc., which was a party to the unlawful agreements alleged herein. Assertio is the owner or licensee of the relevant patents.

21. Defendant Santarus, Inc. ("Santarus") is a corporation organized under the laws of Delaware and, during much of the relevant time, had its principal place of business in San Diego, California. Its current principal place of business is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Pursuant to a Commercialization Agreement signed in August 2011, Assertio granted Santarus exclusive rights to manufacture and commercialize Glumetza in the United States and transferred to Santarus the New Drug Application ("NDA") for Glumetza. Santarus was a party to the unlawful agreements alleged herein. On January 2, 2014, Santarus was acquired by defendant Salix Pharmaceuticals, Ltd. and became a wholly-owned subsidiary of Salix Pharmaceuticals, Inc.

22. Defendant Salix Pharmaceuticals, Inc. is a corporation organized under the laws of California with its principal place of business located at 400 Somerset Corporate Blvd.

Bridgewater, New Jersey 08807. Salix Pharmaceuticals, Inc. joined and adhered to the unlawful agreements alleged herein. Salix Pharmaceuticals, Inc. is a wholly-owned subsidiary of Salix Pharmaceuticals, Ltd.

23. Defendant Salix Pharmaceuticals, Ltd. is a corporation organized under the laws of Delaware with its principal place of business located at 400 Somerset Corporate Blvd. Bridgewater, New Jersey 08807. Effective January 1, 2014, Salix Pharmaceuticals, Inc. and Salix Pharmaceutical Ltd. (together "Salix") assumed Santarus's rights and obligations under its Commercialization Agreement with Assertio. Salix Pharmaceuticals, Ltd. joined and adhered to the unlawful agreements alleged herein.

24. On April 1, 2015, Salix was acquired by Valeant Pharmaceuticals International, Inc., which, on or about that date, assumed Santarus's and Salix's rights and obligations under the Commercialization Agreement with Assertio. Valeant Pharmaceuticals International, Inc. joined and adhered to the unlawful agreements alleged herein. Effective on July 13, 2018, Valeant Pharmaceuticals International, Inc. changed its corporate name to Bausch Health Companies Inc. Salix Pharmaceuticals, Ltd. is now a wholly-owned subsidiary of Bausch Health Companies Inc.

25. Defendant Bausch Health Companies Inc. ("Bausch") is a corporation organized and existing under the laws of British Columbia, Canada with its U.S. headquarters located at 400 Somerset Corporate Blvd. Bridgewater, New Jersey 08807. Bausch joined and adhered to the unlawful agreements alleged herein.

26. Except where otherwise noted, Defendants Santarus, Salix, and Bausch are collectively referred to herein as "Valeant."

27. Defendant Lupin Pharmaceuticals, Inc. is a corporation organized under the laws of Virginia with its principal place of business located at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals is a wholly-owned subsidiary of Defendant Lupin Ltd. and was a party to the unlawful agreements alleged herein.

28. Defendant Lupin Ltd. is a company organized under the laws of India with its principal place of business located at B/4 Laxami Towers, Bandra Kurla Complex, Bandra

(East), Mumbai, Maharashtra 400051, India, and was a party to the unlawful agreements alleged herein.

29. Lupin Pharmaceuticals, Inc. and Lupin Ltd. are collectively referred to herein as "Lupin."

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

IV. REGULATORY FRAMEWORK

A. Regulatory Structure for Approval and Substitution of Generic Drugs

31. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"),[4] a manufacturer that creates a new drug must obtain approval from the Food and Drug Administration ("FDA") to sell the product by filing a NDA.[5] Complete NDAs include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[6]

32. When the FDA approves a brand manufacturer's NDA, the manufacturer may cause the FDA to list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") certain kinds of patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patent(s). A brand manufacturer has 30 days in which to list patents issued after approval of an NDA in the Orange Book in order for the patent to be considered timely filed.[7]

33. The FDA performs only a ministerial act in listing the patents identified by the brand manufacturer in the Orange Book. The FDA does not have the authority, or resources, to

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

[5] 21 U.S.C. §§ 301-392.

[6] 21 U.S.C. § 355(a), (b).

[7] 21 U.S.C. § 355(b)(1), (c)(2).

verify the manufacturer's representations for accuracy or trustworthiness and relies completely on the manufacturer's truthfulness about the validity and applicability of any Orange Book-listed patents.

1. Hatch-Waxman Amendments

34. In 1984, Congress modified the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), more commonly known as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a generic manufacturer to file an Abbreviated New Drug Application ("ANDA") with the FDA that relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA. An ANDA filer need demonstrate only that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the active ingredient of the brand counterpart.[8] The premise—codified by Congress and implemented by the FDA for the past thirty years—is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, absorbed into the bloodstream 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 relative to their brand counterparts an "AB" rating.

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

36. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all

[8] *See* 21 U.S.C. § 355(j)(8)(B).

did. In 1984, prescription drug revenues for brands and generics totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions.[9] When a generic form is available, generics are dispensed approximately 95% of the time.[10]

2. ANDA Paragraph IV Certifications

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

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

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

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

(d) That the patent for the brand is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").[11]

38. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer has the ability to delay FDA approval of that generic manufacturer's ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (i) the passage of 30 months,[12] or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions is met, the FDA may grant "tentative approval" but cannot authorize the generic

[9] *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013*, 30, 51 (2014).

[10] *Id.* at 51.

[11] 21 U.S.C. § 355(j)(2)(A)(vii).

[12] 21 U.S.C. § 355(j)(5)(B)(iii).

manufacturer to market its product (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA is ready for final approval but for the 30-month stay.

39. The 30-month period is commonly called a "30-month Hatch-Waxman stay" or "30-month stay." The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval and must instead satisfy the significantly stronger showing required to obtain a preliminary injunction to prevent the generic's launch.

3. The First Filer's 180-Day Exclusivity Period

40. Generics may be classified as (i) first-filer generics, (ii) later-filer generics, or (iii) authorized generics.

41. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first Paragraph IV generic manufacturer ANDA filer ("first filer") a 180-day exclusivity period to market the generic version of the drug, during which time the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.[13] That is, when a first filer submits a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book are either invalid or not infringed by the generic, the FDA cannot grant final approval to a later-filed ANDA until that first generic has been on the market for 180 days.

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

[13] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

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43. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first filer.[14]

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

B. The Competitive Effects of AB-Rated Generic Competition

45. 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. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic equivalent, or between generic versions, is price. Typically, generics are at least 10% less expensive than their brand counterparts when there is a single generic manufacturer. This discount typically increases to 50%-80% (or more) when multiple generic competitors compete in the sale for a given drug. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers.

46. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use facilitate both a rapid price decline and a rapid sales shift from the brand to the generic purchasing following the launch of AB-rated generic. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months after entry. The Federal Trade Commission ("FTC") has found that, on average, within a year of generic entry, generics had captured 90%

[14] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

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of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%.[15]

47. Generic competition enables all end-payor purchasers of a drug to purchase generic versions of the drug at substantially lower prices.

48. Until a generic version of the brand enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand, and the brand manufacturer can therefore continue profitably to charge supra-competitive prices. Brand manufacturers, such as Valeant, are well aware that generic entry leads to rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopolies for as long as possible, sometimes resorting to illegal means to delay or prevent generic competition.

1. The First AB-Rated Generic Is Priced Below the Brand

49. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[16] Because state substitution laws often require that pharmacists fill brand prescriptions with an available AB-rated generic, the first generic manufacturer almost always captures a large share of sales from the brand. Consequently, there is a reduction in the average price paid for the drug at issue.

50. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market, though the brand's AG can be, and often is, on the market during the 180-day exclusivity period. Without competition from other generics, during the 180-day exclusivity period a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

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

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

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2. Later Generics Drive Prices Down Further

51. Once the second wave of generic competitors enter the market—after the first filer's 180-day exclusivity period ends—the competitive process accelerates, multiple generic manufacturers compete vigorously with each other over price, and the price of generics is driven down toward marginal manufacturing costs.[17]

52. According to the FDA and the FTC, the greatest price reductions happen after the 180-day exclusivity period ends, when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some common estimates are that a single generic results in a near term retail price reduction of around 10% as compared to the brand price but that with two generic entrants the near term retail price reduction is about 50%.

53. In a 2011 report by the FTC issued at the request of Congress, the FTC found that generics captured 80% or more of sales in the first six months.[18] (This percentage erosion of brand sales holds regardless of the number of generic entrants.) In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[19]

54. Generic competition enables Plaintiff and all members of the proposed Class to purchase generic versions of a drug at substantially lower prices.

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

[18] FTC 2011 AG Study, at 66-67.

[19] *See* FDA, *Generic Drugs: Questions and Answers*, http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm (last visited Jan. 11, 2018).

3. Brand Manufacturers Are Incentivized to Sell an AG When Facing Generic Entry

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

56. An AG is chemically identical to the brand but sold as a generic, typically through either the brand manufacturer's subsidiary (if it has one) or a third-party distributor. An AG is essentially the brand product in a different package but sold at a lower price.

57. A brand manufacturer may sell an AG at any time, but, early in the life of the patents pertaining to a branded drug, the brand manufacturer has little incentive to sell an AG—doing so would simply cannibalize sales from the more profitable brand product. But when the prospect of generic competition arises, the brand manufacturer's incentive to sell an AG increases.

58. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[20]

59. Brand manufacturers sometimes begin selling AGs before the first-filer generic enters the market so they can secure multiyear purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer generic.

60. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period).[21] A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[22]

61. The FTC found that AGs capture a significant portion of sales, reducing the first filer's revenues by about 50% on average.[23] The first filer makes much less money when it

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

[21] Jeremiah Helm, *The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives*, 14 MICH. TELECOMM. L. REV. 175, 189 (2007).

[22] Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 HEALTH AFFAIRS 790, 796 (2007).

[23] FTC 2011 AG Study, at 139.

faces competition from an AG because (i) the AG takes a large share of unit sales away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

62. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic's 180-day exclusivity period. PhRMA, a branded drug industry trade group, sponsored a study that concluded that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic.[24] A generic manufacturer stated that "[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario." Another generic quantified the fiscal consequences of competing with an authorized generic version of the brand drug Paxil, determining that the authorized generic reduced the first filer's revenues by two-thirds, or by approximately $400 million. In 2004, generic company Teva acknowledged that an authorized generic would "severely devalu[e]" its 180-day exclusivity because an authorized generic "effectively transfers much of the profit value from the generic challenger [to the authorized generic]" and "allows the [authorized generic] to seize a significant share of the generic supply chain." Commenting on Teva's FDA petition, branded-drug manufacturer Pfizer stated, "Teva's petition [to prevent the launch of an authorized generic] is a flagrant effort to stifle price competition—to Teva's benefit and the public's detriment."[25]

C. Pharmaceutical Manufacturers Game the Regulatory Structure to Impair Competition

63. When they do not face generic competition, brand manufacturers can usually sell the branded drug far above the marginal cost of production, generating profit margins in excess

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

[25] Comment of Pfizer at 7, Docket No. 2004P-0261 (June 23, 2004), http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/062904.htm#04P0261; Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf.

of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins—without losing so many sales to competitors that the higher price becomes unprofitable—is what economists call market or monopoly power. When generics enter the market, however, they quickly take 80% or more of the unit sales. When multiple generics are in the market, the competition between the generics drives their prices to near the marginal cost of production, this competition puts an end to the brand manufacturer's market or monopoly power and delivers enormous savings to drug purchasers.

64. A brand manufacturer in the marketplace without competition from generics receives all of the profits on all of the unit sales.

65. When the brand manufacturer competes against only the first-filer generic manufacturer, the two manufacturers enjoy a duopoly—both tend to sell at close to the monopoly price and make near-monopoly profits.

66. When multiple generic manufacturers enter, the brand manufacturer loses most of the unit sales, and generic manufacturers sell most of the units but at drastically reduced prices. And the competition that exists in that scenario delivers enormous savings to drug purchasers.

