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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

FWK HOLDINGS, LLC, Plaintiffs v. BAUSCH HEALTH COMPANIES INC., SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., SANTARUS, INC., ASSERTIO THERAPEUTICS, INC., LUPIN PHARMACEUTICALS, INC., and LUPIN LTD., Defendants	No. 3:19-cv-05426 **CONSOLIDATED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**
MEIJER, INC. and MEIJER DISTRIBUTION, INC., Plaintiffs, v. BAUSCH HEALTH COMPANIES INC., SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., SANTARUS, INC., ASSERTIO THERAPEUTICS, INC., LUPIN PHARMACEUTICALS, INC., and LUPIN LTD., Defendants.	No. 3:19-cv-05822

BI-LO, LLC and WINN-DIXIE LOGISTICS, INC., Plaintiff, v. BAUSCH HEALTH COMPANIES INC., SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., SANTARUS, INC., ASSERTIO THERAPEUTICS, INC., LUPIN PHARMACEUTICALS, INC., and LUPIN LTD., Defendant.	No. 3:19-cv-06138
KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS, INC., individually and on behalf of all others similarly situated, Plaintiff, v. BAUSCH HEALTH COMPANIES INC., SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., SANTARUS, INC., ASSERTIO THERAPEUTICS, INC., LUPIN PHARMACEUTICALS, INC., and LUPIN LTD., Defendant.	No. 3:19-cv-06839

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I. INTRODUCTION

1. Diabetes is a life-threatening condition. Millions of Americans depend on metformin to help control this condition, taking the medication for years and sometimes the rest of their lives. While metformin's benefits for treating diabetes are well known, it comes with significant gastrointestinal side effects. In 2005, when Assertio Therapeutics, Inc. introduced an extended-release version of metformin, called Glumetza, with reduced gastrointestinal side effects, diabetes patients rejoiced.[1] Glumetza experienced mild success for several years, with sales of the brand drug moving from $12 million in 2007 to $45 million in 2010.

2. Until the FDA approved one or more generic versions of Glumetza, Assertio would enjoy a lawful monopoly on the drug. Assertio also sought patent protection for Glumetza, another form of lawful, government-granted monopoly if the patents are valid and not infringed. Given metformin's long and well-known use, Assertio could not patent the drug itself. Instead, Assertio obtained four patents covering extended-release forms and claimed that they covered Glumetza. But like metformin, extended or controlled-release technologies have been known in the art for decades and Assertio's patents were both weak and easy to design around.

3. In 2009, Lupin Pharmaceuticals, Inc. and Lupin Ltd. sought approval to market a generic version of Glumetza. As the first company to file an Abbreviated New Drug Application, or ANDA, for generic Glumetza, Lupin would be statutorily entitled, once approved, to 180 days as the only ANDA generic on the market.

4. When generic versions of a drug enter the market, the price of the drug falls. With only one on the market, the price of the generic is typically 10-25% off of the brand price, but prices plummet as more generics enter. Within a year of generic entry, generics capture about 90% of sales but at 10% of the brand's price. Given these dynamics, at least three things are clear: 1) brand drug companies have an incentive to delay generic entry and the accompanying erosion of brand sales; 2) the first-to-file generic company makes most of its profits during the 180-day period of exclusivity, when it can price at a discount from the brand but much higher than it would with other generic

[1] At the time, Assertio was known as Depomed.

versions available; and 3) purchasers and patients benefit most when multiple generics are available and prices are at their lowest point.

5. When Lupin sought FDA approval of the first ANDA Glumetza generic, Assertio sued, alleging Lupin would infringe its patents. But Lupin had designed around Assertio's patents; indeed, before suit, Lupin detailed in a 112-page letter both how its generic would not infringe Assertio's patents and why the patents were invalid.

6. Assertio had held a monopoly on Glumetza since 2005. But it abused and manipulated the system to unlawfully prolong that monopoly at the expense of purchasers and patients. Knowing that its patents would not withstand court scrutiny, in February 2012, Assertio and Lupin entered into a pay-for-delay deal: Assertio paid its would-be competitor to delay entry by up to four years, until February 2016.

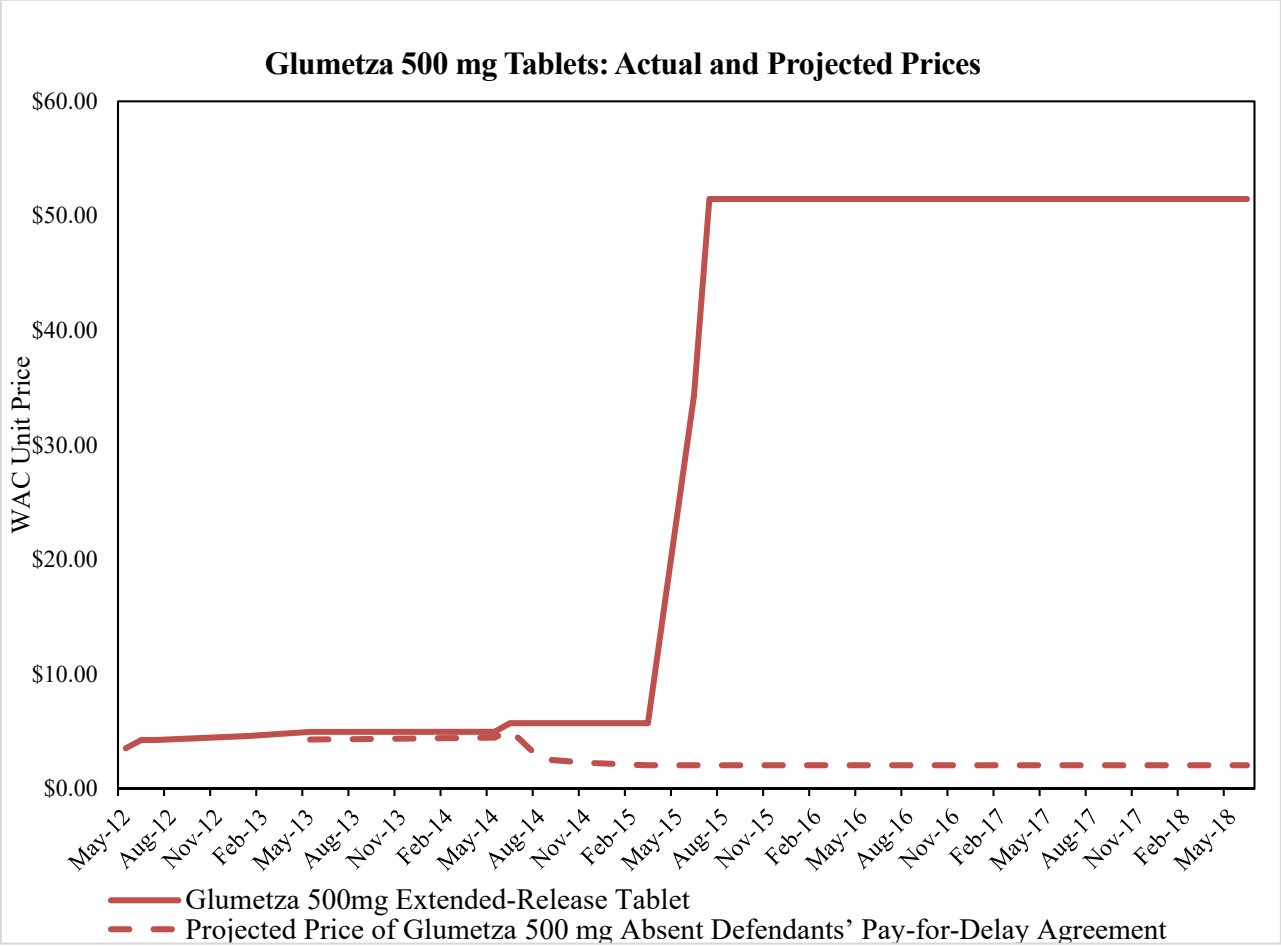
7. Lupin's payment took the form of a guarantee of exclusivity. While federal statute prevents any other ANDA generic from competing with the first-filer for 180 days, nothing prevents the brand company from launching its own generic, referred to as an "authorized generic" or AG, during that period. And that is the usual course: over the last 20 years, most every generic first-filer has faced competition from an AG during its first 180 days, fostering competition and benefitting purchasers.

8. In return for Lupin's delay, Assertio promised that it would not market a Glumetza AG during at least Lupin's first six months on the market. At 2012 Glumetza prices, that promise was worth at least $56 million to Lupin. To ensure no other generic would disrupt the apple cart, Assertio and Lupin also agreed that Lupin could enter earlier if any other generic company successfully challenged Assertio's patents, undercutting other generics' incentive to spend time and expense to challenge the patents.

9. Assertio and Lupin allocated the market between them, extending Assertio's monopoly for brand Glumetza for up to four years and granting Lupin a monopoly for generic Glumetza for at least six months. Assertio's monopoly was safe. Unlawful, but safe.

10. Assertio used the intervening years it bought to add insult to injury. Sold from one company to the next, Glumetza ended up in the hands of Valeant Pharmaceuticals International, Inc.,

now known as Bausch Health Companies Inc. In 2015, Bausch skyrocketed the price of Glumetza, jumping it from approximately $5 per 500 mg tablet to more than $50 per tablet in just a few months' time, ahead of generic entry.[2] When Assertio had $45 million in Glumetza sales in 2010, after several years on the market, Bausch saw Glumetza sales of nearly $1 billion in 2015. Had generic entry begun in 2012, history and economics tell us that brand Glumetza's price would have remained on par with its 2012 prices.



11. The delay lined Lupin's pockets too. With the Glumetza price surge in 2015, Lupin launched its generic at $44 per 500 mg tablet in February 2016, rather than the $4 or less per tablet it would have charged had it launched in 2012 or thereafter. Ultimately, the price hikes that the defendants' pay-for-delay deal enabled amounted to a $280-million-dollar reverse payment to Lupin,

[2] Bausch offered Glumetza in 1000 mg tablets, at roughly proportional prices and price increases.

billions of dollars in extra sales for Bausch, and $2.8 billion in overcharges suffered by direct purchasers.

12. Plaintiffs FWK Holdings, LLC, Meijer, Inc. and Meijer Distribution, Inc., BI-LO LLC and Winn-Dixie Logistics, Inc., and KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. bring this class action, on behalf of themselves and all others similarly situated, under federal antitrust law, alleging violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. § 1 *et seq*. and seeking damages and injunctive relief to remedy the ongoing competitive effects of the defendants' unlawful conduct.

II. INTRADISTRICT ASSIGNMENT

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

III. PARTIES

14. Plaintiff FWK Holdings, LLC is a limited liability company organized under the laws of the state of Illinois, with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of the claims of the Frank W. Kerr Company, which purchased branded and/or generic Glumetza directly from Santarus, Salix, Valeant, Bausch, and/or Lupin (as defined below) during the class period. Frank W. Kerr Company suffered antitrust injury as a result of Defendants' unlawful conduct.

15. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, Meijer) are corporations organized under the laws of the state of Michigan, with their principal place of business in Grand Rapids, Michigan. Meijer is the assignee of the claims of the Frank W. Kerr Company, which purchased branded and/or generic Glumetza directly from Santarus, Salix, Valeant, Bausch, and/or Lupin (as defined below) during the class period. Frank W. Kerr Company suffered antitrust injury as a result of the defendants' unlawful conduct.

16. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. (KPH) is a corporation organized under the laws of the state of New York, with its principal place of business in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH is the assignee of McKesson Corporation, which purchased branded and/or

generic Glumetza directly from Santarus, Salix, Valeant, Bausch, and/or Lupin during the class period. KPH suffered antitrust injury as a result of the defendants' unlawful conduct.

17. Plaintiff BI-LO, LLC is a corporation organized under the laws of the state of Delaware, with its principal place of business in Jacksonville, Florida. BI-LO, LLC purchased branded Glumetza from QK Healthcare, Inc. and is the assignee of the claims of QK Healthcare, Inc., which purchased branded and/or generic Glumetza directly from Santarus, Salix, Valeant, Bausch, and/or Lupin during the class period. QK Healthcare, Inc. suffered antitrust injury as a result of the defendants' unlawful conduct.

18. Plaintiff Winn-Dixie Logistics, Inc. is a corporation organized under the laws of the state of Florida, with its principal place of business located in Jacksonville, Florida. Winn-Dixie Logistics, Inc. purchased branded Glumetza from QK Healthcare, Inc. and is the assignee of the claims of QK Healthcare, Inc., which purchased branded and/or generic Glumetza directly from Santarus, Salix, Valeant, Bausch, and/or Lupin during the class period. QK Healthcare, Inc. suffered antitrust injury as a result of Defendants' unlawful conduct.

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

20. 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 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. Santarus is a party to the unlawful agreements alleged in this complaint. On January 2, 2014, defendant Salix Pharmaceuticals, Ltd. acquired Santarus, which became a wholly owned subsidiary of Salix Pharmaceuticals, Inc.

21. Defendant Salix Pharmaceuticals, Inc. is a corporation organized under the laws of California with its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Salix Pharmaceuticals, Inc. joined and adhered to the unlawful agreements alleged here. Salix Pharmaceuticals, Inc. is a wholly owned subsidiary of Salix Pharmaceuticals, Ltd.

