UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE OPANA ER ANTITRUST LITIGATION	MDL No. 2580 Lead Case No. 14 C 10150
THIS DOCUMENT RELATES TO: ALL END-PAYOR ACTIONS Case Nos. 14 C 6171; 14 C 4651; 14 C 7742; 14 C 10153; 14 C 10154; 14 C 10289; 15 C 0269; 15 C 1473	Hon. Harry D. Leinenweber JURY TRIAL DEMANDED

END-PAYORS PLAINTIFFS' CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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NATURE OF THE CLAIM

1. Plaintiffs Plumbers and Pipefitters Local 178 Health & Welfare Trust Fund; Louisiana Health Service & Indemnity Company, d/b/a Blue Cross and Blue Shield of Louisiana; Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund; Wisconsin Masons' Health Care Fund; Pennsylvania Employees Benefit Trust Fund; International Union of Operating Engineers, Local 138 Welfare Fund; and Mary Davenport, on behalf of themselves and all others similarly situated, brings this antitrust class action under applicable state laws[1] to recover damages and other equitable remedies against Defendants Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Penwest Pharmaceuticals Co. (together, "Endo"), and Impax Laboratories, Inc. ("Impax"). Plaintiffs' claims stem from Defendants' anticompetitive scheme to allocate and unreasonably restrain competition in the market for Opana ER and its AB-rated generic equivalents sold in the United States ("branded and generic versions of Opana ER"). Opana ER (extended-release oxymorphone hydrochloride tablets) is an opioid agonist that was marketed by Endo for the treatment of moderate to severe pain. Plaintiffs' allegations are made on personal knowledge as to Plaintiffs and Plaintiffs' own acts and upon information and belief as to all other matters.

2. Endo embarked on a strategy to block competition to its flagship drug Opana ER for over two years by ending its patent litigation against Impax—the first-filer potential generic competitor for the vast majority of Opana ER sales (5 mg, 10 mg, 20 mg, 30 mg, and 40 mg dosages)—through a series of anticompetitive agreements (the "Exclusion Payment

[1] Plaintiffs seek damages under antitrust and deceptive trade practices laws in the following states: Alabama, Arizona, California, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, the District of Columbia, and Puerto Rico.

Agreements") whereby Impax agreed to keep its generic extended release oxymorphone hydrochloride off the market for two and a half years in exchange for large future cash payments and other consideration from Endo. The Exclusion Payment Agreements included: (1) a cash payment of $102,049,000 from Endo to Impax conditioned on the sales of Opana ER in the quarter immediately prior to the delayed Impax launch date falling below a predetermined level; (2) a promise by Endo and Penwest not to launch an authorized generic version of Opana ER during Impax's 180-day marketing exclusivity (the "no-AG provision"); and (3) a cash payment from Endo to Impax of $10 million up front with an obligation to pay an additional $30 million—upon reaching certain predetermined milestones—under the guise of a "Development and Co-Promotion Agreement" for a new Parkinson's disease drug that was under development by Impax.

3. While the $102 million cash payment was conditioned on the sales of Opana ER falling below a certain level prior to the agreed-upon launch date for Impax, payment was effectively guaranteed to occur because Endo had already planned to move prescription patterns (*i.e.*, "product hop") away from Opana ER to a new and purportedly crush-resistant formulation of Opana ER ("Opana ER CRF").[2] Indeed, just one month after Endo ended its patent litigation with Impax, Endo initiated its "product hopping" strategy by filing a supplemental New Drug Application with the Food and Drug Administration ("FDA") for the approval of Opana ER CRF.

[2] Endo currently markets Opana ER CRF as "Opana ER" even though it is not the same product as the original Opana ER. Endo refers to Opana ER CRF as "Opana ER with INTAC Technology." However, to avoid confusion, Endo's crush-resistant formulation will be referred to in this complaint as Opana ER CRF.

4. Impax reasonably anticipated (or in fact knew) of Endo's plans with respect to Opana ER CRF and negotiated and agreed to this $102 million "conditional" payment knowing that it was "conditional" in name only. From Impax's perspective, even if Endo's new crush-resistant formulation of Opana ER was successful in converting sales from Opana ER to Opana ER CRF—thereby jeopardizing the marketing success of its generic Opana ER during Impax's 180-day exclusivity period—the bounty of its 180-day exclusivity had already been obtained through the $102 million cash payment, ***without Impax having to make or sell a single tablet***.

5. Moreover, not only did Impax receive the benefit of the $102 million payoff, but it also received the benefit of the no-AG provision, which guaranteed no competition from Endo during Impax's 180-day Hatch-Waxman marketing exclusivity. This no-AG provision conferred tens of millions of dollars to Impax that otherwise would have gone to an Endo-authorized generic. The no-AG provision provided substantial compensation to Impax in the event Endo's product hop from Opana ER to Opana ER CRF was unsuccessful by ensuring that Impax would not have to compete against an authorized generic version of Opana ER while also competing against Opana ER during its 180-day exclusivity period.

6. Further, even if Endo's product hop to Opana ER CRF was successful, under the no-AG provision, Impax would still receive the benefit of having no competition from an Endo authorized generic for its 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg generic versions of Opana ER during its 180-day exclusivity period—a promise that was still worth millions of dollars to Impax. Absent this promise by Endo, Impax would have experienced significant price competition on its generic versions of Opana ER, resulting in lower prices for consumers and third party payors.

7. Endo further sweetened the deal by giving Impax a $10 million payment, with the promise of additional, milestone monetary payments, in exchange for the right to co-promote Impax's under-development Parkinson's drug to non-neurology professionals. The upfront and future payments paid and promised to Impax exceeded the value of Endo's proffered services, and thus served as another means by which to pay Impax to end its patent challenges to Opana ER and delay the launch of its generic versions.

8. Defendants' conduct had the effect of delaying generic competition for Opana ER. Endo paid Impax to stay out of the market for two and a half years to protect Endo's stream of monopoly profits. But for the Exclusion Payment Agreements, generic versions of 5 mg, 10 mg, 20 mg, 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. Plaintiffs and members of the Class would have substituted the less expensive generic versions for their purchases of the more expensive brand Opana ER long before Impax belatedly launched its generic in January 2013.

9. Further, the Exclusion Payment Agreements precluded other generic companies from introducing competing generic versions of Opana ER by creating a roadblock to any other generic manufacturer marketing generic versions of Opana ER until after Impax had been on the market for 180 days with its generic versions of 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg Opana ER tablets.

10. Defendants' Exclusion Payment Agreements were designed to and did in fact: (a) delay the entry of less expensive, AB-rated generic versions of Opana ER; (b) fix, raise, maintain or stabilize the price of branded and generic versions of Opana ER; (c) allow Endo to maintain

Opana ER and Opana ER CRF sales that otherwise would have gone to AB-rated generic versions of Opana ER; and (d) allocate nearly 100 percent of the U.S. market for branded and generic versions of Opana ER to Endo for at least two and one half years.

11. The Exclusion Payment Agreements and Endo's subsequent conduct have not escaped the notice of regulators. The FTC issued civil investigative demands to Endo and Impax relating to "whether [Endo], [Impax], and other companies have engaged or are engaged in unfair methods of competition in or affecting commerce by (i) entering into agreements regarding Opana® ER or its generic equivalents and/or (ii) engaging in other conduct regarding the regulatory filings, sale or marketing of Opana® ER or its generic equivalents."[3] The Alaska Attorney General similarly issued a civil investigative demand to Impax concerning its agreements with respect to Opana ER, among other drugs.[4]

12. To redress the injuries Defendants' conduct has caused and continues to cause, Plaintiffs bring this class action on behalf of all consumers and third-party payors in certain states, the District of Columbia, and Puerto Rico who purchased, paid, and/or provided reimbursement for branded or generic versions of Opana ER, other than for re-sale, since June 14, 2010.

THE PARTIES

A. The Plaintiffs

13. Plaintiff Plumbers and Pipefitters Local 178 Health & Welfare Trust Fund ("Local 178") is located in Springfield, Missouri. Local 178 indirectly purchased, paid and/or provided reimbursement for brand Opana ER other than for resale, and purchased, paid and/or

[3] Impax Labs. Inc., Form 10-Q, at 38 (Nov. 4, 2014).

[4] Impax Labs. Inc., Form 8-K (Feb. 10, 2015).

provided reimbursements for the generic versions of Opana ER other than for resale once they became available in the state of Missouri at supracompetitive prices, during the Class Period as defined below, and was thereby injured.

14. Plaintiff Louisiana Health Service & Indemnity Company, d/b/a Blue Cross and Blue Shield of Louisiana ("BCBSLA") is a domestic health insurance corporation licensed to conduct business in the State of Louisiana and is involved in the business of providing health benefits, among others, to covered lives. BCBSLA 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, in the States of Louisiana, Alabama, Arkansas, Arizona, California, Florida, Georgia, Illinois, Kansas, Massachusetts, Minnesota, Missouri, Mississippi, North Carolina, New York, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Texas, Utah, Virginia, Washington and elsewhere, at supracompetitive prices during the Class Period, and was thereby injured.

15. Plaintiff Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund ("FOP") is a governmental plan established and funded through contributions from the City of Miami and the plan's members, who are current and retired sworn officers of the City of Miami Police Department and their dependents. FOP was established pursuant to a duly executed Trust Agreement for the purpose of providing medical, surgical and hospital care or benefits, including prescription drug benefits, to its members. FOP maintains its principal place of business at 400 NW 2nd Avenue, Miami, Florida and, thus, is a citizen of Florida. FOP 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, in the states of Florida and North Carolina at supracompetitive prices during the Class Period, and was thereby injured.

16. Plaintiff Wisconsin Masons' Health Care Fund ("Wisconsin Masons") is a self-funded, multi-employer health and welfare plan governed by the Employee Retirement Income Security Act of 1974, as amended. Wisconsin Masons is administered by Benefit Plan Administration of Wisconsin, whose offices are at 2901 W. Beltline Highway, Suite 100, Madison, Wisconsin. Wisconsin Masons 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 re-sale once they became available, in the state of Wisconsin at supracompetitive prices during the Class Period, and was thereby injured.

17. Plaintiff Pennsylvania Employees Benefit Trust Fund ("PEBTF") 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. 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, in the states of 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 at supracompetitive prices during the Class Period, and was thereby injured.

18. Plaintiff International Union of Operating Engineers, Local 138 Welfare Fund ("IUOE") is a self-insured health and welfare benefit fund with its principal place of business in Farmingdale, New York. IUOE was established pursuant to a duly executed Trust Agreement for the purpose of providing medical, surgical and hospital care or benefits, including prescription drug benefits, to its members. IUOE 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, in the state of New York, at supracompetitive prices during the Class Period, and was thereby injured.

19. Plaintiff Mary Davenport is an individual residing in Norfolk County, Massachusetts. During the Class Period, Ms. Davenport purchased Opana ER for herself. Ms. Davenport paid more for Opana ER than she would have absent Defendants' anticompetitive conduct to delay generic entry and was thereby injured.

B. The Defendants

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

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

22. Defendant Penwest Pharmaceuticals Co. is a pharmaceutical company with its last known place of business at 2981 Route 22, Suite 2, Patterson, New York. Penwest Pharmaceuticals was acquired by Endo Pharmaceuticals Holdings on November 4, 2010 for $144 million. Prior to November 4, 2010, Endo Pharmaceuticals and Penwest Pharmaceuticals developed and marketed Opana ER together. Penwest was previously known as Edward Mendell Co.

23. Defendant Impax Laboratories, Inc. is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California. Impax Laboratories is a technology-based specialty pharmaceutical company utilizing its core competency in drug delivery and formulation expertise.

