

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS**

MEIJER, INC. and MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated, Plaintiff, v. ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., PENWEST PHARMACEUTICALS CO., and IMPAX LABORATORIES INC., Defendants.	Civil Action No. 14-cv-7320 CLASS ACTION JURY TRIAL DEMANDED
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CLASS ACTION COMPLAINT

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Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, “Meijer” or “Plaintiff”) on behalf of themselves and all others similarly situated, against Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Penwest Pharmaceuticals Co. (collectively “Endo”), and Impax Laboratories, Inc. (“Impax”) (collectively “Defendants”), based upon personal knowledge as to facts pertaining to themselves, and upon information and belief as to all other matters, and allege as follows:

I. Introduction

1. This is a civil antitrust action seeking treble damages arising out of the Defendants’ unlawful scheme to allocate and monopolize the market for extended release oxymorphone hydrochloride, which Endo sells under the brand name Opana ER. As part of Defendants’ unlawful scheme, Endo paid Impax over \$112 million in cash in exchange for Impax agreeing to keep its less expensive generic version of Opana ER out of the market for two and a half years – from June 2010 to January 2013 – during which time Endo switched the market for Opana ER to a new “crush resistant” formulation of Opana ER (“Opana ER CRF”). But for Defendants’ scheme, Impax would have launched its generic extended release oxymorphone hydrochloride as early as June 14, 2010 for 5, 10, 20, and 40 mg dosage strengths, and July 22, 2010 for the 30 mg dosage strength when the Food and Drug Administration (the “FDA”) granted Impax final approval for those strengths, and the vast majority of sales of those strengths would have gone to Impax’s less expensive generic. As alleged below, Defendants’ scheme injured Plaintiff and the Class of direct purchasers it seeks to represent (as defined below), causing them to pay overcharges.

2. Oxymorphone hydrochloride has been marketed and sold by Endo in the United States for almost 50 years in various dosage forms including a rectal suppository and an

intravenous drip. Oxymorphone hydrochloride was also available in a tablet form during the 1960s and early 1970s. In the 1990s Endo decided to revive tablet formulations of oxymorphone hydrochloride. However, Endo knew that the longest period of (non-patent) regulatory exclusivity that Endo could obtain for its revived tablet formulation of oxymorphone hydrochloride was three years. The original United States patent on oxymorphone hydrochloride itself was issued in 1957 and had expired.

3. Seeking to obtain a longer period of exclusivity, Endo licensed four time release patents from Penwest Pharmaceuticals Co. (“Penwest”) and developed extended release oxymorphone hydrochloride tablets, which it named Opana ER. Endo listed the Penwest time release patents in the FDA’s Orange Book as covering Opana ER.

4. Endo then embarked on a scheme to block generic competition to Opana ER beyond three years.

5. *First*, Endo sued generic manufacturers – including Impax, Actavis South Atlantic LLC (“Actavis”), Sandoz, Inc. (“Sandoz”), Barr Laboratories, Inc. (“Barr”), Roxane Laboratories, Inc. (“Roxane”), and Watson Laboratories, Inc. (“Watson”) – each of which sought to market generic extended release oxymorphone hydrochloride (*i.e.*, generic Opana ER) – for purportedly infringing the Penwest time release patents. Under the Hatch-Waxman Act, the mere filing of these lawsuits prevented the FDA from approving the generic drug applications (or ANDAs, as that term is described below) filed by each of these generic manufacturers for 30 months, regardless of the merits of the lawsuits.

6. *Second*, Endo ended the litigation against Impax – the first-filer potential generic competitor for the vast majority of Opana ER sales (the 5, 10, 20, 30, and 40 mg generic Opana ER tablets) – by entering into an anticompetitive agreement (the “Exclusion Payment

Agreement”) whereby Impax agreed to keep its generic extended release oxymorphone hydrochloride off the market for two and a half years in exchange for a large future cash payment and other consideration from Endo. The Exclusion Payment Agreement contained three forms of payment:

- i. A future cash payment from Endo to Impax based on sales of Opana ER in the quarter immediately prior to the delayed Impax launch date established in the Exclusion Payment Agreement (which cash payment in the amount of \$102,049,000 was received by Impax in April 2013);
- ii. Endo’s agreement not to launch an “authorized generic” (basically, brand Opana ER but marketed and priced like a generic, as explained below) during Impax’s first 180 days on the market with its generic extended release oxymorphone hydrochloride; and
- iii. A cash payment from Endo to Impax of \$10 million up front, with an obligation to pay an additional \$30 million later, under the guise of a development and co-promotion agreement for Impax’s yet-to-be approved product to treat Parkinson’s disease.

Thus, in exchange for at least \$112 million in cash (and up to \$142 million in cash) and the agreement by Endo not to launch its authorized generic during Impax’s 180-day exclusivity period and thereby price-compete with Impax, Impax agreed to keep its generic extended release oxymorphone hydrochloride off the market until January 2013 – two and a half years after it received final approval to sell generic versions of Opana ER.

7. *Third*, Endo ended its litigations with Actavis, Sandoz, Barr, Roxane, and Watson and used the Exclusion Payment Agreement to create a “bottleneck” whereby no other generic

manufacturer could come to market until after Impax had been on the market for 180 days with generic versions of 5, 10, 20, 30, and 40 mg Opana ER tablets.

8. *Fourth*, Endo implemented a product hop during the two-and-a-half-year delay period that it purchased from Impax via the Exclusion Payment Agreement whereby it converted a substantial portion of the Opana ER market to a new formulation, Opana ER CRF, which was no more safe or effective than the prior formulation, but which could not be automatically substituted with generic Opana ER at the pharmacy level. Thus, when Impax belatedly launched its generic version of Opana ER in January 2013, the market for Opana ER was substantially eroded and generic manufacturers were able to capture a much smaller share of the extended release oxymorphone hydrochloride market.

9. In apparent anticipation of the market switch from Opana ER to Opana ER CRF, Endo and Impax had structured the bulk of the cash payment to Impax under the Exclusion Payment Agreement to ensure that the payment was based on sales of Opana ER in the quarter prior to Impax's own launch. In this way, the parties agreed that Impax would be paid very well for not competing, *even if* Endo tried to switch the market from Opana ER to Opana ER CRF (as Endo in fact did) and thereby undercut the generic Opana ER sales that Impax and other generics would ultimately obtain.

10. The "basic reason" for the Exclusion Payment Agreement was Defendants' "desire to maintain and to share patent-generated monopoly profits" and therefore the Agreement is "likely" unlawful. *FTC v. Actavis, Inc.*, 570 U.S. _____, 133 S. Ct. 2223, 2237 (2013). Moreover, the millions of dollars Endo paid to Impax as part of the Exclusion Payment Agreement "provide a workable surrogate for [the] patent[s'] weakness[es]." *Id.* at 2236-37.

“An unexplained reverse payment,” like the payment at issue here, “itself would normally suggest that the patentee has serious doubts about the patent’s survival.” *Id.* at 2236.

11. Endo essentially bribed Impax to stay out of the market for two and a half years and converted the market to Opana ER CRF to indefinitely preserve its stream of monopoly profits from the Opana ER franchise.

12. The agreement for Impax to delay market entry in exchange for, *inter alia*, Endo’s reciprocal agreement during Impax’s 180-day exclusivity period by foregoing the launch of an authorized generic is a naked market allocation that is *per se* illegal.

13. But for the unlawful and large reverse payment,¹ Impax would have (a) launched its generic “at-risk” (that is, while the patent litigation was still pending); or (b) after winning the patent suit; or (c) via a lawful settlement agreement *without* a large reverse payment from Endo to Impax. Endo literally bought itself freedom from generic competition. Endo and Impax – competitors – conspired to allocate the market for Opana ER and its generic equivalents in a manner that gave each company more exclusivity than it was entitled to in order to maximize profits at the expense of purchasers of Opana ER.

14. But for the Exclusion Payment Agreement, generic versions of 5, 10, 20, and 40 mg Opana ER would have been available as early as June 14, 2010, when the FDA granted final approval for those dosage strengths of Impax’s generic Opana ER. Generic 30 mg Opana ER would have been available as early as July 22, 2010, when Impax received final approval for that strength. Plaintiff and members of the Class would have substituted the less-expensive generic

¹ In normal patent infringement litigation settlements, the alleged infringer would pay the patent holder. Here, the patent holder (Endo) is paying the alleged infringer (Impax), which is the reverse of what normally occurs.

products for their purchases of brand Opana ER long before Impax belatedly launched its generic in January 2013, which was after Endo had switched from Opana ER to Opana ER CRF.

15. If generics had launched before the switch from Opana ER to Opana ER CRF, Impax's and other generic versions would have captured a much larger share of the extended release oxymorphone hydrochloride market once launched into the market.

16. Defendants' conduct was designed to and did in fact: (a) delay the entry of less expensive, AB-rated generic versions of Opana ER; (b) fix, raise, maintain or stabilize the price of Opana ER and AB-rated generic versions of Opana ER; and (c) allocate nearly 100% of the United States market for Opana ER and its AB-rated generic equivalents to Endo for two and one half years.

17. As alleged in more detail below, Defendants violated sections 1 and 2 of the Sherman Act through their conspiracy to restrain trade by foreclosing competition from lower-priced AB-rated generic versions of Opana ER.

II. Parties

18. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer" or "Plaintiff") are corporations organized under the laws of the State of Michigan, with their principal place of business located in Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of the Frank W. Kerr Co., which, during the Class Period, as defined below, purchased Opana ER directly from Defendants and suffered antitrust injury as a result of the anticompetitive conduct alleged herein. Frank W. Kerr Co. resold to Meijer at least some of the Opana ER that it purchased from Defendants during the relevant period.

19. Defendant Endo Health Solutions Inc. is a Delaware corporation, with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Until May 2012, Endo Health Solutions Inc. was known as Endo Pharmaceuticals Holdings Inc.

20. Defendant Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. Endo Pharmaceuticals Inc. is a Delaware corporation, with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

21. Defendant Penwest Pharmaceuticals Co. was acquired by Endo Pharmaceuticals Holdings Inc. on November 4, 2010. Prior to November 4, 2010, Penwest was a Washington corporation, and Endo and Penwest developed and marketed Opana ER together. Penwest was previously known as Edward Mendell Co.

22. Defendants Endo Health Solutions Inc., Endo Pharmaceuticals Inc., and Penwest Pharmaceuticals Co. are collectively referred to as “Endo.”

23. Defendant Impax Laboratories, Inc. (“Impax”) is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

24. Endo and Impax are collectively referred to as “Defendants.”

25. 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 done 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, or with the actual, apparent, or ostensible authority of Defendants.

III. Jurisdiction and Venue

26. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Meijer and members of the Class (defined below) resulting from Defendants' conspiracy to restrain trade in the United States market for Opana ER and its generic equivalents. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

27. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the class period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the alleged activity affected interstate trade and commerce discussed below has been carried out in this District.

28. 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.