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

23. On April 1, 2015, Valeant Pharmaceuticals International, Inc. acquired Salix and 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 here. 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.

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

25. Defendant Lupin Pharmaceuticals, Inc. is a corporation organized under the laws of Virginia with its principal place of business at Harbor Place 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.

26. 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. Lupin Ltd. was a party to the unlawful agreements alleged here. Lupin Pharmaceuticals, Inc. and Lupin Ltd. are collectively referred to as Lupin.

27. The defendants' wrongful actions described in this complaint are part of, and in furtherance of, the unlawful restraints on trade alleged herein. These actions were authorized, ordered, and/or undertaken by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the 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 the defendants.

IV. JURISDICTION AND VENUE

28. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a), 26. The action seeks to recover treble damages, interest, costs of suit, equitable relief, and reasonable attorneys' fees for the overcharges the plaintiffs and members of the class incurred as a result of the defendants' restraints of trade and conspiracy to monopolize the sale of Glumetza and its generic equivalents.

29. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 (federal question), 1332 (diversity due to a qualifying class action) and 1337(a) (antitrust), and 15 U.S.C. § 15 (antitrust).

30. Venue is appropriate in this district under 15 U.S.C. § 15(a) (Clayton Act), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. § 1391(b) (general venue provision). The defendants conduct business, carry out their affairs, and transact interstate trade and commerce, in substantial part, in this district.

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

V. REGULATORY AND ECONOMIC BACKGROUND

A. Congress created a structure to speed the approval and substitution of affordable generic medications.

32. Under the Federal Food, Drug, and Cosmetic Act (FDCA), a manufacturer that creates a new drug must file a New Drug Application (NDA) with the FDA to obtain the agency's approval to sell the product. An NDA must include specific data documenting the drug's safety and effectiveness.

33. The drug manufacturer must also inform the FDA of any patents that "could reasonably be asserted" against a generic manufacturer who seeks to make, use, or sell a generic version of the drug before the expiration of the listed patents. The FDA then lists these asserted patents in a publication called the *Approved Drug Products with Therapeutic Equivalence Evaluations* publication—known as the "Orange Book." If, after submitting its NDA, the manufacturer obtains one or more additional patents that it claims "could reasonably be asserted" against a generic manufacturer of that drug, the manufacturer has 30 days to inform the FDA about such patent(s) for listing.

34. The FDA does not make any attempt to verify the validity of a drug manufacturer's Orange Book listing. Instead, the agency relies on the brand manufacturer to truthfully represent its patents' validity and applicability.

1. The Hatch-Waxman Amendments eased generic entry.

35. The Hatch-Waxman Amendments to the FDCA, enacted in 1984, simplified the regulatory hurdles that prospective generic manufacturers face by eliminating the need for them to file lengthy and costly NDAs.[3] These amendments enable a generic manufacturer to rely on the brand manufacturer's safety and efficacy data, submitted in the brand's original NDA, to gain FDA approval to make and sell the generic drug rather than repeat the costly studies necessary to collect such data. Instead, the amendments require the generic manufacturers to show that its drug (1) contains the same active ingredient(s), dosage form, route of administration, and strength as the

[3] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984); 21 U.S.C. § 355(a), (b).

brand drug; and (2) is bioequivalent, *i.e.*, absorbed in the human body at the same rate and to the same extent as the brand. The FDA assigns generics that meet these criteria an "AB" rating, which signifies bioequivalence.

36. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and interchangeable. Bioequivalence shows that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.

37. Through the Hatch-Waxman Amendments, Congress sought to reduce healthcare expenses nationwide by expediting the entry of more affordable, generic drugs. But, as explained below, Congress was also careful to protect pharmaceutical manufacturers' patent rights and profitability, seeking to ensure the industry remains innovative.

38. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches while also ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. Today, pharmacies dispense generics 95% of the time when a generic version is available. 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.

2. A brand manufacturer can delay generic entry by filing lawsuits against generic manufacturers seeking to challenge the brand's patent position.

39. As part of the FDA approval process for a generic version of a branded drug, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book as covering that brand. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications with respect to the branded drug and each listed patent:

I. No patent has been filed with the FDA (a paragraph I certification);

II. The patent has expired (a paragraph II certification);

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

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

Generic manufacturers must also notify the relevant brand manufacturer of any paragraph IV certifications they make.

40. If a generic manufacturer files a paragraph IV certification as to one or more of the brand's patents, the brand manufacturer can delay FDA approval of the ANDA 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 the generic's paragraph IV certification, the FDA cannot grant final approval to the ANDA until the earlier of (i) the passage of 30 months, or (ii) a court decision that the patent is invalid or not infringed by the generic manufacturer's ANDA product. This period is referred to as a 30-month stay. Before either (i) or (ii) occurs, the FDA may grant "tentative approval" to the generic manufacturer's drug. Such approval indicates that the generic meets all scientific and regulatory requirements and the ANDA is approvable but for the 30-month stay/pending litigation. However, the FDA cannot authorize the generic manufacturer to market its product (*i.e.*, grant final approval) until condition (i) or (ii) is met.

41. The FDA takes no position on whether the generic actually infringes the listed patent(s) or whether any such patent is invalid. Rather, the stay is automatic. Simply by listing one or more patents in the Orange Book and filing a lawsuit against generic competitors, a brand can delay final FDA approval of generic entry for up to 30 months.

3. The Hatch-Waxman Amendments create a strong incentive for a generic to be the *first* ANDA filer.

42. The Hatch-Waxman Amendments encourage generic manufacturers to challenge or design around brand patents—to ensure more affordable, generic drug are available as soon as possible—by gifting a 180-day period of generic exclusivity to the first manufacturer to file an ANDA with a paragraph IV certification. Put another way, if the first ANDA filer with a paragraph

IV certification obtains FDA approval for its drug, the FDA will not allow *any other ANDA-generic filer* to sell its own generic until 180 days after the first filer enters the market.

43. This statutory mechanism creates a strong incentive for generic manufacturers to test the validity of pharmaceutical patents and invent around them. When a brand and generic litigate patent infringement to a decision on the merits, the challenged patent is more likely to be found invalid or not infringed than upheld. An empirical study of all substantive decisions rendered in patent cases filed in 2008 and 2009—when Assertio filed its infringement suit against Lupin—reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.

44. Nonetheless, an applicant eligible for the 180-day period of exclusivity can forfeit it. Specifically, a first filer forfeits this exclusivity if it fails to market its generic within 75 days after another manufacturer obtains a final decision that the brand's patents are invalid or not infringed. This provision ensures that the first filer does not hold up later manufacturers capable of selling generics, and it creates an incentive for later filers to try to jump ahead of the first filer, challenging invalid patents or demonstrating non-infringement of patents where the first filer is unable or unwilling to.

B. AB-rated generic competition dramatically lowers drug prices.

45. AB-rated generics are as safe and effective as their brand counterparts—the FDA requires it. And because generics do not differ therapeutically from brands, the only true basis for competition between them (or between generic versions of the same drug) is price. Typically, generics are at least 10% to 20% less expensive than their brand counterparts when there is a single generic competitor on the market. This discount increases exponentially as more generics enter: when there are multiple generics on the market for a given brand, the price discount can be 80% or more. According to the FDA and the FTC, the greatest price reductions occur when the number of generics on the market moves from one to two.

46. Since the passage of the Hatch-Waxman Amendments, every state has adopted "generic substitution" laws that either require or permit pharmacies to substitute an AB-rated generic

for a prescription for the branded counterpart.[4] As a result of these laws and other institutional features of the pharmaceutical marketplace, when generic competition begins, brand sales are rapidly converted to generic sales, with generics garnering 80% of sales or more within the first six months. The Federal Trade Commission (FTC) has found that, on average, generics capture 90% of brand unit sales within a year of generic entry, and (with multiple generics on the market) prices drop 85%.

47. Without competition, a brand manufacturer keeps all profit from sales of the drug:

48. When generics enter, competition converts the brand's profits into purchaser savings:

[4] The only exception occurs when the prescribing doctor has specifically orders otherwise.

49. In short, the launch of AB-rated generics typically precipitates significant cost savings for all drug purchasers. It also provides strong incentives for brand manufacturers to forestall such launches.

C. Brands can compete with generics by marketing authorized generics.

50. Brand manufacturers are well aware of the generics' rapid erosion of their sales. They have traditionally lawfully addressed this by one or both of two methods. Sometimes the brand company will lower (by a small amount) the price of its brand product; this is relatively rare. Much more frequently, brand companies opt for the second method: marketing a generic version of their brand product. A brand manufacturer has the right to sell a generic version of its own brand product, known as an "authorized generic" or AG. An authorized generic is essentially the brand product, manufactured and marketed under the authority of the brand manufacturer's NDA, but sold in different packaging. A brand manufacturer need not file an ANDA, or obtain any additional FDA approvals, to market its authorized generic (or to license the AG to a third party for marketing and sale).

51. Authorized generics are not subject to the first filer's 180-day period of exclusivity. The first filer's exclusivity period is effective only against other ANDA filers.

52. Brand manufacturers price their authorized generics similar to other generics. Thus, when a brand markets an authorized generic during the first filer's exclusivity period, the first filer reaps far less profit than it otherwise would have. And the brand manufacturer is able to retain more sales by taking a portion of the generic market. The FTC estimates that a brand manufacturer whose product faces generic competition increases its overall revenues by as much as 21% when it introduces an authorized generic.

53. The generic manufacturers' trade association reported to Congress that from 2003-2006, brands "launched an authorized generic during every 180-day generic exclusivity period."

54. Authorized generic entry signals a healthy, competitive marketplace. While the first ANDA filer enjoys the exclusive right to sell the only ANDA-approved generic product during these six months, having two or more generics on the market benefits purchasers and patients: generic prices—authorized and non—fall farther and faster with two or more generics on the market. Thus, drug purchasers benefit from authorized generic entry during and after the 180-day exclusivity period.

D. Pay-for-delay deals can be more profitable for brand *and* generic manufacturers.

55. Absent generic competition, brand manufacturers typically sell their drugs far above the marginal cost of production, generating profit margins of 70% and more, sometimes up to 98%. They can do this because before generic competition enters, the brand holds a monopoly on the drug. When one generic enters, the brand's monopoly disappears, the generic charges less, and profit margins for the drug begin to shrink. When two or more enter, prices—and profit margins—drop much more precipitously.

56. Brand manufacturers thus have an interest in forestalling generic competition for as long as possible, keeping monopoly profits for themselves. And first filers have an interest in being the only generic on the market for as long as possible, keeping generic sales for themselves.

E. "No AG" pay-offs: a brand manufacturer agrees not to launch an authorized generic as payment for delay.

57. Unscrupulous brand manufacturers may pay a generic competitor to delay entry with a no-AG agreement, forgoing the right to sell an authorized generic for a set period of time—usually 180 days, but sometimes even longer—after the generic manufacturer finally launches. This no-AG promise removes all competition for the first filer generic for those first 180 days.

58. As noted, this period of generic exclusivity is extremely valuable to the first filer. The first filer usually earns the vast majority of its total revenue on a drug—as much as 80% of total profit—during the 180-day period. As a result, the first filer can almost always make more money from a delayed 180-day exclusivity period where it is the only generic on the market than it can by entering sooner but competing against an authorized generic.

59. The Supreme Court has recognized that 180 days of generic exclusivity "can prove valuable, possibly 'worth several hundred million dollars'" to the first filer.[5] And because an authorized generic can reduce the value of that exclusivity by 50% on average, courts have recognized that a "no-AG agreement . . . may be of great value to . . . the first-filing generic."[6]

60. Thus, "no-AG agreements are likely to present the same types of problems as reverse payments of cash."[7] As explained by the then-Chairman of the FTC:

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

61. The no-AG payment is also significantly more profitable for the brand manufacturer: the brand can make far more money from delaying generic competition than it can from launching an

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[5] *FTC v. Actavis, Inc.*, 570 U.S. 136, 143 (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)).