24. Endo and Impax are referred to collectively as "Defendants."

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

JURISDICTION AND VENUE

26. 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 Defendants.

27. Venue is proper in this District under 28 U.S.C. § 1391(b), (c) and (d) because, during the Class Period, Defendants resided, transacted business, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.

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

29. During the Class Period, 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 both intrastate and interstate commerce.

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

REGULATORY AND ECONOMIC BACKGROUND

31. Generic competition allows purchasers at all levels of the pharmaceutical chain of distribution to purchase both brand drugs and their generic equivalents at reduced prices. Generic competition to a single brand drug can provide potentially billions of dollars in savings to consumers, pharmacies, and other drug purchasers, as well as to private health insurers or state Medicaid programs, both of which reimburse the cost of drug purchases by covered individuals.

32. The FDA sets the standards for the approval of generic drugs. Upon satisfaction of FDA regulations governing, among other things, safety, efficacy, and labeling, the FDA

confers upon a generic drug an "AB" rating. The AB rating signifies that the generic version is, for all intents and purposes, bioequivalent[5] to its brand counterpart.

33. The AB rating permits the generic drug to be substituted for the brand drug at a pharmacy counter. All States permit – and indeed, some States require – pharmacists to substitute an AB-rated generic drug for the corresponding brand drug, unless the prescribing healthcare provider has specifically stated that the brand drug is to be used.

34. Many health insurers and other third-party payors have adopted policies to encourage the substitution of AB-rated generic drugs for their brand name counterparts. For example, many third-party payors implement a tiering system that places certain drugs on different benefit tiers. A drug that is placed on one tier may receive only partial reimbursement, while a drug placed on another tier may receive full reimbursement. Typically, branded drugs are usually placed on a different tier than their corresponding generic. Furthermore, branded drugs with a generic equivalent are usually subject to smaller reimbursements or higher co-pays, while generic drugs will be given total (or near total) reimbursement with limited or no co-pay.

35. As a result of these policies, healthcare professionals are incentivized to prescribe generics so that they can receive higher reimbursements. In addition, these policies also incentivize end-users to request generic drugs because of the cost-savings they may receive with respect to their co-pay.

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[5] Bioequivalence is defined as:

> the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.

21 C.F.R. § 320.1(e).

36. Because both healthcare professionals and end-users are economically incentivized to prefer generic drugs, AB-rated generics are usually able to capture a substantial portion of the market.

37. The first AB-rated generic is typically priced at a discount to its brand counterpart. As additional AB-rated generics obtain FDA approval to enter the market, the resulting increase in competition causes prices of both the first generic and the brand counterpart to drop dramatically.

38. Empirical studies show that within a year of generic entry, generics will have obtained about 90% of the market, *i.e.*, pharmacists fill 90 of every 100 prescriptions for the compound with an AB-rated generic. Indeed, an FTC study found that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[6]

A. FDA New Drug Approval Process

39. The Federal Food, Drug and Cosmetic Act (the "FDCA") and its accompanying regulations set the standards for the approval of any new drug compound that is to be marketed, sold, or distributed in the United States. Drug manufacturers seeking to gain FDA approval for a new drug must file a New Drug Application ("NDA"). Applicants filing an NDA are required to provide a host of information demonstrating the safety and efficacy of their drug, including, but not limited to: (1) information and studies regarding the chemistry of the drug substance, which includes information concerning how the drug is manufactured; (2) information and studies regarding nonclinical pharmacology and toxicology for the new drug; (3) information and studies

[6] FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 8 (Jan. 2010), available at http://emmanuelcombe.org/delay.pdf.

regarding the human pharmacokinetics and bioavailability; and (4) information and data from clinical studies on human subjects.[7]

40. Upon satisfying FDA regulations concerning efficacy, safety and labeling, the FDA will approve the NDA, permitting the applicant to market, sell, and distribute the approved drug to the U.S. public.

41. In addition, upon receiving FDA approval, the brand manufacturer will list any patents it believes cover the approved drug in a publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is more commonly referred to as the "Orange Book."[8]

42. However, there are limitations on the types of patents that can be listed. Only drug substance patents (active ingredient), drug product patents (formulation and composition), and method-of-use patents qualify for listing in the Orange Book.[9] Thus, for example, process patents covering a new drug are not eligible for listing in the Orange Book (however, they may be asserted in a future patent litigation against any allegedly infringing product).

43. In listing patents in the Orange Book, the FDA acts in a ministerial capacity. It does not verify whether the patents listed in the Orange Book are properly listed, and instead relies on the accuracy and truthfulness of the NDA applicant.

44. In addition to the protection conferred by patents covering the brand manufacturer's drug, NDA applicants are afforded additional statutory protections for a drug containing a new active ingredient. NDAs for drugs containing a new active ingredient are given

[7] *See* 21 C.F.R. § 314.50(c)-(d).

[8] 21 U.S.C. § 355(j)(7)(A)(iii).

[9] 21 C.F.R. § 314.53(b).

up to five years of marketing exclusivity before any generic drug manufacturer may file an application for the approval of a generic formulation.[10]

B. The Hatch-Waxman Act Encourages and Facilitates the Approval of Generic Drugs

45. In 1984, Congress amended the FDCA with the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), more commonly known as the "Hatch-Waxman Act."

46. The Hatch-Waxman Act simplifies the regulatory hurdles that generic drug manufacturers have to clear prior to marketing and selling generic drugs. Instead of filing a lengthy and highly costly NDA, the Hatch-Waxman Act allows generic drug manufacturers to obtain FDA approval in an expedited fashion through the filing of an Abbreviated New Drug Application ("ANDA").

47. If an ANDA applicant shows that the generic drug is bioequivalent to the brand drug, then the ANDA applicant may rely on scientific and other data compiled in the brand drug NDA it references concerning, among other things, safety and efficacy.[11] The ability to rely on the scientific data published in the referenced NDA obviates the need for duplicative and expensive experimentation and clinical trials, which in some instances can result in out-of-pocket costs of upwards of $130 million.[12] The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to meet the requirements under the Hatch-Waxman Act.[13]

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[10] 21 U.S.C. § 355(j)(5)(F)(ii).

[11] 21 U.S.C. § 355(j)(2)(A).

[12] *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1564 n.36 (2006).

[13] 21 U.S.C. § 355(j)(4).

In sum, the streamlined approval process under the Hatch-Waxman Act makes it easier for generic drug manufacturers to bring competing and cheaper generic products to market.

48. Although the Hatch-Waxman Act seeks to facilitate generic competition, the brand manufacturer retains the right to enforce any patents associated with its brand drug. As part of its ANDA, the applicant must certify that the generic drug will not infringe any of the Orange Book patents because: (1) no patents exist on the brand drug; (2) the patents have expired; (3) the patents will expire by the time the generic product comes to market; or (4) the patents are invalid, unenforceable, or will not be infringed by the sale of the generic product.[14] When a generic drug manufacturer certifies that the patents covering the referenced brand drug are invalid, unenforceable, or will not be infringed, it known as a "Paragraph IV certification."

49. When a generic drug manufacturer files a Paragraph IV certification asserting that one or more patents listed in the Orange Book are invalid, unenforceable or will not be infringed, it must serve notice of its certification to both the brand manufacturer and the owner(s) of the patent.

50. The issuance of a Paragraph IV certification creates an "artificial act" of patent infringement, permitting the patent owner to file a patent infringement suit against the ANDA applicant making the Paragraph IV certification(s).[15]

51. If the brand manufacturer files a patent infringement suit against the ANDA applicant 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

[14] 21 U.S.C. § 335(j)(2)(A)(vii)(I)-(IV).

[15] 35 U.S.C. § 271(e)(2)(A).

invalid, unenforceable, or not infringed by the ANDA.[16] During the 30-month stay, the FDA may grant "tentative approval" of an ANDA if the FDA determines that the ANDA would otherwise qualify for final approval, but for the 30-month stay.

52. Despite the threat of a patent infringement suit and a 30-month stay, the Hatch-Waxman Act creates powerful incentives for generic drug manufacturers to file ANDAs. Specifically, the Hatch-Waxman Act grants a 180-day period of market exclusivity to the first applicant (the "first-filer") to file a substantially complete ANDA containing a Paragraph IV certification.

53. During the 180-day period of market exclusivity, the first-filer only competes against the brand manufacturer and potentially any AG marketed under the brand manufacturer's NDA; all other generic ANDA applicants must wait until either the expiration of the 180-day exclusivity period or a court order finding that each of the patents that are the subject of a Paragraph IV certification are invalid, unenforceable, or not infringed.

54. Because all other ANDA generics are barred from the market during the first-filer's 180-day exclusivity period, the first-filing ANDA applicant is able to price its generic version at a price slightly below the brand drug's price. This allows the first-filer to gain market share, while simultaneously taking advantage of the price umbrella created by the brand manufacturer's pricing. In addition, this pricing strategy effectively allows the first-filer to share the monopoly profits that previously were held exclusively by the brand manufacturer.

[16] 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay is in some instances a misnomer because it can last more than three years. The 30 months is measured from the innovator's receipt of notice, provided that notice is received by the innovator no earlier than the point five years after the innovator's marketing approval. *Id.* Thus, if a generic drug manufacturer files a Paragraph IV certification during its first year of eligibility – *i.e.*, between the fourth and fifth year after the NDA's approval – then the 30-month stay will not begin until the start of the fifth year after the NDA's approval. 21 U.S.C. § 355(j)(5)(F)(ii). *See also* Hemphill, *supra* note 10, at 1566 n.50.

55. However, once the first-filer's 180-day exclusivity period expires, all other FDA-approved ANDA filers can begin to market their generic equivalents, driving down prices substantially and reducing the profitability of both the branded drug and the first-filer's generic.

C. Brand Manufacturers and First-Filers' Manipulate the Regulatory Structure to Delay the Emergence of Generic Competition

56. Because the Hatch-Waxman Act automatically stays the approval of an ANDA when a brand manufacturer files an infringement suit against an ANDA applicant, the brand manufacturers have an incentive to liberally (and sometimes wrongfully) list in the Orange Book all patents potentially covering the brand drug. Upon a generic drug manufacturer's filing of an ANDA with a Paragraph IV certification, the brand manufacturer will then sue on one or more of those Orange Book patents to trigger the stay.

57. Frequently, patent infringement suits arising from Paragraph IV certifications result in settlements. In some of these settlements, the brand manufacturer will offer the generic drug manufacturer some form of consideration (*i.e.*, payment) in exchange for the generic drug manufacturer agreeing to delay entry of its generic product. These settlements commonly are referred to as "pay-for-delay agreements."

58. These pay-for-delay agreements have the practical effect of permitting the settling brand manufacturer to retain a significant portion of its monopoly profits, while only ceding a relatively small portion of those profits to the settling generic drug manufacturer in exchange for the generic drug manufacturer's agreement to delay market entry.

59. The incentive to create these types of agreements is particularly acute between a brand manufacturer and the first-filing ANDA applicant. In these agreements, the brand manufacturer seeks to delay generic entry and preserve its monopoly for as long as possible.

Typically, a generic drug manufacturer will want as early an entry date as possible, if only for the higher present value of earlier sales.

60. However, unlike other generic drug manufacturers, a first-filing ANDA applicant has the potential benefit of 180 days of marketing exclusivity where it can reap substantial revenues as potentially one of two products in the relevant drug market. A first-filing ANDA applicant's continued litigation against the brand manufacturer runs the risk that the court will find the patent(s) at issue valid, enforceable, and/or infringed by the first-filer's ANDA. A finding of validity, enforceability, and/or infringement by a court would negate the first filer's Paragraph IV certification and disqualify that generic drug manufacturer from receiving the benefit of 180 days of marketing exclusivity. Thus, the first-filer has an acute interest in settling the patent infringement lawsuit as a means of guaranteeing its 180-day exclusivity period, and, in turn, the economic bounty associated with it.

