PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

ORIGINAL

In the Matter of: IMPAX LABORATORIES, INC., a corporation.	**Docket No. 9373**

RESPONDENT IMPAX LABORATORIES, INC.'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

Edward D. Hassi
Michael E. Antalics
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, D.C. 20006
Telephone: +1-202-383-5300
Facsimile: +1-202-383-5414

[Additional Counsel on Signature Page]

Counsel for Impax Laboratories, Inc.

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

TABLE OF CONTENTS

Page

RESPONDENT'S PROPOSED FINDINGS OF FACT

I. IMPAX BACKGROUND

1. Impax Laboratories, Inc. ("Impax") is a pharmaceutical company founded in 1995 by Dr. Larry Hsu. (CX4014 (Hsu, IHT at 9)).

2. Impax's business focuses on developing, manufacturing, and marketing generic drugs. (CX4014 (Hsu, IHT at 10); JX-001-001 (¶ 3) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

3. In fact, prior to 2015, Impax had never marketed a brand-name product. (CX4014 (Hsu, IHT at 40)).

4. Impax's first brand-name product was Rytary, a Parkinson's disease treatment, which launched in 2015. (CX4014 (Hsu, IHT at 40); Nestor, Tr. 2931; Reasons, Tr. 1236).

5. Impax is a small company compared to other pharmaceutical manufacturers. (Koch, Tr. 275, 287; *see* Figg, Tr. 1925; Hoxie, Tr. 2772).

6. In 2010, fifteen years after it was founded, Impax only had seventy sales representatives and limited capacity to develop more than one product at a time. (CX4014 (Hsu, IHT at 52, 129)).

7. In 2013, Impax generated roughly $511 million in revenue from all products. (CX0425-059 (Impax 10-K filing for 2013)).

8. Of that revenue, roughly $97 million was revenue from new products, which was about average for the company. (CX0425-004-05 (Impax 10-K filing for 2013); CX4001 (Koch, IHT at 170)).

9. In comparison, [redacted]

10. [redacted]

11. Endo generated over $900 million in revenue from a single product in one year. (CX4005 (Levin, IHT at 100)).

12. Novartis, another pharmaceutical company, generates tens of billions of dollars in revenue annually. (Hoxie, Tr. 2764).

13. Impax's principal place of business is 30831 Huntwood Avenue, Hayward, California. (JX-001-001 (¶ 1) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

14. In addition to its Hayward headquarters, Impax also operates out of its facilities in Middlesex, New Jersey, among other locations. (JX-001-001 (¶ 2) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

II. INDUSTRY BACKGROUND

A. Opioids

15. A patient can obtain a prescription drug only if a doctor (or someone who is authorized to write prescriptions) writes a prescription for that drug. (JX-001-007 (¶ 11) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

16. Opioids are prescription drugs indicated for the treatment of moderate to severe pain. (JX-001-006 (¶ 2) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Savage, Tr. 700-01).

17. Opioid medications are derived from opium. (Michna, Tr. 2104).

18. Opioids are the most potent medication available for treating pain, and are effective at combatting tissue-based pain arising from injury, inflammation, or tissue disruption, as well as neuropathic pain arising from damage to the nerves themselves. (Savage, Tr. 700-01).

19. Opioids treat pain by working at the mu receptor to modulate a patient's perception of pain. (Michna, Tr. 2104).

20. In general, opioids are used for treatment "when other interventions are not effective in treating pain or when opioids present less risk to an individual patient than other therapeutic interventions." (Savage, Tr. 697).

21. There are three types of opioids: ultra-fast-acting, immediate-release, and extended-release. (Michna, Tr. 2105; *see* Savage, Tr. 693).

22. Ultra-fast-acting opioids are medications that are absorbed through the mouth and have an initial onset of pain relief in about fifteen minutes. (Michna, Tr. 2105).

23. Ultra-fast-acting opioids are used to treat pain that comes on very suddenly and that may dissipate within an hour. (Michna, Tr. 2105).

24. Immediate-release opioids are short-acting pain medications that take effect within thirty to forty-five minutes of ingestion. (Michna, Tr. 2106, 2118; *see* Savage, Tr. 693).

25. The effects of immediate-release opioids tend to last three to six hours. (Michna, Tr. 2106, 2118; Savage, Tr. 702).

26. Immediate-release opioids are used to treat acute, short-lived pain as well as chronic pain. (Michna, Tr. 2106; Savage, Tr. 705).

27. Extended-release opioids provide continuous levels of medication in a patient's blood over several hours, with effects lasting from eight to twenty-four hours, and in the case of transdermal applications—patches that deliver medication through the skin—up to seven days. (Michna, Tr. 2106; *see* Savage, Tr. 702).

28. Extended-release opioids have been pharmacologically formulated to provide gradual release of the opioid medication. (Savage, Tr. 693). In particular, the physical chemical

structure of the tablet, capsule, or bead, provides for slower release of the medication and, in turn, more gradual absorption by the body. (Savage, Tr. 704-05).

29. Extended-release opioids generally are used for patients with sustained pain lasting longer than twelve to twenty-four hours, as well as chronic pain that requires relief twenty-four hours a day. (Savage, Tr. 705).

30. Despite the different forms of opioids, there is no difference in the efficacy of immediate-release and extended-release opioids. (Michna, Tr. 2117).

31. And in some instances, patients may take both an extended-release opioid and an immediate-release opioid at the same time. (Michna, Tr. 2114). In so doing, patients are able to treat both chronic pain and "breakthrough pain," intense pain that occurs intermittently or as a result of a particular trigger. (Michna, Tr. 2114-15).

B. <u>Active Pharmaceutical Ingredients in Opioids</u>

32. Active pharmaceutical ingredients ("API") are the elements of a drug that have the therapeutic effect on a patient. (Camargo, Tr. 964; Savage, Tr. 799-802; Noll, Tr. 1369).

33. Both immediate-release opioids and extended-release opioids can contain the same active pharmaceutical ingredient. (Savage, Tr. 704).

34. There are a number of opioid-based APIs used to treat moderate to severe pain. They are sometimes referred to by their molecule names and include at a minimum (1) oxymorphone, (2) morphine, (3) oxycodone, (4) hydromorphone, (5) hydrocodone, (6) fentanyl, (7) tapentadol, and (8) tramadol. (Savage, Tr. 726-27, 782, 797).

35. Oxymorphone is the opioid at issue in this case. It is a semi-synthetic opioid used to relieve pain and was first approved by the United States Food and Drug Administration in 1960. (JX-001-006 (¶ 1) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

36. For several years, the brand name product for extended-release oxymorphone was Opana ER. (Savage, Tr. 797-98).

37. The brand name versions of extended-release morphine include Avinza, Embeda, Kadian, and MS Contin. (Michna, Tr. 2176-77; Addanki, Tr. 2325; RX-549.0014).

38. Brand-name medications utilizing oxycodone include Percocet, OxyContin, and Xtampza. (Savage, Tr. 728-29, 797; RX-549.0014).

39. The brand-name versions of hydromorphone are Exalgo (extended-release) and Dilaudid (short-acting). (Savage, Tr. 796-97).

40. Vicodin and Hysingla are brand-name versions of hydrocodone. (Savage, Tr. 797; Michna, Tr. 2177).

41. Duragesic is a brand-name version of extended-release fentanyl. (Savage, Tr. 740; RX-549.0014).

42. Extended-release tapentadol is sold under the brand name Nucynta ER. (RX-549.0014).

43. Ultram is the branded version of extended-release tramadol. (Savage, Tr. 797).

44. There are generic versions of extended-release oxymorphone, morphine, oxycodone, hydrocodone, hydromorphone, fentanyl, and tapentadol. (Savage, Tr. 782).

C. Direct Customers of Pharmaceutical Manufacturers

45. A number of customers purchase drugs directly from pharmaceutical companies. One set of customers is large national wholesalers. (Engle, Tr. 1706).

46. Wholesalers buy drugs from manufacturers and then distribute the drugs to pharmacies and other down-market buyers. (Engle, Tr. 1781).

47. The three biggest drug wholesalers in the United States are AmerisourceBergen, Cardinal Health, and McKesson Health. (Engle, Tr. 1708).

48. Drug manufacturers compete on price to get their products into a wholesaler's network. (Engle, Tr. 1707).

49. A second category of customers purchasing drugs directly from pharmaceutical companies is large national pharmacy chains, including Rite Aid, CVS, and Walgreens. (Engle, Tr. 1709).

50. Drug manufacturers again compete on price in order to get their products into national pharmacy chains. (Engle, Tr. 1709).

51. A third category of direct customers is smaller pharmacy chains, including Publix and Winn Dixie. (Engle, Tr. 1781-82).

52. A fourth category of direct customers is smaller and regional wholesalers and distributors. (Engle, Tr. 1781-82).

D. <u>The Role of Insurers</u>

53. Third-party payors like insurance companies are often responsible for most or all of a drug's cost when it is prescribed to an individual patient. (Bingol, Tr. 1324).

54. Insurance companies consequently exert significant pressure on the types of drugs that are prescribed by doctors. (Michna, Tr. 2129).

55. Insurance companies "want to use effective drugs that cost the insurance company the least amount of money and cost the patient the least amount of money, so they encourage the use of the lower-cost medications, which are frequently the generics." (Michna, Tr. 2129).

1. Co-Pay

56. A patient's out-of-pocket expense for any medication is known as a co-pay. (Michna, Tr. 2130).

57. Co-pays are paid directly to pharmacists when a patient picks up a prescription. (Michna, Tr. 2130).

2. Formularies

58. Most insurers maintain drug formularies, which are lists of drugs that are covered by their insurance plans. (Noll, Tr. 1396; Michna, Tr. 2146 (formularies are "universal")).

59. Formularies rank drugs, putting them into tiers that represent different levels of coverage—or "access"—as well as different out-of-pocket expenses for plan members. (Bingol, Tr. 1291; Addanki, Tr. 2217; Noll, Tr. 1396).

60. In general, formularies are "all about access": They represent insurance companies' "way of trying to control costs in the marketplace by restricting access to certain categories of product" that are more expensive for the insurer and "steer[ing] their patients to the higher tiers" of preferred, less expensive medications. (Bingol, Tr. 1320-22; *see* Michna, Tr. 2146; Addanki, Tr. 2217-18; Noll, Tr. 1552).

61. Formularies also encourage doctors to use lower-cost medications. (Michna, Tr. 2129-30, 2142).

62. Generally, drugs on the highest tier—tier one—have the lowest net price to the insurance company. (Bingol, Tr. 1291; *see* Noll, Tr. 1396; Michna, Tr. 2141).

63. Tier one drugs also typically have the lowest co-pay for patients—as low as zero dollars—because they are the most economically advantageous product for the insurer. (Bingol, Tr. 1323-24; *see* Michna, Tr. 2141; Addanki, Tr. 2218).

64. Tier one formulary drugs represent the easiest and fastest way for a patient to gain access to a drug. (Bingol, Tr. 1291).

65. An insurer's tier one often includes generic drugs. (Bingol, Tr. 1292; Michna, Tr. 2141).

66. Tier two generally includes generic products that are more expensive to the insurer or branded drugs that do not have a generic equivalent. (Bingol, Tr. 1291; Michna, Tr. 2141-42).

