UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

DROGUERIA BETANCES, LLC, on behalf of itself and all others similarly situated, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS CORPORATION, ENDO PHARMACEUTICALS, INC., ENDO INTERNATIONAL PLC, and PAR PHARMACEUTICAL, INC., Defendants.	Case No. 1:18-cv-04361-AKH
ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS CORPORATION, ENDO PHARMACEUTICALS, INC., ENDO INTERNATIONAL PLC, and PAR PHARMACEUTICAL, INC., Defendants.	Case No. 1:18-cv-05708-AKH
FWK HOLDINGS, LLC, on behalf of itself and all others similarly situated, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS CORPORATION, ENDO PHARMACEUTICALS, INC., ENDO INTERNATIONAL PLC, and PAR PHARMACEUTICAL, INC., Defendants.	Case No. 1:18-cv-05886-AKH

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Drogueria Betances, LLC, Rochester Drug Co-Operative, Inc., and FWK Holdings, LLC, ("Plaintiffs"), on behalf of themselves and all others similarly situated, bring this Consolidated Amended Class Action Complaint against Novartis Pharmaceuticals Corporation, Novartis AG, and Novartis Corporation (collectively, "Novartis"); and Endo Pharmaceuticals, Inc., Endo International plc, and Par Pharmaceutical, Inc. (collectively, "Par") (together, Novartis and Par are "Defendants"), for Defendants' violations of the antitrust laws concerning the pharmaceutical drug Exforge® (fixed combination products comprising the active ingredients amlodipine and valsartan) ("Exforge"). Based on (a) personal knowledge, (b) the investigations of counsel, and (c) information and belief, Plaintiffs allege:

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages arising out of Defendants' anticompetitive conduct that delayed generic competition in the United States and its territories for Exforge, a U.S. Food and Drug Administration ("FDA") approved prescription drug product for the treatment of hypertension, comprising the active ingredients amlodipine and valsartan. Plaintiffs seek overcharge damages arising out of Novartis's unlawful agreement with Par not to compete in the market for Exforge and corresponding AB-rated generic drug products.

2. Prior to the market entry of generic equivalents of Exforge, Novartis's U.S. sales of branded Exforge exceeded $414 million annually.

3. Generic manufacturers Par and Synthon Pharmaceuticals Inc. ("Synthon") recognized the huge market potential for Exforge and, in or about October and November, 2007, became the first generic drug makers to file Abbreviated New Drug Applications ("ANDAs") with the FDA seeking approval to market generic amlodipine and valsartan tablets, with Exforge as their Reference Listed Drug.

4. Par was the first to file an ANDA for the 10/160, 5/160 and 10/320 milligram strengths of amlodipine and valsartan, while Synthon was the first to file an ANDA for the 5/320 milligram strength. On information and belief, upon filing their ANDAs in October and November of 2007, Par and Synthon provided notice to Novartis that: (1) they would not seek final FDA approval for the Exforge ANDAs until the September 21, 2012 expiration of exclusivities associated with U.S. Patent No. 5,399,578 (the "'578 Patent"), which covered the active ingredient valsartan; but (2) they would seek final FDA approval to market, and intended to launch, their ANDA products prior to the expiration of the follow-on patents, U.S. Patent Nos. 6,294,197 (the "'197 Patent") and 6,395,728 (the "'728 Patent"), which they claimed were invalid and/or would not be infringed by Par's and Synthon's proposed generic equivalents.[1]

5. On November 30, 2011, Par entered into an asset purchase agreement with Synthon under which Par would acquire Synthon's ANDA for a generic version of Exforge. On December 30, 2011, the asset purchase agreement closed.

6. On information and belief, Novartis did not sue Par or Synthon for patent infringement, but instead, in or around 2011, Par and Novartis reached an agreement (the "Agreement") under which (1) Par agreed not to compete in the market for fixed combinations of amlodipine and valsartan until September 30, 2014, thereby allocating the entire Exforge market to Novartis for years beyond the expiry of the '578 Patent, and (2) Novartis agreed not to compete in the market for *generic* Exforge by agreeing not to launch an "authorized generic" (or "AG") from September 30, 2014 until March 30, 2015, thereby restricting output and/or allocating 100% of generic sales to Par for six months and depriving the market for fixed combinations of

[1] The regulatory exclusivities associated with the '197 Patent expired on December 18, 2017. The '728 Patent will expire on July 8, 2019.

amlodipine and valsartan of an additional competitor and lower prices.

7. On March 19, 2010, the FDA granted tentative approval to Par's ANDA for generic versions of Exforge, determining that Par's ANDA for generic Exforge was approvable and satisfied all bioequivalence; chemistry, manufacturing, and controls ("CMC"); and labeling requirements.

8. On March 28, 2013, the FDA granted final approval to Par's ANDA for generic versions of Exforge.

9. On information and belief, the FDA granted tentative approval to Synthon's ANDA for a generic version of Exforge prior to March 28, 2013, determining that Synthon's ANDA for generic Exforge was approvable and satisfied all bioequivalence, CMC, and labeling requirements.

10. Because of Defendants' unlawful Agreement and conduct, no generic version of Exforge was available for Plaintiffs and other direct purchasers in the United States, including its territories, possessions, and the Commonwealth of Puerto Rico until September 30, 2014 and, for a period of six months thereafter, the only generic available was Par's product.

11. But for Defendants' unlawful Agreement and conduct, one or more generic versions of Exforge would have entered the market as early as September 21, 2012, when the exclusivities associated with the '578 Patent expired, but no later than March 28, 2013, when FDA granted final approval to Par's ANDA; and Novartis would have simultaneously launched an authorized generic version of Exforge. Thus, absent Defendants' unlawful Agreement and conduct, Plaintiffs and members of the Class would have been able to satisfy their requirements for fixed combinations of amlodipine and valsartan at significantly lower prices substantially earlier than they did.

12. By and through the Agreement, Novartis and Par agreed to divide ill-gotten

revenues, both during the period in which Par agreed to delay generic entry, and during Par's 180-day period of generic market exclusivity over which Novartis agreed not to launch an authorized generic version of Exforge, all of which resulted in anticompetitive overcharges to direct purchasers.

13. Defendants thus violated Sections 1 and 2 of the Sherman Act through their anticompetitive Agreement and conduct that allocated markets, restricted output, and improperly maintained and extended Novartis's market and monopoly power by (1) foreclosing or delaying competition from lower-priced generic versions of Exforge; (2) foreclosing or delaying competition from an authorized generic version of Exforge that otherwise would have appeared on the market at an earlier time; and (3) fixing, raising, maintaining, or stabilizing the prices of Exforge and its generic equivalents at supra-competitive levels.

14. Plaintiffs and all others similarly situated were injured and sustained damages in the form of overcharges for branded and generic forms of Exforge as a direct result of Novartis's and Par's unlawful Agreement. Plaintiffs and the putative class file this suit to recover these overcharges (trebled).

II. JURISDICTION AND VENUE

15. This Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover treble damages and the costs of suit, including reasonable attorneys' fees, for the injuries Plaintiffs and members of the Class sustained because of Defendants' violations, as herein alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. This Court's jurisdiction is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

16. The Defendants named herein transact business within this judicial district, and the

interstate trade and commerce hereinafter described was and is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

17. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

18. During the Class Period (defined below), Novartis and Par manufactured, sold, and shipped Exforge and generic Exforge, respectively, in a continuous and uninterrupted flow of interstate commerce. The contract and conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

19. During the Class Period each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their Agreement and conspiracy.

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

III. THE PARTIES

21. Plaintiff Drogueria Betances, LLC, a limited liability company organized under the laws of the Commonwealth of Puerto Rico and maintaining its principal place of business at Ave. Luis Munoz Marin, Caguas, Puerto Rico 00725, purchased branded and generic Exforge directly from Novartis and Par, respectively, during the Class Period as defined below, and was

injured by the illegal conduct described herein. On or about September, 2015, Drogueria Betances, Inc. converted into a limited liability company and became Drogueria Betances, LLC.

22. Plaintiff Rochester Drug Co-Operative, Inc. is a stock corporation duly formed and existing under the laws of the New York Cooperative Corporations Law and maintains its principal place of business at 50 Jet View Drive, Rochester, New York 14624. Plaintiff Rochester Drug Co-Operative, Inc. purchased branded and generic Exforge directly from Novartis and Par, respectively, during the Class Period as defined below, and was injured by the illegal conduct described herein.

23. Plaintiff FWK Holdings, LLC ("FWK") is an Illinois limited-liability corporation with its principal place of business in Glen Ellyn, Illinois. FWK is the assignee of antitrust claims possessed by Frank W. Kerr Company ("Kerr") and brings this action as successor-in-interest to Kerr's claims arising from its purchase of Exforge and generic Exforge directly from one or more of the Defendants during the Class Period. As a result of Defendants' antitrust conspiracy, FWK, through its assignor Kerr, paid supra-competitive prices for its purchases of branded and generic Exforge and was injured by the illegal conduct alleged herein.

24. Defendant Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware. Novartis Pharmaceuticals Corporation's principal place of business is One Health Plaza, East Hanover, New Jersey 07936. Novartis Pharmaceuticals Corporation is a subsidiary of Defendant Novartis AG and holds the rights to manufacture, market and sell the prescription brand drug Exforge. As the pharmaceuticals unit of Novartis Corporation and Novartis AG, Novartis Pharmaceuticals Corporation develops, manufactures, markets, and sells Novartis Corporation's and Novartis AG's drugs in the United States.

25. Defendant Novartis AG is a corporation organized and existing under the laws of

Switzerland, having an office and a place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland. It is the parent of both Novartis Corporation and Novartis Pharmaceuticals Corporation.

26. Defendant Novartis Corporation is a corporation organized and existing under the laws of the State of New York, having its principal place of business at One Health Plaza, East Hanover, New Jersey 07936. Novartis Corporation is essentially the U.S. headquarters of Switzerland-based Novartis AG. Novartis Corporation handles the administration, sales, and marketing of a wide variety of prescription drugs, vaccines, consumer medicines, and veterinary products. It is the parent corporation of Novartis Pharmaceuticals Corporation—its and Novartis AG's pharmaceuticals unit.

27. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical, Inc. principally develops, manufactures, and markets generic versions of brand name drugs.