61. With the promise of substantial revenue during its generic exclusivity secure, the first-filer cares little about date of ultimate launch sought by the brand manufacturer –that is so long as the brand name manufacturer sufficiently compensates the first-filer for the delay in launching its generic.

62. Moreover, brand manufacturers are willing to pay substantial sums to the first-filer for any delay in generic launch in exchange for the promise that the first-filer will not enter before a certain date. This is because the value of monopoly profits is so great that the brand manufacturer is willing to pay more to ensure the first-filer's acquiescence to the later launch date. The generic drug manufacturer's acquiescence to a later entry date, in turn, preserves a substantial portion of the brand manufacturer's monopoly profits in the period prior to the first-filer's agreed-to launch date.

63. In essence, by settling with the brand manufacturer, the first-filer receives a double bonus in the form of: (1) a substantial payment from the brand manufacturer to forgo early entry; and (2) the guarantee of substantial revenues as the only generic on the market (absent an authorized generic) during that first-filer's 180-day exclusivity period. Under such circumstances, the first-filing ANDA applicant has limited incentive to continue the patent litigation for purposes of securing a judgment of non-infringement, invalidity, or unenforceability—and thus, a potentially earlier entry date—because it still retains the economic bounty associated with its statutory 180-day exclusivity period.

64. Such pay-for-delay agreements also create powerful disincentives for subsequent ANDA filers to continue defending their ANDAs in patent infringement litigations against the brand manufacturer. Specifically, once it becomes apparent that the brand manufacturer and the first-filer have settled their patent litigation, subsequent ANDA filers usually will not pursue litigation aggressively, and, often times, settle as well.

65. Subsequent ANDA filers are unlikely to continue litigating because obtaining a judgment that the patents subject to Paragraph IV certifications are invalid, unenforceable, or not infringed provides little pay-off to them. For example, prior to the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2066, a judgment of patent invalidity or unenforceability would not cause the first-filer to lose its 180-day exclusivity period; rather, the subsequent filer's success in litigation would only accelerate the start of the first-filer's exclusivity period. The subsequent ANDA filer must still wait until the first-filer's 180-day exclusivity period expires, and only at that point can other FDA-approved ANDA applicants enter the market as well. Thus, these pay-for-delay

agreements effectively "park" exclusivity and cause a bottleneck in the timing of full generic entry.

66. More recent legislation has not alleviated the problems caused by pay-for-delay agreements. The MMA attempts to make the incentives underlying pay-for-delay agreements less attractive by enumerating a series of forfeiture events that, if triggered, will deprive a first-filer of its 180-day exclusivity period.

67. For instance, one of the key forfeiture events under the MMA is a "failure-to-market" by the first-filer.[17] A first-filer ANDA applicant forfeits its 180-day exclusivity period if it fails to market the drug by the later of:

> The earlier of:
>
> (i) 75 days after final approval or
>
> (ii) 30 months after ANDA submission; **or**
>
> The date that is 75 days after the date as of which, as to each of the patents that qualified the first-filer for exclusivity (*i.e.*, the filing of a Paragraph IV certification), at least one of the following has occurred:
>
> (iii) A final decision of invalidity or non-infringement;
>
> (iv) A settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or
>
> (v) The NDA holder delists the patents subject to the first-filer's Paragraph IV certification from the Orange Book.

68. While noble in purpose, scholars have found the MMA's "use it or lose it" provision to be woefully inadequate in deterring anticompetitive agreements to delay generic

[17] 21 U.S.C. § 505(j)(5)(D)(i)(I).

competition for two reasons. First, market acceleration clauses, which are standard components of pay-for-delay agreements, allow the first-filer to accelerate its entry into the market ahead of the later date agreed to with the brand manufacturer in its settlement should a subsequent generic challenger prevail in the courts.

69. Second, brand manufacturers can avoid triggering a potential forfeiture event by only suing on some, but not all, of the patents subject to the first-filer's Paragraph IV certifications. Because a subsequent filer needs to obtain a judgment of invalidity or non-infringement with respect to *all* patents that are the subject of a first-filer's Paragraph IV certification in order to trigger the forfeiture event, the brand manufacturer need only sue on a few of the patents to avoid that scenario.

70. The lengthy and expensive nature of patent litigation makes it such that subsequent filing generic drug manufacturers will not have the stomach to pursue litigation to the end. Indeed, by the time a generic drug manufacturer secures the judgments necessary, "the clock [will] simply run[] out on the subsequent generic filers fighting to open the market earlier than the date agreed to by the first filer in its 'parked' exclusivity settlement."[18]

D. No-Authorized Generic Agreements

71. Pay-for-delay agreements can be augmented by including terms in which the brand manufacturer agrees not to launch an authorized generic to compete with the first-filer during its 180-day exclusivity period.

72. As a threshold matter, a first-filer's 180-day exclusivity period does not prevent a brand manufacturer from marketing its own authorized generic during that period of generic

[18] Letter from Michael Carrier, Rutgers School of Law, to Sen. Tom Harkin, at 3 (Apr. 21, 2011), *available at* http://www.hpm.com/pdf/blog/LIPITOR%20-%20Balto-Carrier%20Ltr.pdf.

exclusivity. Authorized generics are chemically identical to the branded drug and are marketed under the brand manufacturer's NDA. An authorized generic can be marketed either through a generic drug division of the brand manufacturer or through a third-party generic drug manufacturer.

73. Competition from an authorized generic during the first-filer's 180-day exclusivity period substantially reduces the first-filer's profit margins and increases price competition that ultimately benefits consumers and other purchasers of the branded drug and the first-filer's generic equivalent.

74. In a 2011 study titled, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (the "FTC 2011 Report"), the FTC found that authorized generics capture a significant number of generic drug sales, reducing the first-filer's revenues by between 40 percent and 52 percent on average during the 180-day exclusivity period.

75. Although first-filers make significantly less money when they are forced to compete with an authorized generic during the first 180 days, consumers benefit from the lower prices caused by competition between the authorized generic and the first-filer.

76. In light of the very substantial negative effects on a first-filer's bottom-line that can be caused by the presence of an authorized generic, a promise by a brand manufacturer to not launch an authorized generic confers significant monetary value to a first-filer. The value conferred to a first-filer is tantamount to a payment for agreeing to delay generic entry and competition.

FACTUAL ALLEGATIONS

A. Background on Oxymorphone Hydrochloride and Endo's Early Efforts at Marketing the Drug Compound

77. Oxymorphone hydrochloride is an opioid indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."[19]

78. Oxymorphone was first developed in Germany in 1914. Some 40 years later, Endo received FDA approval for Oxymorphone IR ("immediate release") in 1959, but was removed from the market for commercial reasons sometime thereafter.

79. In the 1990s, Endo decided to seek FDA approval to re-launch a tablet form of oxymorphone hydrochloride. Endo was aware that 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. Indeed, Endo recognized this when it submitted its patent information and exclusivity forms to the FDA in December 17, 2002. With respect to each patent mentioned in the form, it only sought three years of exclusivity from the date the FDA issued final approval of its NDA for Opana ER.

B. Endo Acquires Additional Patent Protection from Penwest

80. Prior to submitting its NDA for Opana ER, Endo purchased from Penwest the rights to patents that it could use to block generic entry beyond those three years. On September 17, 1997, Endo entered into a collaboration agreement with Penwest to exclusively co-develop

[19] http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=557e9610-62d7-42bf-90c1-44215bd8c1f8#section-12.1

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 patents related to time release formulations: U.S. Patent No. 5,128,143 entitled "Sustained release excipient and tablet formulation" ("the '143 patent"); U.S. Patent No. 5,958,456 entitled "Controlled release formulation (albuterol)" ("the '456 patent"); and U.S. Patent No. 5,662,933 entitled "Controlled release formulation (albuterol)" ("the '933 patent").

81. In 2002, Penwest also filed the application for what ultimately issued as U.S. Patent No. 7,276,250 patent entitled "Sustained release formulations of oxymorphone hydrochloride" ("the '250 patent").

82. The '143, '456, '933, and '250 patents (collectively, the "Penwest time-release patents") were set to expire in 2008, 2013, 2013, and 2023, respectively.[20]

83. Penwest licensed the Penwest time-release patents to Endo.

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

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

86. 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 through June 22, 2009, after which Endo's Opana ER monopoly would be subject to generic competition.

[20] http://www.wikinvest.com/stock/Penwest_Pharmaceuticals_(PPCO)/Actavis_Anda_Litigation

87. However, prior to its first sales of Opana ER, Endo only listed the '143 patent in the Orange Book, a patent that was set to expire in 2008. Because Opana ER's three-year clinical exclusivity would run in June 2009, Endo knew it needed additional protection to maintain its monopoly over Opana ER. Thus, over a year after it made its first commercial sales of Opana ER, Endo late-listed the '456, and '933 patents in the Orange Book, in violation of 21 C.F.R. § 314.53.[21]

88. In doing, Endo effectively forced all would-be ANDA filers to file paragraph IV certifications in connection with each of these patents if they sought to market their generic product before those patents expired. This in turn would permit Endo to sue for patent infringement and trigger the operation of the statutory 30-month stay under the Hatch-Waxman Act, delaying FDA approval of any filed ANDA by at least two and one-half years and preserving its monopoly over the extend-release oxymorphone hydrochloride market during that time.

C. Endo Sues Impax For Patent Infringement

89. Impax filed ANDA 79-087 for its generic extended release oxymorphone hydrochloride in June 2007. However, because of deficiencies within the ANDA, the FDA rescinded its acceptance of the application and required Impax to resubmit the application.

90. On or prior to October 2, 2007, Impax resubmitted ANDA 79-087 and included a Paragraph IV certification stating that Impax's proposed generic extended release oxymorphone hydrochloride tablets in 5 mg, 10 mg, 20 mg, and 40 mg strengths did not infringe the '250,

[21] As required by 21 C.F.R. § 314.53, brand drug manufacturers are required to 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.

'456, or '933 patents. On October 2, 2007, Impax sent Endo a Paragraph IV Notice explaining that it had submitted ANDA 79-087 seeking approval to manufacture, use, or sell generic extended-release oxymorphone hydrochloride tablets prior to the expiration of the '250 patent. Additional notices with respect to the '250 patent were sent to Endo on October 3, 4, 5, and 9, 2007. In addition, on October 29, 2007, Impax sent Endo Paragraph IV Notices with respect to the '933 and '456 patents.

91. On November 15, 2007, Endo sued Impax for declaratory judgment in the United States District Court for the District of Delaware, 1:07-cv-00731-KSH, seeking a declaration that Impax's previous Paragraph IV notices were null and void because Endo claimed that Impax did not have an acceptable ANDA on file with the FDA. Endo also sued Impax for infringement of the '456 and '933 patents. Impax asserted affirmative defenses and counterclaimed that the '456 and '933 patents were invalid because they failed to comply with "one or more provisions of Title 35 of the United States Code [patents], including but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description and indefiniteness" or were invalid due to double-patenting.

92. 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."

93. On December 14, 2007, Impax presented notices to Endo 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.

94. Upon resubmission of these Paragraph IV Notices to Penwest and Endo, Endo sued Impax on January 25, 2008 in the United States District Court for the District of Delaware for infringement of the '456 and '933 patents—but not for the '250 patent. By filing this lawsuit, Endo triggered the automatic 30-month stay under the Hatch-Waxman Act, through mid-June 2010, during which time the FDA could not approve Impax's ANDA 79-087 for 5 mg, 10 mg, 20 mg, and 40 mg generic Opana ER. Impax again asserted affirmative defenses and counterclaimed that the '456 and '933 patents were invalid.