67. Medications listed on tier two have higher co-pays for patients at the pharmacy, and often come with additional restrictions before doctors can prescribe the medication. (Bingol, Tr. 1291; Michna, Tr. 2140-42; Addanki, Tr. 2218).

68. Indeed, many drugs on lower tiers require prior authorization before a doctor can prescribe them. (Michna, Tr. 2140).

69. Prior authorization requires a doctor to submit additional paperwork and documentation detailing why the doctor believes the medication should be used for a particular patient. (Michna, Tr. 2140).

70. Tier three on formularies typically contains more expensive medications than those on tiers one or two—generally branded medications that are preferred over tier four medications because they are cheaper to the insurer than the medications on tier four. (Michna, Tr. 2142).

71. Co-pays for drugs listed on tier three are higher than those for either tier one or tier two. (Bingol, Tr. 1324; *see* Michna, Tr. 2142). There may also be additional restrictions before doctors can prescribe tier three medications. (Bingol, Tr. 1291).

72. Plan members may only be able to access drugs listed on tier three or other low tiers if treatment with lower-cost alternatives on tiers one and two are unsuccessful. (Bingol, Tr. 1319-20). This requirement is known as "step therapy." (Michna, Tr. 2141).

73. Tier four generally includes drugs that are more expensive to the insurance company than those on tiers one, two, or three, and therefore come with even greater restrictions on access. (Michna, Tr. 2142; Addanki, Tr. 2218).

74. Tier four medications are also more expensive for patients, with higher co-payments up to the full cost of the medication. (Michna, Tr. 2142; Addanki, Tr. 2218).

75. To the extent an insurance plan has additional tiers, those tiers generally include drugs that are more expensive to the insurance company than those on higher tiers. As a result, there are greater restrictions on access to the lower-tiered drugs—with some drugs not covered at all and others requiring special approvals—and higher co-pay costs to plan-members. (Bingol, Tr. 1291; Addanki, Tr. 2218; Noll, Tr. 1396).

76. The majority of patients in the United States have private insurance plans that employ formularies structured in this manner. (Noll, Tr. 1506).

77. Insurance companies and their pharmacy directors, however, determine the specific contours of any given formulary. (Michna, Tr. 2130).

78. And while all formularies are a function of the cost of medications to the insurer, those costs vary from insurer to insurer, depending on pricing arrangements between the insurer and pharmaceutical companies. (Bingol, Tr. 1320-22; Michna, Tr. 2136).

79. As a result, different insurance companies have different formularies as well as different tier configurations. (Bingol, Tr. 1319; Michna, Tr. 2135; Noll, Tr. 1543 ("[F]ormularies are all very similar. [I]t's just that the placement of a specific drug can be different on different formularies.")).

80. Even within a single insurance company, different insurance plans can have different formularies. (Michna, Tr. 2135).

3. Pharmacies

81. Pharmacies fill prescriptions for individual consumers. To do so, pharmacies often purchase medicine from wholesale suppliers. (Addanki, Tr. 2221-23).

82. After a prescription is filled, the pharmacy receives a reimbursement from the consumer's insurance company, which makes the pharmacy whole for its purchase of the drug and any other relevant costs. (Addanki, Tr. 2221-23).

83. The pharmacy will also receive partial reimbursement from individual consumers via their co-pays. (Addanki, Tr. 2223).

III. THE ENDO-IMPAX LITIGATION

A. Opana ER

84. Opana ER is an extended-release formulation of oxymorphone. (JX-001-006 (¶ 3) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Bingol, Tr. 1261-62).

85. Stated differently, oxymorphone is the active pharmaceutical ingredient in Opana ER. (Bingol, Tr. 1262).

86. Opana ER is used to treat pain for a wide variety of conditions, ranging from chronic back problems to cancer. (JX-001-006 (¶ 5) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

87. Endo and Penwest Pharmaceuticals collaborated on the development and commercialization of Opana ER. (JX-001-011 (¶ 47) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

88. The FDA approved Opana ER (NDA No. 021610) in June 2006 "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." (JX-001-006 (¶ 4) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

89. Endo announced commercial availability of Opana ER in July 2006. (JX-001-006 (¶ 6) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

90. Endo launched Opana ER in 2006, and Opana ER was the only extended-release version of oxymorphone on the market at that time. (JX-001-006 (¶ 8) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

91. Endo ultimately sold Opana ER in seven dosage strengths—5, 7.5, 10, 15, 20, 30 and 40 mg. (JX-001-006 (¶ 7) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

B. Opana ER's Initial Patents

92. In October 2007, Endo listed three patents in the Orange Book as covering Opana ER: U.S. Patent Nos. 7,276,250, 5,662,933, and 5,958,456. Endo listed the '250 patent in the Orange Book on October 2, 2007, and the '933 and '456 patents on October 19, 2007. (JX-001-006 (¶ 9) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); *see also* Snowden, Tr. 349-51).

93. The '933 and '456 patents expired in September 2013. The '250 patent will expire in February 2023. (JX-001-006 (¶ 10) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 351).

C. Impax's Abbreviated New Drug Application

94. Impax initially filed an Abbreviated New Drug Application ("ANDA") for a generic version of Opana ER (No. 79-087) in June 2007. (JX-001-007 (¶ 11) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

95. Following Endo's listing of additional patents in the Orange Book in October 2007, Impax amended its ANDA to include Paragraph IV certifications for the '250, '933, and '456 patents, attesting that Impax's product did not infringe the patents and/or that the patents

were invalid. (JX-001-007 (¶ 12) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 355, 413).

96. Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosages of Opana ER. (JX-001-007 (¶ 13) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 353-54, 414).

97. Impax consequently was eligible for first-filer exclusivity for the 5, 10, 20, 30, and 40 mg dosages. (JX-001-007 (¶ 14) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

98. This means that Impax was eligible for 180 days of generic exclusivity on those dosages after it launched, as long as Impax did not forfeit its eligibility. (Snowden, Tr. 414-15).

99. The 5, 10, 20, 30, and 40 mg dosages comprised over [redacted] of Endo's Opana ER sales. (JX-001-007 (¶ 13) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); CX0203; CX4017 (Levin, Dep. at 112-13)).

100. Several other generic companies subsequently filed ANDAs for Opana ER, including Actavis South Atlantic LLC ("Actavis"). (CX6039-001).

101. Actavis was the first to file an ANDA for the two remaining strengths of Opana ER (7.5 mg and 15 mg), although its ANDA covered all dosage strengths. (Snowden, Tr. 370; CX6039-003).

D. <u>The Endo-Impax Lawsuit</u>

102. In December 2007, Impax notified Endo and Penwest that it had filed Paragraph IV certifications with respect to the Opana ER patents listed in the Orange Book. (Snowden, Tr. 355, 413; CX2714 (Impax's certification notice to Endo)).

103. Endo and Penwest sued Impax on January 25, 2008, alleging that Impax's ANDA for generic oxymorphone ER infringed the '456 and '933 patents. (JX-001-007 (¶ 15) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 413-14).

104. Endo and Penwest initially filed their suit against Impax in the District of Delaware. (Snowden, Tr. 357).

105. Impax successfully transferred the case to the District of New Jersey because the Delaware court was overloaded and Impax sought to secure an earlier trial date. (Snowden, Tr. 357-58).

106. The trial in the original patent litigation between Endo and Impax relating to Impax's generic Opana ER product began on June 3, 2010, and was settled by agreement of the parties on June 8, 2010. (JX-001-007 (¶ 18) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 358-59, 360). That settlement is the subject of these proceedings.

107. The Endo-Impax trial was scheduled to conclude on June 17, 2010. (JX-003-005 (¶ 25) (Second Set of Joint Stipulations); Figg, Tr. 1906; Hoxie, Tr. 2767).

E. FDA Approval of Impax's ANDA

108. The Endo lawsuit triggered a statutory thirty-month stay, meaning that the FDA could not approve Impax's ANDA until the earlier of the expiration of thirty months or resolution of the patent dispute in Impax's favor. (JX-001-007 (¶ 15) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

109. The thirty-month stay was set to expire on June 14, 2010. (JX-001-007 (¶ 16) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

110. The FDA granted tentative approval to Impax's ANDA on May 13, 2010. (JX-001-007 (¶ 17) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

111. Impax received Final Approval for Impax's Generic Oxymorphone ER Product on the 5, 10, 20, and 40 mg dosage strengths on June 14, 2010, upon expiry of the stay under 21 U.S.C. § 355(j)(5)(B)(iii). (JX-001-008 (¶ 21) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

112. The FDA granted Final Approval to Impax's ANDA for the 30 mg dosage on July 22, 2010. (JX-001-008 (¶ 22) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

F. Endo's Suits Against Other ANDA Filers

113. Endo also sued Actavis and all other Opana ER ANDA filers, alleging patent infringement as a result of their respective ANDAs. (Snowden, Tr. 440).

114. Those suits also settled, with the generic companies receiving patent licenses covering only the patents-in-suit. (Snowden, Tr. 440; RX-441; RX-442; RX-443; CX3192).

115. The Endo-Actavis settlement agreement contained a license date of July 15, 2011. (Snowden, Tr. 370-71).

116. Actavis launched its 7.5 mg and 15 mg generic Opana ER products—for which it possessed first-to-file exclusivity—in July 2011. (CX4034 (Rogerson, Dep. at 13)).

117. Actavis did not launch its 5, 10, 20, 30, or 40 mg generic Opana ER products until September 17, 2013, several months after the expiration of Impax's first-to-file exclusivity. (CX2973; *see* CX4034 (Rogerson, Dep. at 13) (noting launch in fall 2013)).

IV. THE ENDO-IMPAX SETTLEMENT AGREEMENT

A. Settlement Negotiations Background

118. Impax and Endo first attempted to settle their patent dispute in the fall of 2009. (Snowden, Tr. 418; RX-359 (October 2009 emails between parties); RX-285 (November 2009 email between parties)).

119. Those preliminary discussions focused on high-level business interests as well as opportunities for the companies to work together, but were unsuccessful. (Snowden, Tr. 418-19).

120. Impax and Endo reinitiated settlement discussions in May 2010, shortly before the expiration of the thirty-month stay of Impax's ANDA imposed by the Hatch-Waxman Act. (Snowden, Tr. 418; RX-333 (Endo's initial term sheet)).

121. On June 8, 2010, Impax and Endo entered into the Settlement and License Agreement ("SLA"). (JX-001-007-09 (¶¶ 19, 33) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); CX2626 (executed SLA)).

122. Impax explored settlement with Endo because patent challenges are inherently risky and have uncertain outcomes. (Mengler, Tr. 563-64; Hoxie, Tr. 2665, 2753).

123. Courts can disagree with a generic company's Paragraph IV certifications and deem the patents valid and infringed, an outcome Impax had experienced prior to its suit against Endo. (Snowden, Tr. 412-13).

124. And if a court upholds the relevant patents, a generic company has to wait for the patents to expire before it can launch its product. (Mengler, Tr. 564).

125. If Impax did not settle, and the court upheld any of Endo's patents-in-suit, Impax would have been enjoined from making and selling generic Opana ER until after September 9, 2013. (Figg, Tr. 1973; Hoxie, Tr. 2834).