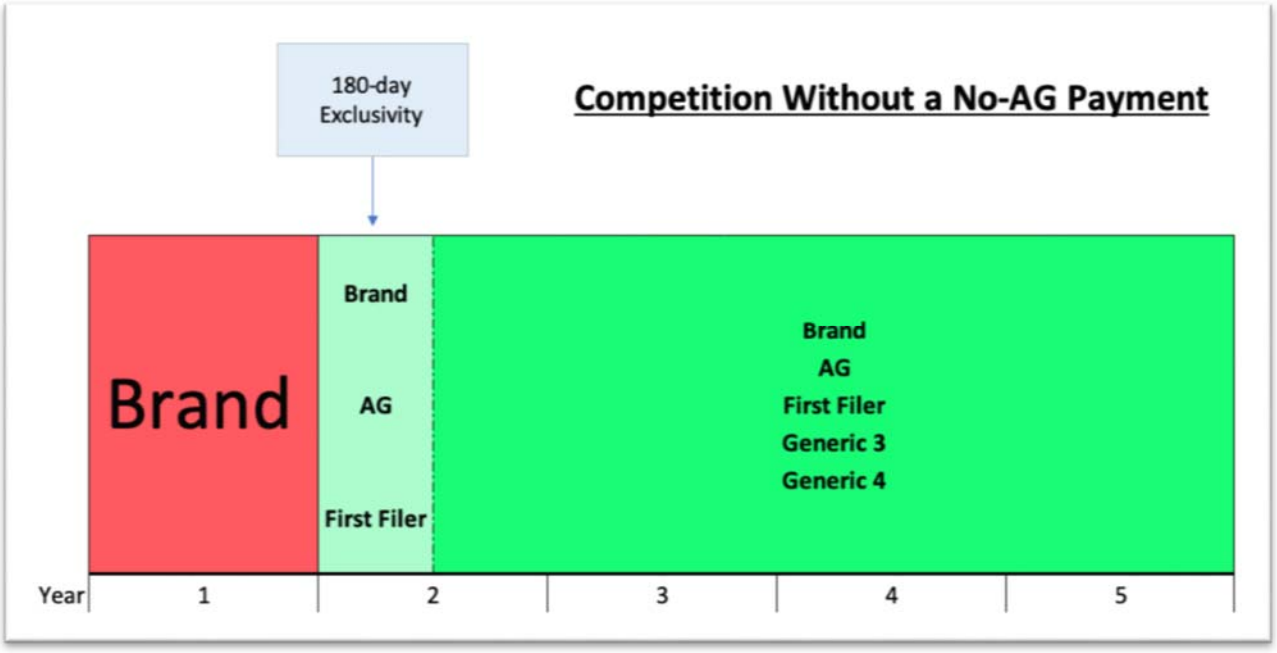
[6] *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 404 (3d Cir. 2015).

[7] *King Drug*, 791 F.3d at 404.

authorized generic. Standard industry economics establish that the value to a brand manufacturer of a four-year delay in generic entry for a brand drug with $200 million in annual sales is more than $575 million.

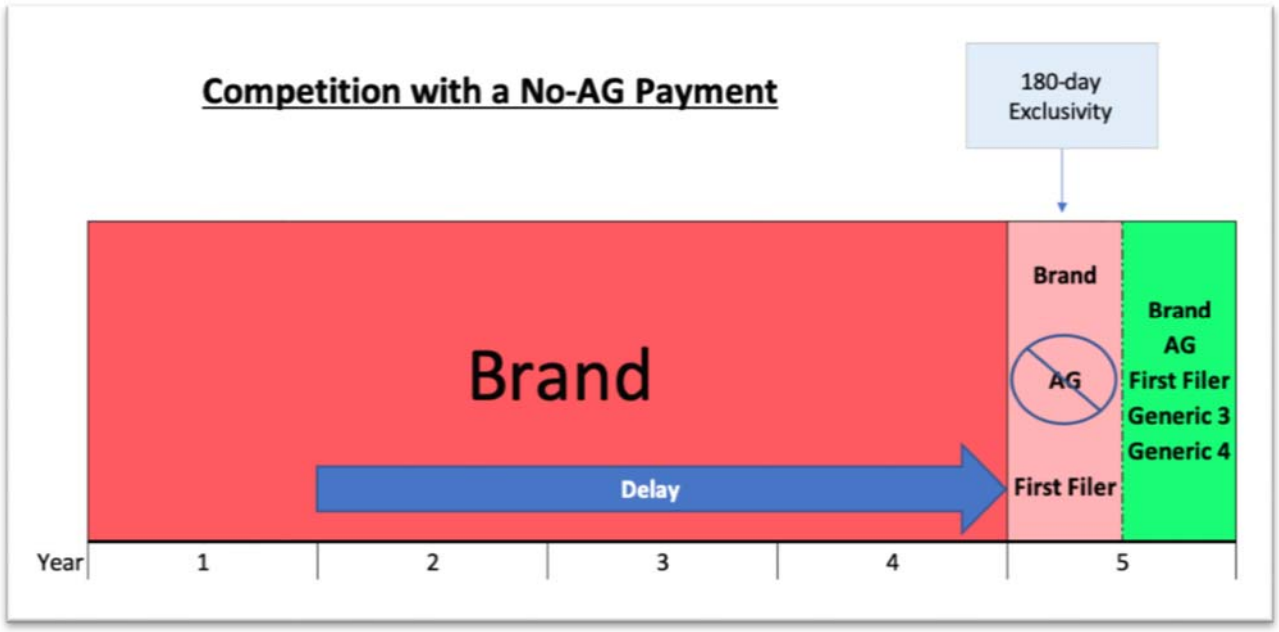
62. Thus, the no-AG payment puts both the brand and the first filer in more profitable positions than they would have been in absent the unlawful deal—at the expense of purchasers and patients.

63. The state of a lawful, healthy market is depicted here:



In this example, the brand product is alone in the market for one year (the red area); three products—the brand product, the authorized generic, and the first filer's generic—are on the market during the 180-day exclusivity period (the light green area); and two or more generics enter the market after the 180-day exclusivity period runs (the dark green area).

64. Contrast this lawful competition with a no-AG payment:



Due to the no-AG payment, the brand product now enjoys an extra three years of exclusivity (the red area); the first filer's only competition for 180-days is the brand (the pink area); and all other generic entries are delayed until year five (the green area).

65. This scheme harms drug purchasers in at least two ways: (1) continued supracompetitive prices for the brand drug for longer and (2) higher generic prices when the first filer enters due to a lack of generic competition. And other generics, bottlenecked by the first filer's statutory right to exclusivity absent forfeiture, have few methods to break through.

F. Most-favored-entry clauses: a brand manufacturer erases any incentive for later generic filers to challenge the patents and dislodge the bottleneck.

66. The Hatch-Waxman Amendments leave open at least two pathways for later filers to enter the market before a first filer that has agreed to delay entry into the market. The later filer could win the patent litigation and trigger forfeiture of the first filer's exclusivity when it fails to enter the market within 75 days of the court decision; and the later filer could negotiate an earlier entry date from the brand manufacturer and enter the market if the first filer has forfeited, or might forfeit, its exclusivity. The brand and first filer can further harm competition by agreeing to most-favored-entry clauses that block these pathways.

67. A standard most-favored-entry clause—incorporated into the brand and generic's pay-for-delay agreement—allows the generic first filer to enter the market before the agreed (delayed) entry date if one or more other generics are able to come onto the market before that date. It provides that: (1) the first filer will delay entering the market until, say, four years in the future; but (2) if any other generic manufacturer (*i.e.*, a later filer) succeeds in entering the market before that agreed future date, the first filer's entry date is moved up to match the later filer's entry date.

68. Most-favored-entry clauses delay robust generic competition by undermining the incentives of later filers to attempt to enter the market before the first filer. Absent these clauses, the first filer's prolonged period of delay would provide a later filer the opportunity to try to jump the queue and enter the market before the first filer. The later filer would then enjoy a period where it was the only ANDA-based generic product on the market. This prospect motivates a later filer to incur the substantial costs associated with litigating invalidity or non-infringement of the brand's patent.

69. If a later filer obtains a final court decision that the brand's patents are invalid or its generic product does not infringe and the first filer does not enter the market within 75 days of that decision, the first filer forfeits its 180-day exclusivity. Thus, the first filer would forfeit its exclusivity, if, for example, it agreed to delay entry until year 4 and then a later filer secured a decision invalidating the brand's patents at year 2.

70. The presence of a most-favored-entry clause eliminates the potential reward for later filers associated with litigating invalidity and infringement. Even if the later filer succeeds in invalidating the brand's patents (or proving its product does not infringe), the first filer will enter the market the minute the later filer does so, freeriding on the later filer's resource outlay and gobbling up a significant percentage of the generic market. This changes the later filer's calculus dramatically: the potential reward from successfully litigating the patent case is not worth the financial burden of litigation.

71. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—testified to Congress that most-favored-entry clauses "eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry." As he explained,

> no subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. *Consumers are the biggest losers under this system.* 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.

72. In addition to the standard most-favored-entry clause, brand manufacturers and first filers can use other another tactic—a most-favored-entry-*plus* clauses—to deter competition from later generic filers. A most-favored-entry-plus clause provides that the brand manufacturer will not grant a patent license to any other generic manufacturer to enter the market under the authority of the generic competitor's ANDA until a defined period of time after the first filer enters. The clause might provide, for example, that the brand manufacturer will not grant a license to any later filer to enter the market until 180 days after the first filer enters. A most-favored-entry-plus clause differs from both a no-AG clause and a most-favored-entry clause. A no-AG clause prevents the brand owner from marketing its own generic (either by itself or, typically, by license to a third party) under the original brand's NDA. A most-favored-entry clause assures the first filer that its agreed upon entry date will be moved up if a competing generic company earns the right to enter the market before that delayed agreed entry date. But these two provisions—the no-AG clause and the most-favored-entry clause—leave unaddressed the right of the brand to license its patents to a second generic (or beyond) so that the second generic can enter the market under its own ANDA. While the likelihood of such an event happening is rare, the most-favored-entry-plus provision closes this relatively narrow gap by assuring the recipient of the reverse payment that no patent license to any third party will issue until a defined period of time after the first filer enters.

73. The purpose and effect of a most-favored-entry-plus clause, like a most-favored-entry clause, is to protect the delay and exclusivity in the deal, deterring later filers from trying to enter the market before the first filer. Absent the most-favored-entry-plus clause, later filers could use their own challenges to the brand manufacturer's patents as leverage to negotiate from the brand manufacturer a license to enter the market before the first filer, thereby enjoying a substantial period

as the only ANDA product on the market. Those licenses would be very valuable to the later filer where the first filer has forfeited, or might forfeit, its ANDA Exclusivity.

74. Most-favored-entry and most-favored-entry-plus clauses work together to deter later filers from attempting to improve the generic entry date. Armed with these clauses, brand manufacturers can significantly delay healthy generic competition.

VI. ASSERTIO/SANTARUS AND LUPIN EXECUTE AN UNLAWFUL NO-AG AGREEMENT

A. Assertio formulates and, in 2005, receives FDA approval for Glumetza, a controlled release metformin product.

75. Diabetes is an epidemic in the United States. In 1958, only 1.6 million people in the United States had the disease; today, over 30 million people—9.4% of the country—live with it. One in five health care dollars is now spent caring for people living with diabetes.

76. One of the most common medicines used to treat diabetes is also one of the oldest and most affordable. Considered the "gold standard" in diabetes medications, metformin has been available to diabetics since 1957. An orally ingested tablet, metformin works by limiting the production of sugar in the liver, thereby managing glucose levels. Conventional metformin, however, requires multiple daily doses. And doctors often find it difficult to titrate patients up to the maximum daily-recommended dose (2000 mg) due the drug's gastrointestinal side effects, which occur primarily when the drug is released in the lower GI tract. By some estimates, 50% of metformin-treated patients experience GI side effects. Based on these side effects, many patients cannot achieve adequate glycemic control. Pharmaceutical companies looked to develop formulations that neutralized these problems.

77. In 2002, Depomed (which later changed its corporate name to Assertio) used conventional controlled-release techniques to create a version of metformin that delivers the drug to the stomach more slowly (up to 15 hours post-dosage), resulting in fewer GI side effects. Depomed formulated this medication as a 500 mg tablet and branded it as Glumetza. Concurrently, Biovail (now part of Bausch) formulated a 1000 mg controlled release tablet of the same drug and then licensed it to Assertio for U.S. sales.

78. Glumetza's extended-release mechanism works by causing the tablet, once ingested into the stomach, to swell with water. The tablet's increased size both blocks the tablet's exit from the stomach and controls the release of the active pharmaceutical ingredient—metformin—from the tablet over the course of hours. By sustaining Glumetza's time in the stomach, more of the metformin releases in the stomach or upper GI tract, rather than the lower GI tract, therein reducing the risk of GI side effects. Based on these reduced side effects and its slower release mechanism, Glumetza helps people living with Type 2 diabetes reach their optimal dose of metformin.

79. On June 3, 2005, the FDA approved Assertio's NDA for Glumetza 500 mg and 1000 mg extended-release tablets to improve glycemic control in adults with Type 2 diabetes.[8]

B. While developing Glumetza, Assertio obtains the first of its ultimately six controlled-release oral dosage form patents it claims cover Glumetza.

80. Before getting FDA approval for Glumetza, Assertio filed for and received four patents on controlled-release oral dosage forms. (The company later added two more controlled-release oral dosage forms patents, including one by license from Biovail.)

81. The initial patents' expiration dates ranged from September 2016 to October 2021, and Assertio caused each to be listed in the FDA's Orange Book, claiming they covered Glumetza. (Assertio did the same with the latter two patents, both expiring in March 2025.)

Assertio's Orange Book Patents for the 500 mg Formulation			
Patent No.	**Filed Date**	**Issuance Date**	**Expiration Date**
6,340,475 ('475 patent)	March 29, 1999	January 22, 2002	9/16/2016
6,635,280 ('280 patent)	November 6, 2001	October 21, 2003	9/16/2016
6,488,962 ('962 patent)	June 20, 2000	December 3, 2002	6/20/2020
6,723,340 ('340 patent)	October 25, 2001	April 20, 2004	10/25/2021

[8] Assertio developed Glumetza with its then collaborative partner at the time, then-Biovail Corporation.