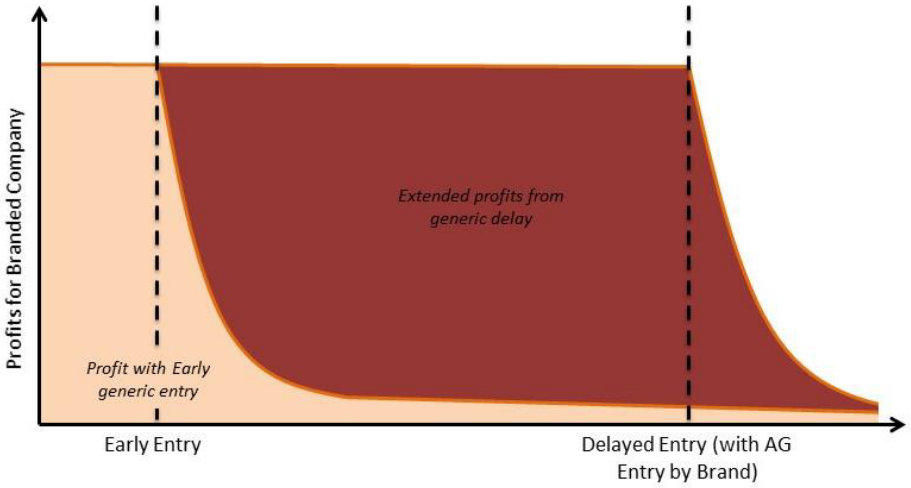
67. Brand and first-filer generic manufacturers have a collective interest to prevent this competition. If they work together to prevent or delay competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. They can keep for themselves the enormous savings that competition would have delivered to drug purchasers.

68. To achieve this goal, brand and generic manufacturers sometimes unlawfully agree—whether or not in writing—not to compete and instead to split the purchaser savings between themselves.

69. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where the brand manufacturer did not pay-off the generic company to delay generic entry and (ii) a situation where the brand manufacturer conspires with the generic manufacturer to delay generic drug entry. In the former situation, the agreed entry date for the generic is

earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later, and the brand manufacturer's profits increase significantly.

Figure 1. Impact of Generic Delay on Brand Profits



70. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide the increased profits because, of course, the generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains. The agreements that govern the payments from the brand manufacturer to the generic manufacturer are often referred to as "pay-for-delay" agreements as they involve a payment from the brand manufacturer in exchange for an agreement from the generic manufacturer to delay its launch.

71. Because the first filer's agreement to delay marketing its drug also prevents other generic manufacturers from marketing their products (due to the statutorily-prescribed 180-day exclusivity period),the brand manufacturer may choose to pay off only the first filer, even if other generic manufacturers are also lined up to challenge the patents.

72. Later ANDA filers have more modest financial expectations because they generally anticipate no market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized.

73. In the absence of an anticompetitive agreement between the brand company and the first filer, later ANDA filers have procompetitive incentives. They are motivated to expend resources to challenge the brand manufacturer's patent(s) (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

74. When an anticompetitive agreement with the first filer is already in place, however, pursuing litigation becomes less attractive to later ANDA filers. The later generic manufacturers know that the first filer is not leading the charge against the brand manufacturer's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive reverse payment agreement) and that they will have to bear the bulk of the litigation costs themselves.

75. Thus, some later generics decide to simply give in to or join the conspiracy between the brand manufacturer and the first-filer generic and agree to drop their challenges to the brand manufacturer's patent(s) and stay off the market until after entry by the first filer.

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

1. No-AG agreements enable brand and generic manufacturers to share the gains resulting from their conspiracy

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

78. One form of pay-off, at issue here, is a no-AG promise. With a no-AG promise, the brand manufacturer agrees not to market an AG version of the brand drug for some period of time after the first generic enters the market.

79. Again, the first filer's ANDA exclusivity does not prohibit the brand manufacturer from marketing its AG under the authority of its NDA. The Hatch-Waxman Amendment's 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based AG.

80. Absent a no-AG promise, it almost always makes economic sense for a brand manufacturer to begin marketing an AG as soon as (or sometimes weeks or months before) the first generic enters the marketplace. But competition from an AG has a drastically negative effect on the first-filer generic's revenues. Competition from an AG typically cuts the first filer's revenues by more than half, as the competing generic takes a substantial volume of the unit sales and drives prices lower—eliminating the duopoly and delivering commensurate savings to drug purchasers.

81. To prevent an AG from causing this substantial loss of revenues and profits, a first-filer generic may be willing to delay its entry into the marketplace in return for the brand manufacturer's agreement to forgo competing with an AG. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than make up for the profits it forgoes by not competing with an AG. Thus, a no-AG agreement is an illegal win-win for both the brand manufacturer and the first filer: the brand manufacturer wins from the delayed onset of generic competition, and the first filer wins from the absence of generic competition for the first 180 days of marketing. Both manufacturers win, but drug purchasers lose.

82. The brand and first filer's reciprocal promises not to compete harm end-payor purchasers like Plaintiff in three ways. First, the pact delays the first filer's entry into the marketplace and thereby extends the time during which the more expensive brand is the only product on the market. Second, by delaying the first filer's entry, the pact also delays the time when other, later, generics enter, and may discourage their entry altogether. And third, the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing price competition during that period between the first filer's generic and the brand's AG.

83. For the first filer, the difference between selling the only generic and competing against an AG for 180 days can amount to a difference in revenues of tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-AG pledge thus has the same economic effect as a pay-off made in cash.[26] Courts agree that no-AG agreements are a form of payment actionable under *FTC v. Actavis* and are anticompetitive.

84. No-AG agreements allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

85. Figure 2 depicts what happens when a brand manufacturer agrees to a no-AG promise. The red area shows the brand manufacturer's additional monopoly profits earned during the period of delay, and the purple area shows the amount of monopoly profit the brand manufacturer gives up (i.e., shares with the generic):

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

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

V. ASSERTIO/SANTARUS AND LUPIN MADE AN UNLAWFUL NO-AG PACT

A. Assertio/Santarus Marketed Branded Glumetza

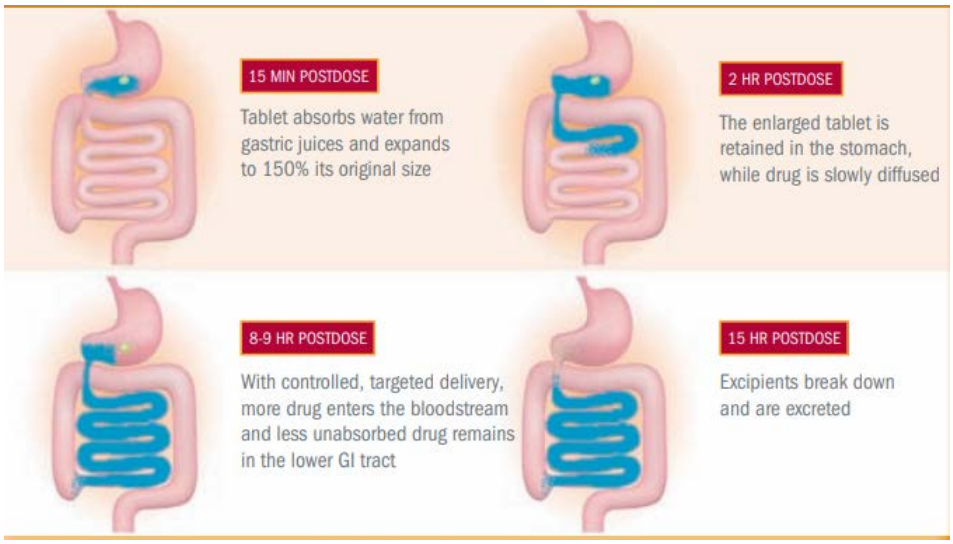
86. The active ingredient in Glumetza is metformin hydrochloride. For decades, metformin, which improves glycemic control, has been one of the most commonly prescribed oral medications for the treatment of Type 2 diabetes.

87. On June 3, 2005, the FDA approved Assertio's NDA for Glumetza 500 mg and 1,000 mg extended-release tablets, with an indication as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes.

88. Glumetza's extended-release formulation was designed for patients experiencing issues with the efficacy of immediate-release metformin products. Doctors often found it difficult to bring patients up to the maximum daily recommended dose of 2,000 mg of metformin due to the occurrence of gastrointestinal ("GI") side effects, such as nausea. Some estimates state that up to 50% of metformin-treated patients report GI side effects.

89. Glumetza's extended-release mechanism works by causing the pill, once ingested into the stomach, to swell with water. The increased size serves the dual purpose of blocking the drug's exit from the stomach while steadily controlling the drug's release over the course of hours. This ensures the drug's release will occur in the stomach or upper GI tract, rather than the lower GI tract, thereby reducing the risk of GI side effects.

Figure 3.[27] Glumetza controlled release of metformin



90. Glumetza was thus uniquely positioned in the market to offer patients with Type 2 diabetes an ability to reach their optimal dose of metformin with fewer GI side effects.

91. Under the NDA, Assertio listed several patents in the Orange Book for which it was the owner or licensee. For the 500 mg Glumetza product, Assertio listed the following patents:

Patent No.	**Expiration**
6,340,475 (’475 patent)	9/16/2016
6,635,280 (’280 patent)	9/16/2016
6,488,962 (’962 patent)	6/20/2020
6,723,340 (’340 patent)	10/25/2021

92. For the 1,000 mg Glumetza product, Assertio listed in the Orange Book the following patents:

[27] US Pharmacist, Product Information Guide: Glumetza (October 2011), *available at* https://www.uspharmacist.com/CMSDocuments/2011/10/Glumtzta%20Product%20Information%20Guide%20October%202011.pdf.

Patent No.	Expiration
6,488,962 ('962 patent)	6/20/2020
7,780,987 ('987 patent)	3/23/2025
8,323,692 ('692 patent)	3/23/2025

93. In October 2008, Santarus began promoting Glumetza under an exclusive-promotion agreement with Assertio. In August 2011, Santarus and Assertio entered into a new Commercialization Agreement pursuant to which Santarus became the NDA owner and assumed broader commercial, manufacturing, and regulatory responsibilities, including exclusive rights to manufacture and commercialize Glumetza in the United States.

94. Under the agreement, Santarus assumed sole decision-making authority on pricing, contracting, and promotion for Glumetza. Santarus also had the exclusive right to commercialize authorized generic versions of the drug.

95. Under the Commercialization Agreement, Santarus agreed to pay Assertio a gradually increasing royalty rate (reaching a ceiling of 34.5% by 2015) on net sales of Glumetza before generic Glumetza entry. In the event of generic Glumetza entry, the parties agreed to equally share proceeds based on a gross margin split.

96. In addition, the Commercialization Agreement provided that Assertio would manage any patent-infringement lawsuits relating to patents covering Glumetza, subject to certain consent rights in favor of Santarus, including with regard to any proposed settlements. The parties also agreed to split the costs of any patent lawsuit, with Santarus responsible for 70% and Assertio responsible for 30%.

B. Glumetza's Narrow Patents Could Not Prevent Generic Competition

97. Glumetza's patent protection was particularly narrow. The patents did not purport to claim metformin. In fact, the drug substance has long been used in pharmaceutical formulations to treat Type 2 diabetes. Nor did they purport to claim a pharmaceutical formulation (e.g., tablet, capsule, injection) of metformin alone or the method of using

metformin alone to treat diabetes. Instead, all of the relevant patents relate to oral dosage forms that provide extended, controlled release of a drug such as metformin.

98. The patents further did not purport to broadly claim controlled-release technology. That technology was developed decades ago and has since been used in a variety of applications. Controlled-release technology typically involves a polymeric formulation, which is a large molecule composed of repeating structural units, using either "reservoir" or "matrix" systems.

99. In a reservoir system, a core containing the active drug is coated with an acrylic polymer composition to help achieve extended release.