B. The SLA Included the Earliest License Date Impax Could Obtain

126. Impax's "top business priority" in its settlement negotiations with Endo was the ability to sell its oxymorphone ER product free from patent risk at the earliest possible date. (Snowden, Tr. 430; *see* Koch, Tr. 235; CX4014 (Hsu, IHT at 36-37) ("when we started

discussion with Endo, to me, the most important thing is we want to see whether we could get agreement to launch the product, as early as possible")).

127. Chris Mengler, President of Impax's Generics Division at the time of settlement and a lead negotiator of the SLA, explained that the "main objective" for Impax was to secure the "earliest possible entry date" to ensure that Impax could "get[] the product on the market as quickly as possible and maximize[] the value to Impax shareholders." (Mengler, Tr. 524-26, 564).

128. Larry Hsu, Impax's CEO at the time of settlement, similarly testified that "launch[ing] the product early is always the most important [goal] for the generic company," as long as it can do so free from patent risk. (CX4030 (Hsu, Dep. at 77); *see* CX4014 (Hsu, IHT at 116-17)).

129. It "is very important for [Impax] to have a . . . risk-free launch" and to "launch the product as early as possible. That's what we are in the business for." (CX4014 (Hsu, IHT at 117); CX4030 (Hsu, Dep. at 28)).

130. Impax "wanted always to get on the market as quickly as possible and stay in the market." (CX4026 (Nguyen, Dep. at 160); *see* Mengler, Tr. 564 (the "only way we make money is selling products, so the sooner we can get in, the better off we are")).

131. Impax's "goal is always to sell as much as [it] can as soon as [it] can." (Mengler, Tr. 534).

132. When Endo and Impax first discussed a potential settlement in 2009, Impax knew that Endo had settled patent litigation against Actavis on terms that included a July 2011 license date. (RX-568; CX4003 (Snowden, IHT at 51)).

133. Impax twice pushed Endo for a comparable entry date, offering a simple settlement with a July 2011 entry date. (Snowden, Tr. 371-73, 423).

134. Impax suggested July 2011 because it was between when Impax could first receive FDA approval (June 2010) and when Endo's patents would expire (September 2013). (Mengler, Tr. 565; Snowden, Tr. 363-64, 419-20, 423-24).

135. Endo rejected the proposals outright. (Snowden, Tr. 374, 423; CX4003 (Snowden, IHT at 51)).

136. Endo maintained that it would only consider a license date between when an appeal of the patent litigation would be decided and the expiration of the patents-in-suit. (Snowden, Tr. 419).

137. Endo consequently proposed a March 10, 2013, entry date in the first term sheet it sent Impax. (Snowden, Tr. 366, 428; RX-333 (Endo's initial term sheet)).

138. As Arthur Koch, Impax's Chief Financial Officer at the time of settlement and another negotiator of the SLA, explained, Impax "met complete resistance to the concept of an earlier launch date." (Koch, Tr. 239).

139. Endo was "adamant about 2013 and not getting anything into 2012" and "was certainly digging in their heels with that date." (Mengler, Tr. 565-67; *see* Noll, Tr. 1599-1600 ("Impax's attempt to get an earlier date met with complete resistance.")).

140. Through hard negotiations, Impax got Endo to move the entry date to February 1, 2013, and then eventually to January 1, 2013. (Mengler, Tr. 566; *see* Noll, Tr. 1598).

141. The executed Settlement and License Agreement granted Impax a license to sell its generic version of Opana ER beginning on January 1, 2013, or earlier upon one of two events: (i) a final federal court decision holding all asserted and adjudicated claims of the patents at issue

to be invalid, unenforceable, or not infringed by a generic version of Opana ER; or (ii) the withdrawal of the patents at issue from the Orange Book. (JX-001-009 (¶ 34) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); CX2626 (executed settlement agreement); Snowden, Tr. 370).

142. At no point during settlement discussions did Endo and Impax discuss Impax accepting a later entry date in exchange for something of value from Endo. (Mengler, Tr. 567-68; CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)).

143. Impax would have "absolutely" accepted an earlier license date if it had been possible. (Mengler, Tr. 567).

144. There is no evidence that Endo ever offered an entry date earlier than January 1, 2013, despite Impax's efforts to secure one. (Mengler, Tr. 566-67).

C. <u>The SLA Contained a Broad Patent License</u>

145. At the time of the settlement, Endo had pending applications for patents relating to Opana ER. (JX-001-010 (¶ 36) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

146. Impax knew of Endo's pending applications, and recognized that Endo could acquire still other patents. (RX-398.0001; RX-568; Mengler, Tr. 571-72; Snowden, Tr. 440, 442-43).

147. In a 2009 email assessing the Endo-Actavis settlement, for example, Impax employees noted that the Actavis settlement did not cover Endo's pending patent applications. (RX-398.0001 (noting Endo was "banking on [its] pending patents")).

148. Given the possible effects of those patent applications, a reasonable litigant would have been concerned with Endo's future patents. (Figg, Tr. 1938).

149. But Impax was more concerned than most. It is "incredibly conservative." (CX4021 (Ben-Maimon, Dep. at 34)).

150. It "is very important for [Impax] to have a . . . risk-free launch" before it markets any generic product. (CX4014 (Hsu, IHT at 117)). Accordingly, Impax seeks "freedom to operate" without patent risks. (CX4026 (Nguyen, Dep. at 155-58)).

151. Every "agreement has to cover all the patent[s], not just the patent [at issue] today, but cover all future patent[s] as well," "otherwise you end up with [a] launch [of] the product and still have to be under [patent] risk, and that doesn't really help us." (CX4014 (Hsu, IHT at 116)).

152. For that reason, Impax fought hard to secure a broad patent license covering all possible patents. Endo's first draft of the settlement agreement only offered Impax a license to current patents and any extensions thereof. (RX-333.0005).

153. During subsequent negotiations, the parties exchanged no fewer than seven separate versions of the license agreement. (CX0324; CX2771; RX-573; CX1813; RX-335; RX-322; RX-336; RX-402).

154. Impax gradually secured greater patent protections, ultimately securing a license and covenant not to sue that covered all patents "that would ever be owned by [Endo and Penwest] that would cover the Impax product, so the patents that existed at the time as well as future patents." (Snowden, Tr. 439; CX2626-009 (executed SLA)).

155. Specifically, Section 4.1(a) of the Settlement and License Agreement grants Impax a license both to the "Opana ER Patents" (meaning the '933, '456, and '250 patents) and to "any patents and patent applications owned by Endo or Penwest . . . that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distribution

of products . . . that are the subject of the Impax ANDA . . . ." (JX-001-009-10 (¶ 35) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

156. The Settlement and License Agreement identified "the patent applications (and any patents issued thereunder)" as the "Pending Applications." (JX-001-010 (¶ 36) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

157. The broad patent license and covenant not to sue ensured that Impax could launch its generic oxymorphone ER product free from patent risk on January 1, 2013. (Koch, Tr. 236).

D. The Endo Credit and Royalty Provisions

1. The Introduction of Reformulated Products

158. When the FDA approves an ANDA for a generic drug, the FDA has determined that the drug is bioequivalent to the brand-name product. This is often referred to as "AB-rated." (Mengler, Tr. 521-22; Bingol, Tr. 1309; Snowden, Tr. 413; Figg, Tr. 1853-54; Noll, Tr. 1380 (Actavis 7.5 mg and 15 mg generic Opana ER products enjoyed AB-rating when launched in 2011)).

159. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate substitution of lower-cost AB-rated generic drugs for branded drugs. When a pharmacist fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. Conversely, these laws generally do not permit a pharmacist to substitute a non-AB-rated generic for a branded drug unless the physician specifically prescribes it by writing the chemical name of the drug, rather than the brand name, on the prescription. (JX-003-011 (¶ 72) (Second Set of Joint Stipulations); *see* Mengler, Tr. 521-22; Bingol, Tr. 1309; Addanki, Tr. 2272 (seventeen states require substitution, almost all others permit substitution)).

160. Substitution of generic products for brand-name products is the primary way that generic companies make their sales. (Mengler, Tr. 522; Engle, Tr. 1703).

161. Brand pharmaceutical companies sometimes reformulate their brand-name products, "in theory to have some improved properties." (CX4003 (Snowden, IHT at 30)).

162. But introducing a reformulated product can also protect the branded franchise from losing sales to AB-rated generics. (Snowden, Tr. 433-34; CX4043 (Hoxie, Dep. at 144-45); CX4030 (Hsu, Dep. at 108)).

163. Specifically, when brand companies introduce a reformulated drug, they often cease marketing and selling the original product. They can also withdraw the original product's reference-listed drug designation, preventing generic products from having AB-rated status. (CX4003 (Snowden, IHT at 30-31); CX4014 (Hsu, IHT at 152)).

164. In so doing, the brand company can greatly reduce the opportunity for generic versions of the original drug since those generic products are no longer bioequivalent to—and not subject to automatic substitution in place of—the reformulated product. (Snowden, Tr. 434; CX4030 (Hsu, Dep. at 108); Koch, Tr. 238 (reformulation can "switch patients away from the brand product that Impax has the generic to in favor of a line extension" not covered by the ANDA)).

165. Because "the generic would rely on the . . . automatic substitution in the pharmacy," not having a reference brand product means that pharmacists "can't substitute." (CX4014 (Hsu, IHT at 152)).

166. For the generic drug to be sold, doctors must actually write out a prescription for the generic product. (CX4014 (Hsu, IHT at 152); CX4004 (Engle, IHT at 221)).

2. Endo's Opana ER Reformulation Efforts in 2010

167. At the time of settlement in June 2010, Endo was working on a reformulated version of Opana ER that would affect sales of the original Opana ER product. (Cuca, Tr. 618-19; CX4017 (Levin, Dep. at 120)).

168. In fact, development work on the reformulated version of Opana ER had been underway since at least July 2009. (CX4019 (Lortie, Dep. at 118)).

169. Endo had also acquired patented technology to support the reformulation efforts. (Mengler, Tr. 569).

170. At the time of settlement, Endo's reformulation of Opana ER was not yet public. (CX4017 (Levin, Dep. at 120)).

3. Impax's Suspicions Regarding Endo's Reformulation Plans

171. By 2010, many pharmaceutical manufacturers had transitioned (or were publicly working to transition) their opioid products to crush-resistant formulations. (Mengler, Tr. 568-69).

172. In fact, in light of the country's opioid crisis, the FDA encouraged extended-release opioid manufacturers to "figure out a way to make them tamper-resistant and the primary manner in which companies were doing that was to make the tablet in such a manner that they couldn't be crushed." (Mengler, Tr. 569).

173. Purdue, the manufacturer of OxyContin, had done just that, introducing a reformulated, crush-resistant version of its product and withdrawing its original formulation. (Mengler, Tr. 569; CX4017 (Levin, Dep. at 117-19)).

174. Although Impax did not have specific information about Endo's reformulation plans, Impax was concerned that Endo had "a secret plan to damage the market" with the

introduction of a reformulated Opana ER product. (CX0217-001; *see* Snowden, Tr. 433-34; Mengler, Tr. 569-70; CX4017 (Levin, Dep. at 118)).