29. During the Class Period (defined below), Endo manufactured, sold and shipped Opana ER in a continuous and uninterrupted flow of interstate commerce. The conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

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

31. 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

scheme and conspiracy. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. Regulatory Background

A. The Regulatory Structure for Approval and Substitution of Generic Drugs

32. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application (“NDA”). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

33. When the FDA approves a brand manufacturer’s NDA, the manufacturer may list in the “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as the “Orange Book”) any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book within thirty days of issuance any patents issued after the FDA approved the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

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

35. When a brand manufacturer wishes to make changes to a drug that already has an approved NDA, the brand manufacturer must submit a supplemental new drug application

(“sNDA”) to the FDA. An sNDA is required when a brand manufacturer wishes to change a drug label, market a new dosage strength, or change the way it manufactures a drug.

1. The Hatch-Waxman Amendments

36. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, “therapeutically equivalent”) to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to, and are of the same dosage strength and form as their brand counterpart, an “AB” rating.

37. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart. 21 U.S.C. § 355(j)(8)(B).

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

39. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand 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

2. ANDA Paragraph IV certification

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

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

² See IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014), *available at* http://www.imshealth.com/cds/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf (last accessed September 15, 2014).

³ *Id.* at 51.

- iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a “Paragraph III certification”); or
- iv. that the patent for the brand drug is invalid 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).

41. If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the 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). Until one of those conditions occurs, the FDA may grant “tentative approval,” but cannot grant final approval authorizing the generic manufacturer to market its product. The FDA may grant a tentative approval to an ANDA when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

3. First-filer’s 180-day exclusivity period

42. Generics may be classified as (i) first-filer generics, (ii) later generic filers, and (iii) the brand’s own authorized generic.

43. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files a substantially complete 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 manufacturer’s ANDA for a generic version of 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 the unexpired patents listed in the Orange Book as covering the brand product are either invalid or not infringed by the generic's product, the FDA cannot approve a later generic company's ANDA until that first-filing generic has been on the market for 180 days, or until the first-filer exclusivity has been forfeited. The 180 day window is referred to as the first-filer's six month or 180-day "exclusivity."

44. 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

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

46. Although later generic ANDA filers must wait 180 days after the first-filer's market entry to get final FDA approval, a brand drug manufacturer can launch an authorized generic ("AG") version of its own brand drug, under its own NDA, at any time, including during the 180-day exclusivity period, and brand companies frequently do so in response to generic entry in order to recoup some of the sales they would otherwise lose.

B. The Competitive Effects of AB-Rated Generic Competition

47. Generic versions of brand drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generic drugs and their corresponding brand versions is their price. Because generic versions of a corresponding brand drug product are commodities that cannot be

⁴ *FTC v. Actavis*, 133 S. Ct. at 2229 (citation omitted).

differentiated, the primary basis for generic competition is price. Typically, generics are at least 10% less expensive than their brand counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings for all drug purchasers.

48. Since the passage of the Hatch-Waxman Amendments, 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 specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits 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. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%.⁵ As a result, competition from generic drugs is viewed by brand drug companies, such as Endo, as a grave threat to their bottom lines.

49. Generic competition enables all purchasers to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

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 September 15, 2014).

50. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Endo, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes (as here) resorting to illegal means.

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

51. Experience and economic research show that the first generic manufacturer to launch prices its product below the prices of its brand counterpart.⁶ Every state either requires or permits that a prescription written for the brand drug be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand form of the drug. At the same time, there is a reduction in average price paid for a prescription for the drug at issue (brand and AB-rated generic combined).

52. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market (as noted above, the brand's AG can be, and often is, on the market during the 180-day exclusivity period). As recognized by the Supreme Court, it is often the case that most of a first-filer's profits are earned during the 180-day exclusivity period.⁷

53. If there is no AG on the market during the 180-day exclusivity period, the first-filer prices its product below the brand product, but not as low as if it were facing competition

⁶ FTC, *AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT*, at ii-iii, 34 (Aug. 2011) ("FTC 2011 AG Study"), *available at* <http://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 September 15, 2014); FTC Pay-for-Delay Study, at 1.

⁷ *See Actavis*, 133 S. Ct. at 2229.

from other generics, including an AG. Since in these circumstances, the first-filer's product competes only with the brand product, and because the brand company rarely drops the brand product price to match the first-filer, the first-filer does not face the kind of price competition it will when additional generic products, including an AG, are available. Thus, a first-filer earns much greater sales and profits without an AG being marketed alongside it during the 180-day exclusivity period.

2. Later generics drive prices down further

54. Once multiple generic competitors enter the market, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.⁸

55. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near term retail price reduction of around 10%, but that with two generic entrants near term retail price reduction is about 50%.

56. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift to generic sellers. A 2011 FTC Study found that generics captured 80% or more of sales in the first six months.⁹ In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their brand counterparts,

⁸ 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).

⁹ FTC 2011 AG Study, at 66-67.

they are typically sold at substantial discounts from the brand price. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Even more

billions are saved when hospitals use generics.”¹⁰

3. AGs compete on price, like other generics

57. Nothing prevents a brand manufacturer from selling an AG at any time. An AG is chemically identical to the brand drug, but is sold as a generic product typically through either the brand manufacturer’s subsidiary (if it has one) or through a third-party distributor. An AG is essentially the brand drug but in a different package. One study notes that “pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed ‘authorized generics.’”¹¹ Brand manufacturers sometimes begin selling AGs before the first-filer generic launches, in order to secure multi-year purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer generic.

58. Competition from an AG substantially reduces drug prices and the revenue of the first-filer generic (especially during the 180-day exclusivity period when no other generic can be on the market).

59. A study analyzing three examples of AGs found that “[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand.”¹² In a report by the FTC issued at the request of Congress in 2011, the FTC found that AGs capture a significant portion of sales, reducing the first-filer generic’s revenues by approximately 50% on

¹⁰ FDA WEBSITE, GENERIC DRUGS: QUESTIONS AND ANSWERS, *available at* <http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm> (last accessed September 15, 2014).

¹¹ K. A. Hassett & R. J. Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals*, SONECON, p. 3 (May 2007).

¹² E. R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers’ Welfare*, HEALTH AFFAIRS, v. 26, p. 796 & n.3 (May/June 2007).

average.¹³ The first-filer generic makes much less money when it faces competition from an AG because (a) the AG takes a large share of unit sales away from the first filer and (b) the presence of the AG causes prices, particularly generic prices, to decrease. Thus, if a brand manufacturer agrees to refrain from launching its AG, it can double the first-filer's revenue during the 180-day exclusivity period.

60. While a brand manufacturer's agreement not to launch an AG has tremendous financial value to a first-filer generic manufacturer, such an agreement, when used to induce the first-filer to delay its own launch, injures drug purchasers twice over: first, purchasers are forced to pay the high brand prices for longer than they otherwise would; and second, purchasers pay more for the generic in the absence of the AG. In fact, the 2011 FTC AG Study shows prices with AG entry are lower during the 180-day exclusivity period.¹⁴ Drug purchasers (including the proposed Class of direct purchasers) benefit from the lower prices caused by AG entry and are injured by the higher prices resulting from no AG competition.

61. Freedom from an AG is exceedingly valuable to the first-filer because it hands over all generic sales at higher, supracompetitive prices. Consequently, some brand companies – such as Endo – wield the right to launch an AG as a powerful tool to induce the first-filer generic – such as Impax – to delay its entry. The promise of payment to the first-filer generic in the form of an agreement not to launch an AG is economically equivalent to the promise of a cash payment by the brand manufacturer to the generic because refraining from launching an AG under the agreement effectively and predictably doubles the revenues and profits of that generic company from its generic, and the brand manufacturer forgoes the sales and revenues it

¹³ FTC 2011 AG Study, at 139.

¹⁴ FTC 2011 AG Study, at 113-14.

otherwise would have made with its AG. It's as if the brand launched the AG, then handed over its revenues to the first-filer.

62. For a first-filer, like Impax, seeking to sell a generic version of a brand product that sold hundreds of millions of dollars annually, like Opana ER, the difference between selling its generic alone, without having to compete against an AG, versus selling in competition with an AG can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. "No AG" agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

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

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

64. Later ANDA filers have more modest financial prospects because they have no expectation of any form of market exclusivity. By the time they enter the market there is at least the brand and one other generic on the market (if not also a second, in the form of an authorized generic) and thus, the drug has already been commoditized.

65. 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 motivated to expend resources to challenge the brand company's patent (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

66. When an anticompetitive agreement with the first-filer is already in place, however, litigation becomes less attractive to later filers. The later generic manufacturers know

that the first-filer is not leading the charge against the brand's patent (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive, reverse payment settlement). The later generics have to bear the brunt of the litigation costs themselves, and, upon prevailing in the patent litigation, expect to face competition from at least the first filer generic, and typically an authorized generic as well. The first settlement between a brand and first-filer generic (such as the Exclusion Payment Agreement at issue here) will often provide that, if a later generic filer launches its generic before the delayed date agreed to by the brand and the first-filer, the first-filer is permitted to launch then as well – greatly reducing the incentive the later filer would otherwise have to continue fighting to enter as soon as possible.

67. Thus, some later generics decide to simply give in to, or even join, the conspiracy between the brand company and the first-filer generic and decide to drop their challenges to the brand's patents and stay off the market until after entry by the first-filer.

68. Exclusion payment agreements 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.

69. Here, Endo and Impax's illegal Exclusion Payment Agreement resulted in two years and six months of unlawful monopolization in the market for Opana ER and its AB-rated generic equivalents. Endo delayed generic entry by buying off Impax, the first-filer generic. Then Endo's settlements with subsequent generic manufacturers (Actavis, Sandoz, Barr, Roxane, and Watson) kept them from entering the market until Impax – the first-filer – did so.

D. Brand Companies Have Strong Financial Incentives to Introduce New Versions of Products Solely to Protect Their Monopoly Profits by Impeding Generic Substitution.

70. The threat of AB-rated generic competition creates a powerful incentive for brand companies to protect their revenue streams. This incentive can prompt brand companies to create innovative new products or new versions of old products that offer real medical benefits to patients. It may also drive brand companies to seek to obstruct generic drug competition by making changes to existing products that offer patients little or, as here, no clinical advantages whatsoever, but are intended to interfere with the normal brand-to-generic competition contemplated and encouraged by the Hatch-Waxman Act and various state laws.

71. Such tactics, often referred to as “product switching” or “product hopping,” can be an effective, albeit anticompetitive, way to game the regulatory structure that governs the approval and sale of generic drugs, thereby frustrating the efforts of federal and state law designed to promote and facilitate price competition in pharmaceutical markets. As discussed in detail below, a brand company can interfere with the mechanism by which generic drugs compete by making non-therapeutic changes to its branded product, and can effectively prevent generic competition, not because the reformulated product is an improvement over the original version of the product or is preferred by consumers, but simply because it differs in strength, route of administration, or, as here, dosage form.

72. An AB-rating is particularly significant to a generic manufacturer because, under Hatch-Waxman and most state Drug Product Selection laws (“DPS laws”), pharmacists may (and in many states, must) substitute an AB-rated generic version of a drug for the brand-name drug without seeking or obtaining permission from the prescribing physician (unless the prescription is denominated “Dispense as Written” or “DAW”). Indeed, both Congress and state

legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously (a) engaging in the type of heavy promotion or “detailing” typically done by brand-name manufacturers, and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

73. AB-rated generic competition enables direct purchasers to (a) purchase generic versions of brand-name drugs at substantially lower prices, and/or (b) purchase the brand-name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic product, there is no bioequivalent generic drug which competes with the brand-name drug and therefore, the brand-name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales.