Assertio's Orange Book Patents for the 1000 mg Formulation			
Patent No.	**Filed Date**	**Issuance Date**	**Expiration Date**
6,488,962 ('962 patent)	June 20, 2000	December 3, 2002	6/20/2020
7,780,987 ('987 patent)	February 21, 2003	August 24, 2010	3/23/2025
8,323,692 ('692 patent)	December 5, 2008	December 4, 2012	3/23/2025

82. Despite having, ultimately, six patents, Assertio's alleged patent protection for Glumetza was exceptionally weak and easy to design around.

83. Assertio's patents did not claim metformin, a pharmaceutical formulation (*e.g.*, tablet, capsule, injection) of metformin alone, or a method of using metformin alone to treat diabetes. Indeed, metformin was an old drug, used to treat Type 2 diabetes since the 1950s.

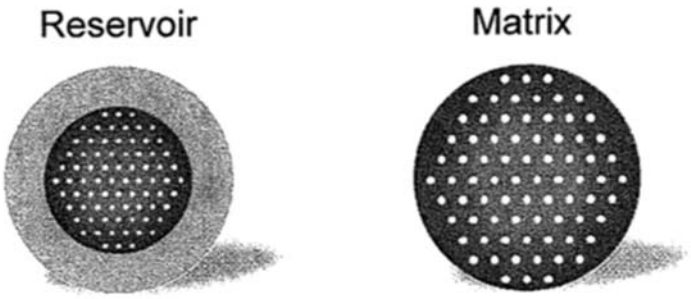
84. Assertio's patents also did not claim broad controlled-release technology. Such technology had been developed and used since at least the 1970s in a variety of applications. Instead, Assertio's patents more narrowly claimed oral dosage forms that provide for the controlled release of drugs such as metformin.

85. Controlled-release technology typically involves a polymeric formulation that uses either a "reservoir" or "matrix" system. A polymeric formulation is a large molecule composed of repeating structural units.

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

87. 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 pill in the stomach after a meal. This bloated polymeric matrix controls the rate at which the drug is released from the pill.

88. Thus, the difference between the matrix and reservoir systems is the rate-controlling mechanism. In a matrix system, the polymeric matrix controls the drug's release rate. In a reservoir system, a polymeric membrane encasing the drug core controls the drug's release rate.



89. Assertio's patents focus on formulations, and methods of using them, that require a *matrix* controlled-release system. At the time Assertio applied for the patents, multiple prior art[9] publications described extended-release delivery vehicles targeting the stomach, including: (i) a solid matrix form of a substance that absorbs gastric fluid to extend gastric retention of the delivery vehicle; (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. As a result, Assertio's patents could not broadly claim a matrix release system for metformin.

90. Instead, Assertio's patents narrowly claimed a particular type of water-swollen polymeric matrix that is responsible for controlled drug delivery. Assertio's patents claimed, among other things: specific drug-release rates, specific drug-to-polymer ratios, specific dosage forms of specific sizes and shapes and duration, specific use of specific polymers in sufficient quantities to perform the required functions, and specific manufacturing processes. These specific parameters are known as "claim limitations." A product must meet, or fall within, each of these specific parameters to infringe the patent; products that fall outside these specific parameters do not infringe the patent.

91. To design around Assertio's patents, a generic would only have to tweak its product such that it fell outside one of these specific parameters for each patent claim. In contrast, to prove patent infringement, Assertio would have to show that the generic met every limitation of one of the patents' claims.

[9] Prior art are publications, patents, products, or other public materials that pre-date a particular invention. An inventor cannot patent his or her claimed invention if the "prior art" renders that invention obvious.

92. Generic competitors had an easy design-around option. Because each of the Glumetza patents claimed a matrix system, generic manufacturers could avoid infringing simply by forgoing the matrix system. By opting for a reservoir system instead of a matrix system, a generic manufacturer could ensure that its product fell outside *all* of the patents' claims.

93. Assertio's '475 and '280 patents are based on the same initial patent application. 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, "the 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 [i.e., after meal consumption], 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 drug is therefore controlled diffusion of the drug from the matrix." As a result, the purportedly novel properties of the '475 and '280 patents are their *polymeric matrices* and these matrices' ability to control the drug release and erosion rate.

94. The '475 and '280 patent claim only a release rate mechanism wherein a matrix controls the drug's diffusion and therefore release rate. A reservoir system can achieve the same controlled release without using a polymeric matrix as claimed in '475 and '280 patents. A reservoir system limits the rate of the drug's release by wrapping the drug's core with an insoluble barrier. As a result, a reservoir system cannot infringe the '475 and '280 patents—the system falls outside the patents' claims.

95. Use of a reservoir system would also enable generic manufacturer to design around others of Assertio's patents. The '962 patent differs only slightly from the '475 and '280 patents and covers "tablet shapes to enhance gastric retention of swellable controlled-release oral dosage forms," such as "oval, triangle, almond, peanut, 'bow tie,' parallelogram, trapezoidal, pentagonal, and hexagonal." Like the '475 and '280 patents, however, the '962 patent's claims are limited to a dosage form using a matrix structure. Thus, a generic manufacturer could avoid infringing the '962 patent by using a reservoir system rather than a matrix system.

96. Assertio's '340 patent claims optimal material to be used in the *matrix* to control the drug's release. As with the others, a generic manufacturer using a *reservoir* system could avoid infringing this claim.

97. Both of the later issued '987 and '692 patents claim a dosage form with a controlled-release coating prepared by "curing the coated oral dosage form at a temperature of at least 55° C" and consisting of a neutral ester copolymer, a polyethylene glycol, one or more hydrophilic agents, and a pharmaceutically acceptable excipient. A generic manufacturer could design around these patents claims by applying a different coating to control the drug's release.

98. What's more, the '987 and '692 patents were listed in the Orange Book as covering only the 1000 mg Glumetza product. Thus, they could not block a 500 mg generic Glumetza ANDA.

99. Finally, designing a reservoir system for metformin was not difficult. Numerous prior art publications taught pharmaceutical formulators how to implement a reservoir system to extend the release of a drug. For example, U.S. Patent No. 4,954,350 discloses controlled-release pharmaceutical formulations for oral administration of acrivastine (an anti-histamine) using a core containing the drug coated with acrylic polymers.

100. Although the FDA requires generics to meet certain "sameness" requirements, an identical controlled-release mechanism is not among them. A generic manufacturer need only show that its generic product is bioequivalent to the brand product—it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed in the human body at the same rate and to the same extent as the brand. Therefore, generic manufacturers could use a reservoir systems and still obtain FDA approval for generic versions of Glumetza.

C. Assertio and Santarus partner in July 2008 to market and sell Glumetza and enter a commercialization agreement in August 2011, handing the reins to Santarus.

101. Sales of Glumetza began slowly, moving from *de minimus* in 2006 to $12 million in 2007 and $30 million in 2008.

102. In July 2008, Assertio entered an exclusive promotion agreement for Glumetza with Santarus. Under this agreement, Santarus was responsible for promoting Glumetza to doctors,

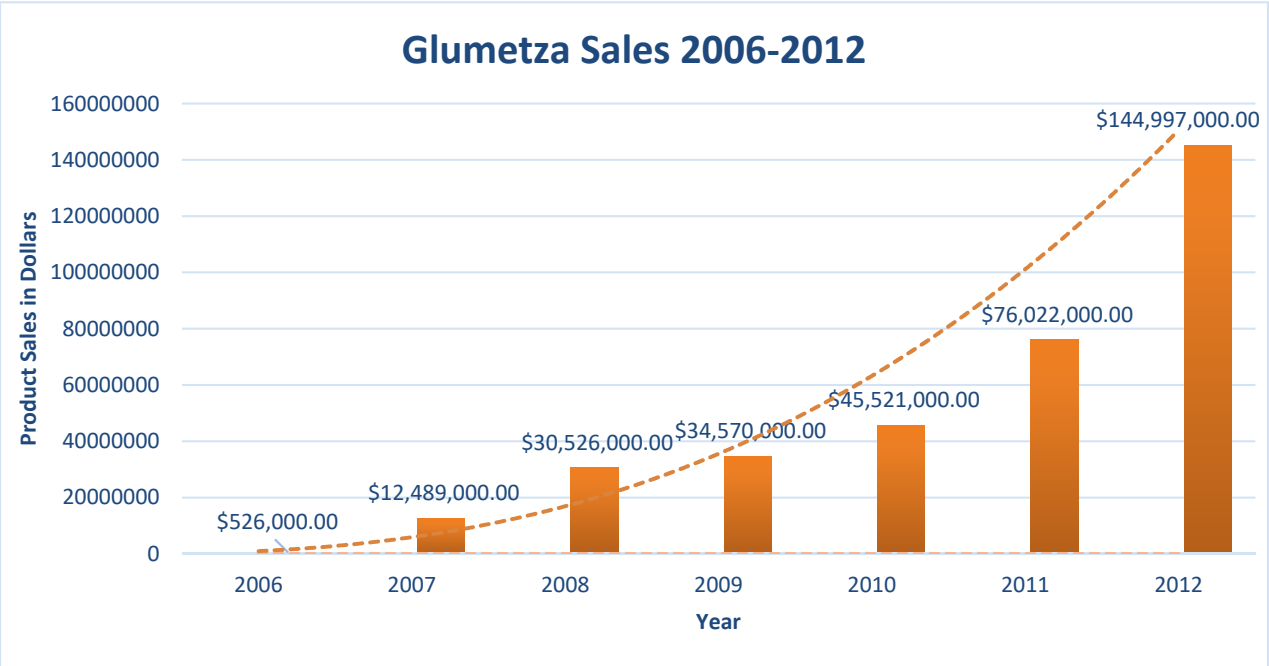
pharmacy benefit managers, and health plans to increase Glumetza sales. Sales grew mildly, reaching $45 million in 2010.

103. In August 2011, Santarus and Assertio replaced their promotion agreement with a commercialization agreement. This agreement made Santarus the owner of the Glumetza NDA and gave Santarus *sole* decision-making authority on pricing, contracting, and promotion for Glumetza. It also gave to Santarus the exclusive rights to manufacture and commercialize Glumetza in the United States, beginning September 2011. And Santarus acquired the exclusive right "(even as to Assertio)" to commercialize authorized-generic versions of the drug.

104. Under their commercialization agreement, Santarus also agreed to pay Assertio a gradually increasing royalty rate (starting at 26.5% in 2011 and reaching a ceiling of 34.5% by 2015) on net sales of Glumetza prior to generic Glumetza entry. If generic versions of Glumetza entered the market, the parties agreed to share proceeds equally based on a gross margin split.

105. The agreement tasked Assertio with managing any lawsuits regarding the Glumetza patents. Nonetheless, Santarus retained key consent rights, including the right to reject proposed settlements. And the parties agreed to split the costs of any patent lawsuit, with Santarus responsible for 70% and Assertio for 30%. Finally, the agreement assigned responsibility for regulatory compliance—including maintaining contacts with the Department of Justice's Antitrust Division and the FTC—to Assertio.

106. The partnership with Santarus helped launch Glumetza into a new realm of sales. For the eight months of 2011 that Assertio was responsible for manufacturing Glumetza, Assertio recognized approximately $40 million in Glumetza product sales. In the remaining four months of 2011, Santarus attained approximately $36 million in product sales, nearly the same revenue in half the time. Sales nearly doubled in 2012, reaching $144 million.



D. Lupin seeks approval of a generic Glumetza product and Assertio/ Santarus sues.

107. On or about July 27, 2009, Lupin filed ANDA 91664 seeking FDA approval to manufacture and sell generic versions of Glumetza 500 mg and 1000 mg. Because Lupin's generic Glumetza product used a reservoir system to control the release of metformin, Lupin's ANDA contained paragraph IV certifications as to the four Orange Book patents Assertio/Santarus had listed at the time: the '475, '280, '962, and '340 patents.

108. On or about November 6, 2009, Lupin notified Assertio that it had filed ANDA 91664. In this notice, Lupin explained why the four patents were both invalid and not infringed by Lupin's ANDA product. Among the information Lupin provided, as to the '475 and '280 patents, Lupin noted that many of the claims require the oral dosage form to remain "substantially intact" until the drug is released, something that Lupin's product did not do. Other claims were directed to methods of administering the drug, claims that Lupin could not infringe because Lupin does not administer medications to patients. As to the '962 and '340 patents, various claims required a solid "monolithic" matrix, which Lupin noted meant "a polymeric matrix that is cast as a single piece – not as two or more layers." Because Lupin's ANDA products "are not cast as a single piece," they could not infringe such claims.

109. Lupin also identified numerous patents, publications, and other pieces of prior art known in the field before each of Assertio's patents that anticipated or rendered the patents obvious.

110. 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 lawsuit triggered the Hatch-Waxman Amendments' automatic, 30-month stay against Lupin, measured from the date Assertio received Lupin's November 6, 2009 paragraph IV notice. Absent a final court adjudication before then, Lupin could not receive FDA approval to launch until the stay expired on May 6, 2012.

111. Assertio filed the patent infringement lawsuit against Lupin without regard to the lawsuit's merits. In fact, Assertio knew that there was an overwhelming likelihood that it would lose the patent litigation. Assertio's true purpose was to ensure it received the 30-month stay, effectively preventing Lupin from obtaining FDA approval and coming to market until at least May 6, 2012.

