

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

<p>Pennsylvania Employees Benefit Trust Fund, Individually And On Behalf Of All Others Similarly Situated,</p> <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">v.</p> <p>ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., PENWEST PHARMACEUTICALS CO., and IMPAX LABORATORIES INC.,</p> <p style="text-align: center;">Defendants.</p>	<p>Civil Action No.</p> <p>CLASS ACTION</p> <p>JURY TRIAL DEMANDED</p>
---	--

CLASS ACTION COMPLAINT

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	PARTIES	6
III.	JURISDICTION AND VENUE	7
IV.	REGULATORY BACKGROUND	8
	A. Generic Drugs Benefit Purchasers	8
	B. The FDA Approval Process	10
	C. The Government Encourages and Facilitates the Approval of Generic Drugs Through the Hatch-Waxman Amendments	10
	D. Pharmaceutical Manufacturers Game the Regulatory Structure.....	12
	E. Agreements Not to Compete Between the Brand’s Authorized Generic and the First-Filing Generic’s Product	13
V.	STATEMENT OF FACTS	15
	A. Endo Revives Tablet Formulations of Oxymorphone Hydrochloride and Acquires Time Release Patents from Penwest.....	15
	1. Opana IR’s new clinical study exclusively expires and generic competition for Opana IR begins.....	18
	2. Endo leverages Penwest’s time release patents to extend Endo’s monopoly on Opana ER.....	19
	3. Endo sues Impax triggering a 30 month Hatch-Waxman Stay.....	19
	4. Endo sues other generic manufacturers who submit ANDAs for Opana ER.	22
	a. Activis	22
	b. Sandoz.....	23
	c. Barr	24

d.	Roxane	25
e.	Watson	25
B.	Endo and Impax Enter the Exclusion Payment Agreement.....	26
1.	Endo and Impax enter the Exclusion Payment Agreement during the Impax Patent Litigation and after FDA’s tentative approval of Impax’s ANDA	26
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.	29
3.	Effects of the Exclusion Payment Agreement	33
C.	Endo Settles the Activis, Barr, Sandoz, Watson, and Roxane Patent Litigation.....	35
1.	Endo settles with Actavis.....	35
2.	Endo settles the Barr, Sandoz, Watson, and Roxane patent litigations.....	36
D.	As a Result of the Delay Endo Bought with the Illegal Exclusion Payment Agreement with Impax, Endo was Able to 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	38
VI.	CLASS ALLEGATIONS	39
VII.	MARKET POWER AND RELEVANT MARKET	43
VIII.	MARKET EFFECTS AND DAMAGES TO THE CLASS	47
IX.	ANTITRUST IMPACT	49
X.	EFFECT OF INTERSTATE AND INTRASTATE COMMERCE.....	50
XI.	CLAIMS FOR RELIEF	51
	COUNT I	
	Conspiracy and Combination in Restrain of Trade Under State Law (Asserted by Plaintiff and the Class Against Endo and Impax).....	51

COUNT II	
Monopolization and Monopolistic Scheme Under State Law (Asserted by Plaintiff and the Class Against Endo Defendants)	57
COUNT III	
Attempted Monopolization Under State Law (Asserted by Plaintiff and the Class Against Endo Defendants)	62
COUNT IV	
State Consumer Protection Violations (Asserted by Plaintiff and the Class Against All Defendants).....	66
COUNT V	
Unjust Enrichment Regarding Opana ER (Asserted by Plaintiff and the Class Against All Defendants).....	69
COUNT VI	
For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Defendants’ Violations of Sections 1 and 2 of the Sherman Act (Against all Defendants)	71
VII. DEMAND FOR JUDGMENT.....	71
VIII. JURY DEMAND	72

Plaintiff Pennsylvania Employees Benefit Trust Fund (“PEBTF” or “Plaintiff”) brings this class action, on behalf of itself and all others similarly situated, against Endo Health Solutions Inc., Endo Pharmaceuticals Inc., and Penwest Pharmaceuticals Co., (collectively “Endo”) and Impax Laboratories Inc. (“Impax”), (Endo and Impax collectively “Defendants”), based upon personal knowledge as to facts pertaining to itself, the investigation of counsel and upon information and belief as to all other matters, and alleges as follows:

1. INTRODUCTION

1. This is a civil antitrust action seeking treble damages arising out of the Defendants’ unlawful scheme to allocate 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 more than \$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. Endo used the period of delay that it bought from Impax to switch the market for Opana ER to a new formulation of Opana ER (“Opana ER CRF”).¹ But for Defendants’ market allocation 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 United States Food and Drug Administration (“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’ market allocation scheme injured Plaintiff and the Class of End-Payor 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

¹ CRF is an acronym for “crush resistant formulation.”

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 the 1950s and expired long ago.

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

4. Endo then embarked on a strategy 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 (discussed below), the mere filing of these lawsuits prevented the FDA from approving the generic drug applications for each of these generic manufacturers for 30 months, regardless of the merits of the lawsuits.

6. *Second*, Endo ended its litigation with Impax - the first-filer potential generic competitor for the vast majority of Opana ER sales (the 5, 10, 20, 30, and 40 mg dosages) - 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 to Impax:

- 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 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 other consideration from Endo, Impax agreed to keep its generic extended release oxymorphone hydrochloride off the market until January 2013 – two and a half years after Impax received final approval from the FDA to sell generic version 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. Beginning in 2012, long after the vast majority of brand Opana ER sales would have switched to the generic but for the illegal Exclusion Payment Agreement, Endo launched Opana ER CRF (Opana ER CRF is purportedly more crush resistant but is otherwise equivalent to Opana ER) and set about converting all Opana ER prescriptions to Opana ER CRF. Thus, when Impax belatedly launched its generic version of Opana ER in January 2013, the market for Opana ER was substantially eroded and, because generic versions of Opana ER are not AB-rated to Opana ER CRF (as discussed below), generic Opana ER cannot be automatically substituted for Opana ER CRF by pharmacists, further magnifying the anticompetitive effect of Defendants' unlawful conduct. Apparently anticipating Endo's market switch from Opana ER to Opana ER CRF, Impax had structured the bulk of the cash payment it would receive 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 belated launch. The Exclusion Payment Agreement provided that if sales of Opana ER were below a predetermined contractual threshold in the quarter immediately prior to January 1, 2013, Endo would make a cash payment to Impax, which cash payment would be larger the further the Opana ER sales fell below the predetermined contractual threshold. In this way, Impax made sure that it would be paid very well for not competing, *even if* Endo successfully switched the market from Opana ER to Opana ER CRF (as Endo in fact did) and thereby undercut the generic Opana ER sales that Impax would ultimately obtain.