74. This statutorily mandated process, however, can be anticompetitively manipulated when brand-name manufacturers, like Endo here, introduce a new version of an already-existing drug that is no safer and no more effective than the original version, and switch the market to the “new” version thereby causing the conversion of prescriptions for the original drug to be written for the “new” version. The result is that, by the time generic versions of the original brand-name drug reach the market, there are few, if any, prescriptions being written for the original brand version and, because there is some slight clinically insignificant difference between the generic drug and the “new” brand drug (*e.g.*, dosage form), the generic will not be “AB-rated” and automatic substitution of the less-expensive generic for the more-expensive brand prescriptions cannot take place.

75. This leaves the generic manufacturer with a couple of choices, all of which result in significantly higher prices for purchasers: (a) implement its own extensive sales and marketing

campaign for its generic drug, which dramatically increases the price for its product (and, as a practical matter, acts as a barrier to meaningful market entry);¹⁵ (b) abandon altogether its generic product, meaning no generics are available; or (c) enter as a normal generic in a greatly and artificially diminished segment of the market resulting in dramatically lower sales and savings to purchasers. This anticompetitive result is only exacerbated when the brand company takes additional steps, as Endo did here, to share its monopoly profits with the first-filing generic through a reverse payment agreement and delay the market entry of other generics while it implements the switch scheme.

V. Statement of Facts

A. Endo Revives Tablet Formulations of Oxymorphone Hydrochloride and Acquires Time Release Patents from Penwest

76. Oxymorphone hydrochloride is a strong opioid agonist indicated to treat pain and also as a preoperative medication to alleviate apprehension, maintain anesthesia, and as an obstetric analgesic. Oxymorphone hydrochloride was first synthesized in 1914.

¹⁵ The barriers to entry by a generic drug manufacturer are high. Such companies must first formulate a non-infringing generic version of the brand name drug; conduct bioequivalence studies and other studies needed to support the ANDA; file the ANDA and work with FDA on any issues that arise regarding approval; either challenge relevant patents or wait for them to expire; wait for expiration of any applicable regulatory exclusivities; and invest in manufacturing facilities for the commercialization of the product. It is not economically rational for generic manufacturers to engage in these costly activities until regulatory and patent exclusivity expirations near. This is all the more so when generic companies have already heavily invested in formulating and pursuing FDA approval of a generic version of a brand name drug only to have the brand name manufacturer make a therapeutically meaningless formulation change and switch the market to that new formulation for the anticompetitive purpose of thwarting meaningful competition from the existing generic product. This puts the generic manufacturer in the position of having to scrap its investment in the initial generic version of the drug and re-invest in developing a second generic product equivalent to the next version of the branded counterpart drug, all in the hopes that additional switches will not take place prior to approval and launch of the second generation generic product. See generally *Abbott Laboratories v. Teva Pharm. USA, Inc.*, 432 F.Supp.2d 408 (D. Del. 2006).

77. Endo has marketed and sold oxymorphone hydrochloride in the United States for almost 50 years. On April 2, 1959, the FDA approved Endo's NDA for an injectable form of oxymorphone hydrochloride. On May 31, 1960, the FDA approved Endo's NDA for a rectal suppository form of oxymorphone hydrochloride. Endo marketed the rectal suppository under the brand name Numorphan. In the 1960s, oxymorphone hydrochloride was also made available in an oral immediate release tablet, but the tablet formulation was withdrawn from the market in 1972. Endo continued to market Numorphan in injectable and rectal suppository formulations, but these dosage forms were used relatively infrequently.

78. In the 1990s, Endo decided to seek FDA approval to re-launch a tablet form of oxymorphone hydrochloride. Endo was aware that the original patent on oxymorphone hydrochloride, issued in 1957, had expired, and because oxymorphone hydrochloride was a previously approved molecule, it would not be eligible for the five years of regulatory exclusivity awarded to approval of "New Molecules." Instead, at most, Endo could be eligible for three years of regulatory exclusivity if Endo submitted new clinical studies in support of its NDA.

79. Not satisfied with the prospect of having just three years of regulatory exclusivity, Endo purchased from Penwest the rights to patents that it could use to block generic entry beyond those three years. As such, on September 17, 1997, Endo entered into a collaboration agreement with Penwest to exclusively co-develop opioid analgesic products using Penwest's patents. Penwest possessed several patents related to time release formulations for drug tablets (not to be confused with patents on the drug molecules themselves, known as "drug substance patents"). In the 1990s, Penwest (then known as Edward Mendell Co.) obtained three patents all related to time release formulations: United States Patent No. 5,128,143 entitled sustained

release excipient and tablet formulation (the “‘143 patent”), United States Patent No. 5,958,456 entitled controlled release formulation (albuterol) (the “‘456 patent”), and United States Patent No. 5,662,933 entitled controlled release formulation (albuterol) (the “‘933 patent”). In 2002, Penwest also filed the application for what ultimately issued as United States Patent No. 7,276,250 entitled sustained release formulations of oxymorphone hydrochloride (the “‘250 patent”). The ‘143, ‘456, ‘933, and ‘250 patents are collectively referred to as the “Penwest time release patents.”

80. Penwest licensed the Penwest time release patents to Endo.

81. Opana ER is an extended release (hence “ER”) form of oxymorphone hydrochloride indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.

82. Opana IR is an immediate release (hence “IR”) form of oxymorphone hydrochloride indicated for the relief of moderate to severe acute pain.

83. Endo began selling Opana ER and Opana IR on or about July 21, 2006. Opana ER was originally approved and marketed in 5, 10, 20, and 40 mg tablets, and Opana IR was approved and marketed in 5 and 10 mg tablets.

84. In March 2008, the FDA approved three additional dosage strengths of Opana ER: 7.5, 15, and 30 mg tablets. Endo began selling those strengths of Opana ER on April 1, 2008.

85. Based upon Endo’s having conducted new clinical studies, Endo was awarded three years of regulatory exclusivity (preventing the FDA from approving any generic versions for three years) for all strengths of Opana ER and all strengths of Opana IR through June 22,

2009, after which Endo's Opana ER and Opana IR monopolies would be subject to generic competition absent patent protection.

86. The lower dosage strengths of Opana ER (5, 7.5, 10, and 15 mg) are typically used to taper patients on and off of Opana ER whereas the higher dosage strengths of Opana ER (20, 30, and 40 mg) are typically used for the treatment of pain and account for the great majority of Opana ER sales. For example, for the period from January 2009 to March 2011, total sales of Opana ER were just over \$757 million, but sales of the 7.5 and 15 mg strengths were only \$37.8 million or 5% of total sales, whereas sales of the 20, 30, and 40 mg strengths were \$642.8 million, representing 85% of total sales.

1. Opana IR's new clinical study exclusivity expires and generic competition for Opana IR starts immediately

87. Although Opana ER and Opana IR share the same active ingredients,¹⁶ Endo did not have any patents available to assert in order to extend its Opana IR monopoly beyond the three-year new clinical study exclusivity. Thus, Opana IR's exclusivity expired on June 22, 2009, and the normal process of generic entry (including Endo launching an AG) occurred.

88. Following the expiration of Opana IR's exclusivity, generics soon entered and drove the price of immediate release oxymorphone hydrochloride down to competitive levels.

89. Roxane was the first-filer for Opana IR 5 and 10 mg tablets. Roxane's ANDA was approved on September 27, 2010, and Roxane began selling generic oxymorphone hydrochloride 5 and 10 mg tablets on or about that day.

90. On or about November 1, 2010, Endo launched an AG form of 5 and 10 mg Opana IR tablets.

¹⁶ However, Opana ER and Opana IR are not AB-rated to each other.

91. Teva was the second to file for 5 and 10 mg Opana IR tablets. The FDA approved Teva's ANDA on February 15, 2011, and Teva began selling generic oxymorphone hydrochloride 5 and 10 mg tablets soon thereafter. Avanthi, Inc. ("Avanthi") was the third to file for 5 and 10 mg Opana IR tablets. Avanthi's ANDA was approved on January 30, 2013, and Avanthi launched thereafter through Avanthi's United States agent KVK-Tech, Inc.

92. But for the anticompetitive Exclusion Payment Agreement alleged herein, generic competition would have similarly begun for Opana ER in June 2010 and driven the price for extended release oxymorphone hydrochloride down to competitive levels.

2. Endo leverages Penwest's time release patents to extend Endo's monopoly on Opana ER

93. As noted above, Penwest licensed the '143, '250, '456, and '933 patents to Endo for the manufacture and sale of Opana ER. However, at the time of launch in 2006, Endo listed only the '143 patent in the Orange Book as covering Opana ER. The '143 patent was set to expire in 2008 before the expiration of Endo's three year clinical study exclusivity on June 22, 2009, and thus offered no relevant protection from generic competition.

94. The '456, and '933 patents were not listed in the Orange Book within 30 days of the FDA approving Endo's NDA for Opana ER as required under 21 C.F.R. § 314.53.

95. Pursuant to 21 C.F.R. § 314.53, brand companies must declare all patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product" for listing in the Orange Book within 30 days of filing an NDA. Late listing means listing a patent in the Orange Book more than 30 days after an NDA is approved in violation of 21 C.F.R. § 314.53.

96. Aware that generics would soon submit ANDAs that could be approved in time to allow for the sale of generic Opana ER as soon as Endo's three year clinical study exclusivity expired on June 22, 2009 – as was the case with Opana IR – in October 2007, over a year after Opana ER was launched, Endo late listed three additional Penwest patents – the '250, '456, and '933 patents – in the Orange Book.

3. Endo sues Impax triggering a 30-month Hatch-Waxman Stay

97. On or about June 29, 2007, Impax filed ANDA 79-087 for its generic extended release oxymorphone hydrochloride. Although the FDA initially accepted Impax's June 29, 2007 ANDA for substantive review, it later rescinded that acceptance due to certain deficiencies.

98. In or before November 2007, Impax resubmitted ANDA 79-087 to the FDA (rectifying the previous deficiencies) and included a Paragraph IV certification stating that Impax's proposed generic extended release oxymorphone hydrochloride tablets in 5, 10, 20, and 40 mg strengths did not infringe the '250, '456, or '933 patents.

99. On December 12, 2007, the FDA advised Impax that its ANDA 79-087 "has been deemed acceptable for filing and substantive review by FDA as of November 23, 2007."

100. On December 13, 2007, Impax sent Endo a notice stating that it had submitted ANDA 79-087 seeking approval to manufacture, use, or sell generic extended release oxymorphone hydrochloride tablets prior to the expiration of the '250, '456, and '933 patents. The December 13, 2007 notice also advised Endo that Impax's ANDA 79-087 included a Paragraph IV certification that the proposed manufacture, importation, use or sale of the generic extended release hydrochloride tablets described in Impax's ANDA 79-087 would not infringe any claim of the '250, '456, or '933 patents.