100. In a matrix system, the drug is dissolved or dispersed throughout the polymer and then formulated into a pill. After the patient swallows the pill, gastric fluids cause the matrix to swell to a size large enough to maintain the dosage form in the stomach during the fed mode, i.e., after a meal. This water-swollen polymeric matrix controls the rate at which the drug is released from the dosage form.

101. Assertio's Glumetza patents focus on a narrow range of formulations and methods that require a matrix controlled-release system. Assertio's patents did not even purport to invent the matrix system for metformin. Indeed, there were many prior-art options for extended-release delivery vehicles targeting the stomach through a matrix system, including: (i) a solid matrix formed of a substance that absorbs gastric fluid and swells as it absorbs fluid to extend gastric retention of the delivery vehicle, such as disclosed in U.S. Patent No. 5,007,790, "Sustained-Release Oral Drug Dosage Form," issued April 16, 1991; (ii) a matrix that limits the rate at which the surrounding gastric fluid diffuses through the matrix, reaches the drug, dissolves the drug, and diffuses out again; and (iii) a matrix that slowly erodes, continuously exposing fresh drug to the surrounding fluid, such as disclosed in U.S. Patent No. 4,915,952, "Composition Comprising Drug, HPC, HPMC, and PEO," issued April 10, 1990.

102. Glumetza's patents narrowly pertained to a particular type of water-swollen polymeric matrix that is responsible for controlled drug delivery. Glumetza's patents require, among other things, particular drug-release rates, drug-to-polymer ratios, dosage forms of

particular sizes and shapes and duration, the use of specific polymers in sufficient quantities to perform the required functions, and specific manufacturing processes. One or more of these claim limitations define the purported inventions.

103. Assertio, as the party asserting infringement, would have the burden of proving that the generic manufacturer's product falls within every limitation of an asserted patent's claim; a generic manufacturer would prevail if its product fell outside even just one limitation of each asserted claim.

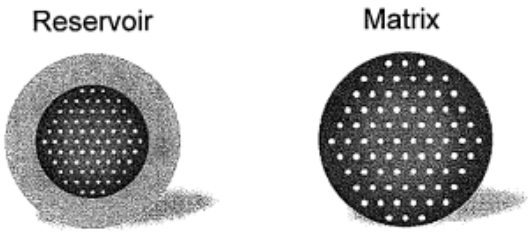
104. Generic manufacturers could avoid infringing—*i.e.*, "design around"—the patents by forgoing the "matrix system" altogether. They could instead use the entirely different "reservoir system," designed to provide controlled release of the drug without, for example, substantially retaining its size and shape without deterioration "until the plateau of the dissolution profile characterizing drug release from the swollen dosage form is reached" or remaining substantially intact until substantially all of the drug is released.[28] A generic version of Glumetza using such a reservoir system would necessarily fall outside all the relevant patents' claims.

105. As noted, the prior art already taught how to incorporate a reservoir system, defined as using a core containing the active drug that is coated with an acrylic polymer composition to help achieve extended release. For example, U.S. Patent No. 4,954,350, "Pharmaceutical Formulations Containing Acrivastine," issued September 4, 1990, (the "PFCA patent") discloses controlled-release pharmaceutical formulations for oral administration of acrivastine (an anti-histamine) utilizing a core containing the drug coated with acrylic polymers. The PFCA patent specifically identifies a neutral polymer based on ethyl acrylate and methyl methacrylate, Eudragit E30D ("Eudragit"), as one of the commercially available acrylic polymers that can be used as a coating. The PFCA Patent also discloses other prior art references of delayed-release formulations containing a core of other active ingredients coated with a polyacrylate insoluble that is dispersible in water, such as Eudragit.

[28] *See* Amended Joint Claim Construction Statement 22, *Depomed Inc. v. Lupin Pharms., Inc.*, 09-CV-05587 (N.D. Cal. Oct. 15, 2010).

106. In short, a pivotal difference between the matrix and reservoir systems is the rate-controlling mechanism. In a matrix system, the mechanism controlling the rate of drug release is the polymeric matrix. In a reservoir system, by contrast, the rate-controlling mechanism is a polymeric membrane encasing the drug core.

Figure 4.[29] Reservoir and Matrix Systems



107. Although the FDA requires generics to meet certain "sameness" requirements, having an identical controlled-release mechanism is not among them. So long as the generic manufacturer can assure the FDA that its product releases the drug at a similar rate and to a similar extent as the branded reference drug (thereby establishing bioequivalence), the FDA will not block the generic's approval on the ground that it uses a different controlled-release mechanism, such as a reservoir system.

108. Lupin's use of a reservoir system avoided each of Assertio's patents listed in the Orange Book as identified above.

109. Assertio's '475 and '280 patents are based on the same initial patent application and thus disclose the same invention. Both patents require a controlled-release dosage form in which a "drug is dispersed in a polymeric matrix that is water-swellable." As the patents explain, "[T]he swelling of the polymeric matrix . . . achieves two objectives—(i) the tablet swells to a size large enough to cause it to be retained in the stomach during the fed mode, and (ii) it . . . provide[s] multi-hour, controlled delivery of the drug into the stomach." In this way, "[t]he rate-limiting factor in the release of the drug is therefore controlled diffusion of the drug from the matrix." Accordingly, the basic and purportedly novel properties of the '475 and '280

[29] Defendant Lupin's First Supplemental Responses and Objections to Plaintiffs' Interrogatories 11, *Depomed Inc. v. Lupin Pharms., Inc.*, 09-CV-05587 (N.D. Cal. Aug. 26, 2011).

patents are the *polymeric matrix*'s ability to control the rate of drug release from the dosage form by swelling to promote retention in the stomach and having an erosion rate that is substantially slower than its swelling rate.

110. A reservoir system can achieve the desired controlled release without relying on a polymeric matrix that has the properties required by the '475 and '280 patents. A reservoir system wraps the drug core with a separate polymer coat that contains distinct chemical properties and represents an insoluble, physical barrier. The rate-limiting factor in the release of the drug is controlled by the diffusion not from the matrix, as would be required under the '475 and '280 patents but from the polymer coat.

111. Due to their narrowness, neither the '475 patent nor the '280 patent could prevent a generic Glumetza product from launching before those patents expired in September 2016—especially not one using a reservoir system.

112. Assertio's '962 patent would fare no better in an attempt to block a generic entrant. The '962 patent, which merely purports to offer an improvement over the '475 and '280 patents, covers "tablet shapes to enhance gastric retention of swellable controlled-release oral dosage forms." In terms of avoiding infringement, the "consisting essentially of" claims of the '962 patent can be avoided either by a dosage form having a shape that differs from that claimed or by using a delivery vehicle that materially differs from that of a solid monolithic matrix. A generic manufacturer would avoid infringing the '962 patent simply by virtue of using a non-swellable polymer coat, rather than a matrix, which materially affects the dosage form to control the drug's release.

113. Also very narrow, the '340 patent purportedly covers optimal material to be used in the matrix in order for it to control the drug's release. So, again, a generic manufacturer would easily avoid infringing the '340 patent by using the host of other available materials to carry the drug rather than the specific claimed matrix of poly(ethylene oxide) and hydroxypropyl methylcellulose, to control the drug's release.

114. Both the '987 and '692 patents disclose a dosage form requiring a controlled-release coating that must be prepared by "curing the coated oral dosage form at a temperature of

at least 55° C" and must consist of a neutral ester copolymer, a polyethylene glycol, one or more hydrophilic agents, and a pharmaceutically acceptable excipient. A generic manufacturer would easily design around those patents' claims by applying a different prior art coating to control the drug's release.

115. Therefore, on multiple levels, the patents' narrow scope could not prevent a generic manufacturer from receiving FDA approval and marketing generic versions of Glumetza 500 and 1,000 mg.

116. Moreover, all of that said, having been listed in the Orange Book for only Glumetza's 500 mg strength, the '987 and '692 patents clearly could not block approval of a generic Glumetza 1,000 mg ANDA.

C. Assertio Sued Lupin, Whose Potential Competition Threatened Assertio's Growing Glumetza Business

117. The active ingredient in Glumetza, i.e., metformin, was not patent protected, and other acceptable delivery vehicles existed in the prior art. Lupin therefore recognized the opportunity to develop and market a competing generic Glumetza product substantially before Glumetza's patents expired.

118. On or about July 27, 2009, Lupin filed ANDA 91664 seeking FDA approval to manufacture and sell generic versions of Glumetza in the 500 mg and 1,000 mg strengths. Lupin's ANDA contained a Paragraph IV certification to all applicable Glumetza patents. At the time, Assertio had listed in the Orange Book only the '475, '280, '962, and '340 patents for Glumetza.

119. On or about November 6, 2009, Lupin notified Assertio that Lupin had filed ANDA 91664, detailing why the relevant patents were both invalid and not infringed by Lupin's ANDA product.

120. On November 25, 2009, Assertio sued Lupin in the U.S. District Court for the Northern District of California, claiming infringement of the '475, '280, '962, and '340 patents. Assertio's timely lawsuit triggered the Hatch-Waxman Act's automatic 30-month stay against

Lupin's entry into the market, measured from the date Assertio received Lupin's November 6, 2009 Paragraph IV notice letter.

121. On January 29, 2010, Lupin filed its answer to Assertio's complaint, asserting that the manufacture, use, offer for sale, sale, or importation of its ANDA product would not infringe any valid and enforceable claim of the relevant patents.

122. As the litigation proceeded, Assertio dropped its claim of infringement relating to the '340 patent.

123. On August 26, 2011, Lupin provided supplemental interrogatory responses disclosing that its ANDA product does not and cannot infringe Assertio's patents because it uses a reservoir system rather than a polymeric matrix system to extend the drug's release.

124. Relying on key differences between its reservoir-system product and the matrix-system products claimed under the Glumetza patents, Lupin established that its product does not meet the patents' requirements that: (i) the product remain "substantially intact" until all of the drug is released; (ii) the product's drug core "substantially retain its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles" until "at least about 80% of the drug has been released after eight hours of immersion in gastric fluid"; and (iii) "the drug is released at a rate controlled by the rate of diffusion" out of the polymeric matrix.

125. Lupin further explained that its reservoir delivery system used a coating that included Eudragit to control the drug's release, rather than being controlled by the polymeric matrix core as required by the Glumetza patents. As stated above, controlled-release delivery vehicles based on a coating containing acrylic polymers, such as Eudragit, were well known in the prior art.

126. On January 27, 2012, the FDA tentatively approved Lupin's ANDA, meaning that Lupin's generic product could receive final approval for marketing as an AB-rated generic as early as the expiration of the 30-month stay (in May 2012). The tentative approval thus signaled to Assertio and Santarus a significant risk that Lupin was close to receiving FDA final approval from launching a non-infringing AB-rated generic Glumetza. And, after final approval,

Lupin would be eligible to launch its generic Glumetza at risk—*i.e.*, before a final, non-appealable judgment in the patent case.

127. Lupin posed a particularly significant threat of launching at-risk. In September 2011, Lupin had launched at-risk a generic version of Fortamet®. Like Glumetza, Fortamet consisted of 500 mg and 1,000 mg extended-release tablets of metformin hydrochloride. And Lupin had launched generic Fortamet shortly after expiration of that 30-month stay—exactly the same juncture that Lupin was then approaching in the Glumetza litigation.

128. Santarus and Assertio also knew that, if the litigation proceeded, the overwhelming likelihood was that the Lupin product would be found not to infringe the Glumetza patents. As alleged above, Lupin's generic used a reservoir system, which is not covered by the relevant patents. Lupin thus had an extraordinarily small likelihood that any at-risk launch would later subject it to liability for patent damages.

129. In short, Santarus and Assertio believed, correctly, that Lupin intended to begin marketing generic Glumetza as soon as it received FDA final approval unless the parties reached some sort of agreement. And, Lupin's launch of its generic Glumetza would have devastated Assertio/Santarus's bottom line. In 2012, Glumetza represented more than 50% of Santarus's sales.