9. The "basic reason" for the Exclusion Payment Agreement was Defendants' "desire to maintain and to share patent-generated monopoly profits" and therefore the Exclusion Payment 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.

10. Endo essentially bribed Impax to stay out of the market for two and a half years to protect Endo’s stream of monopoly profits. But for Endo’s unlawful and large reverse payment,² Impax would have launched its generic earlier than it finally did: (a) “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.

11. 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, and a generic version of 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 versions for their purchases of brand Opana ER long before Impax belatedly launched its generic in January 2013.

12. Defendants’ Exclusion Payment Agreement 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

² 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 (a “reverse payment”).

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 at least two and a half years.

13. PEBTF brings this action as a class action on behalf of all consumers and third-party payors (collectively, “End-Payers”) in certain states, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for brand and/or generic Opana ER, other than for re-sale since June 14, 2010 (see Class Definition below).

14. Plaintiff asserts claims for compensatory and/or treble damages for violations of the State laws enumerated below.

II. PARTIES

15. Plaintiff Pennsylvania Employees Benefit Trust Fund, is a labor-management trust fund duly organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 150 South 43rd Street, Suite 1, Harrisburg, Pennsylvania 17111-5700. PEBTF provides comprehensive healthcare benefits, including prescription drug coverage, to over 270,000 participants and beneficiaries, which include active and retired employees of the Commonwealth of Pennsylvania and their spouses and dependents. PEBTF indirectly purchased, paid, and/or provided reimbursement for brand Opana ER other than for resale, and purchased, paid and/or provided reimbursement for the generic versions of Opana ER other than for resale once they became available, at supracompetitive prices during the Class Period, and was thereby injured. PEBTF paid for purchases of Opana ER in several states, including Arizona, California, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Illinois, Indiana Kansas, Kentucky, Louisiana, Michigan, North Carolina, Nevada, New York, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, Wisconsin and West Virginia.

16. 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.

17. 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.

18. 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 Pharmaceuticals Inc. and Penwest developed and marketed Opana ER together. Penwest was previously known as Edward Mendell Co.

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

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

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

22. 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

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

24. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c), and (d) because during the class period, the Defendants 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. PEBTF paid for purchases of Opana ER in Illinois.

25. 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 this District.

26. During the class period, 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.

27. 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.

28. This Court has personal jurisdiction over each Defendant, because each Defendant – throughout the United States and including this District – has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal schemes and conspiracy. The Defendants' actions 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 persons in this District.

IV. REGULATORY BACKGROUND

A. Generic Drugs Benefit Purchasers

29. Generic competition for pharmaceuticals allows purchasers at all levels of the supply chain to buy drugs at reduced prices. Generic competition for a single branded drug can provide billions of dollars in savings to consumers, insurers, pharmacies, and other drug purchasers.

30. Generics that meet all of the requirements for approval are assigned an “AB” rating by the FDA. The AB rating permits the generic drug to be substituted for the brand name drug at the pharmacy counter. All states permit, and some states require, pharmacists to automatically substitute an AB-rated generic drug for the corresponding brand name drug unless the doctor has said that the prescription for the brand name product must be dispensed as written.

31. Until a generic manufacturer enters the market, the brand name manufacturer can charge monopolistic prices without a material loss in sales volume, because the drug faces no competition. Brand name drug manufacturers therefore have a strong interest in seeking to restrain or delay generic competition.

32. Many end-payors have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. And many consumers routinely switch from a branded drug to an AB-rated generic drug once the generic becomes available. AB-rated generic drugs therefore capture a significant share of their branded counterparts’ sales, causing a significant reduction in the branded drug’s unit and dollar sales.

33. The first AB-rated generic drug is typically priced significantly below its branded counterpart. As more AB-rated generics enter the market, the brand and generic drug prices usually continue to decline as the generics compete with one another and the brand name drug.

34. The first generic equivalent to reach the market often captures 80% or more of the market within the first six months. Within one year of market entry, the generic often accounts for 90% of the branded drug's unit sales and sells for 15% of the price of the brand name drug.

B. The FDA Approval Process

35. Under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), manufacturers who seek to market a new drug must apply for FDA approval to sell the drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. NDAs must include specific data concerning the safety and effectiveness of the drug and identify applicable patents.

36. When the FDA approves a brand manufacturer's NDA, the brand name manufacturer lists any patents it contends apply to the approved drug in a publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." The FDA does not confirm the accuracy of the information supplied by the brand manufacturer. After the NDA is approved, the brand manufacturer may list additional patents relating to the drug in the Orange Book.

C. The Government Encourages and Facilitates the Approval of Generic Drugs Through the Hatch-Waxman Amendments

37. In 1984, Congress amended the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), known as the Hatch-Waxman Amendments (Hatch-Waxman").

38. Hatch-Waxman simplifies the regulatory hurdles that generic manufacturers have to clear to enter the market. Instead of filing a lengthy and costly NDA, Hatch-Waxman allows

generic manufacturers to seek FDA approval on an expedited basis by filing an Abbreviated New Drug Application (“ANDA”).

39. If an ANDA applicant shows that the generic drug is “bioequivalent” to the brand name drug—that it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug—then the ANDA may rely on the scientific safety and effectiveness findings included in the brand name drug manufacturer’s original NDA. The streamlined approval process under Hatch-Waxman makes it easier for manufacturers to bring competing generic products to the market.