101. On January 25, 2008, Endo sued Impax in the United States District Court for the District of Delaware for alleged infringement of the ‘456 and ‘933 patents – but not for the ‘250 patent. Merely by filing this suit (and regardless of its merit or lack thereof), Endo triggered the automatic 30-month Hatch-Waxman stay, through June 2010, during which time the FDA could not approve Impax’s ANDA 79-087 for 5, 10, 20, and 40 mg generic Opana ER.

102. Impax was the first generic company to file an ANDA with a Paragraph IV certification as against the ‘250, ‘456, and ‘933 patents for the 5, 10, 20, and 40 mg strengths of Opana ER. This meant that Impax, as first-filer, was entitled to 180 days of exclusivity for those strengths as against other ANDA filers. As such, by delaying Impax’s entry into the market, Endo could delay all generics from entering the market for the 5, 10, 20, and 40 mg strengths of Opana ER.

103. With the Impax patent litigation pending, in March 2008, the FDA approved three additional dosage strengths of Opana ER: 7.5, 15, and 30 mg. Endo launched these strengths of Opana ER on April 1, 2008.

104. Soon thereafter, on June 13, 2008, Impax sent Endo a notice stating that Impax had filed an amendment to ANDA 79-087 to include the 7.5, 15, and 30 mg strengths. The June 13, 2008 notice also advised Endo that Impax’s amended ANDA included a Paragraph IV certification that the proposed manufacture, importation, use or sale of the generic extended release hydrochloride tablets described in its ANDA would not infringe any claim of the ‘250, ‘456, or ‘933 patents.

105. Impax was the first Paragraph IV filer against the 250, ‘456, and ‘933 patents for the 30 mg strength of Opana ER. As a result, Impax was entitled to 180 days of marketing

exclusivity for the 30 mg strength of generic Opana ER (as discussed below, Actavis was the first filer for the 7.5 and 15 mg strengths of generic Opana ER).

106. On July 25, 2008, Endo filed another lawsuit against Impax in the United States District Court for the District of Delaware alleging that Impax's amendment to its ANDA covering the 7.5, 15, and 30 mg tablets of generic Opana ER infringed the '456 and '933 patents (but not the '250 patent).

107. In February 2009, the lawsuits that Endo filed against Impax relating to Opana ER were consolidated and transferred to the United States District Court for the District of New Jersey under the lead docket number 09-831 (the "Impax Patent Litigation").

4. Endo sues other generic manufacturers who submit ANDAs for Opana ER

108. Endo sued all other generic ANDA filers for extended release oxymorphone hydrochloride.

a. Actavis

109. In February 2008, Endo received a notice from Actavis stating that Actavis had submitted ANDA 79-046 seeking approval to manufacture, use, or sell generic extended release oxymorphone hydrochloride tablets prior to the expiration of the '250, '456, and '933 patents. The Actavis notice advised Endo that Actavis's ANDA 79-046 included a Paragraph IV certification that the proposed manufacture, importation, use, or sale of the generic extended release hydrochloride tablets described in Actavis's ANDA would not infringe any claim of the '250, '456, or '933 patents and that the claims in those patents are invalid.

110. On March 28, 2008, Endo sued Actavis in the United States District Court for the District of New Jersey alleging infringement of only the '456 patent (it did not sue on the '250 or '933 patents). By filing this suit, Endo triggered the automatic 30-month stay during which the

FDA could not approve Actavis's ANDA for 5, 10, 20, and 40 mg generic Opana ER until August 2010 at the earliest.

111. On or about May 29, 2008 (covering 7.5 and 15 mg Opana ER) and June 30, 2008 (covering 30 mg Opana ER), Actavis sent Paragraph IV notices to Endo informing it that Actavis had amended its ANDA to include the new dosage strengths of Opana ER and that the Actavis generic Opana ER would not infringe the '250, '456, or '933 patents and that the claims in those patents are invalid.

112. Actavis was the first generic company to file a Paragraph IV certification with respect to the patents that Endo listed for the 7.5 and 15 mg strengths of Opana ER and therefore entitled to the 180 days of market exclusivity upon final FDA approval as against other ANDA filers (as discussed above, Impax was the first filer for all other dosage strengths). The 7.5 and 15 mg strengths, however, are used primarily to taper patients on and off of extended release oxymorphone hydrochloride and constitute a very small part of all Opana ER sales.

113. On July 11, 2008, Endo filed a second suit against Actavis in the United States District Court for the District of New Jersey alleging infringement of the '456 patent only (not the '250 or '933 patents), triggering the 30-month Hatch-Waxman automatic stay with regard to the 7.5, 15, and 30 mg strengths of Actavis's generic Opana ER.

114. The Actavis suits were later consolidated in the United States District Court for the District of New Jersey under the lead docket number 08-1563 (the "Actavis Patent Litigation").

b. Sandoz

115. On or about July 9, 2008, Sandoz sent a Paragraph IV notice to Endo with regard to Sandoz's ANDA 90-565 covering generic Opana ER in 5, 10, 20, and 40 mg dosage strengths explaining that the Sandoz generic would not infringe the '250, '456 or '933 patents.

116. On August 22, 2008, Endo sued Sandoz in the United States District Court for the District of Delaware alleging infringement of the '456 patent only (but not the '250 or '933 patents), triggering the 30-month Hatch-Waxman stay.

117. On or about November 17, 2008, by way of Paragraph IV notice and again explaining that its generic Opana ER would not infringe the '250, '456 or '933 patents, Sandoz informed Endo that it had amended its ANDA to include 7.5, 15 and 30 mg strengths of generic Opana ER.

118. On or about December 30, 2008, Endo filed a second suit against Sandoz in the United States District Court for the District of Delaware alleging infringement of the '456 patent (but not the '250 or '933 patents) for 7.5, 15 and 30 mg strengths of generic Opana ER, again triggering the 30 month Hatch-Waxman stay.

119. The two Sandoz suits were transferred to and consolidated in the United States District Court for the District of New Jersey under the lead docket number 09-836 (the "Sandoz Patent Litigation").

c. Barr

120. On or about September 11, 2008 (40 mg tablets) and September 12, 2008 (5, 10 and 20 mg tablets), Barr sent Endo Paragraph IV notices with respect to Barr's generic Opana ER ANDA 90-106 and asserting that Barr's generic products would not infringe the '250, '456 or '933 patents or the patents were invalid or not enforceable.

121. On October 20, 2008, Endo sued Barr in the United States District Court for the District of Delaware alleging that Barr's ANDA product would infringe the '456 and '933 patents (but not the '250 patent), triggering the 30 month Hatch-Waxman stay.

122. On or about June 1, 2009, Endo received another Paragraph IV notice from Barr covering the 7.5, 15, and 30 mg strengths of generic Opana ER.

123. Soon thereafter, on July 2, 2009, Endo filed another suit against Barr in the United States District Court for the District of New Jersey alleging infringement of only the '456 and '933 patents (but not the '250 patent), again triggering the 30-month Hatch-Waxman stay for the 7.5, 15, and 30 mg strengths of Barr's generic Opana ER

124. The two Barr suits were transferred to and consolidated in the United States District Court for the District of New Jersey under the lead docket number 09-838 (the "Barr Patent Litigation").

d. Roxane

125. 125. On or about December 28, 2009, Roxane sent Endo a Paragraph IV notice with respect to Roxane's ANDA 20-0822 for generic Opana ER in a 40 mg dosage strength, explaining that the Roxane generic would not infringe the '250, '456 or '933 patents.

126. On or about January 29, 2010, Endo filed a lawsuit against Roxane in the United States District Court for the District of New Jersey alleging infringement of only the '456 patent (but not '933 or '250 patents), triggering the 30-month Hatch-Waxman stay.

127. On or about March 18, 2010, Roxane sent a second Paragraph IV notice to Endo (covering generic Opana ER in the 7.5, 10, 15, 20 and 30 mg strengths) and again asserting that the Roxane generic product would not infringe the '250, '456 or '933 patents.

128. On or about April 16, 2010, Endo again sued Roxane, alleging infringement of the ‘456 patent (but not ‘933 or ‘250 patents), triggering the 30-month Hatch-Waxman stay.

129. The Roxane suits were later consolidated in the United States District Court for the District of New Jersey under the lead docket number 10-534 (the “Roxane Patent Litigation”).

e. Watson

130. On or about January 19, 2010, Endo received a Paragraph IV notice from Watson advising that Watson’s ANDA 20-0792 for generic Opana ER in a 40 mg dosage strength would not infringe the ‘250, ‘456 or ‘933 patents.

131. On or about March 4, 2010, Endo sued Watson in the United States District Court for the District of New Jersey alleging infringement of the ‘456 and ‘933 patents (but not the ‘250 patent), triggering the 30-month Hatch-Waxman stay.

132. On or about March 18, 2010, Watson sent a Paragraph IV notice regarding its ANDA for generic Opana ER in 5, 7.5, 10, 15, 20, and 30 mg dosage strengths.

133. On April 23, 2010, Endo amended the Watson complaint to include infringement allegations regarding the additional dosage strengths and therefore triggered the 30-month Hatch- Waxman stay with regard to the 5, 7.5, 10, 15, 20, and 30 mg strengths as well.

134. The Watson litigation continued in the United States District Court for the District of New Jersey (the “Watson Patent Litigation”).

B. Endo and Impax Enter the Exclusion Payment Agreement

1. Endo and Impax enter the Exclusion Payment Agreement during the Impax Patent Litigation and after FDA’s tentative approval of Impax’s ANDA

135. From 2007 to 2010, during the 30-month stay period, Endo and Impax litigated their patent infringement suit in the United States District Court for the District of Delaware and

then, following transfer and consolidation of the Impax Patent Litigation, in the United States District Court for the District of New Jersey. The Impax Patent Litigation was consolidated for pretrial purposes with the Sandoz Patent Litigation and the Barr Patent Litigation.

136. The case proceeded through discovery and claim construction briefing. Judge Katherine S. Hayden of the District of New Jersey conducted a *Markman* hearing on December 21, 2009, and March 19, 2010. Judge Hayden then entered an order on claim construction on March 30, 2010.

137. In the March 8, 2010 Final Pretrial Order, Impax asserted that it would prove that the '456 and '933 patents were invalid because they were: (1) anticipated by prior art; (2) obvious; and (3) constituted obvious-type double patenting. Further, Impax intended to prove that the '933 patent lacked an adequate written description. Finally, Impax contended that its generic Opana ER did not infringe the '250, 456, and '933 patents (even if those patents were valid).

138. As noted above, the 30-month stay on Impax's ANDA 79-087 was set to expire (and did expire) on or about June 14, 2010.

139. On May 4, 2010, Impax held its first quarter 2010 earnings call. During that call, Impax's then-President and CEO indicated that Impax was expecting to receive tentative approval of its generic Opana ER ANDA 79-087 by May 23, 2010, and that Impax was preparing to launch generic Opana ER.

140. On May 13, 2010, the FDA tentatively approved Impax's ANDA 79-087 for all dosage strengths of Opana ER; final approval of Impax's generic Opana ER had to wait for the running of the 30-month Hatch-Waxman stay on June 14, 2010.