175. Impax had also seen analyst reports suggesting that Endo was working on crush-resistant drugs generally. (CX2540-001; Mengler, Tr. 579-80).

176. If Endo did introduce a reformulated Opana ER product, it would negatively affect Impax's ability to sell its generic oxymorphone ER through automatic substitution, undermining the consumer benefits of "getting a generic version of what would have been an important drug." (Mengler, Tr. 526-27, 528).

177. Chris Mengler, Impax's lead settlement negotiator, consequently raised his concerns with Endo's CFO, Alan Levin, on multiple occasions during settlement discussions. (Mengler, Tr. 580; CX4012 (Donatiello, IHT at 125, 151-52); CX0217-001 (June 2, 2010, email noting that Mr. Mengler "followed up with [A]lan [Levin] and told him I think they have a secret plan to damage the market")).

178. Mr. Levin categorically denied any plans to develop a reformulated Opana ER product and "[r]eiterated over and over that there was no intention or plan to switch the market." (Mengler, Tr. 570, 580).

179. Specifically, Mr. Levin told Impax that "[y]ou don't have to worry about that. We're not going to do that. We have every intention of putting a lot of resources behind marketing [the original Opana ER] product. You should be grateful, by the time you launch, it's going to be an even bigger and more robust opportunity for you, and you should pay us a royalty because it's going to be such a big opportunity for you after we, you know, continue to promote it." (Snowden, Tr. 432-33; *see* CX4017 (Levin, Dep. at 120)).

180. Mr. Mengler did not believe Endo's representations and told Mr. Levin as much. (Mengler, Tr. 580). He explained that while Impax was "happy to pay" a royalty, it also wanted contractual provisions to help ensure that Endo stood by its assurances with respect to a reformulated version of Opana ER. (Snowden, Tr. 432-33).

4. Endo Rejected a Market Degradation Trigger

181. Impax initially sought a market degradation trigger, which would have allowed Impax to launch a generic version of Opana ER immediately if Endo introduced a reformulated product that degraded sales of original Opana ER. (Koch, Tr. 237-38; Snowden, Tr. 432; Mengler, Tr. 532; RX-318.0001).

182. Endo categorically refused a market degradation trigger, considering it a "nonnegotiable" concept, even though Impax pressed the issue "very hard." (Koch, Tr. 314-16; *see* Snowden, Tr. 432; Mengler, Tr. 581).

183. Endo would not "let [Impax] go past a certain date," no matter what happened to the generic opportunity. (CX4026 (Nguyen, Dep. at 163)).

5. The Endo Credit was Intended to Encourage Endo to Support Original Opana ER

184. In the face of Endo's categorical rejection of a market degradation trigger, the parties devised "a carrot and a stick approach"—known as the Endo Credit and Royalty Provisions—as a way to ensure Impax had a measure of control over its generic opportunity. (Koch, Tr. 236-37, 240-41).

185. The Endo Credit required Endo to pay a penalty if original Opana ER sales in the last quarter of 2012 fell below 50 percent of their quarterly peak. The specific penalty was calculated by multiplying a "Market Share Profit Value"—defined in the SLA with reference to

quarterly peak sales during the period between settlement and the third quarter of 2012—by the number of percentage points that sales fell below 50 percent. (CX2626-003-04).

186. If, for example, Opana ER sales were 45 percent of their quarterly peak in December 2012, the penalty would be equal to five times the Market Share Profit Value. (CX2626-003).

187. The prospect of a penalty was meant to incentivize Endo to make investments in its original Opana product. (Koch, Tr. 241; Snowden, Tr. 386).

188. Carole Ben-Maimon, Impax's former President of the Generics Division, explained that the Endo Credit was "a deterrent to prevent [Endo] from switching the market." (CX4021 (Ben-Maimon, Dep. at 118, 122); *see* CX4037 (Smolenski, Dep. at 244-45) (Endo Credit "intended to disincentivize Endo from" introducing a reformulated product)).

189. As Mr. Mengler explained, "in the absence of an acceleration trigger . . . we needed an alternative to, one, try to incentivize the product to stay on the market and then, two, in the worst case scenario where the market was in fact destroyed, I at least wanted to be made whole for the profits that we would have[] otherwise achieved." (Mengler, Tr. 533; *see* Koch, Tr. 238-39; Reasons, Tr. 1202-03).

190. And given Impax's distrust of Endo's representations, Impax demanded that the Endo Credit formula incorporate assumptions that "had to go [Impax's] way" in the event that Endo was lying about reformulating Opana ER. (Snowden, Tr. 434-35; *see* CX4026 (Nguyen, Dep. at 163-64) (Endo Credit was used to "put [Endo] to [its] word" with respect to reformulation)).

191. Endo acknowledged that the Endo Credit was intended "to reduce the uncertainty around what each of the parties would experience from cash flows, so the goal was to, if the

market changed substantially before the date that the parties agreed that Impax could launch, there would be a way of making Impax whole." (Cuca, Tr. 617).

192. Importantly, Robert Cuca, Endo's Vice President of Financial Planning and Analysis and the author of the Endo Credit, testified that "I don't know that anyone was anticipating a change in the marketplace, but the provision was designed to insulate against a substantial decrease in sales of the innovator product." (Cuca, Tr. 615, 617).

193. Mr. Cuca explained that he drafted the provision by looking at what "Opana ER sales could be expected to look like if nothing changed the trajectory of its growth, and then tried to understand what the negative impact to Impax would be from a profit perspective if something did disrupt that growth." (Cuca, Tr. 625).

194. Despite minor changes, the final version of the Endo Credit provision captured Mr. Cuca's initial ideas and assumptions. (Cuca, Tr. 633-35).

6. The Royalty Provision Similarly Incentivized Support for Original Opana ER

195. "[T]he mirror image of the Endo Credit," was the Royalty Provision. (Cuca, Tr. 613-14; CX4017 (Levin, Dep. at 120-21) (Endo Credit and Royalty Provision "were intended to be looked at hand in hand")).

196. The Royalty Provision was the "carrot" in the SLA, which required Impax to pay Endo a royalty payments of 28.5 percent on a portion of its generic sales if Opana ER sales rose above a certain threshold. (CX2626-012; Snowden, Tr. 393; Koch, Tr. 241).

197. Like the Endo Credit, the Royalty Provision incentivized Endo to support original Opana ER. (Koch, Tr. 239; Reasons, Tr. 1225-26).

198. Alan Levin, Endo's CFO and one of Endo's lead negotiators, explained that "the Endo Credit was meant to be read in conjunction with the royalty provisions of the settlement

agreement and that the two together provided for an accounting for changes in a very variable opioid marketplace." (CX4017 (Levin, Dep. at 73)).

E. The Co-Exclusive License Term

199. The SLA also contained a co-exclusive license provision—colloquially referred to as a "No-Authorized Generic" or "No-AG" provision—whereby Endo agreed not to "sell, offer to sell, import, or distribute any generic version of products that are the subject of the Opana NDA," or to license or authorize a third party to do the same, during Impax's 180-day exclusivity period. (CX2626-010-11 (SLA § 4.1(c)); Snowden, Tr. 392; Koch, Tr. 234-35).

200. The provision had no effect on Endo's ability to sell its Opana ER product under its branded label or to price that product as it saw fit. (CX2626-010-11 (SLA § 4.1(c))).

201. The co-exclusive license term was not the subject of any meaningful negotiation, and none of the executives that negotiated the SLA recall any significant discussion of the term. (Snowden, Tr. 428-29; Mengler, Tr. 567).

202. Endo offered the provision in the first term sheet it circulated in May 2010, and Impax left it in place without discussion. (Snowden, Tr. 428-29; *see* RX-333 (Endo's initial term sheet); RX-318.0001 (Impax's first counterproposal)).

203. The co-exclusive license term in the final SLA was virtually unchanged from Endo's initial proposal. (CX2626-010-11 (executed settlement agreement with identical term)).

V. POST-SETTLEMENT EVENTS RELEVANT TO THE SLA

A. The Launch of Reformulated Opana ER

204. Despite Endo's assurances to the contrary, Endo filed a supplemental New Drug Application (No. 201655) for a reformulated version of Opana ER ("reformulated Opana ER") in July 2010. (JX-001-011 (¶ 48) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); CX3189).

205. According to Endo, it reformulated Opana ER to "potentially offer a safer product to the market, and therefore allowing us to offer the best products and safest product that we could for our customers." (Bingol, Tr. 1294-95).

206. The crush-resistant nature of reformulated Opana ER was intended to make it "more difficult for potential abusers to prepare [Opana ER] for snorting or injecting." (Bingol, Tr. 1339).

207. Despite suspicions that Endo was working on a reformulated version of Opana ER, Impax was surprised by the announcement. (CX0117-002 (in response to news of Endo's NDA, Impax's Chris Mengler wrote, "So much for 'Chris, I promise we have no plans to not continue to pursue our existing formulation'"); *see also* CX4010 (Mengler, IHT at 41-42)).

208. The FDA approved Endo's supplemental NDA for a reformulated version of Opana ER in December 2011. (JX-001-011 (¶ 48) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

209. Endo initially did not plan to launch reformulated Opana ER until roughly September 2012, with a complete conversion from original Opana ER to the reformulated product within three months. (RX-094.0003).

210. Endo had to accelerate its reformulated-product launch when the FDA discovered manufacturing deficiencies at the plant where Novartis, another pharmaceutical company, manufactured original Opana ER for Endo. (CX4017 (Levin, Dep. at 136-39)).

211. The Novartis plant shut down at the end of 2011, creating a "supply chain crisis" for original Opana ER. (CX4017 (Levin, Dep. at 136-39); *see* RX-094.0003-04; RX-563.0001; RX-139.0001).

212. Endo consequently launched its reformulated version of Opana ER in March 2012. (CX4017 (Levin, Dep. 138-39)).

213. The FDA then ordered Endo to cease selling original Opana ER in order to avoid consumer confusion. (CX4017 (Levin, Dep. at 138-39, 155); RX-100.0001 ("Several of [Endo's] strategies envisioned [Endo] selling both [original and reformulated Opana ER] products at the same time. It was only upon [Endo's] discussions with the FDA in February [2012] that they told [Endo] not to do this in order to avoid patient confusion.")).

214. Specifically, the FDA informed Endo that "once any tablets of CRF [crush-resistant formulation] were sold, [Endo] could no longer sell any tablets of the old formulation." (RX-094.0004).

215. On May 31, 2012, Endo requested the FDA to move the original formulation of Opana ER (NDA No. 21-610) to the Orange Book Discontinued List. (JX-001-012 (¶ 50) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); CX1220; CX3241).

216. The FDA never approved a label for the reformulated version of Opana ER supporting Endo's claim that the product was crush resistant. (CX4014 (Hsu, IHT at 160, 165)).

217. Endo consequently could "verbally talk about" crush-resistance, but could not "say it officially" with respect to its reformulated Opana ER product. (CX4014 (Hsu, IHT at 165)).