95. 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 mg, 10 mg, 20 mg, 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. Thus, by delaying Impax's entry into the market, Endo could delay all generic competitors from entering the market for the 5 mg, 10 mg, 20 mg, and 40 mg strengths of Opana ER.

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

97. 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 mg, 15 mg, and 30 mg strengths. The June 13, 2008 notice also advised Penwest and 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 described in its ANDA would not infringe the '250, '456 or '933 patents.

98. 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 a period of 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 mg and 15 mg strengths of generic Opana ER).

99. On July 25, 2008, Endo filed a third 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 mg, 15 mg, and 30 mg tablets of generic Opana ER infringed the '456 and '933 patents (but not the '250 patent). Impax again asserted affirmative defenses and counterclaims that the '456 and '933 patents were invalid. In addition, Impax claimed that Endo engaged in inequitable conduct before the United States Patent and Trademark Office ("PTO") in connection with the prosecution of the '456 and '933 patents by intentionally failing to disclose various pieces of prior art that would have rendered the claims in the '456 and '933 patents unpatentable.

100. 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").

D. Endo Sues Other Generic Manufacturers Submitting ANDAs for Opana ER

101. Endo sued subsequent generic ANDA filers for extended release oxymorphone hydrochloride tablets as well.

1. **Actavis Patent Infringement Suit**

102. 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 5 mg, 10 mg, 20 mg, and 40 mg tablets prior to the expiration of the '250, '456 and '933 patents. Actavis' notice advised Endo that Actavis's ANDA 79-046 included a Paragraph IV certification that the proposed manufacture, importation, use, or sale of the generic extended release hydrochloride tablets described in Actavis's ANDA would not infringe any claim of the '250, '456, or '933 patents and that the claims in those patents are invalid.

103. On March 28, 2008, Endo sued Actavis in the United States District Court for the District of New Jersey, No. 2:08-cv-01563, alleging infringement of only the '456 patent (it did not sue for the '250 or '933 patents). By filing this suit, Endo triggered the automatic 30-month stay during which the FDA could not approve Actavis' ANDA for 5 mg, 10 mg, 20 mg, and 40 mg generic Opana ER until August 2010 at the earliest.

104. On or around May 29, 2008 (covering 7.5 mg 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.

105. Actavis was the first generic company to file a Paragraph IV certification with respect to the patents that Endo listed for the 7.5 mg and 15 mg strengths of Opana ER, and therefore Actavis was entitled to a period of 180 days of market exclusivity upon final FDA approval against other ANDA filers (as alleged above, Impax was the first filer for all other dosage strengths). The 7.5 mg and 15 mg strengths, however, constitute a very small part of Opana ER sales, accounting for approximately 5 percent.

106. 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 automatic stay under the Hatch-Waxman Act with regard to the 7.5 mg, 15 mg, and 30 mg strengths of Actavis's generic Opana ER.

107. 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").

108. The Actavis Patent Litigation ended in settlement, with Endo granting Actavis licenses to the Opana ER patents in exchange for an entry date of July 2011.

2. **Sandoz Patent Infringement Suit**

109. 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 mg, 10 mg, 20 mg, and 40 mg dosage strengths, explaining that the Sandoz generic would not infringe the '250, '456 or '933 patents.

110. 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 stay under the Hatch-Waxman Act.

111. On or about November 17, 2008, Sandoz sent another Paragraph IV Notice, informing Endo that it had amended its ANDA to include 7.5 mg, 15 mg, and 30 mg strengths of generic Opana ER.

112. 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 mg, 15 mg, and 30 mg strengths of generic Opana ER, again triggering the 30-month stay under the Hatch-Waxman Act.

113. 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”).

3. **Barr Patent Infringement Suit**

114. Between September 11 and 12, 2008, Barr sent Endo Paragraph IV Notices with respect to Barr’s generic Opana ER ANDA 90-106 asserting that Barr’s generic 5 mg, 10 mg, 20 mg, and 40 mg tablets would not infringe the ’250, ’456 or ’933 patents or the patents were invalid or not enforceable.

115. 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 stay under the Hatch-Waxman Act.

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

117. Shortly 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 mg, 15 mg, and 30 mg strengths of Barr’s generic Opana ER.

118. 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”).

4. **Roxane Patent Infringement Suit**

119. 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.

120. 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 stay under the Hatch-Waxman Act.

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

122. 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.

123. 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").

5. **Watson Patent Infringement Suit**

124. 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.

125. 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 stay under the Hatch-Waxman Act (the "Watson Patent Litigation").

126. On or about March 18, 2010, Watson sent additional Paragraph IV Notices regarding ANDA 20-0792 for the 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, and 30 mg dosage strengths.

127. 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 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths as well.

E. Endo and Impax Enter the Exclusion Payment Agreements

1. **Endo and Impax Settle the Impax Patent Litigation**

128. From 2007 to 2010, during the 30-month stay period, Endo and Impax litigated their patent infringement suit in the United States District Court for the District of Delaware and then, following transfer and consolidation of the Impax patent cases, in the United States District Court for the District of New Jersey. The Impax Patent Litigation was consolidated for pretrial purposes with the Sandoz Patent Litigation and the Barr Patent Litigation.[22]

129. The case proceeded through discovery and claim construction briefing. Judge Katherine S. Hayden of the District of New Jersey conducted a *Markman* Hearing and entered an order on claim construction on March 30, 2010.

130. In the March 8, 2010 Final Pretrial Order, Impax asserted that it would prove that the ’456 and ’933 patents were invalid because they were: (1) anticipated by prior art; (2) obvious; and (3) constituted obvious-type double patenting. Further, Impax intended to prove that the ’933 patent lacked an adequate written description. Finally, Impax contended that even

[22] Barr ultimately settled their patent litigation against Endo in 2010.

if those patents were valid, its generic Opana ER did not infringe the '250, '456, and '933 patents.

131. As noted above, the 30-month stay on Impax's ANDA was set to expire on or around June 14, 2010.

132. On May 4, 2010, Impax held its first quarter 2010 earnings call. During that call, Impax's CEO and CFO 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.

133. On May 13, 2010, as Impax had correctly anticipated, the FDA tentatively approved Impax's ANDA for all dosage strengths of Opana ER; final approval of Impax's generic Opana ER had to wait for the expiration of the 30-month stay on June 14, 2010.

134. 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 (that is, Endo understood that Impax was preparing to make an at-risk launch). 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."[23] Counsel for Impax also stated: "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."[24]

[23] *Endo Pharmaceuticals Inc. v. Impax Laboratories Inc.*, 2:09-cv-00831, ECF No. 214, at 10:20-25 (D.N.J. May 17, 2010).

[24] *Id.* at 16:14-19.

135. With the trial of the Impax and Sandoz Patent Litigations set to commence on June 3, 2010 and conclude by June 17, 2010, 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 "not [to] 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.[25]

136. In its pre-trial briefing, Impax presented strong evidence that its ANDA product did not infringe any patent asserted by Endo. For example, Impax argued that the particular compound in Impax's product that Endo claimed infringed on '456 and '933 patents was not a "pharmaceutically acceptable hydrophobic material." The compound in the Impax ANDA product was a *diluent*, not a hydrophobic material. Nor did Impax's ANDA product contain the claimed "homopolysaccharide" in the '933 patent or the claimed "sustained release" in the both the '456 and '933 patents.

137. Moreover, Impax demonstrated that the Opana ER patents were invalid in light of prior art. For example, Impax argued that U.S. Patent No. 5,128,143 disclosed the relevant components of the "sustained release excipient" claimed in both the '456 and '933 patents, including the gelling agent, diluent, and hydrophobic material. Thus, Impax was well positioned to succeed in challenging both the infringement and validity of Endo's patents.

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

139. Endo was aware that their patents and patent infringement claims against Impax were weak and that they would not be able to obtain an injunction to stop Impax from launching

[25] *Id.*, ECF No. 222.

its generic versions of Opana ER after Impax obtained final approval of its generic products from the FDA. Likewise, Impax knew the risk of an adverse decision at trial—regardless of how small the possibility—would jeopardize its 180-day marketing exclusivity for generic Opana ER. It also 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.

140. Had Impax launched generic versions of Opana ER upon receiving FDA final approval for its 5 mg, 10 mg, 20 mg, 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 entering the Exclusion Payment Agreements, Impax's generics would have driven down the price of extended-release oxymorphone hydrochloride tablets. Impax was further aware that once its 180-day exclusivity period ran, there would be multiple generic versions of Opana ER available, accelerating the erosion of prices on both Opana ER and Impax's generic.

141. On or about June 8, 2010, with the bench trial underway, rather than risk potentially losing its patent protection for Opana ER, Endo settled the Impax Patent Litigation by entering into the Exclusion Payment Agreements. The bench trial transcripts were ordered sealed, and on June 15, 2010, the Impax Patent Litigation was dismissed with prejudice.

2. The Exclusion Payment Agreements Provide Impax With Over $112 Million in Cash and Other Consideration to Keep Generic Versions of Opana ER off the Market

142. As part of its settlement with Impax, Endo granted Impax licenses to the patents covering Opana ER. In addition, Endo provided Impax with at least two forms of payment: (1) future cash payments of over $112 million; and (2) a no-AG provision worth tens of millions of dollars. In exchange for this consideration, Impax agreed to delay the launch of its generic Opana ER products until January 1, 2013. Each of these payments is discussed below.

(a) Cash Consideration of $112 million

143. Part of the Exclusion Payment Agreements provided Impax a cash payment from Endo if sales of Opana ER fell below a predetermined threshold in the quarter immediately prior to Impax's agreed-upon launch date of January 1, 2013. As later disclosed in Endo's SEC filings, this payment was worth $102,049,000.

144. Although structured in the Exclusion Payment Agreements as a contingent payment, Endo made sure that this $102 million payment was paid to Impax by engaging in a series of actions that all but guaranteed that Endo's Opana ER sales would fall below the predetermined threshold.

145. Endo quickly signaled its intention to move the market away from Opana ER to its new formulation, Opana ER CRF. On July 7, 2010—just one month after Endo ended its patent litigation with Impax—Endo filed supplemental NDA 201655 for the approval Opana ER CRF.

146. Endo had planned this move prior to settling the Impax Patent Litigation. Indeed, shortly after receiving notice of Impax's ANDA for the approval of generic Opana ER, Endo entered into a License, Development and Supply Agreement with Grüenenthal GmbH "for the exclusive clinical development and commercialization rights in Canada and the United States for a new oral formulation of long-acting oxymorphone [Opana ER], which is designed to be crush resistant."[26] As part of this agreement, Endo received licenses to several patents developed by

[26] Endo 2010 Form 10-K, at 31.

Grüenenthal that would ultimately cover Opana ER CRF, and potentially protect it from competition until at least 2023.[27]

147. On December 9, 2011, the FDA approved Endo's NDA for Opana ER CRF. Upon receiving approval, Endo began an aggressive campaign to promote Opana ER CRF and to move prescriptions away from Opana ER.

148. Impax anticipated (or in fact knew of) Endo's plans to move the market away from Opana ER to a crush-resistant formulation of Opana ER. As a result, Impax negotiated for the provision of a $102 million "conditional" payment knowing that it was all but certain to be paid. From Impax's perspective, even if Endo's marketing efforts were successful in making Opana ER CRF the preferred formulation of Opana ER—thereby jeopardizing the marketing success of Impax's generic version of Opana ER during its 180-day exclusivity period—the bounty of Impax's 180-day exclusivity period would be obtained in part through the $102 million cash payment. Moreover, even if Endo's efforts to switch the market from Opana ER to Opana ER CRF failed, Impax would still receive the benefit of a no-AG provision worth tens of millions of dollars, which is discussed in further detail below. Thus, Impax would receive a large payment regardless of what happened in the market.