141. The next day, May 14, 2010, during a telephonic hearing to discuss Endo's desire to file a motion to extend the statutory stay of FDA approval of Impax's proposed generic tablets, counsel for Endo represented that Endo had "indications" that Impax was "actually going down that road" of making and stockpiling generic Opana ER product. In response, counsel for Impax represented that Impax "certainly . . . will have the right to launch the [Opana ER generic] product upon final approval in mid-June." Counsel for Impax further represented that, "I certainly today could not say that we would agree not to launch on June 14th. It is our statutory right to launch the product after final approval."

142. With the trial of the Impax and Sandoz Patent Litigations set to commence on June 3 and conclude by June 17, 2010 (only three days after the 30-month stay was to end and Impax could receive final approval), and to avoid distractions caused by briefing the preliminary injunction motion filed by Endo, Impax agreed it would "not launch its ANDA product (generic oxymorphone [hydrochloride] extended-release tablets) through and including the last trial day as presently scheduled" in a May 20, 2010 letter to Judge Hayden.

143. The bench trial commenced on June 3, 2010, and continued through two days – June 3 and June 7, 2010.

144. Endo was aware that its patents and its patent infringement claims against Impax were weak and that it would not be able to obtain an injunction to stop Impax from launching its generic versions of Opana ER after Impax obtained final approval from the FDA. Likewise, Impax knew that it could make as much or more money by agreeing not to compete with Endo than by actually launching its generic Opana ER product. Had Impax launched generic versions of Opana ER upon receiving FDA final approval for its 5, 10, 20, and 40 mg strengths on June 14, 2010 (representing the vast majority of Opana ER sales) or at the conclusion of the trial, as it

was preparing and poised to do prior to the Exclusion Payment Agreement, Impax's generics would have rapidly driven down the price of extended release oxymorphone hydrochloride tablets. Impax was further aware that once its 180-day exclusivity period ran and there were multiple generic versions of Opana ER available, the generic becomes a commodity, with little or nothing to distinguish one generic from another except price. Price competition between generics is responsible for much of the dramatic price drop that accompanies generic entry. Impax was well aware of these market dynamics, and knew that it could likely make as much or even more money by agreeing to withhold its generic products in favor of, in effect, splitting Endo's monopoly profits from Opana ER. And that is precisely what happened.

145. With the bench trial underway, Endo and Impax settled the Impax Patent Litigation by contemporaneously entering into the Impax Settlement Agreement and the Impax Development Agreement (together the "Exclusion Payment Agreement") on or about June 8, 2010. The bench trial transcripts were sealed, and on June 15, 2010 the Impax Patent Litigation was dismissed with prejudice.

2. Impax agrees to delay launching generic Opana ER for two and a half years in exchange for a future cash payment of over \$102 million and other consideration from Endo

146. In exchange for a future cash payment of over \$102 million as well as other consideration from Endo, Impax agreed to delay the launch of its generic Opana ER products from June 14, 2010 to January 1, 2013, and to refrain from challenging the validity or enforceability of the '933 and '456 patents as well as the '250 patent, which Endo had not even accused Impax of infringing. Pursuant to the Exclusion Payment Agreement, Endo granted Impax a license and covenant not to sue for infringement of the '250, '456, and '933 patents as

well as any continuations of those patents and to any pending patent applications relating to Opana ER.

147. As a *quid pro quo* for Impax's agreement to delay the entry of generic Opana ER and refrain from challenging Endo's patents, Endo compensated Impax handsomely. In addition to Endo's grant of a license to Impax for the Opana ER patents that Impax asserted it was not infringing, the Exclusion Payment Agreement provided several vehicles to compensate Impax for its agreement to delay.

148. First, the Exclusion Payment Agreement provided for a future cash payment from Endo to Impax if sales of Opana ER fell below a predetermined contractual threshold in the quarter immediately prior to January 1, 2013 (which cash payment in the amount of \$102,049,000 was received by Impax in April 2013).

149. Second, the Exclusion Payment Agreement provided that Endo would withhold launch of an authorized generic ("AG") during Impax's 180-day exclusivity period, which at the time of the agreement would have been worth many millions of dollars, well above any litigation costs saved by Endo (or Impax) by settling. Endo's agreement not to launch an AG meant that Impax would be the sole generic on the market for at least 180 days, and Impax could therefore obtain all generic sales at higher, supracompetitive prices, all at the expense of Plaintiff and the members of the Class. Endo agreed to forego its own potential profits from the launch of an AG. Absent the unlawful Exclusion Payment Agreement, it would have made economic sense for Endo to launch an AG during Impax's 180-day exclusive marketing period so that Endo could retain some of the sales that Impax's less expensive generic otherwise would capture. Endo would have expected its AG to capture approximately 50% of the generic sales during the first 180 days of generic marketing.

150. *Third*, the Exclusion Payment Agreement included a development and co-promotion agreement whereby Endo paid Impax \$10 million in cash up front, with an obligation to pay an additional \$30 million, ostensibly for the right to co-promote Impax's as yet unapproved next generation Parkinson's disease product.

151. To date, pursuant to the Exclusion Payment Agreement, Impax has received at least \$112,049,000 in cash (the payment of \$102,049,000 million explicitly compensating Impax for delaying entry plus an additional \$10 million in cash up front as part of the purported Parkinson's drug agreement), and a "no-AG" agreement with a cash value to Impax in the millions of dollars in exchange for keeping Impax's generic Opana ER off the market for two and a half years.

152. Defendants have no procompetitive explanation or justification for the payments. This large, unjustified reverse payment had no rational connection to, and far exceeds, any approximation of the costs of continuing the patent litigation that was in the middle of trial at the time the agreement was signed. Nor was the payment consideration for the fair value of any procompetitive goods or services provided by Impax to Endo. In fact, Impax was not required to perform any service at all (except for delaying launch of its generic Opana ER) in exchange for the more than \$102 million cash payment. Impax was also not required to perform any service for the additional \$10 million upfront cash payment that was purportedly related to Impax's unapproved drug product. Endo simply paid Impax not to compete.

153. The agreement for Impax to delay market entry in exchange for, *inter alia*, Endo's reciprocal agreement not to price compete during Impax's 180-day exclusivity period by foregoing the launch of an authorized generic is a naked market allocation that is *per se* illegal.

154. Absent Endo's unlawful payments to Impax under the Exclusion Payment Agreement, Endo and Impax would have settled in a manner less restrictive of competition, resulting in much less delay of Impax's generic entry than as happened pursuant to a settlement with unlawful payments. Under such an agreement, or even without one (such as with an at-risk launch by Impax, or launch after a court ruling in Impax's favor), Impax would have launched its generic Opana ER substantially earlier than 2013.

155. The likely reason that the future cash payment (the more than \$102 million cash payment from Endo to Impax) called for by the Exclusion Payment Agreement was linked to the sales of Opana ER in the quarter immediately prior to Impax's launch was that Impax was concerned that Endo would switch the market in the interim.

156. In other words, Impax feared that, while it stayed out of the market, Endo would use this period to switch prescriptions and sales from branded Opana ER to some other branded formulation that Impax's generic would not be AB-rated to (and so not automatically substitutable for). If Endo implemented such a switch (often called a "product hop"), Impax's ability to sell its generic would be greatly impaired, because its generic could not be automatically substituted by pharmacists in filling prescriptions for the new formulation. Hence, the large reverse payment to Impax was triggered by branded Opana ER falling below a certain threshold in the quarter immediately before the (delayed) launch date Impax had agreed to (January 2013). In short, Impax made sure that it would be well paid for staying off the market.

157. And, as described below, Endo *did* undertake efforts to switch the market from Opana ER to a new formulation of Opana ER called Opana ER CRF that was purportedly crush resistant. When Impax entered the Exclusion Payment Agreement, Impax plainly anticipated Endo's product hop plan. Impax understood that if Endo was successful in switching the market

to a new formulation before Impax launched its generic Opana ER in January 2013, Impax would make significantly fewer sales than if it entered after final approval in June 2010 as planned because Impax would expect that its generic Opana ER would not be AB-rated to the new brand formulation.

158. Thus, the amount of the reverse payment to Impax was calculated based on the sales of Opana ER in the quarter immediately prior to Impax's own delayed launch, so that if Opana ER sales fell below a certain threshold in that quarter, the payment to Impax for agreeing not to compete for two and a half years would be greater. And, if Endo did not successfully switch the market to a new formulation (or did not try), then the monetary value of Endo's promise not to compete with an AG would be much greater, as the sales of branded Opana ER would have remained stable or grown while Impax agreed not to enter the market, and without competition from Endo's AG, Impax could expect to sell its generic at supracompetitive prices and obtain roughly twice as much revenue from selling its generic during its first 180 days than it would otherwise had it faced AG competition.

159. On June 14, 2010, just days after the parties entered into the Exclusion Payment Agreement, Impax received final approval for 5, 10, 20, and 40 mg strengths of generic Opana ER (representing the vast majority of Opana ER sales). On July 22, 2010, Impax received final approval for its 30 mg strength. But, because of the Exclusion Payment Agreement, Impax did not launch until two and half years later in January 2013.

3. Effects of the Exclusion Payment Agreement

160. The Exclusion Payment Agreement enabled Endo and Impax to (a) delay entry of less expensive generic versions of Opana ER 5, 10, 20, 30, and 40 mg strengths in the United States, (b) fix, raise, maintain or stabilize the price of 5, 10, 20, 30, and 40 mg strengths of

Opana ER and its generic equivalents, (c) permit Endo to maintain a monopoly in the United States market for 5, 10, 20, 30, and 40 mg strengths of Opana ER and its generic equivalents, (d) allocate the market for 5, 10, 20, 30, and 40 mg strength Opana ER and its generic equivalents almost exclusively to Endo through January 2013, and (e) eliminate price competition between Endo and Impax during Impax's 180-day exclusivity period by Endo withholding launch of its authorized generic until Impax's exclusivity expired.

161. The Exclusion Payment Agreement had the effect of delaying competition for 5, 10, 20, 30, and 40 mg oxymorphone hydrochloride extended release tablets for two and a half years. But for this reverse payment agreement, Impax would have begun marketing and selling its generic Opana ER as early as June 14, 2010 for the 5, 10, 20, and 40 mg strengths (and July 22, 2010 for the 30 mg strength), which is when Impax obtained final FDA approval of these strengths of generic Opana ER. Further, but for the no AG provision in the Exclusion Payment Agreement, when Impax did come on the market, Endo would have launched an AG to compete with Impax's generic Opana ER product, pushing generic prices lower.

162. Instead, as a result of the Exclusion Payment Agreement, Impax did not launch its 5, 10, 20, 30, and 40 mg generic Opana ER tablets until January 4, 2013. Further, pursuant to the terms of the Exclusion Payment Agreement, Endo did not launch a competing AG during Impax's 180-day exclusivity period (thus, Impax got paid in cash *and* through the "no AG" agreement to withhold its generic for two and a half years).

163. In addition, Endo and Impax, the first generic filer for the 5, 10, 20, 30, and 40 mg strengths generic Opana ER tablets, also knew and intended that their Exclusion Payment Agreement would prevent other generic companies from launching their own generic products in those strengths.