28. Defendant Endo International plc is a private limited company incorporated and existing under the laws of Ireland, having its principal place of business at 1st Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland, and a U.S. headquarters at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

29. Defendant Endo Pharmaceuticals, Inc. is a Delaware corporation, having its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Endo Pharmaceuticals, Inc. and Endo International plc are referred to collectively as "Endo." On September 28, 2015, Endo completed an acquisition of Defendant Par Pharmaceutical, Inc. On information and belief, Endo assumed all of Par Pharmaceutical, Inc.'s liabilities upon acquiring it.

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

IV. CLASS ACTION ALLEGATIONS

31. Plaintiffs bring this action on behalf of themselves and, under Federal Rule of Civil Procedure 23(a) and (b)(3), as representatives of a class of direct purchasers (the "Class" or "Direct Purchaser Class") defined as follows:

> All persons or entities in the United States, including its territories, possessions, and the Commonwealth of Puerto Rico, who purchased Exforge directly from Novartis, or who purchased a generic version of Exforge directly from Par, at any time during the Class Period from September 21, 2012, until the effects of Defendants' conduct ceases. Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.

32. Members of the Direct Purchaser Class are so numerous and/or geographically dispersed, that joinder is impracticable. While the exact number of Class members is unknown to Plaintiffs, it is believed to be between approximately fifty and one-hundred fifty. The Class is readily identifiable from information and records in Defendants' possession.

33. Plaintiffs' claims are typical of members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, Defendants' anticompetitive conduct deprived them of the benefits of competition from less-expensive generic versions of Exforge, causing them to pay artificially inflated prices for Exforge and its generic equivalents.

34. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

35. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and particularly class action antitrust litigation in the pharmaceutical industry.

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

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

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

b. whether a relevant market needs to be defined in this case in light of the existence of direct proof of Novartis's power to exclude generic competition and charge supra-competitive prices for Exforge and/or the *per se* illegal nature of the challenged conduct;

c. if a relevant market needs to be defined, what the definition of the relevant market for analyzing Novartis's monopoly power is, and whether Novartis had monopoly power in the relevant market;

d. whether Defendants' illegally obtained or maintained monopoly power in the relevant market;

e. whether Defendants' actions constituted a *per se* illegal market allocation or output restriction agreement;

f. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

g. whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiffs and the Direct Purchaser Class; and

h. if so, the appropriate measure of damages.

38. Class action treatment is a superior method for the fair and efficient adjudication of

the controversy. Among other things, class 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, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that could not be practicably pursued individually, substantially outweighs potential difficulties in management of this class action.

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

V. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Drugs

40. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer who creates a new drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-92. A NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. §§ 355(a), (b).

41. When the FDA approves a brand manufacturer's NDA, the brand manufacturer may list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (called the "Orange Book") any patent that it certifies (1) claims either the approved drug product or approved methods of using the drug product and (2) could reasonably be asserted against a generic manufacturer who makes, uses, or sells the drug product without authorization prior to the expiration of the listed patent(s). Patents issued after NDA approval must be listed in the Orange Book within 30 days of issuance. 21 U.S.C. §§ 355(b)(1), (c)(2).

42. The FDA relies completely on the brand manufacturer's certification about its patents, as the FDA does not have the resources or authority to verify for accuracy or trustworthiness whether those patents are valid and enforceable, and actually cover the drug. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

43. In 1984, Congress enacted the Hatch-Waxman Amendments to the FDCA to expedite the entry of less expensive generic competitors to brand drugs to reduce healthcare expenses nationwide, while also providing for patent term extensions and the ability to file pre-launch infringement suits to bolster pharmaceutical companies' financial incentives to create new and innovative products. *See generally*, Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

44. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historic revenues and profits for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 86% of prescriptions.[2] Generics are now dispensed 95% of the time when a generic form is available.[3]

45. The Hatch-Waxman Amendments simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A

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[2] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014).

[3] *Id.* at 51.

manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA. The ANDA applicant must further show that the generic drug is bioequivalent (*e.g.*, that the active ingredient of the proposed generic drug is absorbed in the patient's blood stream to the same extent and for the same amount of time as the brand counterpart, 21 U.S.C. § 355(j)(8)(B)), and that it is pharmaceutically equivalent (*e.g.*, that it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug). Generic drugs that are both bioequivalent and pharmaceutically equivalent are considered "therapeutically equivalent" to the brand drug. *See generally* 21 U.S.C. §355(j) *et seq*.

46. The FDCA and Hatch-Waxman Amendments operate on the proven scientific principle that therapeutically equivalent drugs are substitutable. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by the FDA, a designation which causes a pharmacy presented with a prescription for the brand to automatically dispense the generic instead.

2. Paragraph IV Certifications

47. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

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

b. that the patent for the brand drug has expired (a "Paragraph II certification");

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

d. that the patent for the brand drug is invalid, unenforceable, and/or will not be infringed by the generic manufacturer's proposed product (a "Paragraph

IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

48. To obtain FDA approval of an ANDA prior to the expiration of a patent or patents listed in the Orange Book, a generic manufacturer must file a Paragraph IV certification and serve timely notice to the brand manufacturer. The filing of an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement pursuant to 35 U.S.C. § 271(e)(2). If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notice of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months (the "30-month stay"), or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA may grant tentative approval to an ANDA when it determines that the ANDA would otherwise be ready for final approval but for the existence of an unexpired patent for which the generic filer has submitted a Paragraph III certification (*i.e.*, that the generic does not intend to market the ANDA product prior to the expiration of the patent) or the existence of a regulatory exclusivity, such as the 30-month stay.

49. While a brand manufacturer could bring suit after the 45th day post-receipt of a Paragraph IV certification, such a suit would not trigger a 30-month stay, and the FDA would not be prevented from granting final approval to the ANDA assuming other regulatory requirements (such as bioequivalence) are satisfied.

3. First-filer's 180 Day Exclusivity Period

50. Generics may be classified as (1) first-filer generics, (2) later-filing generics, or (3) the brand's own authorized generic.

51. To encourage manufacturers to seek approval of generic versions of brand drugs,

the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification (the "first-filer") a 180-day period to market the generic version of the drug, during which the FDA may not grant final approval to any other later-filing generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that at least one unexpired patent listed in the Orange Book as covering the brand product is either invalid, unenforceable, or not infringed by the generic's product, the FDA cannot approve a later-filing generic company's ANDA until that first-filer generic has been on the market for 180-days, or until the first-filer's 180-day exclusivity has been forfeited. The 180-day window is referred to as the first-filer's 180-day "exclusivity."

52. By contrast, a first-filer that informs the FDA that it intends to wait until all Orange Book listed patents expire before marketing its product (*e.g.*, one that files a Paragraph III certification as to all Orange Book-listed patents) will not receive a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to file Paragraph IV certifications challenging weak patents, or to invent around such patents by creating non-infringing generics.

53. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first-filer.[4]

54. An authorized generic, or AG, is simply the brand product, sold or licensed by the brand for sale, under generic trade dress, at a cheaper price than the brand price. Because the AG is already approved under the brand manufacturer's NDA, it can be marketed at any time, including during the first-filer's 180-day exclusivity period.

[4] *FTC v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223, 2229 (2013).

55. If the only versions of a drug on the market are the brand and the first-filer's generic product, then the first-filer prices its product below the brand product, but above what it would if there was more than one generic (such as an authorized generic). The lack of competition from an authorized generic therefore inflates the price of a first-filer generic.

B. The Competitive Benefits of AB-Rated Generic Competition.

56. Since the FDA deems AB-rated generic versions of brand drugs to be just as safe and effective as their brand counterparts, the only material mode of differentiating the two is their price. On average, generics are at least 25% less expensive than their brand counterparts when there is a single generic competitor.This discount typically increases to 50% - 80% (or more) when there are multiple generic competitors on the market for a given brand.

57. Every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has affirmatively requested the brand). Accordingly, once one generic equivalent enters the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months.

58. By 12 months post-generic entry, the Federal Trade Commission ("FTC") found that on average, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85% relative to brand prices.[5] That is because once multiple generic competitors enter, the competitive process accelerates and multiple generic sellers

[5] *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (Jan. 2010) ("FTC Pay-for-Delay Study"), available at http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (last accessed July 10, 2018).

typically compete vigorously with each other for market share by driving prices further down toward marginal manufacturing costs.[6] As a result, competition from generic drugs is viewed by brand drug companies, such as Novartis, as a grave financial threat.

59. By contrast, generic competition enables purchasers (like Class members here) to purchase substantially cheaper generic versions of a drug instead of the more expensive brand, and to purchase generic versions of a drug at increasingly lower prices as more generic versions of that brand drug enter the market.

60. Once exclusivity is lost and generic entry occurs – an event sometimes referred to as the "patent cliff" – the brand manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales. The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act, and embraced by the states in their generic substitution laws. "According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[7]

C. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

61. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand

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[6] *See, e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, J.L. & ECON. (Oct. 2000); Tracy Regan, *Generic Entry and Price Competition in the Prescription Drug Market--18 Years after the Waxman-Hatch Act* (Univ. of Miami, Dep't of Econ., Working Paper, Feb. 14, 2004); R. Frank, *The Ongoing Regulation of Generic Drugs*, NEW ENG. J. MED., v. 357, pp. 1993-96 & n.20 (Nov. 2007).

[7] FDA WEBSITE, GENERIC DRUGS UNDERGO RIGOROUS FDA SCRUTINY, available at https://www.fda.gov/ForConsumers/ucm340343.htm (last accessed July 10, 2018).

manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Novartis, are well aware of generics' rapid erosion of their brand sales, and thus seek to stall the impact of generic competition for as long as possible, sometimes (as here) resorting to illegal means.

62. One way that brand manufacturers game the system to anticompetitive effect is by paying generic manufacturers to delay entering the market. These agreements not to compete are sometimes known as "exclusion payment agreements" or "pay-for-delay agreements," which have long concerned the FTC. Brand and generic manufacturers execute exclusion payment agreements to take advantage of the regulatory consequences associated with the generic manufacturers' Paragraph IV certifications.

63. In a typical exclusion payment agreement, the brand manufacturer pays a generic manufacturer to delay or abandon market entry. The brand manufacturer preserves its monopoly by effectively paying some of its monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product.