112. On January 29, 2010, Lupin answered Assertio's complaint and counterclaimed, seeking declaratory judgments that Lupin's product did not infringe any of the four patents and that each of the four patents was invalid.

113. Lupin's discovery responses in the litigation reiterated that its generic does not and *could not* infringe because the drug relies on a reservoir system—as opposed to the claimed polymeric matrix system in Glumetza—to extend the drug's release. 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[s] 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.

114. Lupin explained that its reservoir delivery system relied on a *coating* that incorporated a material called Eudragit to control the drug's release. In contrast, Assertio's patents required a polymeric matrix core to control the drug's release.

115. Lupin also continued to assert that Assertio's patents were invalid.

116. On January 27, 2012, the FDA granted tentative approval to Lupin's ANDA, meaning Lupin had satisfied all regulatory and scientific requirements and was approvable but for the pendency of the patent litigation and the 30-month stay. Getting tentative approval in January 2012 ensured that Lupin could receive final approval for its generic Glumetza when the 30-month stay expired in May 2012.

117. After final approval, Lupin would be eligible to launch its generic at risk, *i.e.*, before a final, non-appealable judgment in the patent case. An "at risk" launch occurs when a generic manufacturer begins to sell its generic product after the 30-month stay ends but before a final judgment on infringement, therefore risking having to pay damages should it lose the patent infringement litigation. If Lupin launched at risk and won the infringement lawsuit, it would not be liable for any damages. If Lupin launched at risk and lost the lawsuit, it would have to pay damages to Assertio for its period of sales after the 30-month stay elapsed.

118. Lupin was no stranger to at-risk launches: just the previous year, Lupin launched at risk with a generic version of an extended-release metformin hydrochloride product (Fortamet 500 mg and 1000 mg) shortly after the relevant 30-month stay expired.

119. The FDA's tentative approval of Lupin's generic signaled to Assertio/Santarus that generic competition was potentially only a few months away. And even if Lupin decided against the at-risk launch, it was still likely to enter in late 2012 or early 2013 following a win in the patent trial set for October 2012.

E. Assertio/Santarus pay Lupin to stay off the market to delay competition and retain their monopoly.

120. As of January 2012, Glumetza represented more than *50%* of Santarus's sales. Lupin's sale of generic Glumetza would devastate Assertio/Santarus's bottom line.

121. So Assertio/Santarus paid Lupin to delay sales of its generic product. On February 22, 2012—a month after the FDA tentatively approved Lupin's generic and shortly before the 30-month stay would expire—the companies resolved the patent litigation by signing an unlawful reverse payment agreement.

122. Under the deal, Lupin agreed not to enter the market until February 1, 2016, nearly four years down the road.

123. As payment for Lupin's agreement to delay entry, Assertio/Santarus promised not to launch (or allow any third party to launch) an authorized generic Glumetza 500 mg or 1000 mg product for at least 180 days following Lupin's market entry. (Indeed, the plaintiffs have reason to believe that Assertio/Santarus and Lupin's no-AG clause extended an *entire year* following Lupin's launch, not just 180 days: Bausch (which later acquired Assertio/Santarus), refrained from launching an authorized generic Glumetza until February 2017—a year after Lupin's entry.)

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

125. Absent the no-AG payment, Assertio/Santarus had the incentive and the ability to market an authorized generic version of Glumetza as soon as (if not before) Lupin launched. For example, Santarus launched an authorized generic when Par, the first filing generic Zegerid manufacturer, launched generic Zegerid. A lawful rational profit-maximizing entity in Santarus's position would not forgo the opportunity to gain additional sales by marketing an authorized generic. Indeed, in the 2011 commercialization agreement, Santarus specifically negotiated for, and received from Assertio, the right to launch a Glumetza authorized generic.

126. By ceding its right to earn profits from its own authorized generic for at least 180-days, Santarus enabled Lupin to more than double its profits. As the only generic on the market for 180 days, Lupin would retain 100% of the generic market rather than approximately half had an AG launched. And as the only generic on the market for 180 days, Lupin could charge a higher price than it would if it faced generic competition.

127. Thus, the no-AG payment served as substantial compensation for Lupin's agreement to delay entry—a payment Lupin could not have gained from winning the patent litigation.

128. The value of the no-AG payment to Lupin is readily calculable using the known economics of the pharmaceutical industry and the impact of generic competition. Assuming, conservatively, that the term of the no-AG clause extended only six months, rather than a year as suspected, the value from Lupin's perspective is the difference between the revenue it expected to earn during in the first six months of 2016, as the only generic on the market, and the revenue it expected to earn during the first six months of 2012, when, without the no-AG payment, it would have faced competition from Santarus's authorized generic.

129. For 2012, annual sales of Glumetza were approximately $150 million. Six months (180 days) of brand Glumetza sales would generate $75 million in revenue to Assertio/Santarus (6/12 x $150 million).

130. Lupin expected generics to take 80% of Glumetza unit sales during those six months. Thus, Lupin expected all generics to capture about $60 million during those six months ($75 million x 0.8).

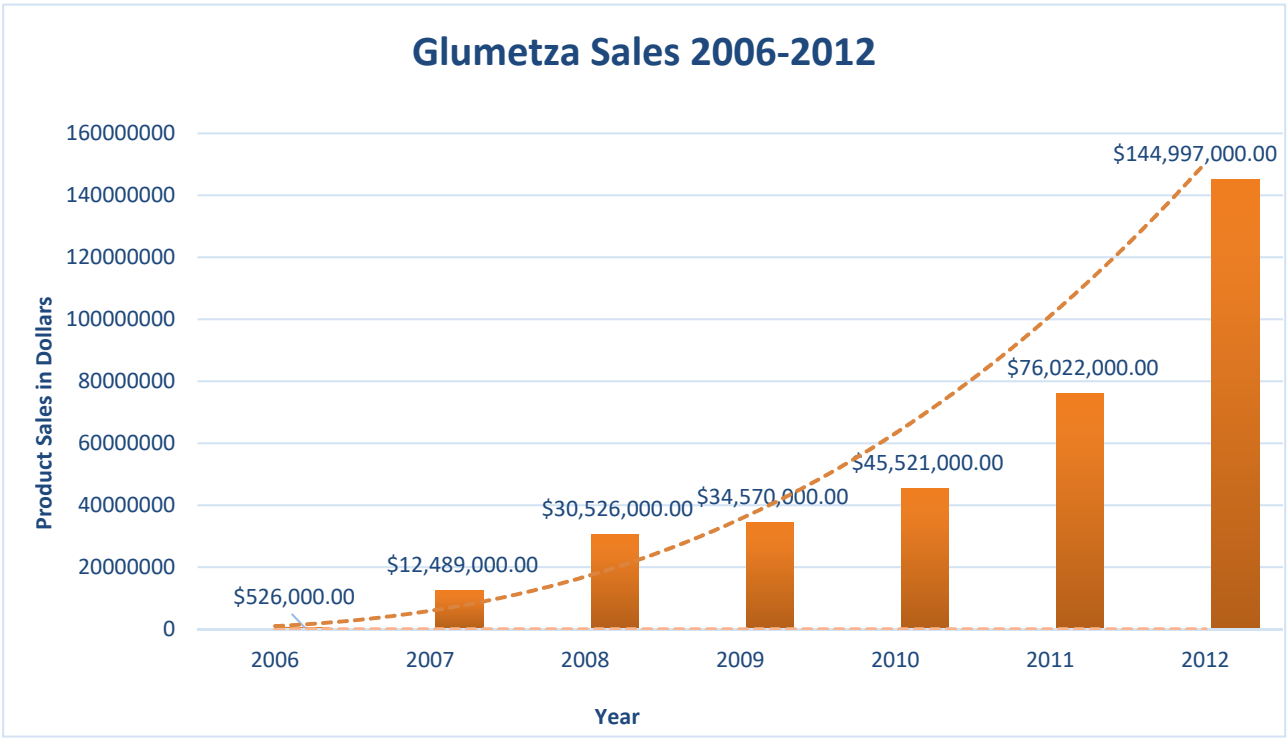
131. Absent a no-AG payment, Lupin expected two generics—its own and Assertio/Santarus's—to sell generic Glumetza during those 180 days. Studies by the FDA and others show that, with two generics in the market, the average generic price is 48% less than the brand price. Thus, Lupin expected that the two generics would take in a total $31.2 million in those first six months ($60 million x 0.52).

132. Only half of those revenues would go to Lupin, though. During the six months, the unit sales of generic Glumetza would be split (roughly evenly) between Lupin's generic and Assertio/Santarus's authorized generic. In fact, the authorized generic often captures more than half of the unit sales due to its "first-mover" and other marketing advantages. As a result, absent a no-AG payment, Lupin could expect revenues of only $15.6 million during the six-month period ($31.2 million x 0.5).

133. Lupin would fare far better with an anticompetitive no-AG payment for at least three reasons. First, Lupin would take in 100%—not 50%—of generic sales in the six-month exclusivity window.

134. Second, Lupin would be able to sell its generic Glumetza at a far higher price. Without a second generic on the market, Lupin would be able to sell its generic Glumetza at only a 10% discount off the price of the brand, rather than a 48% discount.

135. Third, brand sales, driven by both increased unit and sales and increased prices, were increasing. Santarus had recently assumed full responsibility for commercializing Glumetza and sales had risen by 67% in 2011 over the prior year.



136. Santarus had just hired about 30% more sales representatives and rolled out a new promotional program, prompting analysts to predict significant growth in the years ahead. Consequently, Lupin expected annual brand sales to be at least $200 million by 2016. As a result, Lupin expected its six months of exclusive generic Glumetza sales in 2016 to be worth *at least $72 million*: $200 [annual brand sales] x 0.5 [six months] x 0.8 [percent of the market the generic would capture] x 0.9 [10% price discount].

137. Thus, the value of the no-AG payment to Lupin was, at a minimum, the difference between Lupin's expected revenue from generic sales in 2012 with authorized generic competition

and six months of marketing in 2016 without an authorized generic. That difference is $56.4 million ($72 – $15.6). This was far more than Lupin could have made even if it had won the patent litigation.

138. In reality, Lupin knew the no-AG payment was likely worth far more than $56.4 million. Lupin knew and intended that its agreement to delay entry until 2016 would encourage Assertio/Santarus to exploit its extended market power that Lupin's agreement secured for them, aggressively promoting the drug and raising its price. Lupin would then benefit from these increased prices and sales volumes when it entered.

139. And as explained below, that is exactly what happened: Assertio/Santarus sold its prolonged and unlawful monopoly to another brand manufacturer—Valeant, now known as Bausch—that spiked Glumetza's price *by more than 800%* before generic entry began. Branded Glumetza sales topped $1.2 billion in 2016.

140. As a result of this price escalation, the value of the no-AG payment climbed to $295 million—$280 million more than Lupin would have made marketing the product for six months in 2012 with an authorized generic on the market. And this calculation assumes that the no-AG term was only six months rather than a year.

141. For Assertio/Santarus, the no-AG payment was worth far more. In the four-year period when Lupin agreed not to enter the market, Assertio/Santarus and their successors earned $2.8 billion in revenue on the drug.

142. Assertio/Santarus's no-AG payment to Lupin impaired competition in at least three ways: (1) it allocated 100% of the Glumetza market to Assertio/Santarus for the period before generic competition; (2) it allocated 100% of the generic market to Lupin for at least 180 days; and (3) it substantially delayed entry by *all* generic manufacturers.

143. Had Assertio/Santarus not paid Lupin to drop its patent challenge and delay entry onto the market, a rational economic company in Lupin's position 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. Absent the no-AG payment, a rational economic

company in the position of Assertio/Santarus, seeking to recoup lost branded sales, would have sold authorized generic Glumetza in competition with Lupin, driving prices down even further.

144. The defendants have no procompetitive explanation or justification for their 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. Typical litigation costs for patent cases of this nature rarely exceed $5.5 million. And Assertio/Santarus's expected future litigation costs at the time it unlawfully paid-off Lupin—after two years of patent litigation—were much less than that.

145. Simply put, Lupin stood to make much more money from the Assertio/Santarus's no-AG payment than from successful patent litigation. The no-AG payment was anticompetitive and unlawful regardless of whether it constitutes a reverse payment.

VII. ASSERTIO/SANTARUS AND LUPIN NEUTRALIZE COMPETITION FROM LATER FILERS.

A. Later filers were posed to upend the defendants' no-AG deal.

146. The no-AG payment significantly delayed competition between Assertio/Santarus and Lupin, depriving Glumetza purchasers of dramatically lower prices. But another potential source of competition remained: other generic manufacturers.

147. To defuse these threats, Assertio/Santarus and Lupin included other anticompetitive provisions in their deal.

148. As the first filer, Lupin was eligible to receive 180 days of exclusivity as against other ANDA filers. However, Congress purposefully created a pathway for later generic manufacturers to circumvent the first filer's exclusivity should the first filer delay in selling its generic. If a later ANDA filer obtained a final court decision that its generic Glumetza product did not infringe any of Assertio's valid patents and if Lupin failed to market its generic Glumetza within 75 days of that court decision, Lupin would forfeit its 180-day exclusivity. Because Lupin agreed to delay entry until February 1, 2016, Lupin *would* fail to enter within 75 days, and therefore *would* forfeit its exclusivity, if a later filer obtained a final, favorable court decision before November 18, 2015. That forfeiture would then enable the later filer to enter before Lupin. It would also allow other ANDA

filers to enter before Lupin if they proved in court that their products did not infringe Assertio's patents or if they reached better licensing agreements with Assertio/Santarus.