B. Endo Made a Payment Under the Endo Credit

218. On January 18, 2013, Impax provided Endo with written documentation supporting its demand for payment of the Endo Credit in the amount of $102,049,199.64, pursuant to Section 4.4 of the Settlement and License Agreement. (JX-001-011 (¶ 45) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

219. Endo initially resisted making a payment pursuant to the Endo Credit. (CX0330-002-03; CX0331).

220. On April 18, 2013, pursuant to Section 4.4 of the Settlement and License Agreement, Impax received a payment from Endo in the amount of $102,049,199.64 via wire transfer. (JX-001-011 (¶ 46) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 390-91; Reasons, Tr. 1204).

C. Even After Learning It Would Receive an Endo-Credit Payment, Impax Worked to Ensure Consumers Had Access to Generic Opana ER

221. In 2012 and 2013, Impax fought hard to ensure that consumers had access to a low-cost version of oxymorphone ER despite the lack of automatic substitution and various efforts by Endo to block or complicate Impax's sales. (Snowden, Tr. 476-77, 479-80). These efforts continued long after Impax learned it would receive a payment under the Endo Credit term. (Snowden, Tr. 476-77, 479-80).

222. First, Endo filed multiple citizen petitions with the FDA in August 2012, in which it argued that the FDA should (1) determine that original Opana ER was discontinued for safety reasons and could no longer serve as a reference-listed drug for any ANDA; (2) refuse to approve any ANDA pending for original Opana ER; and (3) withdraw any already-granted approvals for original Opana ER ANDAs. (Snowden, Tr. 476-77, 479-80; CX3203 (Endo's citizen petitions)).

223. Impax formally responded to the petition and offered scientific evidence that the discontinuation of Endo's original Opana ER was unrelated to safety or effectiveness. (Snowden, Tr. 480).

224. The United States Food and Drug Administration concluded that Endo did not withdraw its Original Opana ER product for safety or efficacy reasons. (JX-001-012 (¶ 51) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

225. Second, Endo filed a federal lawsuit seeking expedited review of its NDA for reformulated Opana ER and an order requiring the FDA to suspend approval of any ANDAs citing original Opana ER as the reference listed drug. (CX1223-028; Snowden, Tr. 480-81).

226. Impax intervened to contest Endo's position. (Snowden, Tr. 480-81).

227. The court sided with Impax and denied Endo's request for a preliminary injunction, concluding that the FDA could use its normal process to determine whether Opana ER was discontinued for safety reasons, as alleged in Endo's Citizen Petition. (Snowden, Tr. 480-81).

228. Finally, Endo's discontinuation of original Opana ER meant that consumers would not benefit from automatic substitution of a low-cost Opana ER product since Impax's oxymorphone ER product was not AB-rated to Endo's reformulated Opana ER. (Engle, Tr. 1705; RX-379.0001 (lack of branded product was "unprecedented" and "[u]ncharted territory")).

229. Impax consequently developed marketing and physician awareness strategies to help consumers gain access to generic Opana ER, commissioning market research, communicating with healthcare providers nationwide, writing letters to pharmacists, and placing traditional advertisements intended to raise awareness about the drug. (CX4004 (Engle, IHT at 218-22); RX-347.0002; RX-394.0001).

230. Impax also used its sales force to visit pain clinics and other prescribers of pain medication to inform health care providers of the availability of generic oxymorphone ER, its

relationship to reformulated Opana ER, and the significant cost savings it could offer consumers. (CX4021 (Ben-Maimon, Dep. at 49-51)).

231. These efforts were intended to educate physicians and pharmacists about how doctors should write prescriptions in order to ensure oxymorphone ER was dispensed, despite the lack of automatic substitution. (CX4004 (Engle, IHT at 218-21)).

232. Impax then studied the effect of its efforts nationwide and region-by-region in order to calibrate its efforts and promote its low-cost product. (CX4036 (Fatholahi, Dep. at 143-44)).

D. Endo Acquired Additional Patents and Secured Permanent Injunctions Against All Original Opana ER ANDA Filers—Except Impax

233. After entering the Settlement and License Agreement, Endo obtained additional patents and patent licenses that it has asserted cover both original and reformulated Opana ER. (JX-001-012 (¶ 55) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

234. Some of the patents acquired after entering the SLA were pending at the time of the settlement. (Snowden, Tr. 440, 442-43).

1. The Johnson Matthey Patent

235. Endo acquired its first post-settlement patent—Patent No. 7,851,482—from Johnson Matthey in March 2012. (Snowden, Tr. 442-43; RX-127 (Endo's February 2011 evaluation of the Johnson Matthey patent); Addanki, Tr. 2362; Figg, Tr. 1949).

236. The Johnson Matthey patent addressed a process for making a purified type of oxymorphone. (Snowden, Tr. 443; CX4017 (Levin, Dep. at 150-51)).

237. Endo was aware of the Johnson Matthey patent as early as October 2009, when Johnson Matthey's President reached out to Endo about the patent application and Johnson Matthey's "game plan on patent execution." (RX-102.0003).

238. Johnson Matthey also contacted Impax requesting that Impax license the patent before it launch any oxymorphone ER product. (CX3329 (email from Johnson Matthey to Impax); Snowden, Tr. 443-44).

2. 2012 Patents and New York Litigation

239. The Patent and Trademark Office subsequently issued Patent Nos. 8,309,060 and 8,309,122 to Endo on November 13, 2012. (JX-001-012 (¶ 56) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

240. The Patent and Trademark Office issued Patent No. 8,329,216 to Endo on December 11, 2012. (JX-001-012 (¶ 57) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

241. In December 2012, Endo began asserting the ’060, ’122, and ’216 patents against drug manufacturers seeking to market generic versions of both original and reformulated Opana ER. (JX-001-012-13 (¶ 58) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 444-45).

242. Endo did not assert these patents against Impax’s generic version of original Opana ER because of the SLA’s broad license provision. (JX-001-012-13 (¶ 58) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 445).

243. In August 2015, the U.S. District Court for the Southern District of New York held that the ’122 and ’216 patents were not invalid and were infringed by other ANDA filers’ generic versions of original Opana ER, but not by Impax’s product, and by generic versions of reformulated Opana ER, including Impax’s. (JX-001-013 (¶ 62) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 441, 445-46).

244. The court issued an injunction barring all defendants except Impax from selling their generic versions of original Opana ER until 2023. The ruling is currently on appeal to the

Federal Circuit. (JX-001-013 (¶ 62) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

3. 2014 Patents and Delaware Litigation

245. The Patent and Trademark Office issued U.S. Patent No. 8,808,737 to Endo on August 19, 2014. (JX-001-013 (¶ 59) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

246. The Patent and Trademark Office issued U.S. Patent No. 8,871,779 on October 28, 2014. (JX-001-013 (¶ 60) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

247. Endo also acquired an exclusive field-of-use license to U.S. Patent No. 8,871,779 from Mallinckrodt. (JX-001-013 (¶ 61) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

248. The ’779 patent specifies the maximum levels of impurity that can be contained in the active pharmaceutical ingredient for generic Opana ER. (Figg, Tr. 1965).

249. Endo asserted these patents in the District of Delaware against drug manufacturers seeking to market both original and reformulated Opana ER. (Snowden, Tr. 450-51).

250. Endo did not assert these patents against Impax’s generic version of original Opana ER because of the SLA’s broad license provision, but did assert them against Impax’s ANDA for reformulated Opana ER. (Snowden, Tr. 450).

251. In October 2016, the U.S. District Court for the District of Delaware held that the ’779 patent was not invalid and was infringed by a generic version of reformulated Opana ER. The ruling is currently on appeal to the Federal Circuit. (JX-001-013 (¶ 64) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); *see* Snowden, Tr. 441).

252. In August 2017, the District of Delaware court again ruled that the '779 patent was not invalid following a bench trial against certain ANDA filers. (JX-003-008 (¶ 56) (Second Set of Joint Stipulations); RX-544 (not admitted or cited for the truth of the matters asserted therein)). In September 2017, Judge Andrews released his final order, enjoining all defendants from selling generic Opana ER until the patents expire in 2029. (JX-003-008 (¶ 58) (Second Set of Joint Stipulations); RX-575 (not admitted or cited for the truth of the matters asserted therein)).

253. The '779 patent expires in 2029. (Snowden, Tr. 451; CX3255).

4. Implied License Arguments Rejected

254. Actavis and other pharmaceutical companies argued that their original settlements with Endo included an implied license to Endo's later-acquired patents. (Snowden, Tr. 440-41).

255. The Federal Circuit rejected the position, determining that Actavis and other pharmaceutical companies did not have an implied license. (Snowden, Tr. 440-41).

*** * ***

256. Taken together, Endo's acquisition and litigation of additional patents has led to all generic manufacturers other than Impax being enjoined from selling a generic version of Opana ER until Endo's patents expire. (Snowden, Tr. 441-42).

257. Impax has sold Opana ER without interruption since launching its product in January 2013. (Snowden, Tr. 476).

E. <u>Endo No Longer Sells Reformulated Opana ER</u>

258. On June 8, 2017, the United States Food and Drug Administration publicly requested that Endo voluntarily withdraw its Reformulated Opana ER product (NDA No. 201655) from the market. (JX-001-012 (¶ 52) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 446).

259. The FDA made its request following an investigation that uncovered "a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation." (CX6048-001).

260. The FDA concluded that "the benefits of reformulated Opana ER no longer outweigh its risks" because the "injection abuse of reformulated Opana ER has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of serious blood disorder (thrombotic microangiopathy)." (CX6048-001).

261. In July 2017, Endo announced that it would cease shipping Reformulated Opana ER. (JX-001-012 (¶ 53) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

262. Endo ceased selling reformulated Opana ER (NDA No. 201655) effective September 1, 2017. (JX-001-012 (¶ 54) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 446).

263. Because the FDA requested that Endo cease selling reformulated Opana ER, no generic can sell reformulated Opana ER either. (Snowden, Tr. 447-48).

264. Indeed, the FDA has instructed ANDA filers for reformulated Opana ER to withdraw their ANDAs. (Snowden, Tr. 447-48). As of December 20, 2017, Impax is the only drug company selling any version of Opana ER. (JX-003-008 (¶ 59) (Second Set of Joint Stipulations)).

VI. THE DEVELOPMENT AND CO-PROMOTION AGREEMENT

A. The DCA Terms

265. On June 7, 2010, Endo and Impax Executed a Development and Co-Promotion agreement ("DCA") with respect to Parkinson's treatment known internally at Impax as IPX-203. (Snowden, Tr. 397, 398-99; Nestor, Tr. 2935; RX-365 (executed DCA)).

266. Under the Development and Co-Promotion Agreement, Impax and Endo agreed to collaborate with respect to the development and marketing of a potential treatment for Parkinson's disease using an extended release, orally administered product containing a combination of levodopa-ester and carbidopa. (JX-001-010 (¶ 37) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

267. Endo agreed to pay Impax an "Upfront Payment" of $10 million within five days of the agreement's effective date. The $10 million payment was guaranteed and non-refundable. (JX-001-010 (¶ 39) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 399-400).

268. The agreement contained the possibility that Endo would make up to $30 million in additional "Milestone Payments" for achieving specified events in the development and commercialization of the product. (JX-001-010 (¶ 40) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 408).

269. If the target product was successfully commercialized, Endo would be entitled to a share of the profits resulting from prescriptions by non-neurologists. (RX-365 (executed DCA)).