40. While Hatch-Waxman seeks to facilitate generic competition, the brand name manufacturer retains the right to enforce any patents associated with the drug. To gain regulatory approval, an ANDA application must also certify that the generic drug will not infringe the brand name drug’s patents listed in the Orange Book, because either (a) no patents exist on the brand name product; (b) the patents have expired; (c) the patents will expire by the time the generic product comes to market; or (d) the patents are invalid or will not be infringed by the sale of the generic product. The last certification, that the patents are invalid or not infringed, is known as a “Paragraph IV certification.”

41. When a generic manufacturer files a Paragraph IV certification asserting that a patent listed in the Orange Book is invalid or will not be infringed, it must promptly give notice of its certification to both the brand manufacturer and the owner of the patent. If the brand manufacturer files a patent infringement lawsuit against the ANDA filer within 45 days of receiving the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) 30 months or (b) a court ruling that the patent is invalid or not infringed by the generic manufacturer’s ANDA. During the 30-month stay, the FDA may grant “tentative

approval” to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval, but cannot authorize the generic manufacturer to market its drug before the 30-month stay expires or a court rules on invalidity and infringement.

42. Congress also created incentives for generic drug manufacturers to create generic alternatives and challenge weak patents. Hatch-Waxman gives a 180-day period of market exclusivity to the first ANDA applicant to file a substantially complete ANDA containing a Paragraph IV certification. During this period the first filer enjoys protection from other generic competitors, and is thus able to sell the generic for a higher price than when multiple generics enter the market. The brand name manufacturer may, however, market its own generic equivalent of the brand name drug (known as an “authorized generic”) during the 180-day period.

Pharmaceutical Manufacturers Game the Regulatory Structure

43. Because ANDA approval (and thus generic competition) is temporarily delayed whenever a brand name manufacturer sues the potential generic competitor for patent infringement, brand name manufacturers frequently take aggressive positions in listing patents in the Orange Book, and then bring patent lawsuits against any generic competitor that files an ANDA with a Paragraph IV certification. Brand name manufacturers often sue generics simply to delay generic competition, rather than to enforce valid patents against infringing products.

44. Brand name manufacturers have also developed a practice of entering into “settlements” of Paragraph IV litigation under which a brand name manufacturer pays off its generic competitors in exchange for a delay in generic competition. These exclusion payment agreements among horizontal competitors not to compete are commonly known as “pay-for-delay” or “reverse payment agreements.” By making a reverse payment settlement the brand

name manufacturer preserves its monopoly profits by paying of some of those profits to the generic manufacturer, which in turn agrees to delay marketing its product. Initially these agreements took the form of a straight cash payment from the brand name manufacturer to the generic competitor. Over time, brand name manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements. Because the profits to be gained by delaying generic competition are so great, however, drug manufacturers retain the incentive to enter into such agreements.

45. If the first-filed generic manufacturer is eligible for 180-days of marketing exclusivity, no other generic manufacturer can enter the market until the end of the exclusivity period. So the first filer's agreement to stay off the market effectively prevents all generic competition. This "bottlenecking" tactic is known as exclusivity "parking."

D. Agreements Not to Compete Between the Brand's Authorized Generic and the First-Filing Generic's Product.

46. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period. Such an authorized generic is chemically identical to the brand drug, but is sold as a generic. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

47. In its recent study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011) (the "FTC Study"), the Federal Trade Commission ("FTC") found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized

generic because: (a) the authorized generic takes a large share of unit sales away from the first filer; and (b) the presence of an additional generic in the market causes prices to decrease.

48. Given the significant negative effect of an authorized generic on the first-filing generic's revenues, a brand manufacturer's agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a form of payoff to the first-filer. Such non-competition agreements deprive consumers and other drug purchasers such as Plaintiff and the End-Payor Class of the lower prices resulting from two forms of competition: (a) among the branded and the generic products; and (b) between the generic products.

49. Agreements not to compete with an authorized generic can take many forms. According to the FTC Study, one such form includes agreements like the Agreement here whereby the brand manufacturer agrees to exclusively supply the first-filing generic with the authorized generic product. As confirmed by the FTC, the result is the same as if the brand agreed not to launch any authorized generic: no competition between an authorized generic and the first-filing generic's product for a period of time. *See* FTC Study at 146.

V. STATEMENT OF FACTS

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

50. Oxymorphone hydrochloride is a strong opioid antagonist 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.

51. 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 modalities were used relatively infrequently.

52. In the 1990s, Endo decided to seek FDA approval to re-launch a tablet form of oxymorphone hydrochloride. Endo knew 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.

53. Not satisfied with the prospect of having just three years of regulatory exclusivity, Endo Pharmaceuticals Inc. 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 Pharmaceuticals Inc. 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 “compound patents”). In the 1990s, Penwest (then known as Edward Mendell Co.) obtained four 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.”

54. Penwest licensed the Penwest time release patents to Endo Pharmaceuticals Inc.

55. 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.

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

57. 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.

58. 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 or about April 1, 2008.

59. Based upon Endo 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.

60. 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 exclusively expires and generic competition for Opana IR begins.

61. Although Opana ER and Opana IR³ share the same active ingredients, 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.

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

63. 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 immediate release oxymorphone hydrochloride 5 and 10 mg tablets on or about that day.

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

65. Teva was the second generic company to file an ANDA for 5 and 10 mg Opana IR tablets. The FDA approved Teva's ANDA on February 15, 2011, and Teva began selling generic immediate release oxymorphone hydrochloride 5 and 10 mg tablets soon thereafter. Avanthi, Inc. ("Avanthi") was the third generic company to file an ANDA for 5 and 10 mg

³ However, Opana ER and Opana IR are not AB-rated to each other.

Opana IR tablets. Avanathi's ANDA was approved on January 30, 2013, and Avanathi launched thereafter through Avanathi's United States agent KVK-Tech, Inc.

66. 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.

67. As noted above, Penwest licensed the '143, '250, '456, and '933 patents to Endo Pharmaceuticals Inc. At the time of launch in 2006, however, 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.

68. 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.

69. 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.

70. 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 later listed three additional Penwest time release patents - the '250, '456, and '933 patents - in the Orange Book.