64. One method of payment to a first-filer generic company comes in the form of the brand company's promise to not launch an "authorized generic" version of the brand drug during the first-filer's 180-day exclusivity. As discussed above, an authorized generic is the brand drug, sold under the brand NDA, but sold by the brand or a licensee under generic trade dress. Because the brand manufacturer already has approval to sell its brand drug, it does not need to file an ANDA or obtain any additional approval to market an authorized generic. Multiple courts have recognized that ANDA filers have no right to be free from competition from an authorized generic.

65. In a 2011 report issued at the request of Congress, the FTC concluded that no-authorized-generic promises were being used as a payment by brands to generics for delayed

generic entry, noting that "there is strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic competitors for delaying entry."[8]

66. For the brand company, an authorized generic launched during the first-filer's 180-day exclusivity (or longer) provides a low cost, low risk means to regain some of the revenue lost from the patent-cliff. For the first-filer, however, an authorized generic launch has a huge negative impact on its revenue. A first-filer generally earns about 80% of its total income from a given generic product during its exclusivity period. An authorized generic, when launched during that time, will capture 50% or more of total generic unit sales during that period,[9] and will cause generic prices to decrease as a result of the price competition.[10] A brand's promise not to launch an authorized generic during the first-filer's 180-day exclusivity is thus a very valuable payment to the first-filer, doubling its unit sales and more than doubling its revenues and profits (by removing a source of price competition). Correspondingly, a brand's promise not to launch an authorized generic represents a substantial sacrifice of the revenues and profits for the brand that it would have otherwise earned by launching an authorized generic. Those revenues and profits are instead ceded, by way of the no-authorized-generic promise, to the first-filer, who has no patent or other

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[8] FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT ("Authorized Generic Drugs") (August 2011) at vi, available at https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (last accessed July 6, 2018).

[9] *Id.* at iii, vi, 41-48, 57-59.

[10] *Id.* at 5 n.21 (citing IMS CONSULTING, IMS HEALTH, ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. (2006) (written for PhRMA), available at http://replay.web.archive.org/20061009134405/http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf).

right to be free from competition from an authorized generic.

67. For a first-filer generic, like Par, of a brand product like Exforge, the difference between (1) selling the only generic product and (2) selling a generic product while competing against an authorized generic, for the first six months of generic marketing, constitutes a payment that can reach hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry, and the FTC's authorized generic report cites numerous documents from industry participants confirming the financial impact of an authorized generic and, by necessary implication, its absence.

68. A no-authorized-generic agreement between brand and generic drug companies — horizontal competitors — unjustly enriches both companies and injures consumers twice over: first, it prolongs the period during which only the high-priced brand is available; and second, it ensures that, once delayed generic competition begins, generic prices are artificially inflated by the absence of the authorized generic.

69. Here, Par agreed to delay competing in the market for Exforge in exchange for Novartis's no-authorized-generic promise. As set forth further below, this constituted a large payment to Par for which there can be no redeeming pro-competitive justification, because it represents a *per se* illegal market allocation or output restriction agreement, or because even if analyzed under the rule of reason a no-authorized-generic promise lacks any cognizable procompetitive justification as a matter of law.

D. Pay-for-Delay Agreements with First-Filers Can Create Bottlenecks for Later-Filing Generics

70. An anticompetitive agreement entered into between the brand and the first-filer generic often subjects later ANDA filers to the delayed generic entry date agreed to between the brand manufacturer and the conspiring first-filer generic.

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

72. Nevertheless, in the absence of an anticompetitive agreement between the brand company and the first-filer, the later ANDA filers have pro-competitive incentives. They are still motivated to enter the market as early as possible because the sooner they enter, the sooner they can compete, which results in lower prices.

73. However, later ANDA filers cannot obtain final FDA approval to enter the market, until the first-filer's 180-day exclusivity has run or been forfeited. An agreement between the brand and the first-filer that delays the first-filer's entry, also delays the first filer's 180-day exclusivity, and consequently, the later ANDA filers' entry.

74. While later ANDA filers may, in theory, force the first-filer to forfeit its 180-day exclusivity by prevailing against the brand in a patent litigation, such as through a declaratory judgment action or in Paragraph IV litigation brought by the brand, such a prospect is not attractive to later ANDA filers. This is because the later ANDA filers would assume the mantle of litigation costs from the first-filer force the first-filer to forfeit its 180-days of exclusivity, only to then enter a highly competitive market with all of the other ANDA filers and an authorized generic. Instead of incurring this expense for no reward, the later ANDA filers will save their money and wait out the bottleneck created by the first-filer's 180-day exclusivity.

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

purchasers to buy the expensive brands instead.

VI. FACTUAL ALLEGATIONS

A. The Defendants' Products and the Nature of Sales of Generic Equivalent Products

76. In the Unites States, high blood pressure (HBP or hypertension) affects an estimated one of three adults or about 75 million people. According to the American Heart Association, if left untreated, high blood pressure can lead to, among other serious health complications: heart attack, stroke, heart failure, kidney disease and peripheral artery disease.[11] High blood pressure was a primary or contributing cause of death for more than 410,000 Americans in 2014; more than 1,100 deaths each day.

77. As of 2007, the most commonly prescribed branded high blood pressure medicines in their respective classes were the calcium channel blocker ("CCB") amlodipine (marketed as the besylate salt under the brand name Norvasc) and the angiotensin-II receptor blocker ("ARB") valsartan (marketed under the brand name Diovan).

78. Novartis already had intellectual property rights to Diovan, but its plan was to combine the active ingredients in Diovan and Norvasc, the latter of which is a Pfizer product, as soon as Pfizer's patents expired in September, 2007. However, on March 22, 2007 the Federal Circuit invalidated Pfizer's Norvasc patents, paving the way for earlier FDA approval of Novartis's Diovan/Norvasc combination (Exforge).

79. On June 20, 2007, the FDA approved Novartis's NDA No. 21-990 for Exforge tablets, the first high blood pressure medication to combine both amlodipine and valstartan in a single medication. Shortly thereafter, Exforge tablets were launched into the U.S. marketplace.

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[11] Heart Threats From High Blood Pressure, available at http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/LearnHowHBPHarmsYourHealth/Health-Threats-From-High-Blood-Pressure_UCM_002051_Article.jsp#.WwLUBkgvyUk.

Exforge quickly became one of the most commonly prescribed branded high blood pressure medicines.

80. Novartis claimed that Exforge, the combination of valsartan and amlodipine, offered patients the convenience of a reduced pill load for their hypertension medication, increasing patient adherence.

B. Novartis's Patents

81. Novartis listed three patents in the FDA Orange Book under NDA No. 21-990 for Exforge: the '578 Patent; the '197 Patent; and the '728 Patent. The '578 Patent, which disclosed and claimed the chemical compound valsartan, expired on March 21, 2012. A regulatory exclusivity known as pediatric exclusivity[12] attached to the '578 Patent expired on September 21, 2012. Neither the '197 Patent nor the '728 Patent afforded Novartis the right or ability to exclude generic competition for Exforge, and therefore Novartis had no legitimate basis for excluding generic competition after September 21, 2012. Had the '197 or '728 Patents been litigated in the courts, they would have been adjudged invalid, unenforceable and/or not infringed.

82. On or about October 1, 2007, Par filed ANDA No. 90-011. March 28, 2013 FDA Approval Letter at 1. Par's ANDA No. 90-011 included Paragraph IV certifications for the '197 and '728 Patents. *Id.* at 2. According to the FDA, the Paragraph IV certifications stated that "each of these [two] patents is invalid, unenforceable, or will not be infringed by [Par's] manufacture, use, or sale of Amlodipine and Valsartan Tablets, 5 mg/160 mg, 10 mg/160 mg, and 10 mg/320 mg" described in ANDA No. 90-011. *Id.* Par notified Novartis of its Paragraph IV certifications and the bases for them, but Novartis never sued Par for patent infringement. *Id.* On information

[12] As a result of conducting tests in pediatric age groups, the FDA granted Novartis a six-month regulatory exclusivity called pediatric exclusivity.

and belief, the patent defenses set forth in Par's Paragraph IV certification notice letter were meritorious and would have succeeded had they been litigated.

83. No valid claim of the '728 Patent was infringed by Par's filing of ANDA No. 90-011 or the manufacture or sale of Par's generic version of Exforge. First, the claims of the '728 Patent are properly construed to be limited to the use of a combination of valsartan and amlodipine for the treatment of hypertension in the limited subset of patients suffering from diabetes and could not have afforded Novartis any right to exclude generic competition beyond that very narrow use. The '728 Patent issued from United States Application Serial No. 09/757,413 (the "'413 Application"), which is a divisional of United States Application Serial No. 09/349,654 (the "'654 Application"). The original claims of the '654 Application broadly recited (1) "[a] method for the treatment or prevention of [a wide variety of different disease states] comprising administering a therapeutically effective amount of a combination" of valsartan, a calcium channel blocker and a pharmaceutically acceptable carrier; and (2) "[a] pharmaceutical combination composition comprising" those same ingredients. '654 Application at 11. As originally filed, those claims were not limited to the use of valsartan and amlodipine in the treatment of patients suffering from diabetes. *Id.*

84. However, the examiner at the United States Patent and Trademark Office rejected each of those claims as obvious in view of United States Patent No. 5,492,904 (the "'904 Prior Art Patent") and the prescribing information for DIOVAN (the "Prior Art Diovan Literature"). Office Action dated May 25, 2000. The examiner noted that the '904 Prior Art Patent taught the combined use of an angiotensin-II antagonist (like valsartan) and a calcium channel blocker (like amlodipine):

> [The '904 Prior Art Patent] teach[es] pharmaceutical compositions which comprise an angiotensin-II antagonist and a calcium channel blocker of the type presently

> claimed which are useful in the treatment of hypertension and congestive heart failure. See the abstract and column l, lines 25-40. It is further taught that the compositions may comprise from 10 to 300 mg of the desired calcium channel blocker and from 1 to 100 mg of the angiotensin-II antagonist.

Id. at 2. The examiner acknowledged that the '904 Prior Art Patent did not teach valsartan, but noted that the Prior Art Diovan Literature "discloses that valsartan was a well-known angiotensin-II antagonist." *Id.* Accordingly, the examiner deemed the originally-claimed subject matter to be obvious. *Id.* at 3.

85. The applicants for the '654 Application amended their claims, but the examiner reiterated his rejection. Office Action dated August 29, 2000 at 3-4. In response to the rejection, the applicants amended method of use claim 1 by deleting the broad recitation of disease conditions and narrowing it to the treatment of "hypertension ***associated with diabetes***." Amendment After Final Rejection dated October 20, 2000 at 1-2. Thereafter, the '654 Application issued as United States Patent No. 6,204,281.