149. Endo was willing pay that large amount because the payment would: (1) preserve Endo's monopoly over branded and generic versions of Opana ER because Opana ER would be without a generic competitor until January 1, 2013; and (2) give Endo time to move the market to

[27] Susan Jeffrey, FDA Approves Tamper-Resistant Oxymorphone Formulation, MedScape Multispecialty (Dec. 12, 2011), http://www.medscape.com/viewarticle/755260 ("The company [Endo] also announced that the US Patent and Trademark Office will issue a patent on December 13, 2011, to cover the new formulation of Opana ER. This patent is expected to provide patent protection until November 2023. The new patent will be listed in the FDA's Orange Book, the statement notes.").

its forthcoming crush resistant formulation of Opana ER. As revealed in SEC filings, Impax received the $102 million payment in April 2013.

150. However, the $102 million payment was only one component of the cash consideration given by the Exclusion Payment Agreements. The Exclusion Payment Agreements also included a "Development and Co-promotion Agreement" for a new Parkinson's disease drug that was at the time under development by Impax. Under this Agreement, Impax granted Endo the right to co-promote its new drug to non-neurology healthcare professionals. In exchange for this right to co-promote this drug, Endo agreed to pay Impax $10 million up-front, with an obligation to pay $30 million in additional payments if certain milestones were met.

151. The money Endo agreed to pay for the right to co-promote the new drug exceeded any value Endo would offer for its co-promotional services, and thus served as another way to compensate Impax in exchange for its agreement to delay the launch of its generic Opana ER products. Impax, "a neurology-focused, specialty pharmaceutical company, dedicated to developing products for unmet needs in the treatment of Central Nervous System (CNS) disorders," was fully capable of developing and marketing its new Parkinson's disease drug.[28] Indeed, Impax states on its website that it has "extensive experience developing and marketing products for CNS disorders."[29] Thus, Impax is capable of effectively promoting these products to the healthcare professionals most likely to prescribe them. By contrast, Endo has no specialized expertise in the treatment of CNS disorders like Parkinson's disease. As a result, Endo's purported co-promotion efforts to non-neurology healthcare professionals did not provide significant value to either Impax or Endo.

[28] http://www.impaxlabs.com/our_divisions/impax_pharma_branded.

[29] http://www.impaxlabs.com/our_divisions/impax_pharma_branded.

152. To date, pursuant to the Exclusion Payment Agreements, Endo has paid Impax least $112,049,000 in cash (a deferred 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) in exchange for Impax's agreement to keep generic Opana ER off the market for two and a half years.

(b) The No-AG Provision

153. In addition to the over $112 million in cash paid by Endo to Impax under the Exclusion Payment Agreements, Endo also agreed not to launch authorized generic versions of Opana ER during Impax's 180-day marketing exclusivity.

154. As explained above, authorized generics can offer significant competition to first-filing generics during their 180-day marketing exclusivity period. Endo's promise not to launch an authorized generic during Impax's 180-day marketing exclusivity period conferred at least tens of millions of dollars to Impax.

155. According to IMS data, Endo's sales of Opana ER for the period between March 2010 and May 2010 (*i.e.*, the three months just prior to Defendants' entry into the Exclusion Payment Agreements) equaled approximately $83 million. Using this figure as a base, Opana ER sales over a period of six months (*i.e.*, the length of the Hatch-Waxman Act's exclusivity period) would be roughly $166 million. From this $166 million figure, the no-AG provision's value to Impax can be estimated to be between at least $33 million and $49 million, depending on various reasonable assumptions and methodologies used. However, this is a conservative estimate of the effect of the no-AG provision because it assumes that sales of Opana ER would have remained flat in the time between the Exclusion Payment Agreements in June 2010 and Impax's agreed-upon delayed launch date in January 2013.

156. Endo and Impax both knew what an authorized generic could do Impax's sales during Impax's 180-day exclusivity. By agreeing not to compete on this level, both Endo and Impax received something of significant value. For Endo, it was Impax's agreement to end the patent litigation and delay the launch of its generic versions of Opana ER. For Impax, it was the guarantee that it would be able to maximize revenues during its 180-day exclusivity period—particularly, in the event that Impax had to compete against Endo's Opana ER had Endo failed in its efforts to convert Opana ER sales to Opana ER CRF.

157. Further, the no-AG provision still had substantial value for Impax even if Endo was able to product hop from Opana ER to Opana ER CRF. This is because Impax would still be free from competition from an Endo authorized generic during Impax's 180-day exclusivity period.

158. As explained below, Endo's product hop to Opana ER CRF was very successful and by the time Impax launched its generic version of Opana ER in January 2013, over 90 percent of the market had been converted to Opana ER CRF. The product hop had the effect of marginally reducing the value of the no-AG provision because Impax could not simply rely on automatic substitution of its generic version of Opana ER with Opana ER CRF. Because of Endo's product hop to Opana ER CRF, Impax made around $26 million during its 180-day exclusivity period, an amount which is lower than Impax would have made had Endo's product hop not occurred.

159. However, Impax was still well compensated because, as explained above, Impax received $112 million in cash from Endo pursuant to the Exclusion Payment Agreements. It also still received the benefit of the no-AG provision, which insulated Impax's generic product from competition from Endo. Had the no-AG provision not been a part of the Exclusion Payment

Agreements, Impax would have made even less than the $26 million in revenue it received during its 180-day exclusivity period because it would have had to compete against an Endo authorized generic.

160. As a direct consequence of this no-AG provision, consumers and third-party payors, including Plaintiffs and the Class, lost the benefit of the lower prices that would have resulted from price competition between an Endo authorized generic and Impax's generic during Impax's 180-day exclusivity period. Because of the no-AG provision in the Exclusion Payment Agreements, customers did not realize the benefit of these lower prices.

(c) Defendants Can Offer No Pro-Competitive Reasons for the Payments

161. Defendants have no pro-competitive explanation or justification for the $112 million in cash payments or the no-AG provision. These large, unjustified payments had no rational connection to, and far exceeded, any approximation of the costs of continuing the patent litigation that was in the middle of trial at the time the agreement was signed. Moreover, the size the payment suggests that Endo perceived the risk of losing its patent protection for Opana ER was substantial. Endo would not have paid such large sums absent the very real risk that Impax would prevail in the Impax Patent Litigation. Thus, these large payments serve as proxies for Endo's and Impax's views regarding the weakness of the Opana ER patents at issue in the Impax Patent Litigation.

162. Nor was the payment consideration for the fair value of any pro-competitive services provided by Impax to Endo. Impax was not required to perform any service at all in exchange for the more than $102 million cash payment. Impax was also not required to perform any service for the $10 million upfront cash payment that was purportedly related to Impax's unapproved drug product. Endo simply paid Impax not to compete.

163. Moreover, any suggestion that the kind of pay for delay agreement reached by Endo and Impax is necessary to end patent litigation is untenable. The FTC has found that 75 percent of brand-generic patent cases settle *without* reverse payments.[30] Under such an agreement, or even without one (such as with an at-risk launch after receiving final FDA approval but before the trial court ruled, or a launch after (as expected) the trial court rules in the generic's favor), Impax would have launched its generic versions of Opana ER substantially earlier than January 2013.

164. Absent Endo's unlawful payments to Impax under the Exclusion Payment Agreements, consumers and third party payors, including Plaintiffs and members of the Class, would have received the benefits of early competition from an Impax generic for Opana ER in the form of lower prices for extended-release oxymorphone hydrochloride tablets. Moreover, early competition from generic Opana ER would have limited Impax's ability to successfully product hop from Opana ER to Opana ER CRF because generic forms of Opana ER would have rapidly taken market share from *all* branded versions of extended-release oxymorphone tablets marketed by Endo.

3. Endo "Product Hops" from Opana ER to Opana ER CRF, Which Triggers the Payment of $102 million to Impax Pursuant to the Exclusion Payment Agreements

165. As explained above, shortly after settling the Impax Patent Litigation, Endo filed an application for the approval of Opana ER CRF. Endo received FDA approval in December 2011, and shortly thereafter, began marketing Opana ER CRF as a purportedly safer and abuse-resistant formulation of Opana ER.

[30] FTC, Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2010* (2011).

166. However, Opana ER CRF and Opana ER, as well as AB-rated generic equivalents of Opana ER, were effectively the same from a therapeutic standpoint. Indeed, in its letter of approval for Opana ER CRF, the FDA stated that Endo's new crush-resistant formulation was substantially similar to Opana ER, and that Endo's "support for the efficacy and safety of this new product was intended to be based entirely on bioequivalence to the previously approved product [Opana ER]."[31] Endo submitted no new safety, clinical efficacy, or nonclinical pharmacology and toxicology data in connection with its application—it only submitted a new blood sample analysis that confirmed the new formulation's bioequivalence to Opana ER.

167. Because Opana ER CRF is therapeutically equivalent to Opana ER, generic versions of Opana ER could be prescribed by healthcare professionals in lieu of Opana ER or Opana ER CRF. However, although the FDA found that Opana ER CRF and Opana ER "have the same therapeutic benefits," to date, the FDA has not formally determined that generic versions of Opana ER would be AB-rated generic equivalents of Opana ER CRF.[32] Because generic versions of Opana ER are not given the "AB" designation with respect to Opana ER CRF, pharmacies are not permitted to automatically substitute generic versions of Opana ER with Opana ER CRF scripts.

168. Nonetheless, recognizing the potential risk that was posed by generic competition to Opana ER CRF, Endo took other measures to preserve the commercial success of its Opana ER franchise, including the withdrawal of Opana ER in favor of Opana ER CRF.

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[31] FDA Division Director's Review and Summary Basis for Approval Action NDA 201655 – Opana ER (New Formulation), at 1 (Dec. 9, 2011).

[32] Endo CP Final Decision at 8.

169. Endo discontinued its marketing and sale of the 7.5 mg and 15 mg strengths of Opana ER in March 2011. By the end of May the following year, Endo had discontinued the remaining strengths of Opana ER.

170. Endo later claimed to both the public and the FDA via a Citizen Petition that the withdrawal was for reasons of "[p]atient safety."[33] However, Endo's purported safety concerns were overblown and pretextual, as demonstrated in a Citizen Petition filed by Endo in August 2012. On August 10, 2012, Endo filed a Citizen Petition, requesting that the FDA withdraw marketing approval for approved Opana ER generics—as well as any ANDA seeking FDA approval of generic versions Opana ER—on the grounds that non-crush resistant versions of Opana ER were no longer safe to use.[34]

171. Specifically, Endo's Citizen Petition asked the FDA to:

> Determine that the discontinued, non-crush resistant version of Opana ER approved under NDA No. 021610 was discontinued for reasons of safety and can no longer serve as an RLD [Reference Listed Drug] for an ANDA applicant;
>
> Refuse to approve any pending ANDA for a generic version of the non-crush-resistant version of Opana ER approved under NDA No. 021610; and

[33] Press Release, Endo Pharmaceuticals Announces Reformulated Version of OPANA® ER with INTAC® Technology Designed to be Crush-Resistant Accounts for more than 90 Percent of OPANA ER Total Prescription Volume (Sept. 6, 2012), http://www.prnewswire.com/news-releases/endo-pharmaceuticals-announces-reformulated-version-of-opana-er-with-intac-technology-designed-to-be-crush-resistant-accounts-for-more-than-90-percent-of-opana-er-total-prescription-volume-168750546.html.