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

71. As Endo expected, 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.

72. 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.

73. 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."

74. On December 13, 2007, Impax sent Endo a notice stating that it had submitted ANDA 79-807 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 oxymorphone hydrochloride tablets described in Impax's ANDA 79-087 would not infringe any claim of the '250, '456, or '933 patents.

75. 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 mid-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.

76. 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.

77. 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 or about April 1, 2008.

78. 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 oxymorphone hydrochloride tablets described in its ANDA would not infringe any claim of the '250, '456, or '933 patents.

79. 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).

80. 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).

81. 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.

82. Endo sued subsequent generic ANDA filers for extended release oxymorphone hydrochloride.

a. Actavis

83. 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 oxymorphone 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.

84. 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.

85. 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.

86. 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 Actavis was 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.

87. 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.

88. 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

89. 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.

90. 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.

91. On or about November 17, 2008, by way of Paragraph IV notice and again explaining that its generic Opana ER does 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.

92. 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.

93. 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

94. 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 asserting that Barr's generic products would not infringe the '250, '456 or '933 patents or the patents were invalid or not enforceable.

95. 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.

96. 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.

97. 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.

98. 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

99. 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.

100. 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.

101. On or about March 18, 2010, Roxanne 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.

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

103. 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

104. 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.

105. 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.

106. 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.

107. 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.

108. 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

109. From 2007 to 2010, during the 30 month stay period, Endo and Impax litigated their patent infringement suit. The Impax Patent Litigation was consolidated for pretrial purposes with the Sandoz Patent Litigation and the Barr Patent Litigation.

110. The case proceeded through discovery and claim construction briefing. The Honorable Katherine S. Hayden of the United States District Court for 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.

111. In a 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; (3) and 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).

112. As noted above, the 30 month stay on Impax's ANDA 79-046 was set to expire (and did expire) on or about June 14, 2010.

113. 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 79-046 by May 23, 2010, and that Impax was preparing to launch generic Opana ER.

114. On May 13, 2010, the FDA tentatively approved Impax's ANDA 79-046 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.

115. The next day, May 14, 2010, during a telephonic hearing to discuss Endo's desire to file a preliminary injunction 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 (*i.e.*,

Endo understood that Impax was preparing to launch at risk). 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.”

116. With the trial of the Impax and Sandoz Patent Litigations set to commence on June 3, 2010 and to 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 seeking to extend the statutory stay of FDA approval of Impax’s proposed generic tablets 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.

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

118. 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 generics would become 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.

119. 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.

120. 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 did not even accuse 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.

121. 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 Penwest time release patents that Impax asserted it was not infringing, the Exclusion Payment Agreement provided several vehicles to provide large and unexplained payments to compensate Impax for its agreement to delay launching its generic.

122. *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, an amount far above any litigation costs saved by Endo (or Impax) by settling).

123. *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 to Impax, 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.

124. *Third*, the payment 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 certain rights related to Impax's as yet unapproved next generation Parkinson's disease product.

125. To date, pursuant to the Exclusion Payment Agreement, Impax has received at least \$112,049,000 in cash (the payment of \$102,049,000 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 of millions of dollars in exchange for keeping Impax's generic Opana ER off the market for two and a half years.

126. 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.

127. 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.

128. 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.

129. In other words, Impax feared that, while it stayed out of the market for two and a half years, Endo would use this period to switch prescriptions and sales from branded Opana ER to some other brand formulation that Impax's generic would not be AB-rated to (and so not automatically substitutable for). If Endo successfully implemented such a switch before Impax launched its generic, Impax's ability to sell its generic would be greatly impaired, and Impax would make significantly fewer sales than it would have made if it entered after final approval in June 2010 as it had planned because Impax's generic Opana ER would not be AB-rated to the new brand formulation. Hence, in the Exclusion Payment Agreement, Impax made sure that the large reverse payment to Impax was triggered by brand Opana ER sales falling below a certain threshold in the quarter immediately before the delayed launch date (January 2013) that Impax had agreed to in the Exclusion Payment Agreement. In short, Impax made sure that it would be well paid for staying off the market no matter what happened during the two and a half years of delay.

130. 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 brand 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.

131. 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 a half years later in January 2013.

132. And, indeed, Endo ultimately *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. As a result, Impax received a reverse cash payment of more than \$102 million, and purchasers were left holding the bag.

3. Effects of the Exclusion Payment Agreement

133. 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 Opana ER and its generic equivalents, and (d) allocate the market for Opana ER and its generic equivalents almost exclusively to Endo through January 2013.

134. 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.

135. 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).

136. In addition, Endo and Impax, the first generic filer for the 5, 10, 20, 30, and 40 mg strengths of 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.

137. As the first-filer of an ANDA with a Paragraph IV certification for generic Opana ER for 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]."

138. In other words, Impax served as a "cork in the bottle." So long as there was not a court 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 market until July 2013.

139. Thus, Defendants' Exclusion Payment Agreement 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.

140. 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 Endo's 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 Litigation.

1. Endo settles with Actavis

141. 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.

142. 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.

143. 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 generic Opana ER 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).

144. 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-2013.⁴

⁴ 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 and greatly reducing the sales Actavis otherwise would have made upon launching the first generic version of the 7.5 and 15mg strengths.

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

145. 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.

146. The Sandoz litigation had proceeded to a bench trial that commenced on June 3, 2010 before Judge Hayden. On or about June 8, 2010 (the same time as the Endo/Impax Exclusion Payment Agreement and prior to Judge Hayden issuing any dispositive rulings 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.

147. 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.

148. 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.

149. Notwithstanding agreements for nominal 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 Endo’s Exclusion Payment Agreement with Impax.

150. The importance of the Barr, Sandoz, Watson, and Roxane settlements for Endo was that they prevented a court 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 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.

151. 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.”

152. 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.