270. Impax and Endo also agreed to share the promotional responsibilities, with Impax promoting IPX-203 to its network of neurologists, and Endo promoting IPX-203 to its network of non-neurologists, including primary care physicians who frequently prescribe Parkinson's disease medications. (RX-365 (executed DCA)).

B. <u>The DCA Payment</u>

271. On June 24, 2010, Endo wired payment of $10 million to Impax in accordance with Section 3.1 of the Development and Co-Promotion Agreement. (JX-001-011 (¶ 44) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

272. Upon receipt of Endo's $10 million investment, Impax deferred the accounting of the money, recognizing it as an investment related to Research and Development work that would be accomplished in the future. (Reasons, Tr. 1242-43).

273. This meant that when Impax received the money, it recognized no income, and as it did R&D work, it began to recognize portions of it over time. (Reasons, Tr. 1243).

274. Traditional accounting rules, including widely accepted guidelines, independent accountant reviews, and annual audits all factored into Impax's accounting approach to the initial DCA investment by Endo. (Reasons, Tr. 1243).

C. The Origins of Endo-Impax Collaboration

1. Endo's Reliance on Collaboration Agreements

275. Endo generally does not research or discover new drug molecules on its own. It instead acquires and licenses drugs from other pharmaceutical companies. (Cobuzzi, Tr. 2515).

276. This means that Endo enters many collaboration agreements with other pharmaceutical companies. (Cobuzzi, Tr. 2513-14).

277. Those pharmaceutical agreements can relate to drugs at every stage of development. Dr. Robert Cobuzzi, Endo's Senior Vice President of Corporate Development at the time of settlement, explained that Endo's product licensing efforts "were across the spectrum" of the development lifecycle. (Cobuzzi, Tr. 2516).

278. In fact, Endo's collaboration agreements regularly include early-stage development agreements. Because Endo has "no discovery pipeline ourselves in place," Endo must enter "very early, very speculative agreements" for promising drugs. (Cobuzzi, Tr. 2516).

279. In those instances, Endo will pursue collaboration agreements by identifying therapeutic areas of interest and companies that own promising drug molecules in that area. (Cobuzzi, Tr. 2516).

280. But even for more developed products, Endo regularly licenses technology from and collaborates with other companies. With respect to Opana ER, for example, Endo licensed the technology necessary to make both original and reformulated Opana ER. (Cobuzzi, Tr. 2517).

281. For original Opana ER, Endo licensed technology from Penwest Pharmaceutical. For reformulated Opana ER, Endo licensed technology from a German company called Grunenthal. (Cobuzzi, Tr. 2517).

282. Endo acquired Penwest in September 2010. (RX-491.0005).

283. Similarly for Endo's Lidoderm product, Endo licensed the drug from Teikoku, a Japanese pharmaceutical company, and the individual creator of the drug. (Cobuzzi, Tr. 2516-17).

2. Endo and Impax's Prior Efforts to Collaborate

284. Before Endo and Impax entered the DCA, they had long pursued other collaborative opportunities. (Koch, Tr. 319).

285. As early as 2006, for example, Impax sought to collaborate with Penwest, the pharmaceutical company that worked with Endo to develop and commercialize Opana ER, on products treating diseases of the central nervous system, including Parkinson's disease and epilepsy. (RX-296).

286. [redacted] (RX-393.0014; *see* Nestor, Tr. 2932; Koch, Tr. 318-19; CX4036 (Fatholahi, Dep. at 51-52)).

287. Impax was interested in collaborating with Endo on Frova because the product fit with Impax's focus on the central nervous system and neurology products. (Snowden, Tr. 453-54; Nestor, Tr. 2929). In fact, Shawn Fatholahi, the head of sales and marketing for Impax's

brand division, specifically expressed interest in working with Endo on Frova. (Snowden, Tr. 454).

288. Endo rejected Impax's proposal to collaborate on Frova at that time. (Nestor, Tr. 2932).

289. After Endo and Impax began settlement discussions in late 2009, Mr. Fatholahi contacted Margaret Snowden, the highest ranking lawyer at Impax at the time of the settlement and one of Impax's settlement negotiators, to express his interest in a co-development arrangement with Endo. (Snowden, Tr. 454-55).

290. In October 2009, Impax and Endo again discussed a potential business collaboration and executed a non-disclosure agreement in connection with those talks. (Snowden, Tr. 455-56; RX-359; CX1816 (non-disclosure agreement)).

291. The parties revisited their discussions in April 2010, and their focus narrowed to drugs treating Parkinson's disease. (RX-296.0001; Koch, Tr. 323-24).

3. Parkinson's Disease Treatments Generally

292. The "gold standard" treatment for Parkinson's disease is a combination of carbidopa and levodopa molecules. (Nestor, Tr. 2929).

293. The majority of carbidopa-levodopa medications are available only in immediate-release formulations. (Nestor, Tr. 2929). In fact, Endo's previous Parkinson's drug, Sinemet, was an immediate-release treatment utilizing carbidopa and levodopa. (Nestor, Tr. 2938; *see* Cobuzzi, Tr. 2524).

294. But immediate release carbidopa-levodopa requires frequent dosing and often results in patients losing control of their motor skills as they experience rapid increases and decreases in the concentration of medicine in their bodies, especially as the disease progresses. (Nestor, Tr. 2929-30, 2939).

295. When Impax and Endo entered into the DCA, the only actively promoted branded product using carbidopa and levodopa for Parkinson's treatment was an infusion product called Duopa, which is administered directly into the intestines. (Nester, Tr. 2938).

4. Endo's Interests in Parkinson's Treatments and Neurology Products

296. Endo long had an interest in neurology and Parkinson's disease treatments. As early as 2005, for example, Endo's strategic focus included drugs that addressed neurology as it related to movement disorders, which includes treatments for Parkinson's disease. (Cobuzzi, Tr. 2518).

297. By 2010, Endo and its sales force still had a focus on neurology. (Cobuzzi, Tr. 2519). At that time, Endo was selling Frova, a drug used to treat migraines. (Cobuzzi, Tr. 2519-20).

298. Frova was marketed to neurologists and primary care physicians who treated migraine sufferers. (Cobuzzi, Tr. 2520-21). And Endo generally was interested in other products that were compatible with Endo's existing products and sales efforts. (Cobuzzi, Tr. 2518-19).

299. For a number of years, Endo also sold an immediate-release Parkinson's disease treatment known as Sinemet. (Cobuzzi, Tr. 2524).

300. And Endo evaluated a number of collaborations with other companies related to treatments for Parkinson's disease. (Cobuzzi, Tr. 2522).

301. For instance, Endo explored potential Parkinson's collaboration opportunities with an Italian company called Newron, which had multiple Parkinson's products. (Cobuzzi, Tr. 2522).

302. Endo also conducted due diligence on a Parkinson's product with a novel mechanism of action that was owned by a Finnish company. (Cobuzzi, Tr. 2522).

303. And Endo considered "a couple of other" collaboration opportunities regarding Parkinson's treatments. (Cobuzzi, Tr. 2522).

5. Impax's Efforts to Develop a Parkinson's Treatment

304. When Impax's brand division was founded in 2006, it immediately focused its efforts on the central nervous system and neurology products, with a specific focus on improved treatments for Parkinson's disease. (Nestor, Tr. 2929).

305. As part of this focus on the central nervous system and neurology, Impax's brand division also concentrated on developing a network of relationships with neurology physicians. (Nestor, Tr. 2931).

306. In fact, Impax was promoting other companies' products to the neurology community, including Carbitol, an epilepsy product. (Nestor, Tr. 2931). Impax also in-licensed Zoming, a migraine drug created by AstraZeneca. (Nestor, Tr. 2932). It did so because Impax "wanted to begin the process of developing those relationships with the neurology physicians." (Nestor, Tr. 2931).

307. Impax's first attempt to develop an extended-release carbidopa-levodopa treatment for Parkinson's disease was known as Vadova. (Nestor, Tr. 2930). That product was intended to combine carbidopa-levodopa with controlled-release technology to "give a much smoother effect" to the amount of medication in Parkinson's patients' blood, providing for more control over motor symptoms. (Nestor, Tr. 2926, 2929-30). Vadova was never fully developed or marketed. (Nestor, Tr. 2930).

308. By 2010, Impax's second attempt at an extended-release Parkinson's medication, IPX-066—which would be marketed under the brand name Rytary when it launched in 2015—had reached publicly-disclosed Phase III clinical trials. (Snowden, Tr. 401; Nestor, Tr. 2930-31).

309. IPX-066 was a "well-known combination of drugs, carbidopa and levodopa, that had been formulated to extend the release profile" of Parkinson's drugs. (Cobuzzi, Tr. 2524; *see* Reasons, Tr. 1236).

310. As with Vadova, IPX-066 was intended to better treat Parkinson's patients by allowing for less frequent and more consistent dosing of up to six hours as well as more consistent motor symptom control. (Nestor, Tr. 2930-31; *see* RX-247).

311. By significantly extending the absorption of the drug, IPX-066 would provide "significant improvement of the patient's quality of life." (CX4014 (Hsu, IHT at 38-39)).

312. By 2010, Impax had also begun efforts to develop a "next generation" of IPX-066. The goal of the next-generation product, which is now known as IPX-203, was to further improve treatment to Parkinson's disease patients by extending dosing time even further than IPX-066 and to "begin laying the foundation for [Impax's] brand business over a long period of time." (Nestor, Tr. 2935-36; *see* RX-247 [redacted]).

313. In particular, IPX-203 was intended to help create "a Parkinson's disease franchise" and "further establish the business foundation that we had laid out for ourselves with the neurology community in the Parkinson's space." (Nestor, Tr. 2936-37).

D. DCA Negotiations

1. Endo Proposed a Partnership Regarding IPX-066 and All Follow-On Products

314. In 2010, IPX-066 was Impax's only publicly-announced branded product candidate. (Snowden, Tr. 457).

315. At the start of discussions about possible partnership arrangements, Endo proposed that the companies work together on the entire IPX-066 franchise, which would include

all potential follow-on products and line extensions. (Snowden, Tr. 405-06; Koch, Tr. 320; CX0320-002 (Endo's initial DCA term sheet)).

316. Dr. Robert Cobuzzi, Endo's head of Corporate Development, explained that Endo was interested in Impax's Parkinson's treatments because (1) Endo believed the treatments were compatible with the Endo's existing sales force, (2) Impax's products represented Parkinson's treatment for which Endo had "looked for a number of years," (3) Endo was familiar with the formulation of carbidopa and levodopa because Endo's former drug, Sinemet, used the same molecules, and (4) because Dr. Cobuzzi personally had experience with Parkinson's disease treatments. (Cobuzzi, Tr. 2521, 2524).

317. Endo "had a sales force that was already calling on primary care physicians, and their interest was to expand the portfolio of that sales force and a Parkinson's drug is often . . . prescribed by general practitioners." (Koch, Tr. 323-24).

318. At that time, however, Impax was not looking for a partner in the United States for IPX-066 because Impax planned to market the product domestically on its own, utilizing its established neurologist network. (Snowden, Tr. 456-57; Koch, Tr. 319-20; CX4036 (Fatholahi, Dep. at 77, 80) (Impax "could effectively market [IPX-]066 here in the U.S. ourselves and didn't need any assistance.")).