[34] Endo also filed a second Citizen Petition later that month seeking the FDA to require prospective generic ANDA filers for Opana ER CRF to show that their products are "similarly crush-resistant." Dkt. No. FDA-2012-P-0951. The FDA denied this Citizen Petition "without comment on the approvability of any ANDA for a product citing reformulated Opana ER as the RLD because it would be premature and inappropriate to do so at this time." Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, to Robert Barto, Vice President, Regulatory Affairs, Endo Pharmaceuticals Inc., at 2 (Jan 23, 2013).

> Suspend and withdraw the approval of any ANDA referencing Opana ER approved under NDA No. 021610 as the RLD.

172. Brand drug manufacturers commonly use the filing of Citizen Petitions as a tactic to extend their monopolies. Taking advantage of FDA's practice of delaying ANDA approvals while it evaluates petitions, brand manufacturers routinely submit petitions to the FDA that do not raise legitimate concerns about the safety or effectiveness of generic products.

173. Endo's Citizen Petition was meritless because the new crush-resistant formulation provided little, if any, incremental benefits in terms of safety and efficacy. Several facts support this assessment.

174. *First*, as a threshold matter, when the FDA approved Opana ER CRF, the "approved labeling [for Opana ER CRF] did not describe any abuse-deterrent properties."[35] Indeed, the FDA found that "the 'abuse potential' subsection of the 'Warnings and Precautions' section and 'Drug Abuse and Dependence' section of the [Opana ER CRF] and [Opana ER] product labeling are virtually identical."[36] Thus, Endo's own labeling materials belie any purported advantages Opana ER CRF had over Opana ER in terms of abuse prevention.

175. *Second*, the FDA had previously ruled that Endo's withdrawal of the 7.5 mg and 15 mg dosages for Opana ER were not for reasons of safety or effectiveness.[37] When Endo withdrew these strengths in March 2011, Actavis (not Endo) filed a Citizen Petition seeking a determination from the FDA that the withdrawal was not for reasons of safety or effectiveness. Had Endo's concerns regarding the safety or effectiveness of Opana ER been genuine, Endo

[35] Endo CP Final Decision at 2.

[36] *Id.* at 2.

[37] *See* 76 Fed. Reg. 53908 (Aug. 30, 2011).

would have not only withdrawn the 7.5 mg and 15 mg strengths, but *all strengths* of Opana ER from the market.

176. In response to Actavis' Citizen Petition, the FDA "carefully reviewed" its files and conducted an independent evaluation of "relevant literature and data for possible postmarketing adverse events."[38] The FDA "found no information that would indicate that OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15 mg, were withdrawn from sale for reasons of safety or effectiveness."[39] Indeed, even after filing its own Citizen Petition, Endo acknowledged that "the original formulation of Opana® ER [was] safe and effective when taken as prescribed."[40] Yet, despite this prior FDA ruling and Endo's own admission, Endo pressed its baseless claim that *all* Opana ER dosages were unsafe.

177. *Third*, the evidence Endo presented in connection with its Citizen Petition failed to show that Opana ER CRF was less prone to abuse. While there was some evidence that Opana ER CRF was somewhat more resistant to crushing, the FDA found that

> data from in vitro and pharmacokinetic studies show that [Opana ER CRF's] extended-release features can be compromised, causing the product to 'dose dump,' when subjected to other forms of manipulation such as cutting, grinding, or chewing, followed by swallowing. It also appears that [Opana ER CRF] can be prepared for insufflation (snorting) using commonly available tools and methods.[41]

178. Moreover, despite Endo's claim that Opana ER CRF tablets have "resistance to aqueous extraction (i.e., poor syringeability)," the FDA found that Opana ER CRF "can be

[38] 76 Fed. Reg. at 53909.

[39] *Id.*

[40] Endo Health Solutions Inc. Form 10-Q at 73 (Nov. 5, 2012).

[41] Endo CP Final Decision at 5-6.

readily prepared for injection."[42] Significantly, the FDA found that not only was Opana ER CRF subject to abuse through injection, it found that "certain data suggest that [Opana ER CRF] can more easily be prepared for injection that [Opana ER]."[43]

179. Indeed, post-marketing studies offered by Endo presented data that "suggest that a greater (and rising) percentage of Opana ER abusers are abusing Opana ER via injection since the replacement of [Opana ER] with [Opana ER CRF] in the market."[44] The FDA found these data "consistent with in vitro data showing that while it may be more difficult to prepare [Opana ER CRF] for insufflation using certain tools (although it is possible to do so using other tools) it may actually be *easier* to prepare [Opana ER CRF] for injection."[45] The FDA concluded that "[t]aken together, these data suggest the troubling possibility that the reformulation may be shifting a non-trivial amount of Opana ER abuse from snorting to even more dangerous abuse by intravenous or subcutaneous injection."[46]

180. The FDA's conclusions may have proved prescient. Recently, there was a sharp rise in the number of HIV infections in Scott County in Southern Indiana that health officials believe was caused by the sharing of infected needles used to inject Opana. This HIV epidemic has infected some 71 individuals since mid-December 2014 and has caused Governor Mike Pence to declare a public health emergency.[47]

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[42] *Id.* at 6.

[43] *Id.*.

[44] *Id.* at 8 n.25.

[45] *Id.* at 8 n.25 (italics in original).

[46] *Id.* at 8 n.25.

[47] *See* Alan Schwartz & Mitch Smith, *Needle Exchange Is Allowed After H.I.V. Outbreak in an Indiana County*, N.Y. Times (Mar. 26, 2015), *available at* http://www.nytimes.com/2015/03/27/us/indiana-declares-health-emergency-after-hiv-outbreak.html.

181. *Fourth*, Endo's conduct upon withdrawing Opana ER from the market further belied its concerns regarding Opana ER's safety and efficacy. Although Endo stopped marketing all Opana ER strengths by May 2012, it did not seek to recall any Opana ER that remained in the distribution channels.[48] Had Endo's concerns about Opana ER's safety been genuine, it would have sought the immediate recall of all Opana ER strengths throughout that distribution chain.

182. Thus, as demonstrated above, Endo's purported safety concerns were overstated; Opana ER CRF offered no substantial improvements in abuse prevention.

183. Endo's product hopping strategy has been highly successful. By September 2012, Endo publicly announced that "the reformulated OPANA® ER (oxymorphone HCl) incorporating Grunenthal's INTAC® Technology designed to be crush-resistant accounts for more than ***90 percent of the OPANA ER total prescription volume***."[49]

184. Endo's product hopping strategy inured to the benefit of Impax: The conversion of nearly all sales of Opana ER to Opana ER CRF triggered the $102 million payment under the terms of the Exclusion Payment Agreements because it resulted in the sales of Opana ER falling below the threshold set forth in the Agreements.

[48] FDA Mot. in Opp. to Prelim. Inj. at 1, *Endo Pharmaceuticals, Inc. v. FDA*, No. 12-cv-01936 (D.D.C. Dec. 9, 2012).

[49] Press Release, Endo Pharmaceuticals Announces Reformulated Version of OPANA® ER with INTAC® Technology Designed to be Crush-Resistant Accounts for more than 90 Percent of OPANA ER Total Prescription Volume (Sept. 6, 2012), http://www.prnewswire.com/news-releases/endo-pharmaceuticals-announces-reformulated-version-of-opana-er-with-intac-technology-designed-to-be-crush-resistant-accounts-for-more-than-90-percent-of-opana-er-total-prescription-volume-168750546.html (emphasis added).

4. **Effects of the Exclusion Payment Agreements**

185. The FDA granted final approval of Impax's ANDA for generic Opana ER tablets 5 mg, 10 mg, 20 mg, and 40 mg on June 14, 2010. A little over a month later, on July 22, 2010, the FDA granted final approval of Impax's ANDA for generic Opana ER tablets 30 mg.

186. The Exclusion Payment Agreements enabled Endo and Impax to: (a) delay the entry of less expensive, AB-rated generic versions of Opana ER 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths in the United States; (b) fix, raise, maintain or stabilize the price of branded and generic versions of Opana ER 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg; (c) allow Endo to maintain Opana ER and Opana ER CRF sales that otherwise would have gone to AB-rated generic versions of Opana ER; and (d) allocate nearly 100 percent of the U.S. market for branded and generic versions of Opana ER to Endo for at least two and one half years from June 2010 to January 2013.

187. The Exclusion Payment Agreements had the effect of delaying competition for 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg extended-release oxymorphone hydrochloride tablets for two and a half years. Impax stood ready, willing, and able to launch generic versions of Opana ER and would have done so upon FDA final approval of its ANDA. But for the Exclusion Payment Agreements, Impax could have begun marketing and selling its generic Opana ER as early as June 14, 2010 for the 5 mg, 10 mg, 20 mg, and 40 mg strengths, and July 22, 2010 for the 30 mg strength, the dates when Impax obtained final FDA approval of these strengths of generic Opana ER.

188. Instead, as a result of the Exclusion Payment Agreements, Impax did not launch its 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg of generic Opana ER tablets until January 4, 2013.

189. Further, but for the no-AG provision in the Exclusion Payment Agreements, when Impax did come to the market, Endo could have launched an authorized generic to compete with Impax's generic Opana ER products, pushing the prices of Impax's generic product lower. Pursuant to the no-AG provision, Endo did not launch a competing authorized generic during Impax's 180-day exclusivity period.

190. Endo and Impax knew and intended that their Exclusion Payment Agreements would prevent other generic companies from launching their own generic products in those strengths.

191. As the first-filer of an ANDA with a Paragraph IV certification for generic Opana ER for 5 mg, 10 mg, 20 mg, 30 mg, 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 at those strengths (with the exception of an authorized generic, which, as explained above, Endo promised not to launch). Indeed, Endo admitted this, stating in its year-end 2011 Form 10-K that "[w]e expect Sandoz, Teva, Watson, Roxane and Actavis to launch production and sale of all strengths of their respective versions of generic non-tamper resistant Opana® ER commencing on July 1, 2013 [*i.e.*, 180 days after the Impax launch]."[50]

192. In other words, the Exclusive Payment Agreements with Impax created a roadblock. So long as there was not a court ruling invalidating the '456 and '933 patents (which would trigger Impax's 180-day exclusivity period), Impax's delayed 180-day exclusivity period under the Exclusion Payment Agreements prevented any generic, other than Impax, from entering the market until July 2013.

[50] Endo Pharmaceuticals Holdings Inc. 2011 Form 10-K, at F-75.

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

194. But for Defendants' illegal Exclusion Payment Agreements, generic competition to Opana ER 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths would have occurred as early as June 14, 2010, when Impax received final approval for its ANDA in the 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths and as early as July 22, 2010 for the 30 mg dosage strength. Further, if Impax had launched in June 2010, the market for Opana ER would not have been substantially eroded by the switch to Opana ER CRF, and Impax would have made far more sales.

195. Moreover, the Exclusion Payment Agreements blocked one or more generic manufacturers from launching generic versions Opana ER. Once Endo settled with Impax, the other generics had little incentive to continue litigating because if even they succeeded in defending Endo's claims of infringement, they would still be forced to wait until Impax's 180-day exclusivity period ended before launching their generic products. As a result, each of these generic manufacturers settled their cases.

196. Actavis was the first to settle in February 2009. As the first generic to file an ANDA for the 7.5 mg and 15 mg strengths of Opana ER, it was entitled to 180 days of marketing exclusivity for those strengths. At all relevant times, these two strengths only constituted approximately 5 percent of Endo's Opana ER sales.

197. 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 mg and 15 mg tablets by the

earlier of July 15, 2011, or the date on which any third party commenced commercial sales of generic oxymorphone hydrochloride extended-release tablets, but not before November 28, 2010.