164. As the first filer of an ANDA with a Paragraph IV certification for generic Opana ER 5, 10, 20, 30, and 40 mg strengths, Impax was entitled to market its generic Opana ER in those strengths for 180 days free from competition from other generic Opana ER tablets (other than an AG) at those strengths. The operation of the Exclusion Payment Agreement between Endo and Impax blocked any non-AG generic Opana ER tablets from coming to market until 180 days after January 4, 2013, for those strengths because the FDA will not approve subsequently-filed ANDAs until the first-filer's exclusivity period has run. Endo admitted this in its Annual Report: "We expect Sandoz, Teva, Watson, Roxane and Actavis to launch production and sale of all strengths of generic non-tamper resistant Opana ER commencing on July 1, 2013 [*i.e.*, 180 days after the Impax launch]."

165. In other words, Impax served as a "cork in the bottle." So long as there was not a ruling invalidating the '456 and '933 patents (which would trigger the running of Impax's 180-day exclusivity period), the delayed launch of the Impax generic called for under the Exclusion Payment Agreement prevented any generic other than Impax from entering the marketing until July 2013.

166. Thus, Defendants' Exclusion Payment Agreement has delayed or prevented the sale of generic Opana ER 5, 10, 20, 30, and 40 mg strengths in the United States for more than two and a half years, and unlawfully enabled Endo to sell Opana ER 5, 10, 20, 30, and 40 mg strengths at artificially inflated, supracompetitive prices.

167. But for Defendants' illegal Exclusion Payment Agreement, generic competition to Opana ER 5, 10, 20, 30, and 40 mg strengths would have occurred as early as June 14, 2010, when Impax received final approval for its ANDA in the 5, 10, 20, and 40 mg dosage strengths (and July 22, 2010 for the 30 mg dosage strength). Further, if Impax had launched in June 2010,

the market for Opana ER would not have been substantially eroded by the switch to Opana ER CRF, and Impax would have made far more sales. Moreover, the Exclusion Payment Agreement blocked one or more generic manufacturers from launching generic versions of Opana ER on or about December 2010, when Impax's 180-day exclusivity would have expired absent the Exclusion Payment Agreement.

C. Endo Settles the Actavis, Barr, Sandoz, Watson, and Roxane Patent Litigations

1. Endo settles with Actavis

168. Less than a year after suing Actavis, on or about February 20, 2009, Endo settled all of the Actavis Patent Litigation (the "Actavis Settlement"). On February 25, 2009, the Actavis Patent Litigation was dismissed with prejudice.

169. As discussed above, Actavis was the first-filer on the 7.5 and 15 mg strengths of Opana ER, which are primarily used to taper users on or off of Opana ER. At all relevant times, these two strengths have never constituted more than 10 percent of Endo's Opana ER sales.

170. Under the terms of the Actavis Settlement, Actavis agreed not to challenge the validity or enforceability of the '250, '456, and '933 patents and Endo agreed to grant Actavis a license permitting the production and sale of generic Opana ER 7.5 and 15 mg tablets by the earlier of July 15, 2011, or the date on which any third party commences commercial sales of a generic oxymorphone hydrochloride extended-release tablets, but not before November 28, 2010. Endo also granted Actavis a license to produce and market other strengths of Opana ER generic on the earlier of July 15, 2011 or the date on which any third party commences commercial sales of a generic form of the drug. Endo's subsequent Exclusion Payment Agreement with Impax rendered that portion of the agreement with Actavis illusory as Endo and

Impax used Impax's first-filer status to prevent any other generics from launching those strengths earlier than July 2013 (180 days after Impax's belated January 2013 launch).

171. But for the Exclusion Payment Agreement between Endo and Impax, Actavis would have been able to launch its generic versions of the 5, 10, 20 30, and 40 mg strengths of Opana ER 180 days following Impax's launch of those strengths in June 2010 (and July 2010 for the 30 mg). However, due to the Exclusion Payment Agreement, Actavis did not launch those strengths until mid-2013.

172. Additionally, in March 2011, just before Actavis was able to launch the 7.5 and 15 mg strengths of Opana ER under the terms of the Actavis Agreement, Endo discontinued selling those strengths, impeding Actavis's entry into the market and greatly reducing the sales of its generic versions of the 7.5 and 15 mg dosage strengths.

2. Endo settles the Barr, Sandoz, Watson, and Roxane patent litigations

173. On or about April 12, 2010, Endo settled all of the Barr Patent Litigation relating to Opana ER. Under the terms of the settlement, Barr agreed not to challenge the validity or enforceability of the '250, '456, and '933 patents and Endo agreed to grant Barr a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date became illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Barr could not launch its generic until 180 days after Impax launched in January 2013.

174. The Sandoz litigation had proceeded to a bench trial that was begun on June 3, 2010 before the Honorable Katherine S. Hayden of the United States District Court for the District of New Jersey. On or about June 8, 2010 (the same time as the Endo/Impax Exclusion Payment Agreement and prior to Judge Hayden's ruling in the bench trial), Endo settled all of

the Sandoz Patent Litigation relating to Opana ER. Under the terms of the settlement, Sandoz agreed not to challenge the validity or enforceability of the '250, '456, and '933 patents and Endo agreed to grant Sandoz a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date was illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Sandoz could not launch its generic until 180 days after Impax launched in January 2013.

175. On or about October 4, 2010, Endo settled all of the Watson Patent Litigation relating to Opana ER. Under the terms of the settlement, Endo agreed to grant Watson a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date was illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Watson could not launch its generic until 180 days after Impax launched in January 2013.

176. On or about May 4, 2011, Endo settled all of the Roxane Patent Litigation relating to Opana ER. Under the terms of the settlement, Endo agreed to grant Roxane a license permitting the production and sale of all strengths of Opana ER commencing on September 15, 2012, or earlier under certain circumstances. The launch date was illusory in light of the "cork in the bottle" formed by Endo and Impax in the Exclusion Payment Agreement as Roxane could not launch its generic until 180 days after Impax launched in January 2013.

177. Notwithstanding agreements for entry dates in 2012, Barr, Sandoz, Watson, and Roxane were not able to sell a generic Opana ER product until 180 days after Impax's generic launch. As such, the real launch date for Barr, Sandoz, Watson, and Roxane generics could not

be before July 2013, a delay that Endo secured through its Exclusion Payment Agreement with Impax.

178. The importance of the Barr, Sandoz, Watson, and Roxane settlements for Endo were that they prevented Barr, Sandoz, Watson, and Roxane from obtaining a ruling that could threaten the validity of the '456 and '933 patents and move up the trigger date for Impax's 180-day exclusivity and the launch of generic Opana ER.

D. As a Result of the Delay Endo Bought with the Illegal Exclusion Payment Agreement with Impax, Endo was Able to Improperly Switch the Market from Opana ER to Opana ER CRF, Greatly Reducing the Sales Available to the Generic for Opana ER When it Eventually and Belatedly Entered the Market

179. Endo knew that in 2013 when generics for Opana ER were finally able to come onto the market there would be "substantial share erosion" for brand Opana ER and thus Endo had set about "working on multiple levels to combat that."

180. Accordingly, shortly after buying off Impax and illegally securing an additional two and a half years of its Opana ER monopoly, Endo set about switching the market from Opana ER to Opana ER CRF because generic Opana ER would not be automatically substitutable for Opana ER CRF.

181. On December 9, 2011, the FDA approved Endo's sNDA for Opana ER CRF in the same dosage strengths as were available with Opana ER. In approving Opana ER CRF, the FDA did not address any potential competitive effects associated with the approval of the purportedly new formulation or Endo's efforts to move the market from Opana ER to Opana ER CRF.

182. When the sNDA for Opana ER CRF was approved, Endo knew that according to the FDA, the new formulation had not been demonstrated to be safer, more effective, or more abuse-resistant than Opana ER. In December 2011, the FDA stated:

While the new formulation has demonstrated a minimal improvement in resistance to tampering by crushing, thereby limiting the likelihood of abuse by crushing followed by ingestion, and by insufflation (snorting) to some degree, it can still be...cut...rendering it readily abusable by ingestion and intravenous injection, and possibly still by insufflation; although whether...tablets can be snorted was not studied. Of more concern, when chewed...the new formulation essentially dose dumps like an immediate-release formulation.¹⁷

183. In February 2012, Endo launched Opana ER CRF in all dosage strengths except the lesser prescribed 7.5 and 15 mg. strengths. Three months later, in May 2012, Endo discontinued sales of all prior-generation Opana ER products in the United States citing what it alleged to be safety reasons arising from the availability of the reformulated Opana ER CRF product.

184. The discontinuation, which occurred just over seven months prior to the agreed-upon entry date for the first generic version of Opana ER, forced physicians desiring to prescribe extended release oxymorphone hydrochloride to prescribe Opana ER CRF. It also forced patients desiring to take extended release oxymorphone hydrochloride to take Opana ER CRF. On information and belief, the conversion rate from Opana ER to Opana ER CRF was at or near 100%.

185. In August 2012, Endo filed a citizen petition with the FDA requesting that the agency: (1) determine that the old versions of Opana ER were discontinued for reasons of safety, (2) refuse to approve any pending ANDA for a generic version of the old version of Opana ER, and (3) suspend and withdraw the approval of any ANDA referencing the old versions of Opana ER as the reference listed drug.

¹⁷ See Summary Review for Regulatory Action NDA 201-655 (Dec. 9, 2011) *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201655Orig1s000SumR.pdf (last accessed September 15, 2014).

186. When the FDA failed to act on the citizen petition by November 30, 2012, Endo filed a complaint and motion for preliminary injunction against the FDA seeking to require the FDA to act on the citizen petition by December 31, 2012.¹⁸

187. In its December 3, 2012 response to that petition, the FDA observed as follows: Endo reads into both the statutory provision and the regulation a requirement that FDA act by December 31, 2012. There is no statutory or regulatory support for Endo's claim. Indeed, the December 31 date is a function of Endo's own creation necessitated by its own commercial decision-making. In settlement of patent litigation, Endo granted a license to a generic manufacturer, Impax Laboratories, Inc. ("Impax"), that permits Impax to begin marketing a generic version of the original Opana ER on January 1, 2013...Endo's self-inflicted December 31 deadline is a thinly-veiled attempt to maintain its market-share and block generic competition from Impax.¹⁹

188. On December 19, 2012, Endo's suit against the FDA was dismissed, and on May 10, 2013 the FDA denied Endo's Citizen Petition in its entirety.²⁰

189. Despite Endo's claims to the contrary, the FDA found that Opana ER CRF is not safer than Opana ER and may in fact be more dangerous than Opana ER. In denying Endo's Citizen Petition, the FDA noted that the approved labeling for Opana ER CRF did not describe any abuse-deterrent properties, and the "abuse potential" subsection of the "Warnings and Precautions" section and the "Drug Abuse and Dependence" section of the approved labels for the two formulations are virtually identical.

¹⁸ *Endo Pharm.s Inc. v. U.S. F.D.A., et al.*, Case No. 12-01936-RBW (D.D.C.).

¹⁹ *Id.*, Defendants' Response to the Court's November 30, 2012 Order, ECF No. 9, p.4.

²⁰ Denial of the Citizen Petition (May 10, 2013), Docket No. FDA-2012-P-0895, *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0895-0001> (last accessed September 15, 2014).