319. Additionally, because Impax had already shouldered all development risks and development costs, it made little sense to share potential profits from the drug with a partner. (Nestor, Tr. 2941-42).

320. For these reasons, Dr. Michael Nestor, the head of Impax's brand division, was "absolutely not" willing to consider an agreement with Endo regarding IPX-066. (Nestor, Tr.

3054-55). As president of the brand division, Dr. Nestor had to approve any co-development and co-promotion agreement. (Nestor, Tr. 3054-55).

321. Impax ultimately engaged GlaxoSmithKline as a partner for marketing IPX-066 outside the United States and Taiwan. GlaxoSmithKline would assist with the regulatory and infrastructure hurdles associated with commercializing a product outside the United States and Taiwan. (Nestor, Tr. 2942-43).

322. Impax partnered with GlaxoSmithKline because Glaxo "was fully aware of what the idiosyncrasies [] outside the United States" entailed, "had a full understanding of the different markets," and could ensure the commercialization process proceeded in non-U.S. markets. (Nestor, Tr. 2943).

323. [redacted] (Nestor, Tr. 2974-75).

324. [redacted] (Nestor, Tr. 2975-76; CX3441-009-10).

2. Impax Proposed a Narrower Collaboration Regarding IPX-203, a Follow-On Drug to IPX-066

325. Because Impax did not want a partner for IPX-066 in the United States, it proposed that the parties instead collaborate on a specific line extension known as IPX-203. (Koch, Tr. 243).

326. IPX-203 (sometimes referred to as "IPX-066a") was Impax's "next generation" version of IPX-066 and was a planned "levodopa-based product that [would] hopefully

improve[] the treatment of those symptoms and also ha[ve] favorable dosing over Rytary [IPX-066]." (Reasons, Tr. 1236; *see* Koch, Tr. 320; Nestor, Tr. 2935).

327. As Margaret Snowden testified, "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product." (Snowden, Tr. 405-06).

328. In fact, after Endo proposed an agreement covering all of Impax's Parkinson's products on May 26, 2010, Impax responded on May 27, 2010, that any collaboration would only be "for a product I will designate as [IPX]-066a. This is our next generation of [IPX]-066." (CX0320-002 (Endo's initial DCA term sheet); RX-318.0001 (Impax's response to Endo's initial term sheet)).

329. Like IPX-066, IPX-203 would contain carbidopa and levodopa molecules, but IPX-203 was intended to improve "dramatic control of Parkinson's" even more than IPX-066. (Snowden, Tr. 457-58).

330. [redacted] (Nestor, Tr. 2950-51, 2957; Cobuzzi, Tr. 2529-30).

331. The ultimate goal of IPX-203 was to further extend the amount of time patients have control over their motor symptoms after taking the medication. (Nestor, Tr. 2935 ("the whole idea behind this product . . . is to be able to even extend more the effective time that a patient is on IPX-203, meaning that they have a longer period of time when their motor control

symptoms are under control"); CX4014 (Hsu, IHT at 39) (IPX-203 intended to ensure "patient will have a longer time where they feel . . . like a normal person")).

332. IPX-203 would also employ a "much more simplified" dosing regimen than IPX-066, making it more intuitive for neurologists to prescribe the product. (Nestor, Tr. 2994).

333. Impax was confident that it could develop IPX-203. Dr. Suneel Gupta, the Chief Scientific Officer at Impax in 2010, believed that the product concept for IPX-203 was "doable." (Nestor, Tr. 2946; RX-387.0001).

334. Dr. Gupta had experience reformulating existing chemical compounds to create commercial and clinical improvements through reformulation. In fact, Dr. Gupta "is an expert when it comes to reformulating products." (CX4033 (Nestor, Dep. at 80)).

335. Dr. Gupta "is renowned for taking existing compounds and reformulating them and turning those products into very successful drugs in the marketplace that meet significant medical need[s]." (CX4033 (Nestor, Dep. at 82)).

336. Dr. Gupta is also regularly invited to speak at congresses on the topic of drug reformulation and drug delivery. (CX4033 (Nestor, Dep. at 82-83)).

337. Accordingly, when Dr. Gupta tells Impax management that a product concept is "doable," they believe him and rely on his judgment. (CX4033 (Nestor, Dep. at 83)).

338. More generally, [redacted] (Nestor, Tr. 2955-56; *see* CX4014 (Hsu, IHT at 30) (Impax is "a company specialized in the controlled release" of medications)).

339. In fact, Impax was founded with the business model of focusing on controlled-release technology because it is one of the "the few companies in the country [that] can do good controlled release formulation." (CX4014 (Hsu, IHT at 10)). Such expertise is "a very important asset for" Impax and allows it to regularly "take advantage of that [controlled-release] technology" to compete successfully. (CX4014 (Hsu, IHT at 10)).

340. For these reasons, Impax was already planning to withdraw promotion and sampling of IPX-066 (Rytary) once IPX-203 reached the market, allowing patients to continue successful use of IPX-066 while avoiding any division of Impax's sales force between multiple Parkinson's products. (Nestor, Tr. 2937). This was consistent with the commercial goal of extending the IPX-066 franchise. (Nestor, Tr. 2935-36).

341. At the time of the DCA negotiations, IPX-203 formulation work had been under way since 2009, but the concept had not been tested on humans. (Koch, Tr. 243-44, 321; *see* RX-247).

342. This meant that as of May 2010, Impax had collected and reviewed research supporting the viability of its formulation concept for IPX-203, but it did not have supporting clinical data. (Nestor, Tr. 3026-27; RX-318.0001 (May 27, 2010, email noting that Impax had "significant data" regarding IPX-203)).

343. Impax projected that the total cost of development for IPX-203 would be between $80 million and $100 million. (Nestor, Tr. 2944; Koch, Tr. 321; RX-387.0001). The projected costs were a "natural extrapolation" of the development costs incurred by IPX-066. (Nestor, Tr. 2944-45).

E. The DCA's Relation to the SLA

344. Although Endo and Impax used the same individuals to serve as points of contact for negotiations regarding the SLA and negotiations regarding the DCA, "both Endo and Impax

had separate teams for each of the projects because one was brand and one was generic." (Koch, Tr. 245-46).

345. Impax's negotiating positions regarding and analysis of the DCA came from Dr. Michael Nestor, the President of Impax's Branded Division, and his team. (Mengler, Tr. 586; Koch, Tr. 311-12).

346. This was consistent with instructions from Impax's CEO, Larry Hsu, who "was very clear that each agreement should be evaluated on their own merits as a standalone agreement." (Koch, Tr. 313).

347. Dr. Hsu was the individual responsible for approving both agreements, although he would not approve any co-development deal without the endorsement of Dr. Nestor, the president of Impax's brand division. (Koch, Tr. 313; Nestor, Tr. 3054).

348. Impax consequently assessed the DCA and the SLA individually and considered each a standalone agreement "all the time." (Koch, Tr. 313-14; CX4036 (Fatholahi, Dep. at 138-39)).

349. Endo likewise viewed the SLA and DCA as stand-alone agreements, evaluating each on its own merits. (CX4031 (Bradley, Dep. at 196) (SLA played had no influence on the Endo's valuation of the DCA)).

350. Alan Levin, Endo's CFO at the time of settlement and one of Endo's lead negotiators, testified that the SLA and DCA "were stand-alone legal documents," with the DCA serving "as an integral part of the total collaboration between Endo and Impax." (CX4017 (Levin, Dep. at 157-58)).

351. Like Impax, Endo used different teams to evaluate the two agreements, with Dr. Robert Cobuzzi analyzing the DCA, but having no involvement with the separate settlement agreement. (CX4017 (Levin, Dep. at 159)).

F. Termination of the DCA

352. Impax's IPX-203 development efforts revealed that the formulation of IPX-203 contemplated by the DCA could not achieve the intended clinical benefits. (Snowden, Tr. 459-60; *see* Nestor, Tr. 2960-61).

353. Specifically, Impax's research team could not achieve the desired product profile with a levodopa ester and carbidopa formulation. Impax consequently began pursing alternative approaches to an extended-release formulation of carbidopa and levodopa. (Snowden, Tr. 459-60; *see* Nestor, Tr. 2960-61).

354. [redacted]

(Nestor, Tr. 2961-62).

355. [redacted]

(Nestor, Tr. 2963).

356. [redacted] (Nestor, Tr. 2962).

357. Indeed, it is not uncommon for pharmaceutical companies to try different formulations of a product before discovering one that achieves the project's desired profile and clinical results. (Nestor, Tr. 2947).

358. In 2014, before Impax researchers could consider how to move forward with the new formulation of IPX-203, Impax suspended all research and development activities in order to address an FDA Warning Letter, which related to issues in Impax's manufacturing process that had previously been identified by the FDA but not yet addressed. (Nestor, Tr. 2985-86; RX-206).

359. [redacted] (CX2928-013).

360. [redacted] (Nestor, Tr. 2963-64, RX-208).

361. [redacted] (Nestor, Tr. 2967; CX4033 (Nestor, Dep. at 164)).

362. [redacted] (CX3345-006).

363. [redacted] (Nestor, Tr. 2967-69; *see* CX4033 (Nestor, Dep. at 164)).

364. Indeed, Impax "had to make sure we had a formulation first and that we were ready to go into the clinic" before meetings of the joint development committee "would be relevant." (CX4033 (Nestor, Dep. at 164); *see* Nestor, Tr. 2967-68).

365. [redacted] (Nestor, Tr. 2963).

366. During the parties' April 2015 discussion, Impax offered to amend the DCA [redacted] (Nestor, Tr. 3057; CX2928-013).

367. Impax was "absolutely" prepared to include the new formulation of IPX-203 in the DCA because it wanted to work with Endo in order to move the drug forward and Impax believed the new formulation would give it "an avenue through which we could continue the development of IPX-203." (Nestor, Tr. 3056-57).

368. Endo initially agreed to the amendment, noting that it "would like to maintain or even increase [its] involvement with the development program . . . as [it] remain[ed] optimistic this will be a successfully differentiated product, which Endo looks forward to the opportunity to co-promote it with Impax." (RX-218.0001; *see* Snowden, Tr. 460).

369. Impax consequently prepared an amendment to the DCA and expected the parties to continue collaborating. (Snowden, Tr. 458-59; *see* CX2747-001).

370. Endo subsequently reversed course and informed Impax that Endo had "decided not to amend the existing agreement" and would no longer "participat[e] in [the] program," but did not provide any explanation. (CX2747-001).

371. Endo's decision surprised Impax because "fairly recently" Endo "had said the opposite, that they were interested in continuing forward with the program and amending the agreement." (Snowden, Tr. 460-61; RX-221.0001 (Endo's decision not to amend DCA was "a surprise")).

372. Because Endo retracted its initial expression of interest in amending the DCA, Impax and Endo terminated the Development and Co-Promotion Agreement "by mutual agreement" effective December 23, 2015. (JX-001-011 (¶ 43) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 407; RX-219.0001-02; RX-198.0005-07 (termination agreement)).

373. At the time of termination, Impax had not received additional payments from Endo. (JX-001-011 (¶ 43) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity; Snowden, Tr. 461).