86. The '413 Application was filed as a divisional application on January 9, 2001 along with a preliminary amendment whose claims were similar to those that had been originally filed in the '654 Application. The examiner rejected the claims pending in the '413 Application as obvious for the same reason he had rejected the claims in the '654 Application. April 27, 2001 Office Action at 3. In response to the rejection, and consistent with their amendment in the '654 Application, the applicants limited claim 1 to the treatment of "hypertension associated with diabetes." Amendment dated July 25, 2001 at 3. In explaining why the amendment would overcome the examiner's obviousness rejection, which applied to <u>all</u> pending claims including the method claims, the applicants argued that they had shown unexpected results in the treatment of diabetes:

> Applicants have clearly shown unexpected results in the treatment of diabetic

> associated with hypertension with the combination of valsartan and verapamil. For example, on page 6 to page 7 of the instant application (inserted by this amendment), Applicants have shown that treatment with the combination of valsartan and verapamil resulted in a considerable reduction of sudden death events and significant degree of increase of the survival rate as compared to the administration of the single drugs alone. These unexpected results are sufficient to overcome the obviousness rejection based on the references because a combination of the references do not teach or suggest the treatment of hypertension associated with diabetes.

Id. at 4. Thus, while the composition of matter claims did not refer explicitly to diabetes, the applicants' argument was premised on the view that those claims were also limited to the use of the claimed pharmaceutical composition in patients suffering from diabetes. *Id.* ("Claims 1-9 have been rejected . . . . Applicants respectfully traverse this rejection. *The claims are now directed to hypertension associated with diabetes*.") (emphasis added).

87. The examiner nevertheless again rejected the claims. Office Action dated August 1, 2001. In response, the applicants further amended the claims to limit them to the use of valsartan with amlodipine. In doing so, they again made clear that both the method of use and composition of matter claims should be viewed as limited to the use in the "treatment of hypertension associated with diabetes":

> Claims 1, 4 and 9 have been amended to recite amlodipine as the selected calcium channel blocker. The treatment of hypertension associated with diabetes by administering a combination of valsartan and amlodipine is neither taught nor suggest by the cited references. Accordingly, the rejection has been overcome and should be withdrawn.

Amendment After Final Rejection dated September 24, 2001. Par was not seeking FDA approval to market its product for the treatment of hypertension associated with diabetes, and therefore could not induce infringement of any claim that was limited to this use.

88. In addition, the claims of the '728 Patent are invalid in view of the prior art. United States Patent No. 5,492,904 ("the '904 Prior Art Patent") issued on February 20, 1996, more than

three years before the earliest possible effective filing date of the ’728 Patent, and is therefore prior art to the ‘728 Patent. The ‘904 Prior Art Patent is titled “Composition of Angiotensin-II Receptor Antagonists and Calcium Channel Blockers” and teaches the use of a pharmaceutical composition comprising an angiotensin-II receptor antagonist and a calcium channel blocker for the treatment of hypertension. ‘904 Prior Art Patent at 1:15-40. The ‘904 Patent also teaches that “the combinations of active compounds can be administered alone, but are generally administered with a pharmaceutical carrier selected on the basis of the chosen route of administration and standard pharmaceutical practice.” *Id*. at 4:37-40. It also teaches that “[t]he combinations of this invention can be administered for the treatment of hypertension” and that the “[p]harmaceutical compositions of the invention may contain from 10 to 300 mg of the desired calcium channel blocker and 1 to 100 mg of the angiotensin-II receptor antagonist per unit dose one or more times daily.” *Id.* at 4:4-5 and 44-48. The ‘904 Prior Art Patent also references certain disease states involving “diabetic” conditions. *Id.* at 3:56-4:3.

89. Although the ‘904 Prior Art Patent does not explicitly reference valsartan, that is completely unsurprising. The patent application that issued as the ‘904 Prior Art Patent was filed on July 28, 1994, whereas the prior art ‘578 Patent disclosing valsartan did not issue until March 21, 1995. Thus, the ‘904 Prior Art Patent was filed before valsartan was publicly disclosed by the ‘578 Patent. However, as soon as the ‘578 Patent was issued and disclosed valsartan, it would have been obvious to use valsartan as the angiotensin-II receptor antagonist in the combination treatment taught by the ‘904 Prior Art Patent.

90. No valid claim of the ‘197 Patent was infringed by Par’s filing of ANDA No. 90-011 or the manufacture or sale of Par’s generic version of Exforge. The ‘197 Patent issued on September 25, 2001 from an application filed on June 18, 1997. The ‘197 Patent includes fifty-

three (53) claims, of which only four are independent claims. "It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to be infringed." *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553, 10 U.S.P.Q.2d 1201, 1208 (Fed. Cir. 1989). Each of the independent claims in the '197 Patent requires a compressed solid dosage form (or a process for forming or method of using such a compressed solid dosage form) comprising either (1) greater than 35% by weight valsartan; and/or (2) the active ingredient hydrochlorothiazide ("HCTZ") in combination with valsartan. Neither Exforge nor any generic version of Exforge contains or could contain the active ingredient HCTZ. Accordingly, the claims of the '197 Patent could cover a generic version of Exforge only if valsartan were present at greater than 35% by weight of the dosage form. On information and belief, at all relevant times Par's generic version of Exforge contained less than 35% by weight valsartan, and thus could not literally infringe any of the claims of the '197 Patent.

91. As a matter of law, the claims of the '197 Patent cannot cover generic versions of Exforge that contain 35% or less by weight valsartan under the doctrine of equivalents. First, "[a] doctrine of equivalents theory cannot be asserted if it will encompass or 'ensnare' the prior art." *Jang v. Boston Sci. Corp.*, 872 F.3d 1275, 1285 (Fed. Cir. 2017). Here, the '578 Patent is prior art to the '197 Patent and discloses a tablet that is 35.7% by weight valsartan. '578 Patent at 63:24-52 (example 93). Any doctrine of equivalents theory that encompassed a compressed solid dosage form having 35% or less valsartan would therefore improperly cover the prior art. Second, "[i]f a theory of equivalence would vitiate a claim limitation . . . then there can be no infringement under the doctrine of equivalents as a matter of law." *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998); *see also Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) ("[T]o allow what is undisputedly a minority (i.e., 47.8%) to be equivalent to a majority

would vitiate the requirement that the 'first and second longitudinal strips of adhesive . . . extend the majority of the lengths of said longitudinal marginal portions.'"). Here, allowing a claim limitation that requires solid dosage forms comprising "more than" 35% by weight valsartan to cover solid dosage forms having "less than" 35% by weight valsartan would vitiate a claim limitation and would therefore be improper.

92. In addition, the relevant claims of the '197 Patent are invalid. The earliest effective filing date for the '197 Patent is June 18, 1997, and therefore, the '578 Patent that issued on March 21, 1995 is prior art to the '197 Patent. Claim 1 of the '197 Patent, for example, recites the following:

> 1. A compressed solid dosage form comprising a) an active agent containing an effective amount of Valsartan or a pharmaceutically acceptable salt thereof; and, b) at least one pharmaceutically acceptable additive wherein the active agent is present in an amount of more than 35% by weight based on the total weight of the compressed solid dosage form.

'197 Patent at 10:22-30. The '578 Patent anticipates this claim, thereby rendering it invalid. '578 Patent at 63:25-52 (example 93). More specifically, the prior art '578 Patent teaches a tablet (*i.e.*, a compressed solid dosage form) comprising 35.7% valsartan and a number of pharmaceutically acceptable additives including, for example, lactose. *Id.*

93. The Patent Office examiner apparently did not understand that example 93 of the '578 Patent related to valsartan. Valsartan is a generic name for the chemical compound (S)-N-(1-carboxy-2-methylprop-1-yl)-N-pentanoyl-N-[2'-(1H-tetrazol-5-yl)-biphenyl-4-ylmethyl-] amine. The '578 Patent does not use the term "valsartan" but rather referred to the compound by its chemical name. Had the examiner understood that that example 93 of the '578 Patent referred to valsartan, he would have rejected claim 1 under 35 U.S.C. § 102.

94. Rather than disclose to the examiner that example 93 of the '578 Patent related to

valsartan, the applicants exploited the examiner's lack of appreciation. For example, when the examiner rejected the claims based on a different prior art reference, the applicants made arguments that could not have been made had the examiner appreciated example 93 of the '578 Patent. For example, after the examiner rejected the pending claims based in part on the Muller prior art reference, the applicants argued:

> In this case, the combination of references cited by the Examiner provides no teaching, suggestion or motivation to produce the solid dosage forms of valsartan as claimed by Applicant. Muller teaches a valsartan capsule and does not teach whether the capsule is a compressed dosage form. Muller also fails to disclose any detail about the formulation of the valsartan capsule. Indeed, Muller lacks any disclosure regarding the relative weight of valsartan in the capsule.

Amendment dated July 27, 2010 at 10. Notably, the teaching that the applicants argued was absent from the prior art references cited by the examiner was precisely the teaching supplied by the prior art '578 Patent. The applicants also argued that "[t]he unique chemical properties of angiotensin type II receptor antagonists have made it difficult in some cases to develop formulations useful for the creation of tablets." March 12, 2001 Amendment at 4. But again, this argument could not have been made had the examiner known that the prior art '578 Patent taught a tablet form of valsartan.

95. As another example, claim 5 of the '197 Patent depends from claim 1 and recites that the valsartan dosage range is from "40 to 160 mg." '197 Patent at 10:42-43. Example 93 of the '578 Patent taught a 100 mg valsartan dosage and therefore the '578 Patent also anticipates and renders invalid claim 5.

96. The fact that Novartis never sued Par on the '197 or '728 Patents reflects Novartis's belief that those patents did not afford Novartis any right to exclude Par from marketing its generic version of Exforge. Nor did Novartis sue any of the other later-filing generics (discussed below), which launched after Par's 180-day exclusivity period expired, despite the fact that the '197 and '728 Patents had not yet expired.

C. Par and Synthon File ANDAs for Generic Versions of Exforge and Novartis Chooses Not to Bring Suit

97. Par and Synthon recognized the huge market potential for Exforge and, in or about the fall of 2007, were the first generic firms to file ANDAs with the FDA containing Paragraph IV certifications to certain Exforge patents.