D. Assertio/Santarus Paid Off Lupin to End the Risk of Competition

130. To avoid the substantial probability that Lupin would launch a non-infringing generic Glumetza either at risk or after prevailing in court, Assertio and Santarus decided to extend the period of Glumetza's supracompetitive profits by paying Lupin to withdraw its patent challenges and delay introducing generic Glumetza.

131. On February 22, 2012—just after Lupin's January 2012 tentative approval and shortly before the 30-month stay would expire in May 2012—Assertio/Santarus and Lupin entered into an agreement whereby Lupin agreed to end its challenge to the Glumetza patents and substantially delay entering the market, in exchange for a no-AG pact.

132. Under the agreement, Lupin agreed to refrain from entering the market with a generic Glumetza until February 1, 2016. In exchange for Lupin's agreeing to delay its entry for

nearly four years, Assertio/Santarus agreed not to market an authorized generic Glumetza 500 mg and 1,000 mg product, and not to license any other manufacturer to market such a product under Assertio's NDA, for *at least* 180 days after Lupin's entry into the market (the "no-AG payment").

133. Valeant in fact refrained from entering the market with its authorized generic version of Glumetza until February 2017—a year after Lupin's entry.

134. The purpose and effect of the no-AG payment was to induce Lupin to abandon its patent challenge and agree not to compete with a generic version of Glumetza until February 2016. Assertio/Santarus would not have agreed to the no-AG payment without securing, in exchange, Lupin's agreement not to market a generic version of Glumetza until February 2016. Likewise, Lupin would not have agreed to a delayed February 2016 entry without securing, in exchange, Assertio/Santarus's commitment to the no-AG payment.

135. Absent the no-AG payment, Santarus had the incentive and ability to market an authorized generic version of Glumetza immediately upon (if not before) Lupin's entry. For example, Santarus launched an authorized generic simultaneously with the first filer's launch of generic Zegerid®. A rational profit maximizing entity in Santarus's position would not forgo an opportunity to gain additional sales by marketing an authorized generic. Indeed, Santarus ensured that its commercialization agreement with Assertio gave Santarus the right to launch a Glumetza authorized generic.

136. By giving up the unqualified right to earn profits from marketing its own authorized generic, Santarus enabled Lupin to make approximately twice the unit sales, at a much higher price, all at the expense of Plaintiff and members of the Class. The no-AG payment thus served as substantial compensation for Lupin's agreement to delay its entry, and Lupin could not have obtained a no-AG promise even if Lupin had won the patent litigation against Assertio.

137. The no-AG payment's value to Lupin can be reasonably estimated using established economics of the pharmaceutical industry. Assuming, conservatively, that the term

of the no-AG clause extended only six months, and not a year as it may have, the value of the no-AG at the time of the parties' settlement can be determined as follows:

(a) In 2012, Glumetza's annual sales were approximately $150 million. Six months (180 days) of brand Glumetza sales would generate revenue to Assertio/Santarus of $75 million.

(b) First-filer generics can reasonably be expected to take about 80% of the brand's unit sales during its six months of exclusivity. Thus, Lupin could reasonably expected its generic to capture approximately $60 million worth of brand units during those six months.

(c) According to the FTC, the addition of an AG during a first-filer's 180-day exclusivity can cut the first filer's revenues by 40 to 52% during that period.[30] Thus, at the time of the settlement, Assertio/Santarus could reasonably expect to achieve revenues of at least between $25.2 and $31.2 million from the launch of an AG during Lupin's exclusivity period. And Assertio/Santarus's gain through launching an AG would be at Lupin's expense. This estimate, however, likely undervalues the no-AG promise because it assumes that Glumetza sales remain flat when Lupin's generic launches. As Glumetza sales increase—which they did in the actual world—the value of the no-AG promise increases, accordingly.

138. The value of the no-AG promise, even with the above conservative assumptions, far exceeded Assertio/Santarus's expected future litigation costs. Typical litigation costs for a patent case of this nature rarely exceed $5.5 million.[31] After two years of patent litigation, Assertio/Santarus's future expected litigation costs at the time its settlement were much less than that. Thus, the no-AG payment was large and unjustified.

139. Assertio/Santarus's no-AG payment to Lupin impaired competition in at least three ways. It: (a) allocated 100% of the Glumetza market to Assertio/Santarus for the period

[30] Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects And Long-Term Impact* (Aug. 2011), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[31] John M. Golden, *Litigation in the Middle: The Context of Patent-Infringement Injunctions*, 92 Tex. L. Rev. 2075, 2115 n.63 (2014).

before generic competition; (b) allocated 100% of the generic segment of the market to Lupin for at least 180 days; and (c) substantially delayed entry by *all* generic manufacturers.

140. Had Assertio/Santarus not paid Lupin to drop its patent challenge and delay entry into the market, Lupin would have marketed its less expensive generic Glumetza: (a) "at-risk" (*i.e.*, while the patent litigation was pending) upon the expiration of the 30-month stay; (b) upon winning the patent litigation; or (c) earlier than February 1, 2016, on a date to be determined by a jury, pursuant to a lawful settlement agreement without a large unjustified payment from Assertio/Santarus to Lupin. Absent the no-AG payment, immediately upon Lupin's entry into the market (or before), Assertio/Santarus, as a rational economic actor seeking to recoup lost branded sales, would have sold authorized generic Glumetza in competition with Lupin, driving prices down even further.

141. Defendants have no procompetitive explanation or justification for the no-AG payment. The large, unjustified payment had no rational connection to, and far exceeded, any approximation of the costs of continuing the patent litigation.

VI. ASSERTIO/SANTARUS AND LUPIN NEUTRALIZED COMPETITION FROM LATER FILERS

142. The no-AG payment significantly delayed competition between Assertio/Santarus and deprived Glumetza purchasers of dramatically lower prices. But other potential sources of competition remained: other generic manufacturers. So Assertio/Santarus and Lupin included other anticompetitive provisions in their settlement to neutralize those potential threats.

143. As the first filer, Lupin was eligible to receive the 180-day ANDA exclusivity. However, Congress left open pathways for later-filer generic manufacturers to try to come to market before the entry date agreed to between the first filer and the patent holder, despite the 180-day ANDA exclusivity.

144. As applicable here, a later filer could get a final court decision that its generic Glumetza product did not infringe any of Assertio's valid patents. In that event, Lupin would forfeit its ANDA exclusivity if it failed to enter the market within 75 days of the court decision.

21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb). Having agreed to delay entry until February 1, 2016, Lupin *would* fail to enter within 75 days, and therefore *would* forfeit, if a later filer got the final court decision before November 18, 2015. That forfeiture would allow a later filer to enter before Lupin. After Lupin forfeited its ANDA exclusivity, even more ANDA generics could enter before Lupin either by winning their patent litigations or using the leverage of their patent challenges to get a license from Assertio/Santarus.

145. Two circumstances created a significant chance that subsequent filers could trigger a forfeiture of Lupin's ANDA exclusivity. *First*, Assertio's patents on Glumetza were very narrow and could easily be designed around—something Lupin itself did. Thus, it was reasonable to expect other generic competitors could so as well.

146. *Second*, Lupin agreed to a nearly four-year delay, providing ample time for generic competitors to successfully litigate against the Assertio patents. For example, in February 2012 when Assertio/Santarus and Lupin agreed to their no-AG payment, Sun Pharmaceutical was well into its patent litigation with Assertio/Santarus. That litigation could reasonably be expected to be completed, through a final court decision, by no later than February 2015. With Lupin delayed from entering until 2016, Sun Pharmaceutical could therefore expect a very substantial reward, in the form of a year or more of exclusive or semi-exclusive sales in the generic sector, for launching prior to Lupin.

147. In an attempt to avoid the possibility that another generic could enter the market before Lupin's licensed entry date, Lupin secured a promise from Assertio/Santarus that allowed Lupin to launch earlier if another generic manufacturer was able to launch its generic version of Glumetza ahead of Lupin.

148. Such an "acceleration" provision can be anticompetitive because it dilutes the incentive of other generic rivals to aggressively challenge otherwise weak patents. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—testified before Congress that acceleration provisions "eliminate any incentive for a subsequent

filer to continue to litigate for earlier market entry."[32] The provisions deter others from entering earlier and cause the first filer to accept a later entry date:

> [N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. *Consumers are the biggest losers under this system.* If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase.[33]

149. Acceleration provisions are common enough in patent settlements that when one generic company sees that a generic rival has settled its patent litigation with the brand, it is reasonable for the still-litigating generic to suspect that the settlement included an acceleration provision. The still-litigating generic must then weigh that probability against the value of continuing with its patent challenge. If the settling generic received an acceleration provision, the litigating generic knows that it even if it wins its patent litigation, it must share the fruits of its success—*i.e.*, market entry and generic sales—with the settling generic.

150. Worse still, if the settling generic has first-filer exclusivity, the successful generic in litigation would be sidelined for 180 days, while the first filer's entry date is "accelerated," permitting it to reap the bounty of its 180-day exclusivity. Thus, the mere possibility that a settling generic could have an acceleration provision significantly reduces the incentive for other generic challengers to pursue their patent litigations. The presence of an acceleration clause can also induce the still-litigating generic to settle with the brand on terms that are no better than the previously settling generic—thereby doing nothing to tamp the anticompetitive effects of the prior settlement.

151. Lupin also likely secured additional protection in the form of a promise that no other generic competitor will receive a licensed entry date for its generic version of Glumetza within 180 days of Lupin's entry date. This promise is evidence by the fact that Sun

[32] Statement of Bernard Sherman, CEO, Apotex, Inc., http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf at 228 (May 7, 2007).

[33] *Id.* at 218.

Pharmaceutical and another generic rival, Watson Pharmaceuticals, received licensed entry dates that were exactly 180 days after Lupin's licensed entry date.

152. Together, these provisions enabled Lupin to retain the value of its paid-for 180-day exclusivity period to the exclusion of all potential rivals—whether they were other ANDA generics or an AG of Glumetza.

VII. DEFENDANTS FULLY EXPLOITED THE MONOPOLY THEY CREATED

A. Defendants Sold the Glumetza Monopoly to Valeant—a Known Exploiter of Drug-Product Monopolies

153. The Glumetza monopoly that Assertio/Santarus and Lupin created and maintained was a very valuable asset. They wasted no time in getting it into the hands of a commercial entity that exploited it, with devastating consequences for Glumetza purchasers.

154. As of February 2012, Assertio/Santarus was selling branded Glumetza at more than five times the price that a fully competitive generic sector would have delivered. Glumetza purchasers could get relief from that high price through three potential means: entry by Lupin; entry by a Santarus authorized generic; or entry by later filers. The no-AG payment between Assertio/Santarus and Lupin extended the Glumetza monopoly by four years rather than ending it and compounded the injury by ensuring the absence of an authorized generic (whether sold by Santarus or a licensee) once Lupin belatedly entered the market.

155. That guaranteed four-year monopoly was enormously valuable, and Assertio/Santarus immediately cashed in on it by selling it to those who could more effectively exploit it.

156. On November 7, 2013, Defendant Salix announced that it had reached an agreement to acquire Santarus. Salix withheld final agreement to that acquisition until it was assured that Assertio/Santarus had reached a deal with Watson to delay marketing its generic Glumetza until August 2016. Salix's CEO reported to stock analysts that Salix was "comfortable" with the acquisition because Glumetza would not be "lost to generics" until 2016.[34]

[34] Randy Osborne, "Santarus Clause: Patent Expiry Not a Hitch in $2.6B Salix Pharmaceuticals Deal," *available at* http://www.bioworld.com/content/santarus-clause-patent-expiry-not-hitch-26b-salix-pharmaceuticals-deal.

157. When Salix was negotiating the acquisition, Glumetza accounted for just under half of Santarus's annual sales. Under the acquisition agreement, Salix agreed to pay $2.6 billion for Santarus. That purchase price represented a 37% premium to Santarus's share price before the acquisition was announced.