198. 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 commenced commercial sales of a generic form of the drug. However, the Exclusion Payment Agreements rendered that portion of the settlement with Actavis illusory as Impax's first-filer status prevented any other generics from launching those strengths earlier than July 2013 (180 days after Impax's January 2013 launch).

199. Indeed, the FDA in its December 13, 2010 letter granting final approval to Actavis's 7.5 mg and 15 mg strengths of generic extended-release oxymorphone hydrochloride confirmed that Actavis would not be able to launch its generic Opana ER for the remaining strengths as arranged in its settlement with Endo, stating:

> Your Oxymorphone Hydrochloride Extended-release Tablets, 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg, are **tentatively approved**. . . . .
>
> We are unable to grant final approval to your Oxymorphone Hydrochloride Extended-release Tablets 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg, at this time *because prior to the submission of your ANDA, another applicant submitted an ANDA providing for Oxymorphone Hydrochloride Extended-release Tablets 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg, and containing a paragraph IV certification to the '933, '456, and '250 patents*. Your ANDA insofar as these strengths will be eligible for final approval on the date that is 180 days after the agency receives notice, with respect to the other ANDA, of the commercial marketing date identified in section 505(j)(5)(B)(iv) of the [FDCA].[51]

200. The "other applicant" referred to in the FDA's letter was Impax.

[51] FDA Letter to Actavis, at 5 (Dec. 13, 2010) (bold in original, italics added).

201. But for the Exclusion Payment Agreements between Endo and Impax, Actavis would have been able to launch its generic versions of the 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths of Opana ER 180 days following Impax's launch of those strengths in June 2010 and July 2010.

202. Endo similarly settled its litigations against Barr, Sandoz, Watson, and Roxane. Under the terms of these settlements, Endo agreed to grant these generics licenses permitting the production and sale of all strengths of generic Opana ER commencing on September 15, 2012, or earlier under certain circumstances. This launch date was destined to be unrealized in light of the roadblock formed by Endo and Impax's Exclusion Payment Agreements.

203. Notwithstanding agreements for nominal entry dates in September 2012, Barr, Sandoz, Watson, and Roxane were unable to sell their generic Opana ER products until 180 days after Impax's generic launch. Thus, 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 Agreements with Impax. But for the Exclusion Payment Agreements between Endo and Impax, these generic manufacturers would have been able to launch their generic versions of the 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg strengths of Opana ER 180 days following Impax's launch of those strengths in June 2010 and July 2010.

RELEVANT MARKET AND MARKET POWER

204. At all relevant times, Endo had substantial market power and/or monopoly power in the market for branded and generic versions of Opana ER because Endo had the power to maintain the price of Opana ER at supracompetitive levels without losing substantial sales to other daily pain management products.

205. 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.

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

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

208. 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.

209. 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 exert sufficient pressure on the prices and sales of another product, so that the price of that other product cannot be maintained at supracompetitive levels. No other pain medication apart from AB-rated generic versions of Opana ER could have taken away sufficient sales from Opana ER to prevent Endo from raising or maintaining the price of Opana ER at supracompetitive levels.

210. Opana ER is also not reasonably interchangeable with any products other than AB-rated generic versions of Opana ER because both Opana ER and its AB-rated generic equivalents have different attributes significantly differentiating them from other pain

medications and making them unique. Opana ER and its AB-rated generic equivalents are substantially more powerful than other daily pain management products consisting of different molecules. For example, oxymorphone hydrochloride is twice as powerful as either oxycodone or methadone. Further, the FDA does not consider Opana ER and its AB-rated generic equivalents interchangeable with other pain medications.

211. Similarly, generic equivalents of Opana ER are not considered by the FDA to be AB-rated equivalents to Opana ER CRF. This means that generic versions of Opana ER cannot be automatically substituted for Opana ER CRF at the pharmacy level under state substitution laws.

212. Price does not typically drive prescriptions for medications, including those 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 extended-release oxymorphone hydrochloride tablets, to patients without a prescription written by a doctor. Patients and third-party payors have the obligation to pay for the pharmaceutical product, but it is ultimately the patients' doctors who choose which product the patient will buy.

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

214. 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 generally 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 effective and well-tolerated, it is unlikely that the patient will switch to a different pain management product based on variations of price.

215. 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.

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

217. Endo needed to control only Opana ER and its AB-rated generic equivalents, and no other products, in order to profitably maintain supracompetitive prices for Opana ER. Only the market entry of competing, AB-rated generic versions of Opana ER would have rendered Endo unable to profitably maintain its prices of Opana ER without losing substantial sales.

218. The entry of other brand pain medications (or generic versions of those other brands) also did not take substantial sales from Opana ER or cause Endo to lower its price. For instance when generic Opana IR launched in 2010, Opana ER sales continued to increase unimpeded while the sales of brand Opana IR dropped in response to generic competition. Other opioids such as morphine sulfate and hydromorphone HCl have been available in generic form since 1998, including at prices far below the price of Opana ER, yet again Endo's sales of branded Opana ER increased yearly from 2006 through 2011. By contrast, the competitive impact of an earlier entry of AB-rated generic version of Opana ER on brand Opana ER would

have been substantial. Among other things, the earlier entry of an AB-rated generic Opana ER would have delivered hundreds of millions of dollars of savings to purchasers.

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

220. At all relevant times, Endo had, and exercised, the power to exclude and restrict competition in the market for branded and generic versions of Opana ER.

221. At all relevant times, there were high barriers to entry with respect to competition in the market for branded and generic versions of Opana ER in the form of patent and other regulatory protections, as well as high startup costs.

222. To the extent that Plaintiffs may be required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is the market for branded and generic versions of Opana ER. During the relevant time, Endo has been able to profitably maintain the price of Opana ER well above competitive levels.

223. Endo's market share in the market for branded and generic versions of Opana ER was greater than 90 percent up to at least the time of the switch from Opana ER to Opana ER CRF. Even if, in the alternative, the relevant market were defined to also include Opana ER CRF, Endo's market share would still be above 90 percent up to at least the time of Impax's launch of generic Opana ER in January 2013, and has been greater than 50 percent at all relevant times.

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

ANTITRUST IMPACT

225. Defendants' anticompetitive scheme had the purpose and effect of unreasonably restraining and injuring competition by protecting Opana ER from generic competition. But for Exclusion Payment Agreements, Impax would have entered the market upon receiving final FDA approval or agreed to an unrestrained licensed entry date much earlier than January 1, 2013. Moreover, but for Endo's continued anticompetitive conduct following the Exclusionary Payment Agreements, generic competition in the market for branded and generic versions of Opana ER would have been more robust.

226. But for Defendants' illegal conduct, generic competition would have forced decreases in the prices of Opana ER, as price competition among the suppliers of branded and generic versions of Opana ER would have been intense.

227. Moreover, but for the anticompetitive conduct alleged above, Endo's efforts to product hop from Opana ER to Opana ER CRF (had they been undertaken at all) 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 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 launched at all) at prices below Opana ER or Opana CRF.

228. But for Defendants' illegal conduct, Plaintiffs and Class Members would have paid less for branded and generic versions of Opana ER. Defendants' conduct directly injured Plaintiffs and Class Members because it forced them to pay hundreds of millions of dollars in overcharges on purchases of branded and generic versions of Opana ER.

229. As a result of the delay in generic competition brought about by Defendants' anticompetitive scheme, Plaintiffs and Class Members paid more for branded and generic Opana ER than they would have paid absent Defendants' illegal conduct.

230. Upon entering the market, generic equivalents of brand name drugs are priced below the branded drug to which they are AB-rated. When multiple generic products are on the market, prices for the brand drug and its generic equivalents fall even further because of the increased competition.

231. If generic competition for branded Opana ER had not been unlawfully delayed, Plaintiffs and Class Members would have paid less for both branded and generic versions Opana ER by: (a) substituting their purchases of Opana ER with less-expensive generic versions of Opana ER; (b) purchasing generic Opana ER at lower prices sooner; and (c) purchasing branded Opana ER at a reduced price.

232. Defendants' efforts to restrain competition in the market for branded and generic versions of Opana ER have substantially affected both intrastate and interstate commerce.

233. At all material times, Endo manufactured, promoted, distributed, and sold substantial amounts of branded Opana ER in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase in that, among other things, retailers within each state were foreclosed from offering cheaper generic versions of Opana ER to purchasers within each state, which directly impacted and disrupted commerce for consumers and third-party payors within each state.

234. At all material times, Defendants transmitted funds and 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 branded and generic versions of Opana ER.

235. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. Professor Herbert Hovenkamp explains that "[e]very person at every stage in the chain will be poorer" as a result of the anticompetitive price at the top.[52] He also says 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."[53]

236. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of branded and generic versions of Opana ER to Plaintiffs and Class Members.

237. Both the Exclusion Payment Agreements and Endo's subsequent anticompetitive conduct enabled Endo to charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent the Defendants' unlawful actions.

238. These prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

CLASS ALLEGATIONS

239. Plaintiffs bring this action as a class action, under Fed. R. Civ. P. 23(a) and (b)(3), on behalf of themselves and all similarly situated:

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

[53] *Id.*

> All persons or entities who indirectly purchased, paid for, and/or provided reimbursement for some or all of the purchase price for brand or generic Opana ER 5 mg, 10 mg, 20 mg, 30 mg, and/or 40 mg, other than for resale, in the states and commonwealths of Alabama, Arizona, California, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, the District of Columbia, and Puerto Rico (the "Class"), from June 14, 2010 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased (the "Class Period").

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

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

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

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

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

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

(f) Pharmacy Benefit Managers;

(g) All Counsel of Record; and

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

241. The Class Members are so numerous that joinder is impracticable. Plaintiffs believe that there are thousands of Class Members.

242. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and Class Members were damaged by the same wrongful conduct by Defendants in that they paid artificially inflated prices for branded and generic Opana ER and were deprived of the benefits of earlier and more robust competition from cheaper generic equivalents of Opana ER as a result of Defendants' wrongful conduct.

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

244. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with experience in class action antitrust litigation involving pharmaceutical products.

245. Questions of law and fact common to the Class Members predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire Class, making overcharge damages with respect to the Class as a whole appropriate.

246. Questions of law and fact common to all class members include:

(a) whether Defendants conspired to restrain generic competition to Opana ER;

(b) whether Impax unlawfully agreed to delay the entry of its AB-rated generic versions of Opana ER;

(c) whether Endo paid Impax in exchange for a delay in generic competition for Opana ER;

(d) whether Defendants' conduct suppressed generic competition to branded Opana ER;

(e) whether Defendants' conduct harmed competition in the market for branded and generic versions of Opana ER;

(f) whether Endo possessed market power in the market for branded and generic versions of Opana ER;

(g) whether the relevant antitrust market (if a relevant market must be defined) is the market for branded and generic versions of Opana ER;

(h) whether Defendants' activities alleged herein have substantially affected interstate and intrastate commerce;

(i) whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiffs and members of the Class in the nature of overcharges; and

(j) the quantum of overcharges paid by Plaintiffs and members of the Class in the aggregate.

247. 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.

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

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Conspiracy and Combination in Restraint of Trade Under State Law (Against All Defendants)

249. Plaintiffs incorporate the preceding paragraphs by reference.

250. Endo and Impax entered into Exclusion Payment Agreements to suppress generic competition for branded Opana ER. The Exclusion Payment Agreements involved the conduct set forth above. The Exclusion Payment Agreements are and were contracts, combinations, and/or conspiracies 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 and one-half years 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 Plaintiffs and Class Members would pay for Opana ER or its AB-rated generic equivalents at supracompetitive levels;

(d) Allocate close to 100 percent of United States generic Opana ER sales to Impax during the first 180 days of generic sales; and

(e) Force Plaintiffs and members of the Class to purchase higher-priced Opana ER and Opana ER CRF instead of generic versions of Opana ER.