98. Par filed ANDA 90-011 on October 1, 2007 for the 10/160, 5/160, 10/320 milligram strengths of Exforge, and, on information and belief, was the first applicant to file a substantially complete application containing a Paragraph IV certification for those three strengths, making Par eligible for 180-days of regulatory exclusivity.

99. Synthon filed ANDA 90-144 on November 26, 2007 for the 5/320 milligram strength of Exforge and, on information and belief, was the first applicant to file a substantially complete application containing a Paragraph IV certification for the 5/320 mg strength, making Synthon eligible for 180-days of regulatory exclusivity for that strength.

100. On information and belief, Par and Synthon's ANDAs addressed Novartis's Orange-Book listed patents as follows: (1) they contained Paragraph III certifications to the '578 Patent (meaning that they would not seek to market a generic product prior to the expiration of the regulatory exclusivities associated with that patent on September 21, 2012); and (2) they contained Paragraph IV certifications to the '197 and '728 Patents (meaning they sought to enter into the market prior to the expiration of those patents, which they claimed were invalid, unenforceable, and/or would not be infringed by Par's or Synthon's generic products). Therefore, on or shortly after October 1, 2007 and November 26, 2007, respectively, Par and Synthon disclosed their intention to market their AB-rated generic products as early as September 21, 2012.

101. Because Par and Synthon were the first companies to file substantially complete ANDAs with Paragraph IV certifications, they stood to receive a significant and potentially highly

profitable benefit under 21 U.S.C. 355(j)(5)(B)(iv): 180-days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic equivalent of Exforge.

102. On information and belief, after receiving confirmation of receipt from the FDA for their ANDAs, Par and Synthon sent notice to Novartis of their respective ANDAs containing Paragraph IV certifications in letters that included "a detailed factual and legal statement as to why" the '197 and '728 Patents were "invalid, unenforceable, and/or not infringed" by Par's or Synthon's ANDA Products (the "Paragraph IV Notices"). The Paragraph IV Notices included an offer of confidential access to Par's and Synthon's ANDAs as required under Hatch-Waxman. The Notices give rise to a cause of action for infringement under the Hatch-Waxman Act.

103. Novartis did not file a lawsuit against Par or Synthon for infringement of the '197 and '728 Patents within the 45-day time period set forth in the statute to trigger a 30-month stay of ANDA approval. Accordingly, no 30-month stay ever went into effect for the Par or Synthon ANDAs.

104. On March 19, 2010, the FDA granted tentative approval to Par's ANDA for the generic version of Exforge, determining that, aside from existing patent or regulatory exclusivities, Par's generic Exforge was otherwise approvable, and satisfied all bioequivalence, CMC, and labeling requirements.

105. Therefore, as of March 19, 2010, the only thing preventing Par from obtaining final FDA approval and launching its generic Exforge was the last two-and-a-half years of protection afforded by the '578 Patent covering the active ingredient valsartan.

106. Par intended to so launch as soon as the '578 Patent expired. In 2008, Paul Campanelli, Par's President, Generics Division, publicly stated during Par's Q1 2008 earnings call

that Par expected to launch a generic of Exforge in 2012 (which is when the '578 Patent expired but well before the expiry of the '197 or '728 Patents). A contemporaneous Par press release said the same thing.[13]

107. On information and belief, instead of suing (which it knew would have been futile), Novartis reached an agreement with Par to abandon its efforts to launch generic Exforge at the earliest possible date after the expiration of the '578 Patent and instead agreed upon a delayed launch date of September 30, 2014, roughly two years after expiry of the '578 Patent. In exchange, Novartis agreed not to launch an authorized generic of Exforge for the first six months after Par's entry. Par had no patent covering authorized generic Exforge that would entitle it to file a lawsuit seeking to enjoin the launch of authorized generic Exforge.

108. On information and belief, Novartis provided Par with a release of its weak patent claims, and a reverse payment in the form of a no-authorized-generic agreement. Novartis was motivated to do so because it was a preferable alternative to Novartis than risking an adverse ruling on its patents which would cause earlier generic entry. Evidence of the weakness of the '197 and '728 Patents includes:

a. Par's and Synthon's ability to develop and file ANDAs with Paragraph IV certifications within a few months of FDA approval of Exforge;

b. Novartis's decision not to sue for patent infringement and enforce its intellectual property in court; and

c. The facts set forth above and in Par's and Synthon's Paragraph IV certification notice letters.

109. Thus Par and/or Synthon would have won a patent lawsuit had Novartis filed one.

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[13] PR Newswire, *Par Pharmaceutical Reports First Quarter 2008 Results; Reports First Quarter Adjusted EPS of $0.17 per Diluted Share; Provides Full-year 2008 EPS Guidance and Projects its Pipeline Opportunities*, May 8, 2008.

110. But-for the Agreement, Par would have been ready, able, and willing to launch generic Exforge as early as September 21, 2012, but no later than March 28, 2013, and would have communicated as much to the FDA and requested final approval for its ANDAs well in advance of September 21, 2012. Par would have received final approval from FDA upon the expiry of the exclusivities associated with the '578 Patent on September 21, 2012.

111. By 2009, Exforge was already generating hundreds of millions of dollars per year in revenues for Novartis. Losing a substantial portion of that revenue stream upon expiry of the '578 Patent – as Novartis would have if Par launched upon final FDA approval after expiry of the '578 patent – would have drastically affected Novartis's profits. Thus Novartis had enormous incentives to avoid competition from Par by entering into the Agreement.

112. On information and belief, the Agreement contained confidentiality provisions precluding the parties from disclosing key terms of the agreement, including Novartis's covenant not to launch a competing authorized generic of Exforge during Par's six month exclusivity period. Although the parties subsequently made vague public references to their Agreement, they concealed its anticompetitive purpose and terms. For example, a January 2012 analyst day presentation by Par lists a "Synthon/Exforge" "Business Development" arrangement in 2011.[14] And Par's 10-K for the fiscal year ending December 31, 2011 states "[o]n November 30, 2011, we entered into an asset purchase agreement with Synthon Pharmaceuticals, Inc., and on December 30, 2011, we closed on our acquisition, of Synthon's ANDA for amlodipine besylate and valsartan

[14] Exhibit 99.1 to Par Pharmaceutical Companies, Inc.'s January 6, 2012 Form 8-K, Analyst Day presentation of January 6, 2012. *See* https://www.sec.gov/Archives/edgar/data/878088/000114420412000888/v244735_8k.htm (last accessed July 2, 2018), *and* https://www.sec.gov/Archives/edgar/data/878088/000114420412000888/v244735_ex99-1.htm (las accessed July 2, 2018).

(5 mg/320 mg and 10 mg/320 mg) fixed dose combination tablets, a generic version of Exforge®, for $9,600 thousand. Under the terms of a separate license agreement with Novartis Pharmaceuticals Corporation, we have a certain launch date in October 2014."[15] Similarly, Novartis's 20-F for the fiscal year ending December 31, 2011, filed on January 25, 2012, states "In the US, under a license agreement with a generics manufacturer, the product [Exforge] is expected to face generic competition beginning in October 2014."[16]

113. Nowhere in these disclosures did Defendants disclose the anticompetitive no-authorized-generic provision – *i.e.*, they did not disclose that they arrived at an October 2014 generic launch date only as a result of a *payment* from Novartis to Par to delay its entry to that date. Plaintiffs lacked sufficient indication of any *quid pro quo* until Novartis actually launched its authorized generic on March 31, 2015, immediately after Par's 180-day exclusivity period ended. Until that time, it was not knowable that the entry date was affected (delayed) by a payment. This was a deliberate concealment.

114. Novartis's waiting to launch an authorized generic until Par's 180-day exclusivity expired did not make economic sense since it would have been more lucrative for Novartis to have simply launched its authorized generic immediately on Par's launch. Novartis only agreed to delay its authorized generic launch as *quid pro quo* for Par's agreement to delay generic Exforge competition. As explained below, Plaintiffs would not have been on notice of Novartis's payment to Par until it became clear that Novartis took the plainly irrational path of delaying its authorized

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[15] Par Pharmaceutical Companies, Inc. Form 10-K for the fiscal year ended Dec. 31, 2011, at F-22, available at https://www.sec.gov/Archives/edgar/data/878088/000087808812000027/f201110k2281210amnolinks.htm.

[16] Novartis's 20-F for the fiscal year ending December 31, 2011, at 153, available at https://www.novartis.com/sites/www.novartis.com/files/Novartis-20-F-2012.pdf.

generic launch.

115. On information and belief, as consideration for Par's agreement to forgo selling generic Exforge in competition with Novartis's branded Exforge until almost two years after the expiration of the '578 Patent, Novartis agreed to share with Par the monopoly profits from sales of branded Exforge in the form of a covenant not to compete with Par's generic using an authorized generic. Instead of competing, which would have resulted in lower prices of both generic and branded Exforge, Novartis and Par agreed to keep prices of both products (brand and generic Exforge) at supracompetitive levels.

116. The Agreement benefitted Par by guaranteeing that it would be the sole generic on the market during its 180-day exclusivity period, which more than doubled Par's anticipated sales revenues in the exclusivity period because: (1) Par would capture all of the sales that would otherwise have gone to the authorized generic, and (2) Par would be able to charge significantly higher prices for its generic product without price competition from an authorized generic.

117. A brand company's launch of its own competing authorized generic is extremely costly to any first-filer generic, such as Par, because the authorized generic erodes the first-filer's share of the overall generic volume *and* pushes down generic prices. The authorized generic also cuts into the first-filer's long term "first mover advantage." As the FTC noted in a June 2009 report on authorized generics, "consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an [Authorized Generic] enters the market, due to the greater discounting that accompanies the added competition provided by the [Authorized Generic]."[17]

118. Novartis's covenant not to launch an AG during Par's exclusivity period was extremely valuable to Par. As Novartis has stated in its regulatory filings, "authorized generics

[17] Authorized Generic Drugs at ii.

also reduce the value of the exclusivity for the company that invested in creating the first generic medicine to compete with the originator product."[18]

119. Novartis sacrificed large profits through its agreement not to launch an authorized generic. Absent the unlawful Agreement, it would make economic sense for Novartis to launch an authorized generic during Par's 180-day marketing exclusivity so that Novartis could retain 50% of the sales that Par's less expensive generic otherwise would otherwise capture.