158. Then Salix too cashed in on the Glumetza-monopoly sweepstakes. Just 13 months after acquiring Glumetza, in February 2015 Salix announced that it was being acquired by Valeant in a deal valued at $14.5 billion.

159. The Glumetza monopoly was the perfect asset for Valeant to acquire. Valeant did not believe in developing new drugs for the betterment of people. It believed in buying existing drug-product monopolies and exploiting them to the fullest extent. During the relevant time here, Valeant's annual Research and Development budget was less than 3% of its revenues, about a fifth of the pharmaceutical industry average. The motto of Valeant's CEO was "Don't bet on science—bet on management."[35] And he called investing in pharmaceutical research "a losing proposition."[36]

160. Valeant's board of directors implemented its "forget science, exploit existing monopolies" strategy by operating the company like a hedge fund and paying its executives as if they were hedge-fund managers. Valeant paid relatively little cash compensation to top executives but granted them huge stock options that vested only if the company reached aggressive revenue goals.

161. Valeant reached those goals by acquiring companies like Salix that had existing drug product monopolies. Valeant would then slash the workforce, especially the scientists, and take enormous price increases on the already existing monopolized drugs. As *Forbes* magazine later characterized it, Valeant's strategy "emphasized boosting drug prices, gutting research and

[35] Bethany McClean, "The Valeant Meltdown and Wall Street's Major Drug Problem," *Vanity Fair* (June 5, 2016), *available at* https://www.vanityfair.com/news/2016/06/the-valeant-meltdown-and-wall-streets-major-drug-problem.

[36] *Id.*

(continued)

development budgets, [and] firing employees."[37] "[S]cientists were seen as unnecessary costs to be cut," while Valeant's "drug-price increases became legendary."[38] Some pharmaceutical manufacturers may refrain from fully exploiting drug monopolies, based on their longer-term outlooks or concerns about public scrutiny. Valeant had no such qualms.

162. A former Valeant executive later admitted that its culture was "We're the bad boys, we're successful, we can do whatever we want."[39] The CEO admitted publicly that "[a]ll I care about is our shareholders" and that, "from [an investor's] standpoint [raising prices] is not a bad thing."[40] Unsurprisingly, industry observers concluded that "Valeant was the pure expression of the view that companies are there to make money for shareholders, every other consideration be damned."[41]

163. Glumetza purchasers were among the "every other consideration" that Valeant scorned. Immediately after acquiring the Glumetza monopoly, Valeant applied its corporate strategy of fully exploiting existing monopolies. Valeant bought the Glumetza monopoly from Salix in April 2015. By the end of that July, Valeant had raised the price by about 800%, with a monthly supply increasing for some patients from approximately $500 to $4,600. As a result, Valeant's revenues from Glumetza in the two quarters after the price increase skyrocketed from $145 million to more than $818 million.

164. Glumetza's massive price increase was made possible only by the unlawful agreements that delayed Lupin's generic entry to 2016. Valeant's price hike worked solely because a generic had not already entered the market and taken the unit sales at dramatically lower prices. Absent the no-AG payment, Lupin would have begun marketing generic Glumetza long before Valeant's acquisition of Salix, as early as May 2012. Lupin's earlier entry thus

[37] Nathan Vardi and Antoine Gara, "Valeant Pharmaceuticals' Prescription For Disaster," *Forbes* (May 10, 2016), *available at* https://www.forbes.com/sites/nathanvardi/2016/04/13/valeant-pharmaceuticals-prescription-for-disaster/#443183d9206c.

[38] *Id.*

[39] Bethany McClean, "The Valeant Meltdown and Wall Street's Major Drug Problem," *Vanity Fair* (June 5, 2016), *available at* https://www.vanityfair.com/news/2016/06/the-valeant-meltdown-and-wall-streets-major-drug-problem.

[40] *Id.*

[41] *Id.*

would have deprived Valeant and anyone else of the opportunity to exploit the Glumetza monopoly.

B. Defendants Exploited the Glumetza Monopoly through Four Years of Delayed Generic Entry, Then Another Full Year of No Competition from an Authorized Generic

165. Valeant's exploitation of the Glumetza monopoly and other drug-product monopolies drew the attention of the U.S. Congress, which held a number of hearings into Valeant's strategy of forsaking science in favor of price increases on existing drug-product monopolies. The hearings established that Valeant set drug prices to reach pre-determined revenue goals and exploited its "temporary monopol[ies]" by "increasing prices dramatically to extremely high levels very quickly."[42]

166. In a February 4, 2016 hearing, Representative Cummings specifically highlighted Valeant's exploitation of the Glumetza monopoly, noting that Valeant raised its price "by a whopping 800 percent over a mere 6-week period."[43] He noted that Valeant's "basic strategy has been to buy drugs that are already on the market and then raise the prices astronomically [for a] temporary period of time before other competitors enter the market."[44]

167. In order to placate Congress, Valeant's CEO testified to the U.S. Senate on April 27, 2016 that "it was a mistake to pursue, and in hindsight I regret pursuing, transactions where a central premise was a planned increase in the prices of the medicines."[45] And he gave them the false comfort that, going forward, "[w]e expect our pricing actions to track industry norms."[46]

168. Yet, at that very moment, Valeant was continuing to adhere to the unlawful agreements that extended the Glumetza monopoly. Two months earlier—in February 2016—

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[42] Alex Keown, "Emails Reveal Turing, Valeant Price Increases Were Basis for Revenue Growth," *Biospace* (Feb. 03, 2016), *available at* https://www.biospace.com/article/emails-reveal-turing-valeant-price-increases-were-basis-for-revenue-growth-/.

[43] *Developments in the Prescription Drug Market: Oversight Hearing Before the House Comm. On Oversight and Government Reform*, 114 Cong. 119 (Feb. 4, 2016), *available at* https://www.govinfo.gov/content/pkg/CHRG-114hhrg25500/pdf/CHRG-114hhrg25500.pdf.

[44] *Id.*

[45] *Statement of J. Michael Pearson before the Senate Special Committee on Aging* (Apr. 27, 2016), *available at* https://www.aging.senate.gov/imo/media/doc/SCA_Pearson_4_27_16.PDF.

[46] *Id.*

Defendant Lupin had finally entered the market with generic Glumetza, having unlawfully agreed to stay out of the market from May 2012 until February 2016.

169. By then, Valeant's ruthless exploitation of the Glumetza monopoly had raised the price of the branded product astronomically. And when Lupin entered the market, Valeant adhered to the unlawful agreement by refraining from marketing an authorized generic.

170. The direct result of that unlawful adherence was that Lupin, as the only generic available, was able to price its generic quite close to the price of the brand price—which had been increased to astronomical levels by Valeant. Lupin's agreement to delay entry by four years had allowed Valeant to raise the brand price by nearly 800%. Now Valeant was adhering to the unlawful agreement by not marketing an authorized generic, which would have driven the generic price down to at least a 48% discount off the brand.

171. As a result, throughout 2016 purchasers of Glumetza were paying more than $3,000 per month for the brand product and *more than $2,200 per month for Lupin's generic*—which was a shocking 4.4 times the price that the *brand* had sold for prior to Valeant having purchased it.

172. Altogether, Defendants' unlawful extension of the Glumetza monopoly has caused indirect purchasers to overpay by hundreds of millions of dollars and it continues to cause substantial overcharges today (and will continue to do so for the foreseeable future).

173. On May 15, 2017, Teva Pharmaceutical Industries Ltd. (which had acquired Watson) began marketing its generic Glumetza 500 mg and 1,000 mg products. On July 25, 2018, Sun began marketing its generic Glumetza 500 mg and 1,000 mg products. Watson and Sun had received licenses from Assertio/Santarus to enter the market in August 2016. The reasons for their delays after August 2016 are currently unknown to Plaintiff.

VIII. MARKET EFFECTS

174. By impeding competition from generic Glumetza, Defendants' anticompetitive conduct caused Plaintiff and members of the Class to pay more than they would have paid for both branded and generic Glumetza. Earlier entry of Lupin's generic Glumetza would have given purchasers the choice between branded Glumetza and AB-rated generic substitutes of

Glumetza, which are priced substantially below the brand. Many purchasers would have bought the lower-priced generic drugs rather than the higher-priced branded Glumetza. Every state's pharmacy substitution laws require or encourage pharmacies to substitute AB-rated generics for branded prescription pharmaceuticals whenever possible. Absent Defendants' anticompetitive conduct, Plaintiff and members of the Class would have saved billions of dollars by paying less for branded Glumetza and purchasing generic Glumetza earlier. Defendants' anticompetitive conduct caused Plaintiff and members of the Class to incur overcharges on their purchases of both branded and generic Glumetza.

175. Absent Defendants' anticompetitive conduct, immediately upon Lupin's entry into the market, Assertio/Santarus, as a rational economic actor seeking to recoup lost branded sales, would have sold authorized generic Glumetza in competition with Lupin. As described above (see Section V.D.), Santarus had a history of marketing authorized generics. And Santarus specifically negotiated with Assertio for the right to market an authorized generic version of Glumetza.

176. The economic rationality of marketing an authorized generic (absent an unlawful no-AG pact) is confirmed by Valeant's conduct. Valeant, through its subsidiary Oceanside, frequently markets authorized generics when its branded drugs first experience generic competition. It did so with respect to its drugs Syprine®, Mephyton®, Uceris®, Xenazine Tablets®, Vanos®, and Retin-A Micro®. Indeed, Valeant began marketing an authorized generic version of Glumetza in February 2017, once its no-AG pact with Lupin expired.

177. After Valeant's authorized generic entered the market, Lupin's CEO admitted that "[t]he authorized generic was a pretty tough competitor for us to have and that brought the pricing down for the entire market."[47] Absent the unlawful no-AG payment, the substantial price decreases attendant upon an authorized generic would have occurred sooner and simultaneously with (or before) Lupin's earlier entry into the market.

178. Defendants' anticompetitive conduct created and extended the Glumetza monopoly, ultimately resulting in the acquisition of the Glumetza monopoly by Valeant. Absent

[47] Lupin Ltd., Q1 FY18 Results Conference Call (Aug. 3, 2017).

Defendants' anticompetitive conduct, Lupin would have begun marketing generic Glumetza before Valeant's April 2015 acquisition of the Glumetza monopoly, and as soon as May 2012. The mid-2015 price increases on branded Glumetza never would have occurred.

179. Absent Defendants' unlawful conduct, Lupin would have entered the market in or about 2012, when the brand price for a 30-day supply of 1,000 mg Glumetza was $250. Long before 2015, generic competition would have driven the price down to even lower prices.

180. As a result of the delay in generic entry and Defendants' unconscionable exploitation of the monopoly that the delay created, only the branded product was available in 2015, and the monthly price for 1,000 mg Glumetza after Valeant's price increases was more than $3,000. Plaintiff and members of the Class also incurred substantial overcharges from 2012 until the gigantic price increases in 2015, and they continue to incur ongoing and accumulating overcharges today.

181. Defendants' unlawful conduct also harmed Plaintiff and members of the Class by increasing the prices charged for generic Glumetza. When entering a market, generic manufacturers price their products based on a percentage discount off of the then-prevailing brand price. Absent Defendants' unlawful conduct, the generics would have entered in or about 2012, when the price for a 30-day supply of 1,000 mg brand Glumetza was about $250 rather than $3,000 or more. Thus, Defendants' unlawful conduct has caused Plaintiff and members of the Class to pay substantial overcharges on their purchases of Glumetza generics, beginning in February 2016 and continuing until today.

182. Economics recognizes that an overcharge at a higher level of distribution generally results in higher prices at every level below. Professor Herbert Hovenkamp explains that "[e]very person at every stage in the chain will be poorer" as a result of the anticompetitive price at the top. [48] Professor Hovenkamp also instructs 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

[48] *See* Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice*, at 564 (1994).

(continued)

next level."[49] Here, wholesalers and retailers passed on the inflated prices of branded and generic versions of Glumetza to Plaintiffs and members of the Class.