153. The FDA approved Endo's NDA for Opana ER CRF on December 9, 2011. In approving Opana ER CRF, the FDA did not address any potential competitive effects associated with the approval of the Opana ER CRF formulation or Endo's efforts to switch the market from Opana ER to Opana ER CRF. To accomplish the switch between Opana ER and Opana ER CRF, Endo discontinued the sale of Opana ER, requiring physicians desiring to prescribe extended release oxymorphone hydrochloride to prescribe Opana ER CRF instead. 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. Thus, if generic Opana ER had 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 (even assuming it still would have launched) would have had little effect on the sales of generic Opana ER.

154. 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.

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

VI. CLASS ALLEGATIONS

156. End-Payor Plaintiff PEBTF 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 indirectly purchased and/or paid and/or provided reimbursement for some or all of the purchase price for brand or generic Opana ER 5, 10, 20, 30, and/or 40 mg tablets for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale at any time during the period from June 14, 2010 until the anticompetitive effects of Defendants' conduct cease (the "Class").

157. The following persons or entities are excluded from the proposed Class:
- a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;
 - b. All governmental entities, except for government funded employee benefit plans;
 - c. All persons or entities who purchased Opana ER for purposes of resale or directly from the Defendants or their affiliates;
 - d. Fully insured health plans (plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);
 - e. Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs); and
 - f. The judges in this case and any members of their immediate families.

158. 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.

159. 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 the Defendants' wrongful conduct.

160. 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.

161. 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.

162. 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, and Defendants' unlawful conduct has inflicted antitrust injury in the form of overcharges on the Class. Such generally applicable conduct is inherent in the Defendants' wrongful conduct.

163. 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 non-pretextual;
- 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 and intrastate 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.

164. 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 any potential difficulties in management of this class action.

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

15. MARKET POWER AND RELEVANT MARKET

166. 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 extended release oxymorphone hydrochloride 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.

167. 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.

168. 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.

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

170. 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 with Opana ER. Therapeutic alternatives are not the same as economic alternatives.

171. 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.

172. 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.

173. 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.

174. 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.

175. 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 unlikely that the patient will switch to a different pain management product based on variations of price.

176. 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.

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

178. 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.

179. 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 purchasers.

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

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

182. 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.

183. 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.

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

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

VII. MARKET EFFECTS AND DAMAGES TO THE CLASS

186. 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 extended release oxymorphone hydrochloride strengths, and July 22, 2010 when Impax received final FDA approval for the 30 mg strength. Other generic manufacturers would have entered the market with additional generic versions of Opana ER thereafter.

187. 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 ability to make sales of its generic version 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 bulk (on the order of 90%) of the sales of Opana ER would have switched to Impax's generic product before the launch of Opana ER CRF (assuming it would have still launched at all).

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

189. Impax, Actavis, Barr, Sandoz, Watson, and Roxane 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.

190. 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.

191. 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.

192. 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.

193. 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) paying reduced prices on their remaining brand Opana ER purchases; and (c) purchasing generic Opana ER at lower prices sooner.

194. 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 '456, '933, and '250 patents (*i.e.*, the Penwest time release patents) in court.

195. At all relevant times during the Class Period, Plaintiff and the Class indirectly purchased substantial amounts of Opana ER. As a direct and proximate result of Defendants' illegal conduct, Plaintiff and the Class were compelled to pay, and did pay, artificially inflated prices for Opana ER and its generic equivalents. Plaintiff and the Class paid prices substantially greater than the prices they otherwise would have paid absent Defendants' illegal conduct because Plaintiff and the Class (i) were deprived of the opportunity to purchase lower-priced generic Opana ER instead of expensive brand Opana ER, and (ii) paid artificially inflated prices for Opana ER and its generic equivalents.

196. As a direct and proximate result of Defendants' unlawful anticompetitive scheme and wrongful conduct, Plaintiff and the Class have sustained (and will continue to sustain) substantial losses and damage to their business and property in the form of overcharges they paid for Opana ER and its generic equivalents, the exact amount of which will be proven at trial.

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

VIII. ANTITRUST IMPACT

198. Overcharges for pharmaceuticals at a higher level of distribution generally result in higher prices at every level below.

199. Wholesalers and retailers passed on the inflated prices of branded Opana ER and AB-rated generic Opana ER to Plaintiff and Class.

200. Defendants' anticompetitive conduct enabled them to indirectly charge consumers and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

201. The inflated prices paid by Plaintiff and Class are traceable to, and the direct, proximate and foreseeable result of, Defendants' overcharges.

202. General economic theory recognizes that any overcharge at a higher level of distribution in the chain of distribution for Opana ER results in higher prices at every level below. Herbert Hovenkamp, *FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE*, p. 624 (1994). Professor Herbert Hovenkamp goes on to state that "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." He also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

203. Defendants' anticompetitive conduct enabled them to charge consumers indirectly and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

204. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

205. The inflated prices Plaintiff and members of the Class paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

IX. EFFECT OF INTERSTATE AND INTRASTATE COMMERCE

206. Defendants' anticompetitive conduct has affected interstate and intrastate commerce.

207. At all relevant times, Endo manufactured, promoted, distributed, and sold substantial amounts of Opana ER in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

208. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Opana ER and its generic equivalent.

209. In furtherance of their efforts to monopolize and restrain competition, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and will continue to substantially effect), interstate commerce.

210. Defendants' anticompetitive conduct also had substantial intrastate effects in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic Opana ER to End-Payors inside each respective state. The complete foreclosure of generic Opana ER directly impacted and disrupted commerce for End-Payors within each state (and will continue to do so).

211. During the relevant time period, Opana ER, and its generic equivalent were shipped into each state and were sold to or paid for by End-Payors in each state. Defendants' conduct as set forth in this Complaint had substantial effects on intrastate commerce in each state because Opana ER, and its generic equivalent were sold to End-Payors in each state at

supracompetitive prices and Defendants entered into unlawful anticompetitive agreements that affected commerce in each state.

XI. CLAIMS FOR RELIEF

COUNT I

Conspiracy and Combination in Restrain of Trade Under State Law (Asserted by Plaintiff and the Class Against Endo and Impax)

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

213. Endo and Impax entered into the Exclusion Payment Agreement to suppress generic competition for Opana ER. The Exclusion Payment Agreement has involved the conduct set forth above. The Exclusion Payment Agreement is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which to:

- a. Allocate close to 100% of the market for Opana ER 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 at least 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 End-Payor 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.