149. Generic Glumetza entry before February 2016 was likely for at least two reasons. First, Assertio's patents were narrow and therefore easy for later filers to design around. Lupin itself designed around these patents by using a reservoir system rather than a matrix system. Assertio/Santarus and Lupin knew that other generic manufacturers would do the same.

150. Second, Lupin agreed to a very long delay—nearly four years. As described in the following section, at the time Assertio/Santarus and Lupin agreed to their no-AG payment in February 2012, later generic filer Sun Pharmaceutical[10] was well into its patent litigation with Assertio/Santarus. A final court decision in that litigation would likely arrive no later than February 2015. Sun Pharmaceutical would then enjoy an exclusive or semi-exclusive period of generic Glumetza sales, before Lupin could enter the market.

B. The defendants insert a most-favored-entry clause into their no-AG deal to deter later filers from trying to enter earlier.

151. To prevent later filers from upending the anticompetitive no-AG deal, Assertio/Santarus and Lupin added two more clauses designed to put off efforts by other generic manufacturers to challenge Assertio's patents and jump the queue. First, the deal contained a most-favored-entry clause: if any other generic manufacturer succeeded in entering the market with generic Glumetza before Lupin's scheduled February 1, 2016 date, Lupin's entry would be moved up accordingly. Thus a later filer that challenged the patents and succeeded would never have the benefit of exclusivity. Instead, Lupin's launch would move up and it would share the generic market—and generic profits.

152. Second, Assertio/Santarus and Lupin agreed to a most-favored-entry-plus clause: Assertio/Santarus would not grant a license to any other manufacturer to bring a generic Glumetza to market until at least 180 days after Lupin's entry.

[10] Pharma Global FZE, Sun Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Inc. (collectively, Sun).

153. Together, these clauses prevented later filers from traveling either of the two pathways—a litigation victory or a better licensing agreement—that Congress left open to ensure that later filers could improve on the first filer's entry date.

154. While Assertio/Santarus and Lupin kept the no-AG portion of their deal confidential until 2016, they publicized the most-favored-entry clauses to ward off other generic filers from attempting earlier entry.

155. Without these clauses, Lupin faced the possibility of being stuck on the sidelines while later filers entered the market, reaping the gains associated with being the first ANDA entrants. With these clauses, the defendants were able to undermine all of the incentives that Congress created for earlier entry.

156. Assertio/Santarus and Lupin's purpose in agreeing to the most-favored-entry and most-favored-entry-plus clauses was two-fold: (i) deter later filers from trying to enter before Lupin's delayed February 2016 entry date and (ii) compensate Lupin for agreeing to the up to four years of delay by eliminating the threat that later filers would use the statutory incentives to erase Lupin's ANDA exclusivity.

C. The most-favored-entry clauses have their intended effect.

1. The most-favored-entry clauses delay Sun's entry.

157. The anticompetitive scheme worked: no generic manufacturer entered the market before Lupin's delayed February 2016 entry date.

158. Sun Pharmaceuticals (Pharma Global FZE, Sun Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Inc., collectively, "Sun") was the second manufacturer to file an ANDA seeking to market generic versions of Glumetza 500 mg and 1000 mg tablets before the expiration of the Orange Book-listed patents.

159. On or about May 6, 2011, Sun notified Assertio that it had filed ANDA 202917, detailing why its generic Glumetza did not infringe a valid claim of the relevant Orange Book patents.

160. On June 20, 2011, Assertio sued Sun in the U.S. District Court for the District of New Jersey against Sun asserting infringement of the '962, '340, '280, '475, and '987 patents listed in the

Orange Book. Valeant International Bermuda ("VIB") joined in the lawsuit as a co-plaintiff because it owned the '987 patent and exclusively licensed it to Assertio. Assertio and VIB sued Sun within 45 days of receiving Sun's paragraph IV certification, triggering the 30-month stay; the stay would expire on or about November 6, 2013.

161. Assertio also sued Sun for infringement of U.S. Patent No. 7,736,667 (the '667 patent), which is not listed in the Orange Book. The '667 patent discloses a dual-matrix, controlled-release oral dosage form. The first matrix—the "core"—comprises a water-swellable polymeric material "in which drug is dispersed." The second matrix—the "shell"—forms a "casing that surrounds and fully encases the core." This shell is composed of a water-swellable polymeric material "that swells upon imbibition of water (and hence gastric fluid) to a size large enough to promote retention in the stomach during the fed mode[.]" A drug employing a reservoir system does not, by definition, use a dual-matrix system with a core and shell that each swell upon water intake. Thus, the '667 patent, like the other Glumetza patents, was unlikely to pose a hurdle to generics using reservoir systems.

162. Like Lupin, Sun used a reservoir system to control the release of drug. Thus, like Lupin, Sun argued that its generic fell outside the claim limitations of Assertio's patents.

163. On January 25, 2013, Assertio/Santarus, VIB, and Sun signed an agreement ending the patent litigation. Sun knew that Assertio/Santarus had agreed to a most-favored-entry clause with Lupin, significantly diminishing Sun's incentive to continue its challenge. Faced with this reality, Sun agreed not to sell its generic Glumetza until August 1, 2016—180 days after Lupin entered.

164. Currently, the plaintiffs do not know whether Assertio/Santarus made any payment to Sun to ensure it would not enter the market before August 2016.

2. The most-favored-entry clauses delay Watson's entry.

165. Watson Pharmaceuticals (Watson Laboratories, Inc.-Florida, Watson Pharmaceuticals, Inc., and Watson Pharma, Inc.—collectively, "Watson") filed the third ANDA for generic Glumetza and sought to market its product before expiration of the Orange Book patents. Initially, Watson filed an ANDA for only a 1000 mg product.

166. On or about March 7, 2012, Watson notified Assertio/Santarus and VIB that it filed ANDA 203755, detailing why Watson's generic Glumetza 1000 mg would not infringe a valid claim of the relevant Orange Book patents.

167. On April 18, 2012, Assertio/Santarus and VIB sued Watson in the U.S. District Court for the District of Delaware for infringement of the Orange Book-listed patents listed at the time as covering 1000 mg Glumetza 1000 mg: the '962 and '987 patents. Filed within 45 days of receiving Watson's paragraph IV certification, the lawsuit triggered the 30-month stay and would not expire until September 7, 2014.

168. In February 2013, Assertio and VIB amended their complaint against Watson to add infringement claims for a newly listed Orange Book patent (the '692 patent) as well as two non-Orange Book listed patents (the '667 patent and U.S. Patent No. 8,329,215 (the '215 patent)).

169. The '215 patent, like the '667 patent, discloses a dual-matrix system where the dosage form employs a core and shell that each swell upon water intake. As explained, a product using a reservoir system necessarily excludes the dual-matrix and swelling properties of the '215 patent and therefore falls outside the scope of the '215 patent's claims.

170. On January 18, 2013, Watson sent Assertio/Santarus a second paragraph IV notice, explaining that Watson intended to market a generic version of Glumetza 500 mg tablets before the relevant Orange Book-listed patents expired.

171. In response, on February 28, 2013, Assertio filed a new complaint in the U.S. District Court for the District of Delaware, alleging that Watson infringed the '962, '340, '280, and '475 patents. The automatic 30-month stay precluded Watson from getting final FDA approval or selling its generic Glumetza 500 mg tablets until on or about July 18, 2015.

172. On November 8, 2013, Assertio/Santarus, VIB, and Watson signed a deal ending the patent litigation. Like Sun before it, Watson knew that Assertio/Santarus had agreed to a most-favored-entry clause with Lupin, which significantly diminished Watson's incentive to continue its challenge. Therefore, Watson agreed not to sell its generic versions of Glumetza until August 1, 2016—180 days after Lupin's negotiated entry date.

173. At present, the plaintiffs do not know whether Assertio/Santarus made any payments to Watson to ensure it would not enter the market before August 2016.

174. Absent Assertio/Santarus and Lupin's no-AG payment and most-favored-entry clauses, Sun and Watson would have entered the market years earlier than they did, on dates to be determined by a jury. The delay in generic entry protected more than $2.8 billion in branded Glumetza sales at the expense of the plaintiffs and other class members.

VIII. THE DEFENDANTS FULLY EXPLOIT THE UNLAWFUL MONOPOLY THEY CREATED

A. The defendants sell the Glumetza monopoly to Salix and then to Valeant, now known as Bausch—a ruthless exploiter of drug-product monopolies.

175. The Glumetza monopoly that Assertio/Santarus and Lupin created was a very valuable asset. Assertio/Santarus had pushed Lupin's entry to February 2016 and Sun's and Watson's to August 2016. As a result, it was not hard to find a buyer interested in exploiting it, with devastating consequences for Glumetza purchasers.

176. On November 7, 2013, Salix announced that it would acquire Santarus. Salix withheld its final agreement until it was sure Assertio/Santarus reached a deal with Watson to delay Watson's generic until August 2016. (The deal with Watson was signed the next day.) Salix's CEO reported to stock analysts that Salix was "comfortable" with the acquisition because Glumetza would not be "lost to generics" until 2016.

177. At the time Salix negotiated 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, a 37% premium to Santarus's share price before the acquisition was announced.

178. Salix's acquisition highlighted the value of the Glumetza monopoly to other investors. In February 2015—just over a year after Salix acquired Glumetza—Bausch announced that it would acquire Salix and its Glumetza monopoly.

179. When Bausch acquired Salix in April 2015, Glumetza accounted for more than 25% of Salix's sales. Bausch paid $14.5 billion for the Glumetza monopoly and the other Salix assets.

180. Bausch's business model centered on exploiting existing drug monopolies rather than innovating new medications. During the relevant time, Bausch's annual research and development budget was less than 3% of its total revenues, about a fifth of the pharmaceutical industry average. The motto of the company's CEO was "Don't bet on science—bet on management." He viewed investing in pharmaceutical research as "a losing proposition."

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

182. Bausch met those goals by acquiring companies like Salix that owned existing drug-product monopolies. Once it acquired a company, Bausch would slash the workforce—especially the scientists—and dramatically inflate the prices of the drugs it acquired. As Forbes magazine put it, Bausch's strategy "emphasized boosting drug prices, gutting research and development budgets, [and] firing employees." "[S]cientists were seen as unnecessary costs to be cut," while Bausch's "drug-price increases became legendary." Some pharmaceutical manufacturers refrain from fully exploiting their drug monopolies, due to their longer-term goals, concerns about public access, or concerns about public scrutiny. Bausch had no such concerns.

183. A former Bausch executive described the corporate mindset as, "We're the bad boys, we're successful, we can do whatever we want." The CEO admitted publicly that "[a]ll I care about is our shareholders" and "from [an investor's] standpoint [raising prices] is not a bad thing." Industry observers characterized then Valeant, now Bausch as "the pure expression of the view that companies are there to make money for shareholders, every other consideration be damned."

184. Glumetza purchasers were the "other consideration" that Bausch damned. Bausch bought the Glumetza monopoly in April 2015. By the end of July 2015, Bausch raised the price of Glumetza by more than 800%, jumping from $5.72 per 500 mg tablet in February 2015 to more than $51 per 500 mg tablet a few months later. (The cost of a 1000 mg tablet jumped from just over $12 to more than $111 in the same time.). As a result, Glumetza sales skyrocketed from $145 million in

the first two quarters of 2015 to more than $818 million in the two quarters after Bausch took the price increases.

185. Bausch's massive price increases were possible only because of the unlawful pay-for-delay deal Assertio/Santarus and Lupin agreed to in 2012. Without the unlawful payment from Assertio/Santarus to Lupin, there would have been no extended monopoly for Bausch to exploit: Lupin would have begun marketing generic Glumetza long before Bausch's acquisition of Salix, as early as May 2012. And Assertio/Santarus would have sold an authorized generic, further reducing Glumetza's price.

B. The defendants continue to exploit the Glumetza monopoly during Lupin's period of generic market exclusivity.

186. In February 2016, Lupin finally entered the market with its generic Glumetza. Bausch kept its end of the deal and did not begin marketing an authorized generic at the time. As the only generic on the market, with no competition from an authorized generic, Lupin faced no pricing pressure. It could both price at a substantially smaller discount off of the brand price than it otherwise would have and capitalize on the monstrous price increases for Glumetza that had occurred in the intervening years.

187. By the time Lupin entered, Bausch's price hikes had raised Glumetza prices to over $50 for a 500 mg tablet—or more than $200 per day to take the maximum recommended daily dose.