251. The Exclusion Payment Agreements harmed Plaintiffs and the Class as set forth above.

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

253. The Exclusion Payment Agreements are horizontal market allocation and price fixing agreements between actual and potential competitors and are illegal per se under state antitrust laws. Alternatively, Plaintiffs allege that the Exclusion Payment Agreements are an unreasonable restraint of trade, in violation of state antitrust law, under a "quick look" or "rule of reason" analysis.

254. The Exclusion Payment Agreements between Endo and Impax regarding Opana ER involve (i) large and unjustified payments from Endo to Impax ($102 million and other consideration), (ii) a promise by Endo not to launch an authorized generic version of Opana ER during Impax's 180-day marketing exclusivity; and (iii) an agreement by Impax to delay marketing its generic Opana ER. Absent the Exclusion Payment Agreements, Impax would not have agreed to delay marketing its generic Opana ER and would have entered the market sooner than it did.

255. There is and was no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effect.

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

(a) Ala. Code § 6-5-60, with respect to purchases in Alabama by members of the Class;

(b) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Class;

(c) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class;

(d) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class;

(e) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Class;

(f) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by members of the Class;

(g) Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Class;

(h) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class;

(i) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class;

(j) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class;

(k) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Class;

(l) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class;

(m) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class;

(n) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by members of the Class, in that thousands of sales of branded and generic versions of Opana ER took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct;

(o) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by members of the Class;

(p) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class;

(q) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Class;

(r) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class;

(s) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Class;

(t) Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by members of the Class;

(u) 10 L.P.R.A. §§ 258, *et seq.*, with respect to purchases in Puerto Rico by members of the Class;

(v) R.I. Gen. Laws §§ 6-36-1 *et seq.*, with respect to purchases in Rhode Island by members of the Class;

(w) S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by members of the Class;

(x) Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of Opana ER at Tennessee pharmacies;

(y) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class who are either citizens or residents of Utah;

(z) Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class;

(aa) W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class; and

(bb) Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Opana ER at Wisconsin pharmacies.

257. Plaintiffs and Class Members have been injured in their business or property by Defendants' antitrust violations. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Opana ER, and (2) paying higher prices for branded

and generic versions of Opana ER than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

258. Plaintiffs and Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

259. Defendants are jointly and severally liable for all damages suffered by Plaintiffs and Class Members.

SECOND CLAIM FOR RELIEF

Monopolization and Monopolistic Scheme Under State Law (Against Endo)

260. Plaintiffs incorporate the preceding paragraphs by reference.

261. Endo has knowingly engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Opana ER. The intended and accomplished goal of the scheme was to use restrictive and exclusionary conduct to delay the ability of generic manufacturers to launch competing, generic versions of Opana ER.

262. In June 2010, Endo and Impax entered into the Exclusion Payment Agreements to suppress generic competition with Opana ER. The Exclusion Payment Agreements had the effect of unlawfully maintaining Endo's monopoly over Opana ER by preventing Impax from launching competing generic versions of Opana ER until January 1, 2013.

263. Endo needed to control only Opana ER (and any AB-rated generic equivalent to Opana ER), and no other products, to maintain the price of Opana ER profitably at monopolistic prices. Only the market entry of a competing AB-rated generic equivalent to Opana ER would render Endo unable to profitably maintain monopolistic prices of Opana ER without losing

substantial sales. The Exclusion Payment Agreements enabled Endo to maintain its monopoly and monopolistic prices over Opana ER.

264. Plaintiffs and Class Members have suffered harm as a result of paying higher prices for Opana ER and/or its AB-rated generic equivalents than they would have absent Endo anticompetitive conduct and continuing anticompetitive conduct.

265. Endo's conduct violated the following state antitrust laws::

(a) Ala. Code § 6-5-60, with respect to purchases in Alabama by members of the Class;

(b) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Class;

(c) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class;

(d) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class;

(e) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Class;

(f) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by members of the Class;

(g) Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Class;

(h) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class;

(i) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class;

(j) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class;

(k) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Class;

(l) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class;

(m) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class;

(n) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by members of the Class, in that thousands of sales of branded and generic versions of Opana ER took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct;

(o) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by members of the Class;

(p) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class;

(q) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Class;

(r) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class;

(s) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Class;

(t) Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by members of the Class;

(u) 10 L.P.R.A. §§ 258, *et seq.*, with respect to purchases in Puerto Rico by members of the Class;

(v) R.I. Gen. Laws §§ 6-36-1 *et seq.*, with respect to purchases in Rhode Island by members of the Class;

(w) S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by members of the Class;

(x) Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of Opana ER at Tennessee pharmacies;

(y) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class who are either citizens or residents of Utah;

(z) Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class;

(aa) W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class; and

(bb) Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class, in that the actions alleged herein substantially affected the people of

Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Opana ER at Wisconsin pharmacies.

266. Plaintiffs and Class Members have been injured in their business or property by Endo's antitrust violation. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Opana ER, and (2) paying higher prices for these products than they would have paid in the absence of Endo's wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Endo's conduct unlawful.

267. Plaintiffs and Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Endo's anticompetitive conduct.

THIRD CLAIM FOR RELIEF

Attempted Monopolization Under State Law (Against Endo)

268. Plaintiffs incorporate the preceding paragraphs by reference.

269. Endo has knowingly engaged in an anticompetitive scheme designed to delay and block entry of generic competition to branded Opana ER. The intended and accomplished goal of the scheme was to use restrictive and exclusionary conduct to delay the ability of generic manufacturers to launch competing, generic versions of Opana ER.

270. In June 2010, Endo and Impax entered into the Exclusion Payment Agreements to suppress generic competition with Opana ER. The Exclusion Payment Agreements had the effect of unlawfully maintaining Endo's monopoly over Opana ER by preventing Impax from launching competing generic versions of Opana ER until January 1, 2013.

271. Endo needed to control only Opana ER (and any AB-rated generic equivalent to Opana ER), and no other products, to maintain the price of Opana ER profitably at monopolistic prices. Only the market entry of a competing AB-rated generic equivalent to Opana ER would render Endo unable to profitably maintain monopolistic prices for branded Opana ER without losing substantial sales. The Exclusion Payment Agreements enabled Endo to maintain its monopoly and monopolistic prices over Opana ER.

272. Endo acted with specific intent to monopolize the market for branded and generic versions of Opana ER, causing Plaintiffs and Class Members to pay artificially inflated prices for these products.

273. Endo intentionally and wrongfully attempted to monopolize the market for branded and generic versions of Opana ER in violation of the following state laws:

(a) Ala. Code § 6-5-60, with respect to purchases in Alabama by members of the Class;

(b) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Class;

(c) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class;

(d) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Class;

(e) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Class;

(f) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by members of the Class;

(g) Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Class;

(h) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class;

(i) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class;

(j) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class;

(k) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Class;

(l) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Class;

(m) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class;

(n) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by members of the Class, in that thousands of sales of branded and generic versions of Opana ER took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct;

(o) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by members of the Class;

(p) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class;

(q) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Class;

(r) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class;

(s) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Class;

(t) Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by members of the Class;

(u) 10 L.P.R.A. §§ 258, *et seq.*, with respect to purchases in Puerto Rico by members of the Class;

(v) R.I. Gen. Laws §§ 6-36-1 *et seq.*, with respect to purchases in Rhode Island by members of the Class;

(w) S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by members of the Class;

(x) Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of Opana ER at Tennessee pharmacies;

(y) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Class who are either citizens or residents of Utah;

(z) Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class;

(aa) W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class; and

(bb) Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Opana ER at Wisconsin pharmacies.

274. Plaintiffs and Class Members have been injured in their business or property by Endo's antitrust violation. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Opana ER, and (2) paying higher prices for these products than they would have paid in the absence of Endo's wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Endo's conduct unlawful.

275. Plaintiffs and Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Endo's anticompetitive conduct.

FOURTH CLAIM FOR RELIEF

State Consumer Protection Violations (Against All Defendants)

276. Plaintiffs incorporate the preceding paragraphs by reference.

277. 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, Plaintiffs and Class members were deprived of the

opportunity to purchase generic versions of Opana ER and were forced to pay higher prices branded and generic versions of Opana ER.

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

279. 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, unconscionable, or deceptive acts or practices in violation of Fla. Stat. §§ 501.201, *et seq.*;

(b) Defendants have engaged in unfair, unconscionable, or deceptive acts or practices in violation of Mass. Gen. Laws ch. 93A, *et seq.*, in that thousands of Massachusetts end-payors paid substantially higher prices for branded and generic versions of Opana ER as a result of actions occurring substantially within Massachusetts;

(c) Defendants have engaged in unfair, unconscionable, or deceptive acts or practices in violation of Mo. Rev. Stat. §§ 407.010, *et seq.*; and

(d) Defendants have engaged in unfair, unconscionable, or deceptive acts or practices in violation of 73 Pa. Stat. Ann. §§ 201-1, *et seq.*

280. Plaintiff Mary Davenport has sent Defendants pre-suit demands at least 30 days prior to filing this action, pursuant to Mass. Gen. Laws ch. 93A § 9(3).

281. Plaintiffs and the Class have been injured in their business and property by reason of Defendants' unfair, unconscionable, or deceptive acts or practices alleged in this Complaint. Their injury consists of paying higher prices for branded and generic versions of

Opana ER than they would have paid in the absence of such violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

FIFTH CLAIM FOR RELIEF

Unjust Enrichment
(Against All Defendants)

282. Plaintiffs incorporate the preceding paragraphs by reference.

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

284. Defendants have benefited from the overcharges on sales of branded and generic versions of Opana ER made possible by the unlawful and inequitable acts alleged in this Complaint.

285. Defendants' financial benefits are traceable to Plaintiffs' and Class Members' overpayments for branded and generic versions of Opana ER.

286. Plaintiffs and Class Members have conferred an economic benefit upon Defendants in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiffs and Class Members.

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

288. It would be futile for Plaintiffs and Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they

indirectly purchased Opana ER, as those intermediaries are not liable and would not compensate Plaintiffs and Class Members for Defendants' unlawful conduct.

289. The economic benefit Defendants derived from charging monopolistic and artificially inflated prices for branded and generic versions of Opana ER is a direct and proximate result of Defendants' unlawful practices.

290. The financial benefits defendants derived rightfully belong to Plaintiffs and Class Members, who paid anticompetitive prices that inured to Defendants' benefit.

291. It would be inequitable under unjust enrichment principles under the laws of each of the states in the United States and the District of Columbia and Puerto Rico for Defendants to retain any of the overcharges Plaintiffs and Class Members paid for branded and generic versions of Opana ER that were derived from Defendants' unfair and unconscionable methods, acts, and trade practices.

292. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiffs and the Class.

293. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiffs and Class Members.

294. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received that are traceable to Plaintiffs and Class Members.

295. Plaintiffs and Class Members have no adequate remedy at law.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on their own behalf and on behalf of the proposed Class, demand a judgment that:

A. Determines that this case may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3), directs that reasonable notice of this case be given to Class Members under Rule 23(c)(2), and declares that Plaintiffs are proper representatives of the Class;

B. Enters joint and several judgments against Defendants and in favor of Plaintiffs and the Class;

C. Grants Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy the Defendants' unjust enrichment;

D. Awards Plaintiffs and the Class damages and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial, including interest;

E. Awards Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

F. Grants further relief as necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, as the Court deems just.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury on all issues so triable.

Dated: May 4, 2015

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