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

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

216. The Exclusion Payment Agreement between Endo and Impax regarding Opana ER involves (i) large and unjustified payments from Endo to Impax (\$102 million and other consideration), and (ii) an agreement by Impax to delay marketing its generic Opana ER. The payments from Endo to Impax under the Agreement were the *quid pro quo* for Impax's agreement to delay marketing its generic version of Opana ER. Absent the payments, Impax would not have agreed to delay marketing its generic version of Opana ER and would have entered the market sooner than it did.

217. The purpose and effect of the payments flowing from Endo to Impax under the Exclusion Payment Agreement were to delay generic competition to Opana ER. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effect. Even if there were some conceivable justification, the payments were not necessary to achieve such a purpose.

218. The purpose and effect of the unlawful Exclusion Payment Agreement between Endo and Impax were to allocate 100% of the market for Opana ER and its generic equivalents in the United States to Endo, delay the sale of generic Opana ER products, and fix the prices at which consumers and other End-Payers would pay for Opana ER and its generic equivalents at the higher, branded price.

219. The Exclusion Payment Agreement harmed competition.

220. The Exclusion Payment Agreement between Defendants is a horizontal market allocation and price fixing agreement between the actual and potential competitors and is an unreasonable restraint of trade, in violation of state antitrust law, under a “rule of reason” analysis.

221. As a direct and proximate result of Endo’s and Impax’s unlawful restraint of trade, Plaintiff and the Class paid artificially inflated prices for Opana ER and its generic equivalents as described herein, and were harmed as a result.

222. By engaging in the foregoing conduct, Endo and Impax intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of:

- a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Opana ER in Arizona by members of the Class.
- b. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases of Opana ER in California by members of the Class.
- c. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases of Opana ER in the District of Columbia by members of the Class.
- d. Fla. Stat. §§ 542.15, *et seq.* and §§ 501.201, *et seq.*, with respect to purchases of Opana ER in Florida by members of the Class.
- e. Hawaii Code § 480, *et seq.*, with respect to purchases of Opana ER in Hawaii by members of the Class.
- f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Opana ER in Illinois by members of the Class.
- g. Iowa Code § 553.2 *et seq.*, with respect to purchases of Opana ER in Iowa by members of the Class.

- h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Opana ER in Kansas by members of the Class.
- i. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Opana ER in Massachusetts by members of the Class.
- j. Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Opana ER in Maine by members of the Class.
- k. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Opana ER in Michigan by members of the Class.
- l. Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Opana ER in Minnesota by members of the Class.
- m. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Opana ER in Mississippi by members of the Class.
- n. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Opana ER in Nebraska by members of the Class.
- o. Nev. Rev. Stat. Ann. § 598A, *et seq.*, with respect to purchases of Opana ER in Nevada by members of the Class, in that thousands of sales of Opana ER took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- p. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases of Opana ER in New Hampshire by members of the Class.
- q. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Opana ER in New Mexico by members of the Class.

- r. New York General Business Law § 340, *et seq.*, with respect to purchases of Opana ER in New York by members of the Class.
- s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Opana ER in North Carolina by members of the Class.
- t. N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Opana ER in North Dakota by members of the Class.
- u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Opana ER in Oregon by members of the Class.
- v. 10 L.P.R.A. § 258, *et seq.*, with respect to purchases of Opana ER in the Commonwealth of Puerto Rico by members of the Class.
- w. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases of Opana ER in Rhode Island by members of the Class.
- x. S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Opana ER in South Dakota by members of the Class.
- y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Opana ER in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Opana ER at Tennessee pharmacies.
- z. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Opana ER in Utah by members of the Class who reside in Utah.
- aa. Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Opana ER in Vermont by members of the Class.

- bb. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Opana ER in West Virginia by members of the Class.
- cc. Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Opana ER in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end- payors in Wisconsin paying substantially higher prices for Opana ER at Wisconsin pharmacies.

223. Plaintiff and the Class have been (and will continue to be) injured in their business or property by reason of Endo's and Impax's antitrust violations, in that Plaintiff and Class (i) were denied the opportunity to purchase lower-priced generic Opana ER, and (ii) paid higher prices for branded Opana ER than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

224. Plaintiff and Class seek damages and multiple damages as permitted by law for their injuries.

COUNT II
Monopolization and Monopolistic Scheme Under State Law
(Asserted by Plaintiff and the Class Against Endo Defendants)

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

226. This claim is pled as to the Endo Defendants.

227. At all relevant times, the Endo Defendants possessed substantial market power (i.e., monopoly power) in the relevant market. The Endo Defendants possessed the power to

control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

228. Through the anticompetitive conduct, as alleged extensively above, the Endo Defendants willfully maintained their 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.

229. It was the Endo Defendants' conscious objective to further their dominance in the relevant market by and through the anticompetitive conduct alleged herein.

230. The Endo Defendants' anticompetitive conduct harmed competition as alleged herein.

231. 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.

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

233. By engaging in the foregoing wrongful conduct, the Endo Defendants intentionally and wrongfully maintained monopoly power over the sale of Opana ER and its generic equivalents, in violation of the following state laws:

- a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Opana ER in Arizona by members of the Class.
- b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases of Opana ER in California by members of the Class.

- c. D.C. Code Ann. §§ 28-4503, *et seq.*, with respect to purchases of Opana ER in the District of Columbia by members of the Class.
- d. Fla. Stat. §§ 542.15, *et seq.* and §§ 501.201, *et seq.*, with respect to purchases of Opana ER in Florida by members of the Class.
- e. Hawaii Code § 480, *et seq.*, with respect to purchases of Opana ER in Hawaii by members of the Class.
- f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Opana ER in Illinois by members of the Class.
- g. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Opana ER in Iowa by members of the Class.
- h. Kan. Stat. Ann. § 50-161 (b), *et seq.*, with respect to purchases of Opana ER in Kansas by members of the Class.
- i. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Opana ER in Massachusetts by members of the Class.
- j. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Opana ER in Maine by members of the Class.
- k. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Opana ER in Michigan by members of the Class.
- l. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, with respect to purchases of Opana ER in Minnesota by members of the Class.
- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Opana ER in Mississippi by members of the Class.