188. Lupin fell in line, charging more than $44 per 500 mg tablet when it launched in February 2016.

189. Glumetza purchasers in 2016 were paying more than $6,000 to take the maximum recommended daily dosage of brand Glumetza for a month and nearly $5,300 for the same amount of Lupin's generic. Compare those prices to the prices that would have been available absent the defendants' unlawful agreements: Lupin would have entered the market in 2012, Assertio/Santarus would have immediately entered the market with an authorized generic, both Sun and Watson would have entered shortly thereafter with their generics, and *Bausch's enormous price spikes would not have been possible.*

190. In 2012, the price of an equivalent 30-day supply of 500 mg branded Glumetza was about $500. By the beginning of 2015—before Bausch acquired the product and inflated its price by more than 800%—Lupin, Sun, Watson, and potentially others would have captured almost all of Glumetza's sales, with prices around $100 for the same supply of generic Glumetza.

C. Additional generic competition eventually begins and starts to drive down prices.

191. Bausch finally began marketing an authorized generic Glumetza in February 2017, a year after Lupin's entry.

192. On May 15, 2017, Teva Pharmaceutical Industries Ltd. (which acquired Watson) began marketing its generic Glumetza 500 mg and 1000 mg.

193. By the time Teva entered, prices for a 500 mg tablet of generic Glumetza had fallen by nearly half, from $44 per tablet at Lupin's launch to $23 per tablet. Generic prices continued to fall over the coming months.

194. On July 25, 2018, Sun began marketing its generic Glumetza 500 mg and 1000 mg. By then, the price of a 500 mg tablet of generic Glumetza had fallen to $16—far lower than Lupin's $44 per tablet starting price but still higher than prices would have been absent the defendants' unlawful conduct.

D. There is no shame.

195. The defendants carried out their scheme while testifying to Congress that their delay scheme—"where a central premise was a planned increase in the prices of the medicines"—"was a mistake . . . ," one which the CEO of then Valeant, now Bausch, "in hindsight," "regret[ted] pursuing."

196. On February 4, 2016, Congress held hearings regarding Bausch's exploitation of the Glumetza and other drug monopolies. The hearings established that Bausch set drug prices to reach pre-determined revenue goals and "to exploit [its] temporary monopol[ies] by increasing prices dramatically to extremely high levels very quickly." At these hearings, the late Representative Elijah Cummings lambasted Bausch's exploitation of the Glumetza monopoly, emphasizing that Bausch raised its prices "by a whopping 800 percent over a mere six-week period" and concluded that

Bausch'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."

197. To mollify Congress, the company's CEO testified on April 27, 2016 and promised that, going forward, "[w]e expect our pricing actions to track industry norms." Yet, at this very moment, Bausch continued to both sell branded Glumetza at enormously inflated prices and adhere to its unlawful agreement with Lupin. Had Bausch launched an authorized generic in 2016, Bausch could have driven the generic price down to a 48% discount off the brand. Instead, it kept its brand prices at the monopoly-enabled level and deprived purchasers of the generic competition that would have slashed their prices by approximately half in the immediate term and by even more over time.

198. Altogether, the defendants' unlawful extension of the Glumetza monopoly caused direct purchasers to overpay by more than $2.8 billion. The defendants' anticompetitive conduct continues to cause substantial overcharges today (and will continue to do so for the foreseeable future) at the rate of more than $175 million every year.

IX. MARKET EFFECTS

199. The defendants' anticompetitive conduct caused the plaintiffs and class members to pay $2.8 billion more than they would have if the market had functioned as Congress intended and as unrestrained competition would have required. Earlier entry of Lupin's generic Glumetza would have given purchasers the choice between branded Glumetza and an AB-rated generic substitute of Glumetza, priced substantially below the brand. Many purchasers would have bought the lower-priced generic drugs rather than the higher-priced brand. State law in all 50 states requires or encourages pharmacies to substitute AB-rated generics for branded prescription pharmaceuticals whenever possible. Thus, absent the defendants' anticompetitive conduct, the plaintiffs and other class members would have saved billions of dollars by paying less for branded Glumetza and purchasing generic Glumetza as early as May 2012. Instead, the defendants' anticompetitive conduct caused the plaintiffs and other class members to incur overcharges on their purchases of both branded and generic Glumetza.

200. Absent the defendants' anticompetitive conduct, Assertio/Santarus also would have sold an authorized generic Glumetza as soon as, or even before, Lupin entered the market. As

described in detail above, Santarus had a history of marketing authorized generics. And Santarus specifically negotiated the right to market an authorized generic version of Glumetza from Assertio.

201. Bausch's conduct confirms the economic rationality of marketing an authorized generic (absent an unlawful no-AG pact). Bausch, through its subsidiary Oceanside, frequently markets authorized generics when its brands face generic competition. Bausch launched authorized generics for its brands Syprine, Mephyton, Uceris, Xenazine Tabs, Vanos, and Retin-A Micro. Indeed, Bausch began marketing an authorized generic version of Glumetza in February 2017, after its no-AG pact with Lupin expired. After Bausch'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."

202. Absent the unlawful no-AG payment, Assertio/Santarus would have launched an authorized generic as soon as or before Lupin entered the market as early as May 2012. This authorized generic entry would have significantly reduced the prices of both branded and generic Glumetza beginning in 2012.

203. The defendants' unlawful most-favored-entry clauses compounded the no-AG payment's anticompetitive effects. The most-favored-entry clauses prevented Sun and Watson from undoing the delay in generic entry that the no-AG payment caused. Those anticompetitive clauses undermined the incentives that Congress had provided for Sun, Watson, and other potential competitors to enter the market before Lupin's February 2016 entry date. Absent the most-favored-entry clauses, Sun and Watson would have entered the market much sooner than they did, well before 2015. The most-favored-entry clauses caused plaintiffs and other class members to incur overcharges on their purchases of both branded and generic Glumetza.

204. The defendants' anticompetitive conduct is also responsible for Bausch's acquisition and exploitation of the Glumetza monopoly. Absent the defendants' unlawful reverse payment, Lupin would have begun to market generic Glumetza as soon as May 2012, and there would not have been any Glumetza monopoly for Bausch to exploit. Absent the Glumetza monopoly, the mid-2015 price increases on Glumetza never would have occurred (or, if it occurred, it would have affected

only a minuscule number of unit sales). Bausch's price escalation on the entire prescription base for Glumetza would not have been possible and would not have occurred absent the pay-for-delay deal.

205. Absent the defendants' unlawful conduct, Lupin would have entered the market in or about 2012, when the brand price for Glumetza was about $5 per 500 mg tablet. Generic competition would then have driven the price of Glumetza down to $4 or less per 500 mg tablet had it launched in 2012.

206. As a result of the delay in generic entry and the defendants' exploitation of the monopoly that the delay created, only the branded product was available in 2015, and by the end of July 2015 the price of Glumetza jumped from $5.72 per 500 mg tablet to more than $51 per 500 mg tablet. The plaintiffs and other class members incurred substantial overcharges from 2012 until 2015, and they continue to incur ongoing and accumulating overcharges today.

207. The defendants' unlawful conduct further harmed the plaintiffs and class members by vastly increasing the prices generic Glumetza manufacturers could charge. When entering a market, generic manufacturers price their products based on a percentage discount off of the then-prevailing brand price. Absent the defendants' unlawful conduct, the generics would have entered in or about 2012, when the price for Glumetza was $5 per 500 mg tablet. Thus, the defendants' unlawful conduct has caused the plaintiffs and class members to pay substantial overcharges on their purchases of Glumetza generics, beginning in February 2016 and continuing until today.

X. MARKET POWER

208. At all relevant times, the defendants had substantial market power over Glumetza and its generic equivalents. The defendants had the power to maintain the prices of those drugs at supracompetitive levels without losing sufficient sales to other products, except for AB-rated generic versions of Glumetza, to make the supracompetitive prices unprofitable.

209. A significant, non-transitory increase in the price of brand 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, brand Glumetza does not exhibit significant, positive cross-elasticity of demand with any product or treatment for diabetes other than AB-rated generic versions of Glumetza.

210. Direct evidence of the defendants' market power includes the following: (a) absent the 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; (c) the defendants' gross margin on Glumetza (including the costs of ongoing research/development and marketing) at all relevant times exceeded 70%; (d) the defendants never lost Glumetza sales or lowered the price of Glumetza to the competitive level in response to the pricing of other brand or generic drugs except AB-rated generic Glumetza; (e) from 2012 to 2015, the defendants profitably raised the price of Glumetza by more than 40%; and (f) in 2015, the defendants profitably raised the price of Glumetza by more than 800%.

211. The defendants' power to profitably raise these prices above the competitive level results in substantial part from a significant imperfection in the United States marketplace for prescription pharmaceuticals. Branded drug manufacturers can exploit this imperfection to obtain or maintain market power.

212. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the product choice and the payment obligation, the product's price plays an appropriate role in the person's choice and, consequently, manufacturers have an appropriate incentive to reduce their prices to the competitive level.

213. In the pharmaceutical marketplace, there is a disconnect between product selection and payment. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Glumetza, to patients without a prescription. Patients must obtain prescriptions from their physicians. However, a patient's physician has no role in the purchase of the prescription medication. The patient's doctor chooses which product the patient will buy, while the patient (and in most cases his or her insurer) must pay for it.

214. Brand manufacturers, including Assertio, Santarus, Salix, and Bausch, exploit this disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors on the cost of

their branded products. Studies show that doctors are typically unaware of the relative costs of brand pharmaceuticals and, even when they are aware, are largely insensitive to price differences because they do not pay for the products. The result is a marketplace where price plays a comparatively unimportant role in product selection.

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

216. During the relevant time, the 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 these prices unprofitable.

217. The availability of other diabetes medications did not constrain the price of Glumetza to the competitive level. Brand Glumetza is therapeutically differentiated from all diabetes products other than AB-rated generic versions of Glumetza. As a result, the defendants needed to control only Glumetza and its AB-rated generic equivalents to maintain the price of Glumetza at a supracompetitive level. Only the market entry of a competing, AB-rated generic version of Glumetza could prevent the defendants from profitably maintaining prices at supracompetitive levels.

218. In general, metformin is considered the first-line treatment for type 2 diabetes. It is not reasonably interchangeable with other type 2 diabetes drugs. This reality stems, in part, from 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 a better cardiovascular mortality profile than another class of popular type 2 diabetes medications, sulfonylureas. Metformin is further considered weight neutral or helps people lose weight.

219. Glumetza is not therapeutically interchangeable with metformin products that are unavailable in an extended-release form. Metformin can cause gastrointestinal side effects, which extended-release formulations mitigate. Additionally, extended-release forms of metformin can reduce daily dosing to a single, once-a-day pill, allowing for a simpler dosing regimen. Simpler dosage regimens with more tolerable side-effects significantly improve patient adherence. Doctors take such adherence into account when selecting drugs for their patients. The differing efficacy, dosing, safety, and side-effect profiles of oral, type 2 diabetes drugs play a critical role in doctors' drug selection for each patient.

220. 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 factors, the way different patients react to the products' varying release mechanisms.

221. A substantial number of doctors view Glumetza as offering reduced gastrointestinal side effects as 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 metformin over a period of 8 to 10 hours. The dissolved metformin is then mixed with other contents of the patient's stomach and transported into the duodenum, where it is absorbed. Many doctors believe this process is responsible for the fewer gastrointestinal side effects associated with Glumetza as compared to other extended-release metformin products.

222. In their marketing, Assertio/Santarus, Salix, and Bausch differentiated Glumetza from other extended-release metformin products on the grounds that it keeps metformin in the patient's stomach, allowing for a constant, multi-hour flow of the drug into the gastrointestinal tract. The defendants claimed that Glumetza offered patients an enhanced opportunity for increased absorption of metformin. They touted to investors and others that "physicians are receptive to Glumetza's differentiating features of controlled delivery and [gastrointestinal] tolerability." Moreover, the extended-release mechanism dissolves at the end of its useful life and is passed through the gastrointestinal tract and eliminated.

223. In contrast, 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 moves into the tablet through the holes and dissolves the metformin inside. The tablet then releases the dissolved metformin through those holes at a constant rate as the tablet moves through the small intestine (patients typically will see the pill's shell in their stool). Based on this drug delivery in the small intestine, a substantial number of doctors believe that Fortamet is more likely to cause gastrointestinal side effects.

224. Substantial price decreases for other extended-release metformin products did not constrain the price of brand 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 quarterly unit sales of Glumetza *increased* even though the price increased by more than 40%. The percentage increase in Glumetza net revenue (net of all discounts, rebates, etc.) was at least as great.

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

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

227. To the extent that the plaintiffs are required to prove market power through circumstantial evidence by first defining a relevant product market, they allege that the relevant antitrust market is the market for Glumetza and its AB-rated generic equivalents.

228. At all relevant times, the defendants were protected by high barriers to entry due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician

detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The products in these markets require significant investments of time and money to design, develop, and distribute. In addition, the markets require government approvals to enter and/or the drugs at issue may be covered by patents or other forms of intellectual property. The defendants' unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants could not enter and/or expand output quickly in response to the defendants' higher prices or reduced output.

229. The relevant geographic market is the United States and its territories. The defendants Assertio, Santarus, Salix, and Bausch's market share in the relevant market was 100% until Lupin's entry in 2016.

XI. EFFECT ON INTERSTATE COMMERCE

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

231. During the relevant time period, the plaintiffs and class members purchased substantial amounts of Glumetza and/or generic Glumetza directly from the defendants. As a result of the defendants' illegal conduct, the plaintiffs and class members were compelled to pay, and did pay, artificially inflated prices for Glumetza and generic Glumetza.