183. Defendants' unlawful agreement enabled them to charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent Defendants' agreement. These prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

IX. MONOPOLY POWER AND MARKET DEFINITION

184. To the extent the conduct here may be held subject to the Rule of Reason, the relevant product market is branded Glumetza and its bioequivalent (*i.e.*, AB-rated) generic versions. The relevant geographic market is the United States, including its territories, possessions, and the Commonwealth of Puerto Rico.

185. A small but significant, non-transitory increase in the price of branded Glumetza, above the competitive level, did not cause a significant loss of sales to any product other than AB-rated versions of Glumetza. At competitive prices, branded Glumetza does not exhibit significant, positive cross-elasticity of demand with respect to price with any product or treatment for diabetes other than AB-rated generic versions of Glumetza.

186. Direct evidence of Defendants' market power includes the following: (a) absent Defendants' unlawful conduct, generic Glumetza would have entered the market much earlier at a substantial discount to brand Glumetza; (b) when generic Glumetza eventually entered the market, it quickly took a substantial portion of brand Glumetza's unit sales; (d) from 2012 to 2015, Defendants profitably raised the price of Glumetza by more than 40%; and (e) in 2015 Defendants profitably raised the price of Glumetza by more than 800%.

187. During the relevant time, Defendants had monopoly power in the market for Glumetza and AB-rated generic substitutes because they had the power to exclude competition and/or raise or maintain the price of Glumetza to supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

[49] *Id.*

188. The existence of other branded diabetes drug products did not constrain the price of Glumetza to a competitive level. Defendants needed to control only Glumetza and its AB-rated generic equivalents, and no other products, in order to maintain the price of Glumetza at supracompetitive prices. Only the market entry of a competing, AB-rated version of Glumetza could prevent Defendants from profitably maintaining prices at supracompetitive levels.

189. Brand Glumetza is therapeutically differentiated from all diabetes products other than AB-rated generic versions of Glumetza.

190. In general, metformin is considered the first-choice medication for the treatment of Type 2 diabetes and is not reasonably interchangeable with other Type 2 diabetes drugs. In part, this is the result of metformin's long-term safety profile, which is not available for many newer Type 2 diabetes drugs such as DPP-4 inhibitors. Metformin also has better cardiovascular mortality than sulfonylurea drugs used to treat Type 2 diabetes. Metformin is also considered weight neutral or helps people lose weight.

191. Glumetza is not therapeutically interchangeable with non-extended release metformin products due to the fact that metformin can cause gastrointestinal side effects, which can be reduced by taking an extended-release form. Additionally, extended-release forms of metformin can reduce the daily dosing to a single once-a-day pill providing a simpler dosing regimen. The differing efficacy, dosing, safety, and side-effect profiles of different oral Type 2 diabetes drugs play a critical role in doctors' selection of the most appropriate form of the drug for each patient, and a patient's compliance with taking an oral Type 2 diabetes drug is improved with one that requires fewer doses and that the patient can better tolerate.

192. Glumetza is also not reasonably interchangeable with other extended-release forms of metformin such as Glucophage XR® and Fortamet. This non-interchangeability arises from, among other reasons, the way that different patients react to the products' varying release mechanisms.

193. Specifically, a substantial number of doctors perceive Glumetza to offer the possibility of reduced gastrointestinal side effects for patients, compared to other extended-release metformin products. Glumetza uses a polymer delivery technology that expands from

stomach fluid, preventing the pill from moving into the intestine. The stomach fluid then dissolves and releases the metformin over a period of eight to ten hours. The dissolved metformin is thus mixed, over time, with other contents of the patient's stomach and transported into the duodenum, where it is absorbed.

194. Assertio/Santarus, Salix, and Valeant differentiated Glumetza from extended-release metformin products in their marketing, on the ground that it retains metformin in the patient's stomach, allowing for constant multi-hour flow of the drug into the gastrointestinal tract. And they asserted that this technology offered patients a significantly enhanced opportunity for increased absorption of the drug. They touted to investors and others that "physicians are receptive to Glumetza differentiating features of controlled delivery and GI tolerability."[50] Moreover, the extended-release mechanism dissolves at the end of its useful life and is passed through the gastrointestinal tract and eliminated.

195. In contrast, for example, another extended-release metformin prescription drug—Fortamet—delivers metformin throughout the entire gastrointestinal tract. Fortamet tablets have a membrane surrounding the metformin, and the membrane has two laser-drilled holes. Water is taken into the holes and dissolves the metformin inside, and the dissolved drug is released through those holes at a constant rate all the time that the pill is moving through the small intestine. Patients typically will see the pill's shell in their stool.

196. Very substantial decreases in the price of other extended-release metformin products did not constrain the price of branded Glumetza to the competitive level. For example, generic Fortamet entered the market in 2012, substantially driving down the average price of a Fortamet pill (weighted average of brand and generic price). Despite that substantial price decrease, from 2012 to mid-2015 the quarterly unit sales of Glumetza *increased* while the *price increased more than 40%.* The percentage increase in Glumetza net revenue (net of all discounts, rebates, etc.) was at least that great.

197. A generic version of another extended-release metformin product—Glucophage XR—has been available since 2005. That product's extended-release mechanism is similar to

[50] Santarus, Inc., Q1 2012 Results - Earnings Call Transcript (May 8, 2012).

Fortamet's and dissimilar to Glumetza's. Yet from 2012 through mid-2015 Glumetza had the sales, price, and net revenue gains described above.

198. Neither Glucophage XR (brand or generic) nor Fortamet (brand or generic) prevented the nearly 800% price increase in Glumetza in 2015. That price increase was enormously profitable for Valeant. The dollar sales of brand Glumetza for the third and fourth quarters of 2015 (after the price increase but before Lupin's entry) were more than $800 million; the sales in the prior two quarters were less than $145 million.

199. To the extent that Plaintiff is required to prove market power through circumstantial evidence by first defining a relevant product market, Plaintiff alleges that the relevant antitrust market is the market for Glumetza and its AB-rated generic equivalents.

200. At all relevant times, Defendants were protected by high barriers to entry due to patent and other regulatory protections and high costs of entry and expansion.

201. The relevant geographic market is the United States and its territories. Defendants Assertio, Santarus, and Valeant's market share in the relevant market was 100% until Lupin's entry in 2016.

X. EFFECT ON INTERSTATE COMMERCE

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

203. During the relevant time period, Plaintiff and members of the Class purchased substantial amounts of Glumetza and/or generic Glumetza indirectly from Defendants. As a result of Defendants' illegal conduct, Plaintiff and members of the Class paid artificially inflated prices for Glumetza and generic Glumetza.

204. Defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce, including in this district.

XI. PLAINTIFF'S CLAIMS ARE TIMELY

A. Defendants Concealed Their Unlawful Agreements

205. Due to Defendants' fraudulent concealment of their unlawful conduct, Plaintiff and members of the Class are entitled to recover damages reaching back beyond four years before the filing of this Complaint. Plaintiff and members of the Class had no knowledge of Defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years before the filing of this Complaint.

206. Defendants' scheme was self-concealing, and Defendants employed deceptive tactics and techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and scheme.

207. Defendants wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from Plaintiff and members of the Class. Defendants repeatedly made public reference to Lupin's agreement to delay entry until February 2016 but consistently, consciously, and actively omitted the fact that Lupin had agreed to that delayed date in exchange for a no-AG payment. For example:

(a) In a May 8, 2012 filing with the Securities and Exchange Commission ("SEC"), Assertio included a redacted copy of its settlement agreement with Lupin. Assertio redacted all references to the no-AG payment. Based solely on information received and events occurring within the last four years, Plaintiff now believes that the redacted agreement refers to the no-AG payment as follows:

> "Section 3.5. [***]
>
> Section 3.6. [***] Notwithstanding the provisions of Sections 3.4 and 3.5, Depomed and Santarus shall have the right to: [***]"

(b) On March 27, 2012, pursuant to their settlement, Assertio and Lupin asked this Court to enter a consented-to injunction in the patent litigation. Those Defendants falsely represented to this Court—and placed on the public record—that the terms of their settlement were in "good faith," "serve[] the public interest," were "procompetitive," and "benefit . . . the

parties and consumers alike."[51] Those Defendants affirmatively advised the Court and the public of the agreed entry date of February 1, 2016 but omitted all references to the no-AG payment. *See id*. at 5(a).

(c) In the following SEC filings Santarus affirmatively referred to the agreed February 2016 entry date but omitted all references to the no-AG payment: Santarus Inc., Annual Report (Form 10-K), at 24 (March 5, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 12 (May 8, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 12 (August 7, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 12 (November 8, 2012); Santarus Inc., Quarterly Report (Form 10-Q), at 32 (November 7, 2013); Santarus Inc., Quarterly Report (Form 10-Q), at 13 (May 6, 2013); Santarus Inc., Quarterly Report (Form 10-Q), at 14 (August 6, 2013).

(d) In the following SEC filings Salix affirmatively referred to the agreed February 2016 entry date but omitted all references to the no-AG payment: Salix, Pharmaceuticals, Ltd. Annual Report (Form 10-K), at 9 (February 28, 2014); Salix, Pharmaceuticals, Ltd., Annual Report (Form 10-K), at 7 (March 2, 2015).

(e) In addition to the May 8, 2012 SEC filing discussed above, in the following SEC filings Assertio (formerly known as Depomed, Inc.) affirmatively referred to the agreed February 2016 entry date, but omitted all references to the no-AG payment: Depomed Inc., Annual Report (Form 10-K), at 11 (March 8, 2012); Depomed Inc., Quarterly Report (Form 10-Q), at 22 (August 3, 2012); Depomed Inc., Quarterly Report (Form 10-Q), at 24 (November 5, 2012); Depomed Inc., Quarterly Report (Form 10-Q), at 21 (August 8, 2013); Depomed Inc., Quarterly Report (Form 10-Q), at 23 (November 7, 2013).

(f) In a press release dated May 8, 2012 Santarus affirmatively referred to the agreed February 2016 entry date but omitted all references to the no-AG payment.

(g) In a call with stock analysts on November 7, 2013, Salix referred to the agreed February 2016 entry date but omitted all references to the no-AG payment.

[51] Consent Injunction and Dismissal Order at 1, *Depomed, Inc. v. Lupin Pharms., Inc.*, No. 4:09-cv-05587, ECF 152 (March 27, 2012).

(h) In a call with stock analysts on October 27, 2015 Lupin referred to the agreed February 2016 entry date but omitted all references to the no-AG payment.

208. Defendants did not publicly disclose the no-AG payment until doing so suited their interests. Specifically, on a February 5, 2016 call with stock analysts, Lupin revealed publicly for the first time that the settlement agreement included a no-AG pact to emphasize that it would make extraordinary profits on the sale of generic Glumetza: "No, we have AG free launch . . . . we knew that the 6-months there would be no AG." Plaintiff has filed this Complaint within four years of that first public revelation of the no-AG payment.

209. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by Defendants, Plaintiff and members of the Class had no knowledge of the scheme and conspiracy more than four years before the filing of this Complaint; they did not have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed; and if they would have had the facts or information to cause them to conduct an investigation, any such investigation would not have revealed the existence of Defendants' unlawful conspiracy.

210. Plaintiff and members of the Class lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred. Reasonable diligence on the part of Plaintiff and members of the Class would not have uncovered those facts more than four years before the filing of this Complaint.

211. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff's claims have been tolled.

B. Defendants' Actions Are a Continuing Violation

212. In the alternative, this Complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Plaintiff and members of the Class are entitled to recover damages they suffered during the limitations period.