- n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Opana ER in Nebraska by members of the Class.
- o. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases of Opana ER in Nevada by members of the Class, in that thousands of sales of Opana ER took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- p. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases of Opana ER in New Hampshire by members of the Class.
- q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Opana ER in New Mexico by members of the Class.
- r. New York General Business Law § 340, *et seq.*, ("The Donnelly Act"), with respect to purchases of Opana ER in New York by members of the Class.
- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Opana ER in North Carolina by members of the Class.
- t. N.D. Cent. Code § 51-08.1-03, *et seq.*, with respect to purchases of Opana ER in North Dakota by members of the Class.
- u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Opana ER in Oregon by members of the Class.
- v. 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of Opana ER in the Commonwealth of Puerto Rico by members of the Class.
- w. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases of Opana ER in Rhode Island by members of the Class.

- x. S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Opana ER in South Dakota by members of the Class.
- y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Opana ER in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Opana ER at Tennessee pharmacies.
- z. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Opana ER in Utah by members of the Class who reside in Utah.
- aa. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of Opana ER in Vermont by members of the Class.
- bb. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Opana ER in West Virginia by members of the Class.
- cc. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of Opana ER in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for Opana ER at Wisconsin pharmacies.

234. Plaintiff and the Class have been (and will continue to be) injured in their business or property by reason of the Endo Defendants' antitrust violations, in that Plaintiff and Class members (i) were denied the opportunity to purchase lower-priced generic Opana ER, and (ii) paid higher prices for branded Opana ER than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of

Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

235. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries.

COUNT III
Attempted Monopolization Under State Law
(Asserted by Plaintiff and the Class Against Endo Defendants)

236. Plaintiff hereby incorporated each preceding and succeeding paragraph as though fully set forth herein.

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

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

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

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

241. By engaging in the foregoing conduct, the Endo Defendants intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

- a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Opana ER in Arizona by members of the Class.

- b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases of Opana ER in California by members of the Class.
- c. D.C. Code Ann. §§ 28-4503, *et seq.*, with respect to purchases of Opana ER in the District of Columbia by members of the Class.
- d. Fla. Stat. §§ 542.15, *et seq.* and §§ 501.201, *et seq.*, with respect to purchases of Opana ER in Florida by members of the Class.
- e. Hawaii Code § 480, *et seq.*, with respect to purchases of Opana ER in Hawaii by members of the Class.
- f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Opana ER in Illinois by members of the Class.
- g. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Opana ER in Iowa by members of the Class.
- h. Kan. Stat. Ann. § 50-161 (b), *et seq.*, with respect to purchases of Opana ER in Kansas by members of the Class.
- i. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Opana ER in Massachusetts by members of the Class.
- j. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Opana ER in Maine by members of the Class.
- k. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Opana ER in Michigan by members of the Class.
- l. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, with respect to purchases of Opana ER in Minnesota by members of the Class.

- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Opana ER in Mississippi by members of the Class.
- n. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Opana ER in Nebraska by members of the Class.
- o. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases of Opana ER in Nevada by members of the Class, in that thousands of sales of Opana ER took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- p. N.H. Rev. Stat. Ann. §§ 356.11, with respect to purchases of Opana ER in New Hampshire by members of the Class.
- q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Opana ER in New Mexico by members of the Class.
- r. New York General Business Law § 340, *et seq.*, ("The Donnelly Act"), with respect to purchases of Opana ER in New York by members of the Class.
- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Opana ER in North Carolina by members of the Class.
- t. N.D. Cent. Code § 51-08.1-03, *et seq.*, with respect to purchases of Opana ER in North Dakota by members of the Class.
- u. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Opana ER in Oregon by members of the Class.
- v. 10 L.P.R.A. §§ 260, *et seq.*, with respect to purchases of Opana ER in the Commonwealth of Puerto Rico by members of the Class.

- w. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases of Opana ER in Rhode Island by members of the Class.
- x. S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Opana ER in South Dakota by members of the Class.
- y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Opana ER in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Opana ER at Tennessee pharmacies.
- z. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Opana ER in Utah by members of the Class who reside in Utah.
- aa. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases of Opana ER in Vermont by members of the Class.
- bb. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Opana ER in West Virginia by members of the Class.
- cc. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of Opana ER in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for Opana ER at Wisconsin pharmacies.

242. Plaintiff and the Class have been (and will continue to be) injured in their business or property by reason of the Endo Defendants' antitrust violations, in that Plaintiff and Class members (i) were denied the opportunity to purchase lower-priced generic Opana ER, and

(ii) paid higher prices for branded Opana ER than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes the conduct unlawful.

243. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries.

COUNT IV
State Consumer Protection Violations
(Asserted by Plaintiff and the Class Against All Defendants)

244. Plaintiff hereby incorporated each preceding and succeeding paragraph as though fully set forth herein.

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

246. For years, there was a gross disparity between the price that Plaintiff and the Class paid for the brand product when compared to the less expensive generic products, which should have been available.