120. As alleged above, an authorized generic typically captures approximately 50% of the generic unit sales during the first 180-days of generic marketing. Thus, the no-AG provision was a very large payment to Par. Specifically, as early as May, 2006, financial analysts and the media were projecting annual peak sales for Exforge of $500 million. Similarly, during Novartis AG's third quarter, 2007 earnings call, Thomas Ebeling, the CEO of its pharma division, expressed optimism that Exforge would become a "blockbuster drug" in the United States, which is an industry designation for drugs that reach $1 billion in sales. By 2014, Novartis's annual Exforge sales were over $414 million.[19] Using the most conservative of these numbers, Defendants could assume that 6 months of brand sales (the duration of Novartis's covenant not to launch an authorized generic) would generate revenue of at least $207 million (6/12 * $414 million).

121. As is common in the pharmaceutical industry, the first generic is expected to take 80% (or more) of the brand sales over the first six months. Thus, approximately $165.6 million worth of brand sales would be converted to the generic ($207 million * 0.8) during the period of Par's 180-day exclusivity (the duration of Novartis's covenant not to launch an authorized

[18]Novartis's 20-F for the fiscal year ended December 31, 2014, at 89, available at https://www.sec.gov/Archives/edgar/data/1114448/000104746915000433/a2222787z20-f.htm.

[19] Press Release, *Mylan Launches Generic Exforge® Tablets*, March 31, 2015, available at http://newsroom.mylan.com/press-releases?item=123292 (last accessed July 11, 2018).

generic). As is also common, with only one generic on the market, the generic is typically priced at 90% of the brand, which would result in generic sales of approximately $149.04 million ($165.6 million * 0.9). Thus, the sales revenue during the 180-day exclusivity period that would reasonably have been anticipated by Par without compensation from Novartis's AG would be approximately $149.04 million.

122. Par's expectations would have differed dramatically if Novartis had not promised to refrain from competing with its own AG. According to an FTC study of the dynamics of authorized generic entry during the 180-day generic exclusivity period, the addition of an AG drives the average generic price down to 52% of the brand price.[20] Thus, while the generics would still take 80% of brand sales, or $165.6 million, the generic sales value would drop to $86.112 million ($165.6 million * 0.52). And, it would reasonably be expected that those sales would be split evenly between Par and Novartis's authorized generic.[21] Thus, without the no-AG Agreement, Par's share of the revenue from sales of generic Exforge during the first 6 months would be expected to be approximately $43.056 million ($86.112 million * 0.5).

123. As a result, the expected value at the time of the agreement to Par of the no-AG clause versus facing competition from an AG would have been at least approximately $105.984 million ($149.04 million - $43.056 million). Thus, Novartis's agreement to not launch an AG for 6 months was a payment to Par of $105.984 million or more. The value of this payment to Par was tantamount to Novartis making those sales itself and handing $105.984 million to Par in cash.[22]

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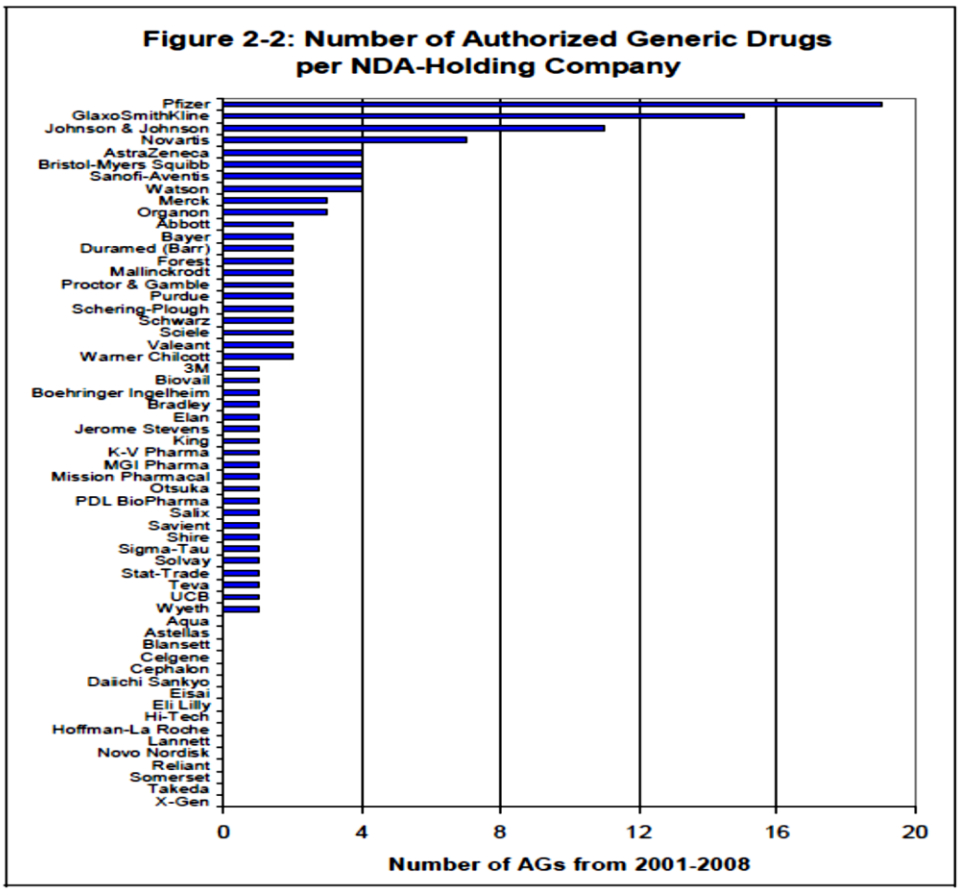
[20] Authorized Generic Drugs at iii.

[21] *Id.* at vi (The Federal Trade Commission has concluded that, when free from competition from an authorized generic, "the first-filer's revenue will approximately double" during the first six months of generic competition, compared to what the first filer would make if it faced authorized generic competition).

[22] The Federal Trade Commission concluded that, when free from competition from an authorized

124. Novartis, which owns the generic company Sandoz, Inc., which often launches authorized generics, has a history of launching authorized generic versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics. The FTC has found that, in the time period from 2001 to 2008, only three companies launched more authorized generics than Novartis:[23]



generic, "the first-filer's revenue will approximately double" during the first six months of generic competition, compared to what the first filer would make if it faced authorized generic competition. *Id*. The Supreme Court has recognized this as well. *See Actavis,* 133 S. Ct. at 2229 (2013) (the "vast majority of potential profits for a generic drug manufacturer materialize during" the first six months of marketing).

[23] Authorized Generic Drugs at p. 16 ("For each company, the graph includes all AGs marketed pursuant to the company's NDAs, whether marketed internally (e.g., by a subsidiary), or through an external generic partner.").

125. On information and belief, Novartis has launched at least nineteen authorized generics between 2005 and 2016, including authorized generic versions of Exelon, Famvir, Focalin XR, Lescol XL, Lopressor HCT, Lotrel, Patanase, Patanol, Ritalin, Ritalin SR, Sandostatin, Tegretol XR, Tobi, Tobradex, Trileptal, Voltaren, Voltaren XR, Ciloxan and VivelleDot.[24]

126. It is economically rational for a brand manufacturer that intends to launch an authorized generic to do so contemporaneously with the first ANDA filer's launch. This is because during the first-filer's 180-day exclusivity, the only possible competitors for generic sales are the first-filer, and the brand's authorized generic. No later-filing generic can launch during this time. Accordingly, the Supreme Court has observed that "the vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." *Actavis*, 133 S. Ct. at 2229.

127. Novartis itself stated in public SEC filings that "[t]he company that launches an authorized generic typically launches its product at the same time as the generic exclusivity holder."[25]

128. Thus it would have been economically rational for Novartis to have launched its authorized generic version of Exforge upon market entry by Par. In the absence of the anticompetitive Agreement here, it would have done so.

129. Conversely, if there was no agreement prevent Novartis from launching immediately upon Par's launch, then Novartis's waiting until Par's 180-day exclusivity period expired to launch an authorized generic was economically irrational. This is because in such a

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[24] *See* FDA's Listing of Authorized Generics as of March 28, 2018, available at*:* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM183605.

[25] Novartis's 20-F for the fiscal year ending December 31, 2014, at 89, available at https://www.sec.gov/Archives/edgar/data/1114448/000104746915000433/a2222787z20-f.htm (last accessed July 2, 2018).

circumstance, Novartis would (and did) enter a market with several later ANDA filers that also launched once Par's 180-day exclusivity expired. There was no economically rational reason for Novartis to forgo competition with Par during Par's 180-day exclusivity period except as part of an anticompetitive market-allocation or output-restriction agreement to compensate Par for delayed generic Exforge competition.

130. Even under the most conservative estimates, the payment flowing from Novartis to Par via the Agreement not to compete with an authorized generic had a cash value exceeding one hundred million dollars. Novartis intended the payment to induce Par to stay out of the market for Exforge and its generic equivalents in return for sharing monopoly profits among Defendants, a naked market allocation or output restriction agreement and thus a *per se* violation of the Sherman Act. But even under the Rule of Reason, the reverse payment from Novartis to Par is unexplained, and Defendants will have no pro-competitive justification or other legitimate explanation for the payment. It is well established that there is no conceivable procompetitive justification for a covenant to delay launch of an authorized generic version of a brand drug.

131. Absent Novartis's unlawful reverse payment to Par, any agreement releasing Novartis's patent claims would have resulted in far less (or no) delay of Par's generic entry than with the reverse payment, generic competition would have been more robust, and generic prices would have been lower. But for the Agreement, Par would have launched generic Exforge as early as September 21, 2012, but no later than March 28, 2013 (when its ANDA received final FDA approval). Par would have launched, without a license from Novartis, as early as September 21, 2012, when the regulatory exclusivities associated with the '578 Patent expired, because '197 and '728 Patents were not a bar to Par's entry. This is evident by the fact that at least Mylan, N.V., ("Mylan"), Teva Pharmaceutical Industries, Ltd. ("Teva"), Torrent Pharms, Ltd. ("Torrent"),

Novel Labs, Inc. ("Novel") and Lupin Pharmaceuticals, Inc. ("Lupin") all launched on or about March 30, 2015, when Par's 180-day exclusivity expired, but before the expiration of the '197 and '728 Patents, and on information and belief, even without a license from Novartis. Novartis also would have launched its authorized generic upon, and simultaneously with, Par's launch.