213. A claim accrued for Plaintiff each time a brand or generic Glumetza product was sold to Plaintiff at a supra-competitive price made possible by Defendants' anticompetitive conduct. And each sale of brand or generic Glumetza at a supra-competitive price constituted

another overt act in furtherance of Defendants' continuing anticompetitive scheme. Other overt acts in furtherance of Defendants' continuing conspiracy include, but are not limited to, Lupin's refraining from entering the market until February 2016 and Valeant's refraining from marketing an authorized generic Glumetza until February 2017. Accordingly, Plaintiff is entitled to recover all damages on all branded and generic Glumetza sales made to Plaintiff at supra-competitive prices within four years of the filing of this lawsuit.

XII. CLASS ACTION ALLEGATIONS

214. Plaintiff brings this action on behalf of itself and all others similarly situated as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of the following class (the "Class"):

> All persons and entities that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Glumetza or its AB-rated generic equivalents from Defendants, beginning at least as early as May 6, 2012 until the effects of Defendants' conduct cease ("Class Period"), in the District of Columbia, Puerto Rico, or any of the following states and commonwealths: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, or Wyoming.

215. The following persons and entities are excluded from the above-described proposed Class:

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

(b) All governmental entities, except for government-funded employee benefit plans;

(c) All persons or entities who purchased Glumetza for purposes of resale or directly from Defendants or their affiliates;

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

(e) Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs);

(f) Pharmacy Benefit Managers;

(g) All Counsel of Record; and

(h) The Court, Court personnel, and any member of their immediate families.

216. Members of the Class are so numerous and geographically dispersed that joinder of all members of the Class is impracticable. Plaintiff believes that there are thousands of members of the Class widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would not be economically viable for many plaintiffs to bring individual claims and join them together.

217. Plaintiff's claims are typical of the claims of members of the Class. Plaintiff and members of the Class were harmed by the same wrongful conduct by Defendants in that they paid artificially inflated prices for branded and generic Glumetza and were deprived of the benefits of earlier and more robust competition from less-expensive generic equivalents of Glumetza as a result of Defendants' wrongful conduct.

218. Plaintiff will fairly and adequately protect and represent the interests of the members of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the members of the Class.

219. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation and with experience in class action antitrust litigation involving pharmaceutical products.

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

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

(a) Whether Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

(b) Whether there exist any legitimate procompetitive reasons for some or all of Defendants' conduct;

(c) To the extent any such procompetitive benefits exist, whether there were less restrictive means of achieving them;

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

(e) Whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

(f) Whether Defendants' scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiff and the Class members;

(g) Whether Defendants conspired to delay generic competition for Glumetza;

(h) Whether, pursuant to the no-AG pact, Assertio/Santarus, Salix, and Valeant's promise not to compete against Lupin's generic product constituted a large an unjustified payment;

(i) Whether Defendants' no-AG payment was necessary to yield some cognizable, non-pretextual procompetitive benefit;

(j) Whether the no-AG payment caused Sun, Watson, and/or other generic manufacturers to delay entry into the market;

(k) Whether Defendants' conduct created a bottleneck to further delay generic competition for Lupin's benefit;

(l) Whether Defendants' conduct harmed competition;

(m) Whether Defendants possessed the ability to control prices and/or exclude competition for Glumetza;

(n) Whether Defendants' unlawful conduct was a substantial contributing factor causing some amount of delay of the entry of AB-rated generic Glumetza;

(o) Whether Defendants' unlawful agreement, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiff and the members of the Class; and

(p) The quantum of overcharges paid by the Class in the aggregate.

222. 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.

223. Plaintiff knows of no special difficulty to be encountered in litigating 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)

224. Plaintiff incorporates the preceding paragraphs by reference.

225. Defendants entered into an unlawful pay-for-delay agreement that restrained competition in the market for Glumetza and its AB-rated generic equivalents. Their agreement is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

(a) delay entry of generic Glumetza in order to lengthen the period in which brand Glumetza could monopolize the market and make supra-competitive profits;

(b) keep a Glumetza AG off the market during Lupin's 180-day generic exclusivity period, thereby allowing Lupin to monopolize the generic market for Glumetza during that period and allowing Lupin to make supra-competitive profits;

(c) allocate 100% of U.S. generic Glumetza sales to Lupin during the first 180 days of generic sales; and

(d) raise and maintain the prices that Plaintiff and members of the Class would pay for Glumetza to and at supra-competitive levels.

226. There is no legitimate, non-pretextual, procompetitive business justification for the payment that outweighs its harmful effect. Specifically, under *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013), a patent settlement agreement between a brand and generic manufacturer may be unlawful, when the brand provides the generic manufacturer a "large and unjustified" payment in exchange for the generic manufacturer dropping its challenge to the brand manufacturer's patents. This is particularly the case when the size of the payment exceeds any saved or avoided litigation costs.

227. Here, in exchange for Lupin's agreement to delay entering the market until February 1, 2016, Lupin obtained a no-AG promise from Assertio/Santarus. The value transferred under the agreement exceeded the costs of continued litigation or any arguably procompetitive benefits—and thus was "large and unjustified." Accordingly, the agreement is unlawful.

228. Defendants' conduct violated the following state antitrust laws:

(a) Ariz. Rev. Stat. Ann. §§ 44-1400, *et seq.*, with respect to purchases in Arizona by Class members and/or purchases by Arizona residents.

(b) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by Class members and/or California residents.

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

(d) D.C. Code §§ 28-4502, *et seq.*, with respect to purchases in D.C. by Class members and/or purchases by D.C. residents.

(e) Haw. Rev. Stat. §§ 480-2, 480-4, *et seq.*, with respect to purchases in Hawaii by Class members and/or purchases by Hawaii residents.

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

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

(h) Kan. Stat. Ann. §§ 50-112, *et seq.*, with respect to purchases in Kansas by Class members and/or purchases by Kansas residents.

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

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

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

(l) Minn. Stat. §§ 325D.51, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases in Minnesota by Class members and/or purchases by Minnesota residents.

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

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

(o) Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases 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 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 in New Mexico by Class members and/or purchases by New Mexico residents.

(r) N.Y. Gen. Bus. Law § 340 with respect to purchases 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 in North Carolina by Class members and/or purchases by North Carolina residents.

(t) N.D. Cent. Code Ann. §§ 51-08.1-02, *et seq.*, with respect to purchases 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 in Oregon by Class members and/or purchases by Oregon residents.

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

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

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

(y) Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases by Utah residents in the Class.

(z) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by Class members and/or purchases by Vermont residents.

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

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

229. Plaintiff and the Class members have been injured in their business or property by Defendants' antitrust violations. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Glumetza and (2) paying higher prices for branded and generic versions of Glumetza than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

230. Plaintiff and members of the Class seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

231. Defendants are jointly and severally liable for all damages suffered by Plaintiff and members of the Class.

SECOND CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme under State Law
(Against All Defendants)

232. Plaintiff incorporates the preceding paragraphs by reference.

233. Defendants have knowingly engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Glumetza. The intended and accomplished goal of the scheme was to use exclusionary conduct to delay the ability of generic manufacturers to launch competing, generic versions of Glumetza. Defendants' exclusionary conduct allowed them to maintain their monopoly over branded and generic Glumetza.

234. Plaintiff and the members of the Class have suffered harm as a result of paying higher prices for Glumetza and/or its AB-rated generic equivalents than they would have absent Defendants' anticompetitive conduct and continuing anticompetitive conduct.

235. Defendants' conduct violated the following state antitrust laws:

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

(b) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by Class members and/or California residents.

(c) C.G.S.A. §§ 35-27, *et seq.*, with respect to purchases in Connecticut by Class members and/or purchases by Connecticut residents.

(d) D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in D.C. by Class members and/or purchases by D.C. residents.

(e) Haw. Rev. Stat. §§ 480-2, 480-9, *et seq.*, with respect to purchases in Hawaii by Class members and/or purchases by Hawaii residents.

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

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

(h) Kan. Stat. Ann. §§ 50-112, *et seq.*, with respect to purchases in Kansas by Class members and/or purchases by Kansas residents.

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

(j) Me. Rev. Stat. Ann. 10 §§ 1102, et seq., with respect to purchases in Maine by Class members and/or purchases by consumer Maine residents.

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

(l) Minn. Stat. §§ 325D.52, *et seq.* and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases in Minnesota by Class members and/or purchases by Minnesota residents.

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

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

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

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

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

(r) N.Y. Gen. Bus. Law § 340 with respect to purchases 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 in North Carolina by Class members and/or purchases by North Carolina residents.

(t) N.D. Cent. Code Ann. §§ 51-08.1-03, *et seq.*, with respect to purchases 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 in Oregon by Class members and/or purchases by Oregon residents.

(v) R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases in Rhode Island by Class members and/or purchases by Rhode Island residents.

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

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

(y) Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases by Utah residents.

(z) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by Class members and/or purchases by Vermont residents.

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

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

THIRD CLAIM FOR RELIEF
State Consumer Protection Violations
(Against All Defendants)

236. Plaintiff incorporates the preceding paragraphs by reference.

237. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and members of the Class were deprived of the opportunity to purchase generic versions of Glumetza and were forced to pay higher prices for branded and generic versions of Glumetza.

238. For years, there was gross disparity between the price that Plaintiff and members of the Class paid for Glumetza compared to what they would have paid for less expensive generic versions of Glumetza, which should and would have been available but for Defendants' unlawful conduct.

239. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state unfair and deceptive trade practices and consumer protection statutes:

Florida Deceptive & Unfair Trade Practices Act ("FDUTPA")

Florida Stat. §§ 501.201, et seq.

240. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Florida Stat. §§ 501.202(2).

241. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

242. Under Florida law, end-payor purchasers have standing to maintain an action under the FDUTPA based on the facts alleged in this Complaint.

243. Defendants' conduct constitutes an unfair method of competition because Defendants restrained trade in the market for branded and generic versions of Glumetza by unreasonably delaying the entry of cheaper, competing generic versions of Glumetza.

244. This delay was the product of an unlawful pay-for-delay agreement, whereby Valeant agreed not to launch a competing Glumetza AG during Lupin's 180-days of marketing exclusivity.

245. Defendants' conduct preserved Valeant's monopoly over Glumetza and stunted the effectiveness of future generic competition. This in turn caused end-payor purchasers of branded and generic versions of Glumetza in Florida to continue to pay supracompetitive prices for those products. Further, Defendants sold branded and generic versions of Glumetza in Florida and their conduct had a direct and substantial impact on trade and commerce in Florida.

246. Accordingly, such conduct falls within the prohibitions in Florida Stat. §§ 501.202(2).

Massachusetts Consumer Protection Act ("MCPA")

Mass. Gen. L. Ch. 93A, et seq.

247. The MCPA regulates trade and commerce "directly or indirectly affecting the people of this commonwealth." Mass. Gen. L. Ch. 93A § 9(1).

248. Under the MCPA, "Any person, who has been injured by another person's use or employment of any method, act or practice" that constitutes "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. L. Ch. 93A §§ 2, 9(1). MCPA § 2(b) provides that these terms are interpreted consistent with Section 5 of the FTC Act (15 U.S.C. § 45(a)), which also prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." Mass. Gen. L. Ch. 93A § 2(b); 15 U.S. § 45(a)(1).

249. Defendants' conduct constitutes an unfair method of competition because Defendants restrained trade in the market for branded and generic versions of Glumetza by unreasonably delaying the entry of cheaper, competing generic versions of Glumetza.

250. This delay was the product of an unlawful pay-for-delay agreement, whereby Valeant agreed not to launch a competing Glumetza AG during Lupin's 180-days of marketing exclusivity.

251. Defendants' conduct preserved Valeant's monopoly over Glumetza and stunted the effectiveness of future generic competition. This in turn caused end-payor purchasers of branded and generic versions of Glumetza in Massachusetts to continue to pay supracompetitive prices for those products. Further, Defendants sold branded and generic versions of Glumetza in Massachusetts, and their conduct had a direct and substantial impact on trade and commerce in Massachusetts. Accordingly, such conduct falls within the prohibitions in Ch. 93A § 2.