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

- a. Defendants have engaged in unfair or unconscionable acts or practices in violation of Ariz. Rev. Stat. §§ 44-1522, *et seq.*
- b. Defendants have engaged in unfair or unconscionable acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*
- c. Defendants have engaged in unfair or unconscionable acts or practices or made false representations in violation of D.C. Code §§ 28-3901, *et seq.*
- d. Defendants have engaged in unfair or unconscionable acts or practices in violation of Fla. Stat. §§ 501.201, *et seq.*
- e. Defendants have engaged in unfair or unconscionable acts or practices in violation of Haw. Rev. Stat. §§ 480, *et seq.*
- f. Defendants have engaged in unfair or unconscionable acts or practices in violation of Idaho Code Am1 §§ 48-601, *et seq.*
- g. Defendants have engaged in unfair or unconscionable acts or practices in violation of 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*
- h. Defendants have engaged in unfair or unconscionable acts or practices in violation of Iowa Code section §§ 714.16, *et seq.*
- i. Defendants have engaged in unfair or unconscionable acts or practices in violation of Kan. Stat. Ann §§ 50-623, *et seq.*
- j. Defendants have engaged in unfair or unconscionable acts or practices in violation of Me. Rev. Stat. tit. 5 §§ 207, *et seq.*
- k. Defendants have engaged in unfair or unconscionable acts or practices in violation of Mass. Gen. Laws Ch. 93A, *et seq.*

- l. Defendants have engaged in deceptive or fraudulent acts or practices in violation of Minn. Stat. §§ 831, 325D.44, subd. 1(5), (7) and (13) and 325F.69, subd. 1.
- m. Defendants have engaged in unfair or unconscionable acts or practices in violation of Mo. Ann. Stat. §§ 407.010, *et seq.*
- n. Defendants have engaged in unfair or unconscionable acts or practices in violation of Neb. Rev. Stat. §§ 59.1601, *et seq.*
- o. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.H. Rev. Stat. Ann. §§ 358-A:1, *et seq.*
- p. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.M. Stat. Ann. §§ 57-12-1, *et seq.*
- q. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.Y. Gen. Bus. Law §§ 349, *et seq.* Plaintiffs seek single damages under this statute.
- r. Defendants have engaged in unfair or unconscionable acts or practices in violation of N.C. Gen. Stat. §§ 75-1.1, *et seq.*
- s. Defendants have engaged in deceptive or fraudulent acts or practices in violation of N.D. Cent. Code §§ 51-15-01, *et seq.*
- t. Defendants have engaged in unfair or unconscionable acts or practices in violation of 73 Pa. State. Ann. §§ 201-1, *et seq.*
- u. Defendants have engaged in unfair or unconscionable acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-1, *et seq.*

- v. Defendants have engaged in deceptive or fraudulent acts or practices in violation of S.D. Codified Laws §§ 37-24-1, *et seq.*
- w. Defendants have engaged in unfair or unconscionable acts or practices in violation of Vt. Stat. Ann. tit. 9 §§ 2451, *et seq.*
- x. Defendants have engaged in unfair or unconscionable acts or practices in violation of W. Va. Code §§ 46A-6-101 *et seq.*

248. Plaintiff and the Class have been injured in their business and property by reason of Defendants' unfair or unconscionable acts or practices alleged herein. There injury consists of paying higher prices for Opana ER than they would have paid in the absence of such violations. This injury is of the type that state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT V
Unjust Enrichment Regarding Opana ER
(Asserted by Plaintiff and the Class Against All Defendants)

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

250. Defendants have benefitted from splitting the supracompetitive profits on Endo's Opana ER sales resulting from the unlawful and inequitable acts alleged herein.

251. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Opana ER by Plaintiff and Class members.

252. Plaintiff and the Class members have conferred upon Defendants an economic benefit in the nature of profits resulting from unlawful overcharges and supracompetitive profits – to the economic detriment of Plaintiff and Class.

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

254. It also would be futile for Plaintiff and the Class to exhaust any remedy they might have against any immediate intermediary in the chain of distribution from which they indirectly purchased Opana ER. Any such intermediaries are not liable and would not compensate Plaintiff and the Class for harm caused by Defendants.

255. The economic benefit in the form of overcharges and unlawful profits derived by Defendants through charging supracompetitive and artificially inflated prices for Opana ER is a direct and proximate result of Defendants' unlawful practices.

256. The financial benefits derived by Defendants rightfully belong to Plaintiff and the Class because they paid anticompetitive and supracompetitive prices during the Class Period that wrongfully inured to the benefit of Defendants.

257. It would be inequitable under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for Defendants to retain any of the overcharges for Opana ER derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged herein.

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

259. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the Class.

260. Plaintiffs and the Class have no adequate remedy at law.

COUNT VI
For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Defendants’
Violations of Sections 1 and 2 of the Sherman Act
(Against all Defendants)

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

262. Plaintiff’s allegations described herein and in the preceding Counts comprise violations of Sections 1 and 2 of the Sherman Act, in addition to the state laws *supra*.

263. Plaintiff and the End-Payor Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants’ conduct, in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

264. Plaintiff and the End-Payor Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

VII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff individually and on behalf of the Class, respectfully demand judgment for the following relief:

A. Certification of this action as a class action, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and (b)(3), direction of reasonable Class notice, pursuant to Fed. R. Civ. P. 23(c)(2), appointment of Plaintiff as representative of the Class, and appointment of Plaintiff’s counsel as Class Counsel;

B. A finding that Defendants’ wrongful conduct alleged herein violated the statutes set forth above, and constitutes unjust enrichment under the common law of all states and jurisdictions within the United States, except Indiana and Ohio;

- C. Joint and several judgments against Defendants in favor of Plaintiff and the Class;
- D. Equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;
- E. Plaintiff's and Class members' damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;
- F. Attorneys' fees, litigation expenses, and costs of suit; and
- G. Such other and further relief as necessary to correct the anticompetitive market effects caused by Defendants' unlawful conduct, and as the Court deems just.

VIII. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff Pennsylvania Employees Benefit Trust Fund, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: August 11, 2014

Respectfully submitted,

/s/ Kenneth A. Wexler
Kenneth A. Wexler
Thomas A. Doyle
Justin N. Boley
WEXLER WALLACE LLP
55 West Monroe Street, Suite 3300
Chicago, IL 60603
Telephone: (312) 346-2222
Facsimile: (312) 346-0022
kaw@wexlerwallace.com
tad@wexlerwallace.com
jnb@wexlerwallace.com

Local Counsel

Jeffrey L. Kodroff
John A. Macoretta
**SPECTOR ROSEMAN KODROFF &
WILLIS, P.C.**
1818 Market Street, 25th Floor

Philadelphia, PA 19103
Tel. (215) 496-0300
Fax: (215) 496-6611
jkodroff@srkw-law.com
jmacoretta@srkw-law.com