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

XII. CLASS ACTION ALLEGATIONS

233. Plaintiffs bring this action on behalf of themselves and, under Federal Rules of Civil Procedure 23(a) and 23(b)(2) and (b)(3), as representatives of a class defined as:

> All persons or entities in the United States and its territories who directly purchased Glumetza or generic Glumetza from a defendant from May 6, 2012 until the effects of the defendants' conduct ceased (the class).

234. Excluded from the class are the defendants and any of their officers, directors, management, employees, subsidiaries, and affiliates.

235. Also excluded from the class are: (1) the government of the United States and all agencies thereof; and (2) all state or local governments and all agencies thereof.

236. Members of the class are so numerous and geographically dispersed that joinder of all members is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The class is readily identifiable from information and records in the defendants' possession.

237. The plaintiffs' claims are typical of those of the class members. The plaintiffs and all class members were damaged by the same wrongful conduct of the defendants—*i.e.*, as a result of the defendants' conduct, class members paid artificially inflated prices for Glumetza and AB-rated generic equivalents.

238. The plaintiffs will fairly and adequately protect and represent the class's interests. The plaintiffs' interests are coincident with, and not antagonistic to, those of the other class members.

239. Counsel who represent the plaintiffs are experienced in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation involving pharmaceutical products.

240. Questions of law and fact common to the class members predominate over questions that may affect only individual class members because the defendants have acted on grounds generally applicable to the entire class. This conduct render overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent to the defendants' wrongful actions.

241. Questions of law and fact common to the class include:

i. Whether the defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

ii. Whether there exist any legitimate procompetitive reasons for some or all of the defendants' conduct;

iii. To the extent any such procompetitive benefits exist, whether there were less restrictive means of achieving them;

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

v. Whether the defendants' scheme, in whole or in part, has substantially affected interstate commerce;

vi. Whether the defendants' scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of the plaintiffs and the class members;

vii. Whether the defendants conspired to delay generic competition for Glumetza;

viii. Whether, pursuant to the no-AG pact, Assertio/Santarus, Salix, and Bausch's promise not to compete against Lupin's generic product constituted a large and unjustified payment;

ix. Whether the defendants' no-AG payment was necessary to yield some cognizable, non-pretextual, procompetitive benefit;

x. Whether the no-AG payment and most-favored-entry clauses caused Sun, Watson, and/or other generic manufacturers to delay entry into the market;

xi. Whether the most-favored-entry clauses were necessary to yield some cognizable, non-pretextual, procompetitive benefit;

xii. Whether the defendants' conduct created a bottleneck to delay generic competition from manufacturers that filed ANDAs after Lupin;

xiii. Whether the defendants' conduct harmed competition;

xiv. Whether the defendants possessed the ability to control prices and/or exclude competition for Glumetza;

xv. Whether the defendants' unlawful conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Glumetza; and

xvi. The quantum of overcharges paid by the class in the aggregate.

242. 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 require. The benefits of proceeding through the class mechanism—including providing injured persons or entities

with a method for obtaining redress on claims that they could not practicably pursue on an individual basis—substantially outweigh potential difficulties in management of this class action.

243. The defendants' anticompetitive conduct has imposed and will continue to impose (unless the plaintiffs obtain equitable relief) a common antitrust injury on plaintiffs and all class members. The defendants' anticompetitive conduct and their relationships with the Class members have been substantially uniform. The defendants have acted and refused to act on grounds that apply to the class generally, and injunctive and other equitable relief is appropriate respecting the class as a whole.

244. The plaintiffs know of no special difficulty in litigating this action that would preclude its maintenance as a class action.

XIII. DEFENDANTS CONCEALED THEIR UNLAWFUL AGREEMENTS

245. A cause of action accrued for the plaintiffs each time a brand or generic Glumetza product was sold to the plaintiffs at the supracompetitive prices the defendants' anticompetitive conduct made possible. And each sale of brand or generic Glumetza at supracompetitive prices constituted an overt act in furtherance of the defendants' continuing anticompetitive scheme. Other overt acts in furtherance of the defendants' continuing conspiracy include, but are not limited to, Lupin's decision not to enter the market until February 2016 and Bausch's decision not to launch an authorized generic Glumetza until February 2017. As a result, the plaintiffs are entitled to recover all damages on all branded and generic Glumetza sales made to the plaintiffs at supracompetitive prices within four years of the filing of this lawsuit.

246. Due to the defendants' fraudulent concealment of their unlawful conduct, however, the plaintiffs and class members are entitled to recover damages extending back beyond four years before the filing of this complaint. Plaintiffs and class members had no knowledge of the defendants' unlawful 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.

247. The defendants' scheme was self-concealing, and the defendants employed deceptive tactics to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and scheme.

248. The defendants wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from the plaintiffs and class members. The 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 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, the plaintiffs now believe 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, under their settlement, Assertio and Lupin asked the 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."[11] 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.[12]

c. In (at least) the following SEC filings, Santarus referred to the 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 5, 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 34 (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 (at least) the following SEC filings, Salix referred to the February 2016 entry date, but omitted all references to the no-AG payment: Salix Pharmaceuticals, Ltd., Annual Report (Form 10-K), at 9 (March 1, 2013); Salix Pharmaceuticals, Ltd., Annual Report (Form 10-K), at 7 (February 28, 2014).

e. In addition to the May 8, 2012 SEC filing discussed above, in (at least) the following SEC filings Assertio (formerly known as Depomed, Inc.) referred to the February

[11] Consent Injunction and Dismissal Order, *Depomed, Inc. v. Lupin Pharmaceuticals*, *Inc., et al.,* No. 4:09-cv-05587-PJH, ECF No. 152, at p. 1 (March 27, 2012).

[12] *See id*. at 5(a).

2016 entry date, but omitted all references to the no-AG payment: Depomed Inc., Annual Report (Form 10-K), at 6, 115 (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 (November 9, 2013); 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 call with stock analysts on May 8, 2012, Assertio referred to the February 2016 entry date, but omitted all references to the no-AG payment.

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

h. In calls with stock analysts on November 7, 2013 and January 16, 2014, Salix referred to the February 2016 entry date, but omitted all references to the no-AG payment.

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

249. The defendants did not publicly disclose the no-AG payment until doing so suited their interests. Specifically, Lupin tried, in a February 5, 2016 call with stock analysts, to inflate the value of its stock. To convince stock analysts that it would make extraordinary profits on the sale of its generic Glumetza, Lupin revealed that the settlement included a no-AG pact. The plaintiffs filed this complaint within four years of that first public revelation of the no-AG payment.

250. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by the defendants, the plaintiffs and class members had no knowledge of the scheme and conspiracy more than four years before the filing of this complaint; they did not have the facts nor information that would have caused a reasonably diligent person to investigate whether a conspiracy existed; and if the facts or information had been available to them and they attempted an investigation, that investigation would not have revealed the existence of the defendants' unlawful conspiracy.

251. The plaintiffs and class members lacked the facts and information necessary to form a good faith basis for the belief that any legal violations occurred. Reasonable diligence on the part of the plaintiffs and class members would not have uncovered those facts more than four years before the filing of this complaint.

252. The partially redacted settlement agreement that Assertio included in its May 8, 2012 SEC filing revealed the existence of a most-favored-entry clause. It also revealed an outline of what may be the most-favored-entry-plus clause, but it did not include that clause's essential terms. The plaintiffs learned of that clause's essential terms—and could have only learned of them (through the exercise of reasonable diligence)—only through information gained and events occurring within the last four years.

253. The plaintiffs do not allege that the most-favored-entry clause or most-favored-entry-plus clause, alone or together with each other, is unlawful. As alleged in detail above, these clauses prevented later filers from unraveling the anticompetitive effects of the no-AG payment. That is, the plaintiffs allege that the most-favored-entry clauses are anticompetitive in the context of an unlawful conspiracy where the no-AG payment is the centerpiece. The plaintiffs became aware of that context—and could have become aware of it (through the exercise of reasonable diligence—only after learning of the no-AG payment.

254. As a result of the defendants' fraudulent concealment, all applicable statutes of limitations affecting the plaintiffs' and class members' claims have been tolled.

XIV. CLAIMS FOR RELIEF

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

255. The plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

256. The defendants violated 15 U.S.C. § 1 by entering into and/or furthering an unreasonable restraint of trade, defined as: Assertio/Santarus, Salix, and Bausch's agreement with Lupin, and adherence to that agreement, to make a reverse payment—the no-AG payment—in exchange for Lupin's agreement to delay its generic Glumetza until February 1, 2016, and to allocate the market for branded and generic Glumetza.

257. At all relevant times, the defendants individually and/or collectively had substantial market power with respect to sales of Glumetza and its AB-rated generic equivalents in the United States.

258. On or about February 22, 2012, the defendants entered into a reverse payment agreement—a continuing illegal contract, combination, and restraint of trade—under which Assertio/Santarus, Salix, and Bausch agreed to pay, and paid, Lupin substantial consideration in exchange for Lupin's agreement to delay market entry of its generic version of Glumetza. The purpose and effect of this agreement was to: (a) delay generic entry of Glumetza to lengthen the period in which brand Glumetza would make supracompetitive profits; (b) keep an authorized generic off the market during Lupin's 180-day ANDA exclusivity period, or longer, therein enabling Lupin to charge supracompetitive prices and make supracompetitive profits on sales of generic Glumetza; (c) delay the date that other generic manufacturers would enter the market; and (d) raise and maintain the prices that the plaintiffs and other class members would pay for Glumetza and its AB-rated equivalents at supracompetitive levels.

259. There is and was no legitimate, non-pretextual, procompetitive justification for the anticompetitive restraint. Even if there was some conceivable and cognizable justification, the no-AG payment was unnecessary to achieve such a purpose, and the restraint's anticompetitive effects on direct purchasers, competition, and consumers outweighed any such procompetitive effects.

260. As a direct result of the defendants' violation of 15 U.S.C. § 1, the plaintiffs and other class members have been injured. Unless the plaintiffs obtain equitable relief, the defendants' violation will continue to injure the plaintiffs in their business or property. The plaintiffs' and class members' injury consists of their past and continued payment of higher prices for their Glumetza requirements than they would have paid in the absence of the violation. Such injury, known as "overcharges," is the type of injury the antitrust laws were designed to prevent. This overcharge injury flows from the defendants' unlawful conduct. The plaintiffs are the proper entities to bring a case concerning this conduct.

COUNT TWO
VIOLATION OF 15 U.S.C. § 2
(AGAINST ALL DEFENDANTS)

261. The plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

262. The defendants violated 15 U.S.C. § 2 by monopolizing and conspiring to monopolize the market for Glumetza and its AB-rated equivalents in the United States.

263. At all relevant times, the defendants possessed substantial market power (*i.e.*, monopoly power) with respect to Glumetza and its AB-rated equivalents. The defendants possessed the power to control prices in the relevant market, to prevent prices from falling in the relevant market, and to exclude competitors from the relevant market.

264. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

265. As alleged extensively above, the defendants willfully maintained monopoly power by using restrictive or exclusionary conduct, rather than using greater business acumen. This conduct injured plaintiffs and the class.

266. The defendants' conscious objective was to further their dominance through exclusionary conduct.

267. As stated more fully above, the defendants knowingly, willfully, and wrongfully maintained monopoly power and harmed competition by:

- Entering into and abiding by the no-AG payment; and
- Entering into and abiding by the most-favored-entry clauses.

268. The defendants' anticompetitive conduct is exclusionary conduct—the purpose and effect of which is to willfully maintain monopoly power, which harms purchasers, the competitive process, and consumers, in violation of § 2 of the Sherman Act.

269. To the extent that the defendants are permitted to assert one, there is and was no cognizable, non-pretextual, procompetitive justification for their exclusionary conduct that outweighs its harmful effects. Even if there were some conceivable justification that the defendants were permitted to assert, their conduct is and was broader than necessary to achieve such a purpose.

270. The plaintiffs and the class have been injured and will continue to be injured —unless they obtain equitable relief—in their business and property as a result of the defendants' continuing monopolization in violation of § 2 of the Sherman Act.

XV. DEMAND FOR JUDGMENT

271. WHEREFORE, the plaintiffs, on behalf of themselves and the proposed class, respectfully demand that this Court:

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

II. Enter joint and several judgments against the defendants and in favor of the plaintiffs and the class;

III. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

IV. Grant permanent injunctive relief pursuant to § 16 of the Clayton Act to remedy the ongoing anticompetitive effects of the defendants' unlawful conduct;

V. Award the plaintiffs and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

VI. Award such further and additional relief as the case may require and the court may deem just and proper under the circumstances.

JURY DEMAND

272. Pursuant to Fed. Civ. P. 38, the plaintiffs on behalf of themselves and the proposed class demand a trial by jury on all issues so triable.

DATED: November 25, 2019

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E-FILING ATTESTATION

I, Lauren Guth Barnes, am the ECF User whose ID and password are being used to file this document. In compliance with Civil Local Rule 5-1(i)(3), I hereby attest that each of the signatories identified above has concurred in this filing.

/s/ Lauren G. Barnes
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