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Missouri Merchandising Practices Act ("MMPA")

Mo. Rev. Stat. 407.020

252. Under Section 407.020, the MMPA prohibits "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Rev. Stat. 407.020.

253. The Missouri Attorney General has defined an "unfair practice" as:

> any practice which . . . [o]ffends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive decisions; or . . . [i]s unethical, oppressive, or unscrupulous; and . . . [p]resents a risk of, or causes, substantial injury to consumers.

Mo. Att'y Gen. Reg., 15 CSR 60-8.02.

254. Defendants' conduct constitutes an unfair method of competition because Defendants restrained trade in the market for branded and generic versions of Glumetza by unreasonably delaying the entry of cheaper, competing generic versions of Glumetza.

255. This delay was the product of an unlawful pay-for-delay agreement, whereby Valeant agreed not to launch a competing Glumetza AG during Lupin's 180-days of marketing exclusivity.

256. Defendants' conduct preserved Valeant's monopoly over Glumetza and stunted the effectiveness of future generic competition. This in turn caused end-payor purchasers of branded and generic versions of Glumetza in Missouri to continue to pay supracompetitive prices for those products. Further, Defendants sold branded and generic versions of Glumetza in Missouri, and Defendants' conduct had a direct and substantial impact on trade and commerce in Missouri. Upon information and belief, Defendants also directed advertising and marketing efforts for branded and generic versions of Glumetza in Missouri. Accordingly, Defendants' conduct falls within the prohibitions in the MMPA.

FOURTH CLAIM FOR RELIEF
Unjust Enrichment
(Against All Defendants)

257. Plaintiff incorporates by reference the preceding allegations.

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

259. This claim is pled by Plaintiff and the Class against all Defendants.

260. Defendants have financially benefited from overcharges on sales of branded and generic versions of Glumetza, which resulted from the unlawful and inequitable acts alleged in this Complaint. These overcharges were borne by Plaintiff and members of the Class who purchased and/or reimbursed all or part of the purchase price of branded and generic Glumetza. The benefits conferred upon Defendants are substantial and measurable, in that the revenues Defendants have earned due to unlawful overcharges are ascertainable by review of both sales records and the unlawful agreement itself.

261. There is gross disparity between the price that Plaintiff and members of the Class paid for Glumetza compared to what they would have paid for less expensive generic versions of Glumetza, which should and would have been available but for Defendants' unlawful and inequitable conduct.

262. Defendants repeatedly and continuously received financial benefits at the expense of Plaintiff and members of the Class through each sale of branded and generic versions of Glumetza at an inflated price.

263. It would be futile for Plaintiff and members of the Class to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to any other person for any of the benefits they received indirectly from Plaintiff and members of the Class.

264. It would be futile for Plaintiff and the members of the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Glumetza, as those intermediaries cannot reasonably be expected to compensate Plaintiff and members of the Class for Defendants' unlawful conduct.

265. The financial benefits that Defendants derived rightfully belong to Plaintiff and members of the Class, which paid anticompetitive prices that inured to Defendants' benefit.

266. It would be inequitable under the unjust enrichment principles of the states listed below for Defendants to retain any of the overcharges that Plaintiff and members of the Class paid for branded and generic versions of Glumetza, which were derived from Defendants' anticompetitive, unfair, and unconscionable methods, acts, and trade practices.

267. Defendants should be compelled to disgorge all unlawful or inequitable proceeds received by them into a common fund for the benefit of Plaintiff and members of the Class.

268. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received, which arise from overpayments for branded and generic versions of Glumetza by Plaintiff and members of the Class.

269. Plaintiff and members of the Class have no adequate remedy at law.

270. By engaging in the foregoing unlawful or inequitable conduct, which deprived Plaintiff and members of the Class of the opportunity to purchase lower-priced generic versions of Glumetza and forced them to pay higher prices for branded and generic versions of Glumetza, Defendants have been unjustly enriched in violation of the common law of various states and commonwealths, as outlined below:

Alabama

271. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Alabama at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have benefitted at the expense of the Class from revenue resulting from unlawful overcharges for branded and generic versions of Glumetza. It is inequitable for Defendants to accept and retain the benefits received without compensating the Class.

Alaska

272. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Alaska at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful

overcharges to the economic detriment of the Class. Defendants appreciated the benefits bestowed upon them by the Class. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Arizona

273. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Arizona at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Glumetza. The Class has been impoverished by the overcharges for branded and generic versions of Glumetza resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment and the Class's impoverishment, because the Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

Arkansas

274. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Arkansas at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

California

275. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in California at prices that

were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class as a direct result of the unlawful overcharges. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Class.

Colorado

276. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Colorado at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants have benefitted at the expense of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Connecticut

277. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Connecticut at prices that were more than they would have been but for Defendants' actions. Defendants were benefitted in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants have paid no consideration to any other person in exchange for this benefit. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Class.

Delaware

278. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Delaware at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Glumetza. The Class has been impoverished by the overcharges for branded and generic versions of Glumetza resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt

of the benefits causing their enrichment, because the Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

District of Columbia

279. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in the District of Columbia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

Florida

280. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Florida at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Georgia

281. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Georgia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Hawaii

282. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Hawaii at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Idaho

283. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Idaho at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Illinois

284. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Illinois at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. It is against equity, justice, and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Iowa

285. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Iowa at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by

revenue resulting from unlawful overcharges for branded and generic versions of Glumetza, which revenue resulted from anticompetitive prices paid by the Class, which inured to Defendants' benefit. Defendants' enrichment has occurred at the expense of the Class. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

Kansas

286. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Kansas at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Kentucky

287. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Kentucky at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Louisiana

288. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Louisiana at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Glumetza. The Class has been impoverished by the overcharges for branded and generic

versions of Glumetza resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no other remedy at law.

Maine

289. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Maine at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Maryland

290. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Maryland at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Massachusetts

291. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Massachusetts at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated

the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Michigan

292. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Michigan at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Minnesota

293. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Minnesota at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated and knowingly accepted the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Mississippi

294. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Mississippi at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges. Defendants retain the benefit of overcharges received on the sales of branded and generic versions of Glumetza, which in equity and good conscience belong to the Class on account of Defendants' anticompetitive conduct. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Missouri

295. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Missouri at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class.

Montana

296. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Montana at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Nebraska

297. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Nebraska at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to the Class.

Nevada

298. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Nevada at prices that were more than they would have been but for Defendants' actions. The Class has conferred an

economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges for branded and generic versions of Glumetza. Defendants appreciated the benefits bestowed upon them by the Class, for which they have paid no consideration to any other person. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

New Hampshire

299. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in New Hampshire at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Under the circumstances, it would be unconscionable for Defendants to retain such benefits.

New Jersey

300. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in New Jersey at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Class. Defendants have paid no consideration to any other person for any of the unlawful benefits they received from the Class with respect to Defendants' sales of branded and generic versions of Glumetza. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

New Mexico

301. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in New Mexico at prices

that were more than they would have been but for Defendants' actions. Defendants have knowingly benefitted at the expense of the Class from revenue resulting from unlawful overcharges for branded and generic versions of Glumetza. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

New York

302. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in New York at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Glumetza, which revenue resulted from anticompetitive prices paid by the Class, which inured to Defendants' benefit. Defendants' enrichment has occurred at the expense of the Class. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

North Carolina

303. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in North Carolina at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. The Class did not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from unlawful overcharges to the Class. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to unlawful overcharges are ascertainable by review of sales records. Defendants consciously accepted the benefits conferred upon them.

North Dakota

304. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in North Dakota at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Glumetza. The Class has been impoverished by the overcharges for branded and generic versions of Glumetza resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

Oklahoma

305. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Oklahoma at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Class as a direct result of the unlawful overcharges and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. The Class has no remedy at law. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Oregon

306. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Oregon at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of the benefit

bestowed upon them by the Class. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Class.

Pennsylvania

307. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Pennsylvania at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Puerto Rico

308. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Puerto Rico at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic versions of Glumetza. The Class has been impoverished by the overcharges for branded and generic versions of Glumetza resulting from Defendants' unlawful conduct. Defendants' enrichment and the Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment and the Class's impoverishment, because the Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Class has no remedy at law.

Rhode Island

309. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Rhode Island at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit

bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

South Carolina

310. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in South Carolina at prices that were more than they would have been but for Defendants' actions. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Class. Defendants realized value from the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

South Dakota

311. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in South Dakota at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants were aware of the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing the Class.

Tennessee

312. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Tennessee at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class. It would be futile for the Class to seek a remedy from any party with whom they have privity of contract. Defendants

have paid no consideration to any other person for any of the unlawful benefits they received indirectly from the Class with respect to Defendants' sales of branded and generic versions of Glumetza. It would be futile for The Class to exhaust all remedies against the entities with which the Class has privity of contract because the Class did not purchase branded and generic versions of Glumetza directly from any Defendant.

Texas

313. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Texas at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. The circumstances under which Defendants have retained the benefits bestowed upon them by the Class are inequitable in that they result from Defendants' unlawful overcharges for branded and generic versions of Glumetza. The Class has no remedy at law.

Utah

314. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Utah at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Vermont

315. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Vermont at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful

overcharges to the economic detriment of the Class. Defendants accepted the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Virginia

316. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Virginia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of the benefit bestowed upon them. Defendants should reasonably have expected to repay the Class. The benefits conferred upon Defendants were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Defendants' illegal and unfair actions to inflate the prices of branded and generic versions of Glumetza. Defendants have paid no consideration to any other person for any of the benefits they have received from the Class.

Washington

317. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Washington at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated the benefit conferred upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

West Virginia

318. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in West Virginia at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants were aware of or appreciated

the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Wisconsin

319. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Wisconsin at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants appreciated the benefit bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

Wyoming

320. Defendants unlawfully overcharged members of the Class, who made purchases of or reimbursements for branded and generic versions of Glumetza in Wyoming at prices that were more than they would have been but for Defendants' actions. The Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Class. Defendants accepted, used and enjoyed the benefits bestowed upon them by the Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Class.

XIV. DEMAND FOR JUDGMENT

321. Accordingly, Plaintiff, on behalf of itself and the proposed Class, respectfully demands that this Court:

(a) Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and declare Plaintiff as the representative of the Class;

(b) Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;

(c) Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

(d) Award the Class damages, and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial;

(e) Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

(f) Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XV. JURY DEMAND

322. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

DATED: September 27, 2019

By */s/ Todd A. Seaver*

Todd A. Seaver (SBN 271067)
Carl N. Hammarskjold (SBN 280961)
Colleen Cleary (SBN 306659)
BERMAN TABACCO
44 Montgomery Street, Suite 650
San Francisco, CA 94104
Tel: (415) 433-3200
Fax: (415) 433-6382
Email: tseaver@bermantabacco.com
chammarskjold@bermantabacco.com
ccleary@bermantabacco.com

Gregory S. Asciolla (*pro hac vice forthcoming*)
Jay L. Himes (*pro hac vice forthcoming*)
Karin E. Garvey (pro hac vice *forthcoming*)
Matthew J. Perez (*pro hac vice forthcoming*)
Domenico Minerva (*pro hac vice forthcoming*)
Jonathan S. Crevier (*pro hac vice forthcoming*)
LABATON SUCHAROW LLP
140 Broadway
New York, NY 10005
Tel: (212) 907-0700
Fax: (212) 818-0477
Email: gasciolla@labaton.com
jhimes@labaton.com
kgarvey@labaton.com
mperez@labaton.com
dminerva@labaton.com
jcrevier@labaton.com

Roberta D. Liebenberg (*pro hac vice forthcoming*)
Jeffrey S. Istvan (*pro hac vice forthcoming*)
Adam J. Pessin (*pro hac vice forthcoming*)
FINE, KAPLAN AND BLACK, R.P.C.
One South Broad Street, 23rd Floor
Philadelphia, PA 19107
Tel: (215) 567-6565
Fax: (215) 568-5872
Email: rliebenberg@finekaplan.com
jistvan@finekaplan.com
apessin@finekaplan.com

Attorneys for Plaintiff