190. Ultimately, the FDA disagreed with Endo's conclusions about the new formulation's safety advantages:

We disagree with Endo's conclusions about OPR [Opana ER CRF]'s alleged safety advantages. While there is an increased ability of OPR to resist crushing relative to OP [Opana ER], data from in vitro and pharmacokinetic studies show that OPR's extended-release features can be compromised, causing the product to "dose dump," when subjected to other forms of manipulation such as cutting, grinding, or chewing, followed by swallowing. It also appears that OPR can be prepared for insufflation (snorting) using commonly available tools and methods. OPR can be readily prepared for injection, despite Endo's claim that OPR tablets have "resistance to aqueous extraction (*i.e.*, poor syringeability)" (Petition at 4). In addition, certain data suggest that OPR can more easily be prepared for injection than OP.²¹

191. The one quality that Opana ER CRF possessed that made it significantly different from the previous version of Opana ER -- and which was crucial to Endo's anticompetitive scheme -- was dosage form. Endo exploited this difference for one reason: it knew that generic Opana ER would not and could not be considered "AB-rated" to branded Opana ER CRF, and thus pharmacists would not and could not legally substitute the less-expensive generic Opana ER when presented with a prescription for Opana ER CRF. Such automatic substitution of less-expensive AB-rated generics at the pharmacy counter is the most efficient market means by which generic competition reduces drug prices. Endo's introduction of Opana ER CRF disrupted this normally occurring efficient competitive mechanism whereby consumers are afforded discounted prices at the expiration of exclusivity periods for branded drugs.

192. Endo's exclusionary conduct has delayed, prevented, and impeded the sale of generic extended release oxymorphone hydrochloride in the United States, and unlawfully enabled Endo to sell significantly more branded extended release oxymorphone hydrochloride at artificially inflated prices. To the extent that Endo had any valid business purpose for the

²¹ *Id.* at 5-6 (internal citations omitted).

product hop to Opana ER CRF, that purpose is outweighed by the anticompetitive effects of the conduct. Endo's conduct has allowed it to maintain and extend its monopoly and exclude competition in the relevant market, to the detriment of all extended release oxymorphone hydrochloride purchasers, including Plaintiff, members of the Class, and consumers. Accordingly, the anticompetitive effects of Endo's conduct clearly outweigh the purported procompetitive benefits (if any) of such conduct.

193. Similarly, Endo cannot justify its conduct with any supposed consumer benefit, as the enormous cost savings offered by generic drugs outweigh any supposed benefit from the new formulation of Opana ER, which benefits are illusory. Endo's exclusionary motive is also illustrated by its willingness to sacrifice profits as part of the product hop strategy: Endo's decision to incur the extra costs necessary to change formulations was economically rational only if the change had the effect of excluding generic competition for Opana ER. But for the impact on generic competition, Endo would not have invested the resources necessary to bring Opana ER CRF to the market. But for the impact on generic competition, it would not have been economically rational to invest in licensing the supposed crush-resistant technology, developing the clinically interchangeable Opana ER CRF formulation, seeking FDA approval of that formulation, and changing the Opana ER manufacturing processes. The conversion from the original Opana ER formulation to the new Opana ER CRF formulation reduced Endo's short term profits and made economic sense only because of the long term anticompetitive effects of obstructing generic challengers' most efficient means of competing.

194. Had Endo not entirely converted the extended release oxymorphone hydrochloride market to the new Opana ER CRF formulation prior to the entry of generic equivalents to Opana ER, physicians and patients would have been able to weigh the relative

medical benefits and prices of the two formulations, and would have been able to choose the formulation and price point they preferred. Endo introduced Opana ER CRF and discontinued Opana ER in order to deny consumers that choice and took the additional affirmative steps to delay market entry of the less-expensive generic versions of Opana ER, all to preserve its monopoly profits.

195. Had Endo not converted the extended release oxymorphone hydrochloride market to the Opana ER CRF formulation, a launch of AB-rated generic equivalent versions of Opana ER would have quickly captured the bulk of extended release oxymorphone hydrochloride sales in the market. As a result, most, if not all, of the prescriptions that have been filled and are now being filled with Opana ER CRF instead would have been filled with generic extended release oxymorphone hydrochloride.

196. Moreover, had generic Opana ER launched before Opana ER CRF (as would have occurred but for the Exclusion Payment Agreement), the generic would have quickly captured the bulk of brand Opana ER sales, and the subsequent launch of Opana ER CRF (assuming it even still would have launched) would have had little effect on the sales of generic Opana ER.

197. But for the illegal Exclusion Payment Agreement, Endo's launch of Opana ER CRF would have occurred (if it occurred at all) long after generics had entered the market on or shortly after June 14, 2010 and captured the vast majority of the United States extended release oxymorphone hydrochloride market. As a result, most, if not all, of the prescriptions that are now being filled with Opana ER CRF instead would have been filled with generic extended release oxymorphone hydrochloride.

198. Thus, due to the Exclusion Payment Agreement and the effects flowing from the delayed entry of Impax, Actavis, Barr, Sandoz, Watson, and Roxane, Plaintiff and the Class continue to suffer overcharges even now.

VI. Class Allegations

199. Plaintiff Meijer brings this action as a class action under Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of itself and as representative of a class defined as follows:

All persons or entities in the United States and its territories who purchased brand or generic Opana ER 5, 10, 20, 30, and/or 40 mg tablets directly from Endo or Impax at any time during the period from June 14, 2010 until the anticompetitive effects of Defendants' conduct cease (the "Class").

Excluded from the Class are the Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

200. Joinder of the members of the Class is impracticable. Plaintiff believes the Class members are numerous and widely dispersed throughout the United States. Further, the Class is readily identifiable from information and records in the possession of Defendants. Direct notice to the members of the Class can be made upon obtaining the relevant information and records in the possession of Defendants.

201. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by Defendants' same wrongful conduct. Specifically, they paid artificially inflated prices for extended release oxymorphone hydrochloride tablets and were deprived of the benefits of competition from and the choice of cheaper generic versions of Opana ER as a result of Defendants' wrongful conduct.

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

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

204. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in the Defendants' wrongful conduct.

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

- a. whether Defendants conspired to restrain generic competition to Opana ER;
- b. whether Impax unlawfully agreed to delay its entry into the market for extended release oxymorphone hydrochloride tablets, *i.e.*, Opana ER and its AB-rated generic bioequivalents;
- c. whether Endo paid Impax in exchange for a delay in generic competition for Opana ER;
- d. whether Endo's compensation to Impax was necessary to yield some procompetitive benefit that is legally cognizable and nonpretextual;
- e. whether Defendants' challenged conduct suppressed generic competition to Opana ER;
- f. whether Defendants' challenged conduct harmed competition in the market for extended release oxymorphone hydrochloride, *i.e.*, Opana ER and its AB-rated generic bioequivalents;

- g. whether Endo possessed market power in the market for extended release oxymorphone hydrochloride, *i.e.*, Opana ER and its AB-rated generic bioequivalents;
- h. whether the relevant antitrust market (if a relevant market must be defined) is the market for extended release oxymorphone hydrochloride, *i.e.*, Opana ER and its AB-rated generic bioequivalents;
- i. whether Defendants' activities alleged herein have substantially affected interstate commerce;
- j. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and members of the Class in the nature of overcharges; and
- k. the quantum of overcharges paid by Plaintiff and the Class in the aggregate.

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

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

VII. Market Power and Relevant Market

208. At all relevant times, Endo had market power over extended release oxymorphone hydrochloride – including Opana ER and its AB-rated generic equivalents – because Endo had the power to maintain the price of these products at supracompetitive levels without losing substantial sales to other daily pain management products. This market power may be shown directly, and therefore no relevant market needs to be defined.

209. A small but significant, non-transitory price increase for Opana ER by Endo would not have caused a significant loss of sales to other pain medications sufficient to make such a price increase unprofitable.

210. Opana ER does not exhibit significant, positive cross-elasticity of demand with respect to price, with any other daily pain management product other than AB-rated generic versions of Opana ER.

211. Opana ER is not reasonably interchangeable with any products other than AB-rated generic versions of Opana ER.

212. The existence of non-Opana ER pain medications did not constrain Endo's ability to raise or maintain Opana ER prices without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust market product market with Opana ER. Therapeutic alternatives are not the same as economic alternatives.

213. Functional similarities between Opana ER and non-Opana ER pain medication products are insufficient to permit inclusion of those other pain medication products in the relevant market with Opana ER. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would be

maintained in a competitive market. No other pain medication (except for AB-rated generic versions of Opana ER) will take away sufficient sales from Opana ER to prevent Endo from raising or maintaining the price of Opana ER above levels that would prevail in a competitive market.

214. Opana ER is also not reasonably interchangeable with any products other than AB-rated generic versions of Opana ER because Opana ER has different attributes significantly differentiating it from other pain medications and making it unique. The FDA does not consider Opana ER and other pain medications interchangeable.

215. Price does not drive prescriptions for pain medications. The pharmaceutical marketplace is characterized by a “disconnect” between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Opana ER, to patients without a prescription written by a doctor. This prohibition introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient’s doctor chooses which product the patient will buy.

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

217. Thus, unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the initial purchasing decision for prescription drugs, such as pain management products, is made by the physician, not by consumers of those products.

Consequently, despite the existence of a number of different pain management products a physician could have started a patient on, or in theory could switch a patient to, once the physician and patient find one that is well-tolerated, it is very unlikely that the patient will switch to a different pain management product based on variations of price of 10% or less.

218. Doctors generally select a pain medication for their patients based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price. For clinical reasons, among others, physicians and patients prefer Opana ER to other pain medications.

219. The existence of other products designed to manage pain has not significantly constrained Endo's pricing of Opana ER.

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

221. The entry of other brand pain medications (or generic versions of those other brands) did not take substantial sales from Opana ER or cause Endo to lower its price. By contrast, the competitive impact of an AB-rated generic version of Opana ER on brand Opana ER would be substantial. Among other things, the entry of an AB-rated generic Opana ER would deliver hundreds of millions of dollars of savings to consumers.

222. At all relevant times, Endo has sold Opana ER at prices well in excess of the competitive price.

223. At all relevant times, Endo had, and exercised, the power to exclude and restrict competition to Opana ER and AB-rated bioequivalents.

224. At all relevant times, Endo enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

225. To the extent that Plaintiff is legally required to prove market power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is extended release oxymorphone hydrochloride tablets (*i.e.*, Opana ER and its AB-rated generic equivalents). During the relevant time, Endo has been able to profitably maintain the price of extended release oxymorphone hydrochloride tablets well above competitive levels.

226. The relevant geographic market is the United States and its territories.

227. Endo's market share in the relevant market was either 100% or close to 100% at all relevant times.

VIII. Market Effects and Damages to the Class

228. But for the anticompetitive conduct alleged above, Impax would have entered the market with its generic Opana ER as early as June 14, 2010 when it received final FDA approval for the 5, 10, 20, and 40 mg oxymorphone hydrochloride extended release strengths and July 22, 2010 when Impax received approval for the 30 mg strength. Other generic manufacturers would have entered the market with additional generic versions of Opana ER thereafter.

229. But for the anticompetitive conduct alleged above, Endo would not have introduced Opana ER CRF and discontinued the prior version of Opana ER, and this conversion of the market would not have significantly affected Impax's and other generics' ability to

penetrate the extended release oxymorphone hydrochloride market with AB-rated versions of Opana ER.