132. Had Par launched its generic Exforge as early as September 21, 2012, but no later than March 28, 2013, at least one subsequent filer would have obtained final FDA approval and launched its generic equivalent of Exforge immediately upon expiration of Par's 180-day exclusivity period. But for the bottleneck of generic competition caused by Defendants' pay-for-delay agreement, and more specifically by that agreement's foreseeable and intentional effect of causing Par's 180-day exclusivity to remain untriggered and thus unelapsed for two additional years, not just Par's generic and Novartis's authorized generic, but also one or more other generic manufacturers would have launched earlier, lowering generic prices farther still.

133. The reason Par did not launch on September 21, 2012 when the regulatory exclusivities associated with the '578 Patent expired had nothing whatsoever to do with any purported infringement risk flowing from the '197 and '728 Patents. Rather, it was because both Par and Novartis, by entering the Agreement leveraged the fact that Par, as the first ANDA filer, had 180-days of regulatory exclusivity during which no subsequent filer could launch an ANDA version of Exforge. Both Par and Novartis recognized that delaying Par's launch in exchange for a no-AG agreement would benefit both companies. Novartis would benefit by continuing to charge ever increasing monopoly prices for Exforge despite the fact that the '197 and '728 Patents were not barriers to generic entry, because Par was willing to be paid to delay, and Par's delay would delay the triggering, and thus the elapsing, of its 180-day exclusivity, thereby bottlenecking all generic Exforge competition. Par would benefit by securing a no-AG agreement to be free from

competition for the first six months after its delayed launch.

134. Alternatively, Par and Novartis would have entered into a license without a no-AG provision that provided for no delay, or only nominal delay.

135. According to information available publicly through the FDA, in addition to Par and Synthon, at least eight additional companies filed ANDAs to sell generic Exforge:

Application No.	Company
202713	Alembic Pharms Ltd
206512	Aurobindo Pharma Ltd
205137	Invagen Pharms
090245	Lupin
090483	Mylan Pharms Inc.
202829	Novel Labs Inc
091235	Teva Pharms USA
202377	Torrent Pharms Ltd

136. According to information available publicly through the FDA, many of these entities received final approval on or around the end of Par's actual 180-day exclusivity of March 30, 2015. These approvals would have been granted earlier if Par's 180-day exclusivity had been triggered and elapsed by Par's own earlier entry into the market absent Novartis's covenant to delay its authorized generic version of Exforge.

137. But for the Defendants' ongoing performance under the Agreement, generic and authorized generic competition for Exforge would have occurred earlier and prices for fixed combination products comprising valsartan and amlodipine would have decreased. But for Defendants' ongoing, illegal anticompetitive conduct, generic and authorized generic versions of Exforge would have become available as early as September 21, 2012, but no later than March 28, 2013. Plaintiffs and other members of the Class would have paid lower prices for Exforge and its generic equivalents. Defendants, by their conduct, have injured Plaintiffs and other members of the Class by causing them to pay millions of dollars in overcharges on their purchases of fixed

combination products comprising valsartan and amlodipine.

VII. CLAIM ACCRUAL AND/OR TOLLING

138. Plaintiffs' Complaint is timely as to all claims accruing on or after May 16, 2014.

139. Plaintiffs' pre-May 16, 2014 damages claims are also timely under the doctrines of equitable tolling, the discovery rule and fraudulent concealment.

140. These doctrines apply because (1) Defendants concealed from Plaintiffs the existence of this cause of action, (2) Plaintiffs remained in ignorance of this cause of action until some point within four years of the commencement of this action (May 16, 2018), and (3) Plaintiffs' continuing ignorance was not attributable to lack of diligence on their part.

141. Defendants concealed from Plaintiffs the existence of their cause of action.

142. Specifically, Defendants concealed from Plaintiffs the term of the Agreement pursuant to which Novartis agreed to delay launching an authorized generic during Par's 180-day exclusivity period – a common form of "pay-for-delay." Even when limited information about the Agreement was made available in SEC filings, that key illegal aspect was not disclosed. Specifically, while Novartis's 20-F for the fiscal year ending December 31, 2011, filed with the SEC on January 25, 2012, states "In the US, under a license agreement with a generics manufacturer, the product [Exforge] is expected to face generic competition beginning in October 2014,"[26] it does *not* state that the license agreement would operate to preclude Novartis from launching an authorized generic for the first six months following Par's launch.

143. Moreover, the Agreement was inherently self-concealing. Had its provisions not been kept secret, it would not have succeeded, because, *inter alia*, of the availability of injunctive

[26] Novartis's 20-F for the fiscal year ending December 31, 2011, at 153, available at https://www.novartis.com/sites/www.novartis.com/files/Novartis-20-F-2012.pdf (last accessed July 11, 2018).

relief to prevent it.

144. Plaintiffs remained in ignorance of this cause of action until some point within four years of commencement of this action and their continuing ignorance was not attributable to a lack of diligence on their part.

145. Specifically, Plaintiffs had insufficient knowledge of the Defendants' anticompetitive conduct to file an antitrust claim until March 31, 2015. It was then when Novartis did launch an authorized generic precisely upon the expiration of Par's 180-day exclusivity that there was sufficient evidence that an antitrust violation (a payment in the form of a no-AG agreement) had occurred.

146. Because Defendants concealed this illegal no-AG term, there was no way to know about it until it transpired.

147. Plaintiffs regularly monitor industry information sources on generic launch timing as part of their business planning and inventory management practices. Here, Plaintiffs detected no suspicious conduct prior to Novartis's failure to launch an authorized generic upon Par's September 30, 2014 entry of generic Exforge.

148. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations the Plaintiffs' and the Class's claims have been tolled.

149. Alternatively, if the statute of limitations is not tolled, this Complaint alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiffs and members of the Class can recover for damages that they suffered during the limitations period.

VIII. ANTICOMPETITIVE EFFECT

150. The Agreement has enabled Defendants to: (a) prevent and delay the entry of less expensive generic versions of Exforge products in the United States, including its territories,

possessions, and the Commonwealth of Puerto Rico; (b) fix, raise, maintain, or stabilize the price of Exforge products; (c) allocate 100% of the U.S. market for Exforge and its generic equivalents to Novartis until September 30, 2014; and (d) allocate 100% of U.S. generic sales for Exforge to Par until March 31, 2015.

151. The '578 Patent expired on March 21, 2012, and the attached pediatric exclusivity expired on September 21, 2012. Par launched its generic version of Exforge on September 30, 2014, and at least five later filing generics (Mylan, Teva, Torrent, Novel and Lupin) launched their generic versions on or shortly after March 31, 2015. Novartis launched an authorized generic of Exforge on or shortly after March 31, 2015 through its subsidiary, Sandoz.

152. But for the continuing illegal Agreement between Par and Novartis , Par would have begun selling a less expensive AB-rated generic version of Exforge as early as as early as September 21, 2012, but no later than March 28, 2013. Such sales would have occurred via market entry by Par upon Par's final FDA approval after expiry of the regulatory exclusivities associated with the '578 Patent on September 21, 2012, or shortly thereafter under a license with Novartis that did not include a no-AG provision. In addition, upon market entry by Par, and simultaneously therewith, Novartis would have begun selling its own less expensive authorized generic version of Exforge in direct competition with the Par generic. Other ANDA-based generic versions of Exforge, including but not limited to the Mylan, Teva, Torrent, Novel and Lupin products, would have followed into the market as early as 180-days after the earlier launch by Par.

153. An increasingly competitive market for Exforge and its generic equivalents would have thereafter emerged as additional generic manufacturers entered the market.

154. Defendants' unlawful concerted action has delayed and suppressed the sale of generic Exforge in the United States, and unlawfully enabled Novartis to sell Exforge, and Par to

sell its generic equivalent of Exforge, at artificially inflated, supra-competitive prices.

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

IX. ANTITRUST IMPACT

156. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Exforge directly from Novartis and substantial amounts of generic equivalents of Exforge directly from Par. As a result of Defendants' illegal conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, artificially inflated prices for their requirements for fixed combination products comprising valsartan and amlodipine. Those prices were substantially greater than the prices that Plaintiffs and members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of Exforge was artificially inflated by Defendants' illegal conduct, and (2) Plaintiffs and Class members were deprived of the opportunity to purchase lower-priced generic versions of Exforge sooner, which they would have purchased had they had the opportunity. When generic versions of Exforge were finally available, prices of generic Exforge were higher than they would have been absent Defendants' illegal conduct, and so Plaintiffs and the Class have incurred overcharges on their purchases of generic Exforge as well.

157. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. EFFECT ON INTERSTATE COMMERCE

158. At all material times, Novartis manufactured, promoted, distributed, and sold substantial amounts of Exforge, and Par manufactured, promoted, distributed, and sold substantial

amounts of generic Exforge, in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States, including its territories, possessions, and the Commonwealth of Puerto Rico. During the relevant time period, in connection with the purchase and sale of Exforge and generic Exforge, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

159. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

XI. MONOPOLY POWER AND MARKET DEFINITION

160. At all relevant times, Novartis had and maintained monopoly power in the market for Exforge and its generic equivalents because it had the power to maintain the price of fixed combination products comprising valsartan and amlodipine at supracompetitive levels without losing sales such as to make the supracompetitive price unprofitable.

161. Direct proof exists that Novartis had monopoly power over the price of fixed combination products comprising amlodipine and valsartan. Such direct evidence includes, among other things, the abnormally-high price-cost margins enjoyed by Novartis prior to entry of generic Exforge and Novartis's ability to profitably maintain the price of Exforge well above competitive levels.

162. Manufacturers attempt to differentiate brand name drugs like Exforge based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Exforge. This

is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Exforge.

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

164. Other products are not substitutes for Exforge or its generic equivalents, and the existence of other products designed to treat hypertension or other illnesses treated by Exforge have not significantly constrained Novartis's pricing of Exforge. On information and belief, Novartis has never lowered the price of Exforge in response to the pricing of other branded or generic treatments.

165. Novartis needed to control only Exforge and its AB-rated generic equivalents, and no other products, in order to maintain the price of Exforge profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Exforge would render Novartis unable to profitably maintain its prices of Exforge without losing substantial sales.