230. But for the anticompetitive conduct alleged above, Endo's efforts to switch the market from Opana ER to Opana ER CRF would not have significantly affected Impax's and other generics' ability to make sales of generic versions of Opana ER because absent the delay paid for by Endo, Impax would have launched well before Endo launched Opana ER CRF, and the vast majority, 90% or so, of the sales of Opana ER would switched to the generic product before the launch of Opana ER CRF (assuming it would have still launched at all).

231. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Opana ER from generic competition.

232. Impax, Actavis, Barr, Roxane, and Watson have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand.

233. Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of 5, 10, 20, 30, and 40 mg Opana ER, has caused Plaintiff and the Class to pay more than they would have paid for extended release oxymorphone hydrochloride tablets absent defendants' illegal conduct.

234. Typically, generic drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, nearly all brand drug purchases are rapidly substituted for generic equivalents of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even

further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its market share to the generic versions of the drug.

235. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices; (b) purchase generic equivalents of the drug at a lower price, sooner; and/or (c) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

236. But for Defendants' anticompetitive conduct, Plaintiff and members of the Class would have paid less for extended release oxymorphone hydrochloride tablets by: (a) substituting purchases of less-expensive AB-rated generic Opana ER for their purchases of more-expensive brand Opana ER; (b) receiving discounts on their remaining brand Opana ER purchases; and (c) purchasing generic Opana ER at lower prices sooner.

237. Moreover, due to Defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (a) launching generic versions of Opana ER, and/or (b) challenging the validity or infringement of the Opana ER Patents in court.

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

IX. Antitrust Impact

239. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Opana ER directly from Endo and/or generic Opana ER directly from Impax. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, artificially inflated prices for their extended release oxymorphone hydrochloride tablet requirements. Those prices were substantially greater than the prices that

Plaintiff and members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of Opana ER and generic Opana ER was artificially inflated by Defendants' illegal conduct, and (2) Plaintiff and Class members were deprived of the opportunity to purchase lower-priced generic versions of Opana ER.

240. As a consequence, Plaintiff 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

241. At all material times, Opana ER, manufactured and sold by Endo, and generic Opana ER, manufactured and sold by Impax, was shipped across state lines and sold to customers located outside its state of manufacture.

242. During the relevant time period, in connection with the purchase and sale of Opana ER and Impax's generic Opana ER, 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.

243. 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. Defendants' activities were within the flow of, and have substantially affected, interstate commerce.

XI. Claims For Relief

COUNT I: VIOLATION OF 15 U.S.C. § 1 AGREEMENT RESTRAINING TRADE

244. Plaintiff incorporates each preceding paragraph as though fully set forth herein.

245. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

246. The unlawful contract, combination, or conspiracy consisted of Endo and Impax entering into the Exclusion Payment Agreement, under which Endo agreed to pay Impax at least \$112 million and other consideration worth millions more in exchange for Impax's agreement to delay bringing its generic version of Opana ER to the market. The purpose and effect of this agreement and conduct were, and are, to: (a) allocate close to 100% of the market for Opana ER products in the United States to Endo; (b) prevent the sale of generic versions of Opana ER in the United States, thereby nearly completely protecting Opana ER from generic competition for two years and six months during which time Endo could switch the market for Opana ER to Opana ER CRF; (c) fix, raise, maintain or stabilize the price at which direct purchasers would pay for Opana ER or its AB-rated generic equivalent at supracompetitive levels; and (d) allocate close to 100% of United States generic Opana ER sales to Impax during the first 180 days of generic sales.

247. The Exclusion Payment Agreement harmed Plaintiff and the Class as set forth above.

248. The Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

249. The Exclusion Payment Agreement between Endo and Impax and their conduct under and pursuant to that agreement constitute an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual, procompetitive business justification for the exclusion payment made by Endo that outweighs its

harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

250. As a direct and proximate result of Endo's and Impax's anticompetitive conduct, as alleged herein, Plaintiff and the Class have been harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

**COUNT II: VIOLATION OF 15 U.S.C. § 2
MONOPOLIZATION**

251. Plaintiff hereby incorporates each preceding paragraph as though fully set forth herein.

252. This claim is pled as to Endo.

253. At all relevant times, Endo possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Endo possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

254. Through the anticompetitive conduct, as alleged extensively above, Endo willfully maintained monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class thereby.

255. It was Endo's conscious object to further its dominance in the relevant market by and through the anticompetitive conduct alleged herein.

256. Endo's anticompetitive conduct harmed competition as alleged herein.

257. There is and was no legitimate, nonpretextual procompetitive justification for the Endo Defendants' actions comprising the anticompetitive conduct that outweighs the scheme's

harmful effects. Even if there were some conceivable such justification, the conduct is and was broader than necessary to achieve such a purpose.

258. As a direct and proximate result of the Endo Defendants' illegal and monopolistic conduct, as alleged herein, Plaintiff and the Class were harmed as alleged herein.

**COUNT III: VIOLATION OF 15 U.S.C. § 2
ATTEMPTED MONOPOLIZATION**

259. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

260. This claim is pled as to Endo.

261. Through the Exclusion Payment Agreement and related conduct, Endo specifically intended to maintain monopoly power in the relevant market. It was Endo's conscious objective to control prices and/or to exclude competition in the relevant market.

262. The natural and probable consequence of Endo's anticompetitive conduct, which was intended by it, and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

263. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Endo would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

264. As a direct and proximate result of Endo's illegal and monopolistic conduct, Plaintiff and the Class were harmed as alleged herein.

**COUNT IV: VIOLATION OF 15 U.S.C. § 2
CONSPIRACY TO MONOPOLIZE**

265. Plaintiff hereby incorporates each preceding paragraph as though fully set forth here.

266. This claim is pleaded as to Endo and Impax. Endo and Impax are two distinct entities that are legally capable of conspiring with each other.

267. Through the Exclusion Payment Agreement and related conduct, Endo and Impax specifically intended to, and did, in fact, conspire and contract to unreasonably and unlawfully restrain and monopolize trade in the United States in the market for extended release oxymorphone hydrochloride (*i.e.*, Opana ER and its AB-rated generic equivalents), and to eliminate competition in the sale of Opana ER and, ultimately, restrict competition in the sale of Opana ER's AB-rated generic equivalents in the United States by effectively allocating the relevant market.

268. The goal and purpose of Endo and Impax's conspiracy was to artificially maintain and extend Endo's monopoly power with respect to Opana ER during the period between June 14, 2010 and January 1, 2013 (the period during which Impax could have, but did not, sell generic Opana ER). The effect of this conspiracy was two-fold, and had anticompetitive effects on both branded Opana ER and its AB-rated generic equivalents. First, introduction of generic versions of Opana ER were delayed until January 1, 2013, increasing prices to supra-competitive levels. Second, the impact of the conspiracy continued at least into the period during which Endo could have (but agreed not to) introduce its authorized generic, increasing prices of Opana ER's AB-rated generic equivalents to supra-competitive levels. Instead of introducing an authorized generic to compete with Impax's generic during Impax's 180-day exclusivity period – which would have allowed Plaintiff and the Class to benefit from lower prices such competition would bring about – Endo instead agreed to refrain from selling its authorized generic during that period. As a result, throughout the entire relevant period, Plaintiff and the Class paid supra-competitive prices for Opana ER and its AB-rated generic equivalents.

269. Endo's agreement to compensate Impax for not launching its generic version of Opana ER for 2 ½ years by paying Impax more than \$112 million, and by agreeing to refrain from selling its authorized generic versions of Opana ER during Impax's 180-day exclusivity period is evidence of Endo's specific intent to monopolize trade in the United States in the market for extended release oxymorphone hydrochloride (*i.e.*, Opana ER and its AB-rated generic equivalents). But for the Exclusion Payment Agreement, Endo had no financial or economic incentive in agreeing not to launch its own authorized generic version of Opana ER during Impax's 180-day exclusivity period. As alleged above in paragraphs 47, 53 – 54 and 58 – 63, there are significant economic incentives for brand manufacturers like Endo to sell authorized generics – particularly during the first-filer's 180-day exclusivity period, typically the most profitable period for the sale of a new generic drug because no other generic can be on the market. As further alleged in paragraph 150, it would have been in Endo's rational self-interest to introduce an AG during Impax's 180-day exclusivity period. However, contrary to that self-interest, Endo agreed to forego its own potential profits from the launch of an AG, instead agreeing with Impax to refrain from selling an authorized generic of Opana ER, guaranteeing that Impax would not have any generic competition during its 180-day exclusivity period.

270. Impax's agreement to delay the launch of its generic Opana ER products, along with Impax's agreement to refrain from challenging the validity or enforceability of the '933 and '456 patents (as well as the '250 patent, which Endo had not even accused Impax of infringing) is evidence of Impax's specific intent to monopolize trade in the United States in the market for extended release oxymorphone hydrochloride (*i.e.*, Opana ER and its AB-rated generic equivalents). As alleged in paragraph 160 above, despite having received final FDA approval for its 5, 10, 20, 30 and 40 mg strengths of generic Opana ER in the summer of 2010, Impax acted

against its economic self-interest by agreeing with Endo to delay the launch of those products for two and a half years.

271. Endo and Impax undertook overt acts in furtherance of their conspiracy, including, *inter alia*: (a) Impax's agreement to refrain from launching its generic Opana ER prior to January 1, 2013; (b) Endo's agreement not to launch its own authorized generic version of Opana ER during Impax's 180-day exclusivity period; and (c) Endo's cash payment of over \$102 million to Impax in April 2013, pursuant to the terms of the Exclusion Payment Agreement.

272. Endo and Impax's illegal conduct had an effect on interstate commerce, and such conduct was, in the aggregate, a conspiracy undertaken with the specific intent to monopolize the market for extended release oxymorphone hydrochloride (*i.e.*, Opana ER and its AB-rated generic equivalents) in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. As a result of Endo and Impax's conspiracy to monopolize the U.S. market for Opana ER and its AB-rated generic equivalents, Plaintiff and the other members of the Class were forced to pay, and did pay, artificially-inflated prices for Opana ER and its AB-rated generic equivalents. The prices that Plaintiff and the Class paid for Opana ER and its AB-rated generic equivalents were substantially greater than the prices that they would have paid absent Endo and Impax's conspiracy because Plaintiff and the Class were: (a) deprived of the opportunity to purchase lower-priced generic Opana ER during the period in which Impax agreed to delay launching its generic version of Opana ER; and (b) forced to pay artificially-inflated prices for generic versions of Opana ER during Impax's 180-day exclusivity period, during which Endo agreed not to launch its authorized generic, which would have reduced generic prices.

XII. Demand for Judgment

WHEREFORE, Meijer, on behalf of itself and the Class, respectfully requests that the Court:

- A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare Meijer to be a representative of the Class;
- B. Enter joint and several judgments against the Defendants and in favor of Meijer and the Class;
- C. Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and
- D. Award Meijer and the Class their costs of suit, including reasonable attorneys' fees as provided by law.

XIII. Jury Demand

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

Dated: September 19, 2014

Respectfully submitted,

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