166. To the extent Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, the only relevant market is Exforge (in all its forms and dosage strengths), and bioequivalent generic versions of Exforge. The relevant geographic market is the United States, including its territories, possessions, and the Commonwealth of Puerto Rico.

167. Novartis's anticompetitive payment to Par demonstrates that Novartis enjoyed

market and/or monopoly power with respect to Exforge (in all its forms and dosage strengths) and bioequivalent generic versions of Exforge.

168. A small but significant non-transitory price increase above the competitive level for Exforge by Novartis would not cause a loss of sales sufficient to make the price increase unprofitable.

169. At competitive price levels, Exforge does not exhibit significant positive cross-price elasticity of demand with any product other than AB-rated generic versions of Exforge.

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

171. During the relevant period, Defendants' anticompetitive conduct has significantly damaged competition and consumers through a reduction of output and higher prices caused by an elimination or reduction of lower cost generic Exforge throughout the United States, including its territories, possessions, and the Commonwealth of Puerto Rico.

172. Novartis has maintained and exercised the power to exclude and restrict competition to Exforge and AB-rated generics.

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

FIRST CAUSE OF ACTION
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1
(AGREEMENT NOT TO COMPETE – NOVARTIS AND PAR)

174. Plaintiffs incorporate and reallege all paragraphs in this Complaint, as though fully set forth below.

175. Novartis and Par, their agents and affiliates and co-conspirators, both known and

unknown, entered into and engaged in a continuing unlawful trust and agreement in restraint of trade and commerce in Exforge and its generic equivalents, in violation of the Sherman Act by entering into an Agreement to extend patent monopolies and to allocate markets and restrict output.

176. In or around 2011, Novartis and Par commenced a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of fixed combination products comprising amlodipine and valsartan in the United States to Novartis until September of 2014; (b) prevent the sale of a generic version of Exforge in the United States until as late as September 30, 2014, and thereafter restrict the supply of generic and authorized versions of Exforge, thereby protecting Exforge from further generic competition; (c) fix the price at which Plaintiffs and the other members of the Class would pay for Exforge and its generic equivalents at a higher, supra-competitive price; and (d) allocate all sales of generic fixed combination products comprising amlodipine and valsartan in the United States to Par until March of 2015.

177. By engaging in this unlawful and continuing conspiracy, Novartis and Par have unlawfully conspired in restraint of trade and committed a *per se* violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. In the alternative, Defendants' conduct is an unreasonable restraint of trade in violation of Section 1 when viewed under a "rule of reason" mode of analysis. Plaintiffs and other members of the Class have been injured in their business and property by reason of Novartis and Par's unlawful contract, combination and conspiracy.

178. Starting with the beginning of the Class Period, and continuing throughout the Class Period, Plaintiffs and other members of the Class have paid more on their purchases of Exforge and its generic equivalents than they would have paid absent Novartis and Par's illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the

more expensive branded and generic Exforge.

179. But for the continuing illegal Agreement between Novartis and Par (which included financial inducements to delay the launch of a less expensive generic version of Exforge), Par would have begun selling a less expensive AB-rated generic version of Exforge as early as September 21, 2012, but no later than March 28, 2013. Such sales would have occurred via market entry by Par upon Par's final FDA approval after expiry of the regulatory exclusivities associated with the '578 patent on September 21, 2012, or shortly thereafter under a license with Novartis that did not include a no-AG provision. In addition, upon market entry by Par, and simultaneously therewith, Novartis would have begun selling its own less expensive authorized generic version of Exforge in direct competition with the Par generic.

180. If manufacturers of generic Exforge entered the market and competed with Exforge in a full and timely fashion, Plaintiffs and other members of the Class would have substituted lower-priced generic versions of Exforge for the higher-priced brand-name Exforge for some or all of their requirements for fixed combination products comprised of valsartan and amlodipine, and/or would have paid lower prices on some or all of such purchases, including generic purchases.

181. During the relevant period, Plaintiffs and other Class members purchased substantial amounts of Exforge tablets directly from Novartis and/or their generic equivalents directly from Par. As a result of the Defendants' illegal conduct alleged herein, Plaintiffs and other Class members were compelled to pay, and did pay, artificially inflated prices for their requirements for fixed combination products comprised of amlodipine and valsartan. Plaintiffs and the other Class members paid prices for such products that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic versions of Exforge instead of

expensive brand-name Exforge tablets; (2) Class members were forced to pay artificially inflated prices for Exforge and generic versions of Exforge; and/or (3) the price of brand-name Exforge was artificially inflated by Novartis's and Par's illegal conduct.

182. There is, and was, no legitimate, non-pretextual procompetitive justification for Defendants' actions comprising the anticompetitive scheme that outweighs their harmful effect. Even if there were some conceivable such justification, the scheme is and was broader than necessary to achieve such a purpose.

SECOND CAUSE OF ACTION
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(MONOPOLIZATION AND MONOPOLISTIC SCHEME – NOVARTIS)

183. Plaintiffs incorporate and reallege all paragraphs in this Complaint, as though fully set forth below.

184. Novartis used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend its monopoly power in the market for Exforge and its generic equivalents, as detailed above.

185. The goal, purpose and/or effect of the scheme was to prevent, delay and/or minimize the success of the entry of generic competitors which would have sold generic versions of Exforge in the United States at prices significantly below Novartis's prices for branded Exforge, which would have effectively caused the average market price of fixed combination products comprising amlodipine and valsartan to decline dramatically.

186. The goal, purpose and/or effect of Novartis's scheme was also to maintain and extend Novartis's monopoly power with respect to Exforge and its generic equivalents.

187. But for Novartis's ongoing, illegal anticompetitive conduct, generic versions of Exforge would have become available as early as September 21, 2012, but no later than March 28,

2013. Plaintiffs and other members of the Class would have paid lower prices for Exforge. Defendants, by their conduct, have injured Plaintiffs and other members of the Class by causing them to pay hundreds of millions of dollars in overcharges on their purchases of Exforge.

188. If manufacturers of generic versions of Exforge had entered the market and competed with Exforge in a full and timely fashion, Plaintiffs and the other members of the Class would have substituted lower-priced generic versions of Exforge for the higher-priced brand-name Exforge for some or all of their requirements and/or would have paid lower prices for some or all of their remaining brand and generic Exforge purchases.

189. During the relevant period, Plaintiffs and other Class members purchased substantial amounts of Exforge directly from Novartis and have purchased substantial amount of the generic version of Exforge from Par. As a result of Novartis's illegal conduct alleged herein, Plaintiffs and other members of the Class have been compelled to pay, and have paid, artificially inflated prices for their requirements for fixed combination products comprising amlodipine and valsartan. Plaintiffs and other members of the Class paid prices for such products that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower priced generic versions of Exforge instead of expensive brand-name Exforge, which Plaintiffs and the Class would have purchased in place of branded Exforge had they had the opportunity; (2) Class members were or will be forced to pay artificially inflated prices for generic versions of Exforge; and/or (3) the price of branded Exforge was artificially inflated by Novartis's illegal conduct. Novartis's scheme was in the aggregate an act of monopolization in the market for amlodipine and valsartan in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

THIRD CAUSE OF ACTION
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2

(ATTEMPT TO MONOPOLIZE - NOVARTIS)

190. Plaintiffs incorporate and reallege all paragraphs in this Complaint, as though fully set forth below.

191. Novartis, through its anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Novartis's conscious objective to control prices and/or to exclude competition in the relevant market.

192. The natural and probable consequence of Novartis's anticompetitive scheme, which was intended by, and plainly foreseeable to, Novartis, was to control prices and exclude competition in the relevant market, to the extent that it did not succeed.

193. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Novartis would succeed in and achieve its goal of maintaining monopoly power in the relevant market. As a direct and proximate result of Novartis illegal and monopolistic conduct, Plaintiffs suffered antitrust injury as alleged above.

FOURTH CAUSE OF ACTION
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE – NOVARTIS AND PAR)

194. Plaintiffs incorporate and reallege all paragraphs in this Complaint, as though fully set forth below.

195. Defendants Novartis and Par combined, conspired and contracted between and among themselves to unreasonably and unlawfully restrain and monopolize trade and to attempt to monopolize trade with specific intent, and Novartis did, in fact, monopolize trade in the United States in the market for Exforge and its generic equivalents thereby eliminating competition in that market.

196. Novartis and Par, their agents and affiliates and co-conspirators, both known and

unknown, entered into and engaged in a continuing unlawful trust in restraint of trade and commerce in Exforge and its generic equivalents, in violation of the Sherman Act, by entering into an Agreement to extend patent monopolies and to divide markets and allocate customers.

197. Novartis and Par each committed at least one overt act in furtherance of the conspiracy.

198. The purpose and effect of such Agreement was to fix, raise, stabilize and maintain the prices for Exforge and its generic equivalents at supra-competitive levels, which increased prices were paid by Plaintiffs and the Class.

199. During the Class Period, Plaintiffs and the other members of the Class purchased substantial amounts of Exforge directly from Novartis, and purchased substantial amounts of generic versions of Exforge directly from Par. As a result of Defendants' illegal conduct, alleged herein, Plaintiffs and other members of the Class have been compelled to pay, and have paid, artificially inflated prices for their requirements for fixed combination products comprising amlodipine and valsartan. Plaintiffs and other members of the Class paid prices for such products that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic versions of Exforge instead of expensive brand-name Exforge and would have purchased such lower-priced generic in place of branded Exforge had they had the opportunity; (2) Class members were or will be forced to pay artificially inflated prices for generic versions of Exforge; and/or (3) the price of brand-name Exforge was artificially inflated by Novartis and Par's illegal conduct**.**

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Class, pray for

judgment against all Defendants, jointly and severally, as follows:

1. That the Court adjudge and decree that Defendants and each of them have violated Sections 1 and 2 of the Sherman Antitrust Act;

2. That Plaintiffs and all others similarly situated be awarded damages suffered by reason of these violations and that those damages be trebled in accordance with the law;

3. That Plaintiffs be awarded reasonable attorneys' fees and costs; and

4. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of all claims and complaints in this Complaint so triable.

DATED: July 17, 2018

Respectfully submitted,

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JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of all claims and complaints in this Complaint so triable.

DATED: July 17, 2018

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CERTIFICATE OF SERVICE

I, Dan Litvin, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system on all counsel of record.

Dated: July 17, 2018

/s/ Dan Litvin

Dan Litvin