VII. THE FTC BEGAN INVESTIGATING THE SLA YEARS AFTER THE PARTIES SETTLED

374. Within a month of executing the SLA and DCA, Endo and Impax filed the settlement agreement with the Federal Trade Commission ("FTC"). (Snowden, Tr. 481).

375. The FTC did not respond to the filing. (Snowden, Tr. 482).

376. In fact, for nearly four years, the FTC did not contact Impax regarding the Settlement and License Agreement or the Development and Co-Promotion Agreement. (Snowden, Tr. 482).

377. The first time the FTC contacted Impax in relation to the SLA was in 2014, when the FTC issued a Civil Investigative Demand. (Snowden, Tr. 482, 502).

378. At the time Endo and Impax settled their patent litigation, the prevailing test in assessing the validity of so-called reverse-payment settlements focused on whether the agreement was within the scope of the patent owner's patent. (Figg, Tr. 1932).

379. The Endo-Impax settlement agreement was within the subject matter and temporal scope of Endo's patents at the time of settlement, meaning that Impax could launch its generic product before Endo's patents expired. (Figg, Tr. 1933-34, 1973).

380. Mr. Hoxie, Complaint Counsel's patent expert, offers no opinion regarding the SLA in relation to the scope of Endo's patents. (Hoxie, Tr. 2745).

381. By the time the FTC issued its Civil Investigative Demand, the Supreme Court's decision in *Actavis* had changed the legal approach to assessing whether a so-called "reverse payment" settlement agreement is anticompetitive. (Noll, Tr. 1626-27).

VIII. COMPLAINT COUNSEL HAS NOT IDENTIFIED A LARGE OR UNJUSTIFIED PAYMENT

A. The DCA Did Not Include a Large or Unjustified Payment

382. Complaint Counsel has not demonstrated that the DCA contained a large or unjustified payment. As described in more length below, the evidence at trial was clear that Endo's investment under the DCA represented fair value for the potentially lucrative profit-sharing rights it received in return. (Cobuzzi, Tr. 2564).

383. Indeed, Endo conducted appropriate due diligence and independently valued the DCA as a good deal for Endo. (Cobuzzi, Tr. 2563; CX2748-001).

384. And Endo made an investment that was not large in relation to other early-stage development and co-promotion agreements it has entered. (Cobuzzi, Tr. 2559).

1. Endo Undertook Appropriate Due Diligence Efforts

a. Endo's Due Diligence Team Included Internal and External Experts

385. Dr. Robert Cobuzzi was the head of Endo's Corporate Development group as well as the lead scientist on the team that evaluated the commercial and scientific merits of the Development and Co-Promotion Agreement with Impax. (Cobuzzi, Tr. 2523).

386. Dr. Cobuzzi helped negotiate the DCA's terms and worked with Endo's CEO and the Board of Directors throughout the DCA approval process. (Cobuzzi, Tr. 2514, 2523).

387. Dr. Cobuzzi holds a Ph.D. in molecular and cellular biochemistry and wrote his dissertation on Parkinson's disease. (Cobuzzi, Tr. 2511-12).

388. Dr. Cobuzzi's team included at least one other scientist with a background in Parkinson's disease treatments. Dr. Kevin Pong, who was in charge of evaluating Endo's scientific licenses, had a "significant amount of experience in" the area of Parkinson's disease treatments. (Cobuzzi, Tr. 2512-13).

389. [redacted] (RX-072).

b. Endo Reviewed Information Regarding IPX-203

390. Impax provided Endo with information regarding the IPX-203 product concept. (Cobuzzi, Tr. 2525-26, 2602; *see* RX-377).

391. This included information regarding Impax's research into the IPX-203 product concept, and information about how such a product would improve upon existing Parkinson's disease therapies, including IPX-066. (*See, e.g.*, RX-270; RX-377).

392. [redacted] (Cobuzzi, Tr. 2530).

393. [redacted] (Cobuzzi, Tr. 2538).

394. [redacted] (Cobuzzi, Tr. 2530; *see* RX-377.0031).

395. [redacted] (RX-377.0040-41; Cobuzzi, Tr. 2534).

396. [redacted] (RX-377.0043-44; Cobuzzi, Tr. 2535).

c. Endo Reviewed Information Regarding IPX-066

397. In addition to information about IPX-203, Impax also sent Endo information about IPX-066. (Cobuzzi, Tr. 2539).

398. Impax sent the IPX-066 materials to Endo because (1) Impax had already established a data room regarding IPX-066 when it sought a partner to market the product outside the United States, and (2) because IPX-203 was a follow-on product to IPX-066, "the foundational aspects of what was in the data room about IPX-066 were relative to the kind of product we envisioned IPX-203 ultimately to be, which is an extended release

carbidopa/levodopa formulation that would offer clinically meaningful benefit[s] over and above what the current standard of care was." (Nestor, Tr. 3056).

399. Those materials aided Endo's assessment of IPX-203 "tremendously." (Cobuzzi, Tr. 2625).

400. Dr. Cobuzzi explained that IPX-066 was relevant to his assessment of IPX-203 because, among other reasons, both products would contain carbidopa and levodopa, and the only difference was the esterification of the levodopa, "which we viewed as being relatively simple, although it does change the chemistry." (Cobuzzi, Tr. 2539-40).

401. Julie McHugh, Endo's Chief Operating Officer at the time of settlement and the individual responsible for assessing the commercial opportunity of any product, deemed IPX-066 an appropriate commercial proxy for assessing IPX-203 as well. (CX2772-001; Cobuzzi, Tr. 2541-42).

402. Endo consequently studied materials regarding IPX-066's clinical, patent, regulatory, commercial, and legal background, to "help [Endo] frame their evaluation of the market environment into which IPX-203 could be launched as a successor to IPX-066." (RX-376.0001; *see* RX-272.0001; RX-080.0006 ("IPX-066 affords a reasonable surrogate for IPX-203 given the anticipated similarities in constituents and formulation")).

403. The IPX-066 materials, as well as Endo's experience with other Parkinson's disease treatments, suggested that the successful development of IPX-203 would more effectively treat Parkinson's disease symptoms. (Cobuzzi, Tr. 2634-35).

404. The information also suggested strong commercial opportunities for any follow-on product to IPX-066, [redacted] (RX-376.0050).

405. Endo used those forecasts to calculate "conservative estimates" for IPX-203 sales. (CX2780-001; *see* RX-080.0011-12; CX2533-001 [redacted].

406. Endo's reliance on information about a related drug when evaluating IPX-203 was not unusual. Endo relies on information about one pharmaceutical asset to assess another, related pharmaceutical asset "all the time." (Cobuzzi, Tr. 2624).

407. It is also common practice in the pharmaceutical industry more generally to assess competitor drugs. (Geltosky, Tr. 1155-56).

408. Endo, for example, reviewed a potential collaboration regarding the drug Belbuca, including information about the relevant market and how the drug would work medically, clinically, and commercially, by analyzing buprenorphine, an element of Belbuca that had been on the market for a number of years. (Cobuzzi, Tr. 2624).

409. When information about related pharmaceutical assets is available, it is "much easier" to evaluate a proposed drug than it is to evaluate a new chemical entity on its own. (Cobuzzi, Tr. 2625).

d. Endo Had Sufficient Time and Information to Conduct Appropriate Due Diligence

410. Endo's corporate development team does not have a standard amount of time it spends reviewing collaboration deals. (Cobuzzi, Tr. 2542-43).

411. It regularly reviews potential agreements in "very, very short periods of time," although those deals may not move forward to execution. (Cobuzzi, Tr. 2566).

412. Dr. Cobuzzi testified that even when co-development agreements are successfully executed, he never feels like he has enough time to evaluate every aspect of the opportunity.

(Cobuzzi, Tr. 2627). For every successful collaboration agreement, Dr. Cobuzzi wants more time and information. (Cobuzzi, Tr. 2627).

413. Dr. Cobuzzi explained that he could not identify "any instance where [Endo] followed the perfect sequence" when conducting due diligence. (Cobuzzi, Tr. 2627).

414. Dr. Cobuzzi nevertheless testified that Endo had sufficient time to assess IPX-203 before entering into the Development and Co-Promotion Agreement, particularly in light of Dr. Cobuzzi's and Endo's familiarity with Parkinson's disease treatments and the detailed nature of the information Impax provided on IPX-066. (Cobuzzi, Tr. 2543, 2625).

415. Contemporaneous documents make the same point. On May 25, 2010, Dr. Cobuzzi sent an email to the Endo team performing due diligence on a potential Parkinson's collaboration with Impax. (CX1007; Cobuzzi, Tr. 2547-48).

416. Dr. Cobuzzi explained that "this is an area we know well as a company both in terms of past evaluations, and by virtue of the fact that we previously held the rights to IR Sinemet [another Parkinson's treatment], this should not be a difficult evaluation." (CX1007-001).

417. Other due diligence documents noted that Endo "as a company is quite familiar with the Parkinson's disease (PD) area." (CX1209-003).

418. Endo knew "the underlying molecules, the carbidopa and levodopa, and we looked at a number of Parkinson's opportunities in the past, so we knew the general landscape of the area in which we were looking at this as a commercial opportunity." (Cobuzzi, Tr. 2548-49).

419. Taken together, Endo believed that had adequate time and "the information we needed" to evaluate the DCA properly. (Cobuzzi, Tr. 2563).

2. Endo Valued IPX-203 and Believed it Justified Investments Under the DCA

420. Dr. Cobuzzi and his due diligence team concluded that Endo should enter the DCA. Dr. Cobuzzi made that recommendation to Endo's CEO, CFO, and Board of Directors. (Cobuzzi, Tr. 2544).

421. Dr. Cobuzzi was unequivocal that the profit-sharing rights Endo received under the DCA justified Endo's payment obligations. (Cobuzzi, Tr. 2564).

422. Put simply, Endo believed that its investments under the DCA would be successful. (Cobuzzi, Tr. 2560).

423. Dr. Cobuzzi also testified that the $10 million investment to buy into the IPX-203 opportunity was not a lot of money for Endo. (Cobuzzi, Tr. 2559).

424. Compared to other collaboration agreements, Endo's payment was "not an uncharacteristically large amount of money." (Cobuzzi, Tr. 2559).

a. Endo Concluded that IPX-203 Would Benefit Endo Commercially

425. Any time Endo considers a pharmaceutical collaboration it completes an opportunity evaluation worksheet ("OEW"), which is Endo's standard method of assessing the science, medical information, commercial opportunity, and related financial considerations behind a potential collaboration project. (Cobuzzi, Tr. 2541, 2547).

426. [redacted] (CX1209-011).

427. Endo's OEW analysis indicated that the DCA was "a good deal for Endo." (CX2748-001; *see* Cobuzzi, Tr. 2545-46, 2554; CX4017 (Levin, Dep. at 166-67)).

428. Specifically, Dr. Cobuzzi recommended the DCA as "an exciting opportunity for Endo" because it "further builds out our product pipeline for the future with a drug candidate that fits with our commercial footprint." (CX1209-001; Cobuzzi, Tr. 2549-50).

429. In fact, Endo did not have many products in its commercial pipeline in 2010, and did not have the capacity to develop new products in house. (Cobuzzi, Tr. 2515, 2562).

430. The DCA provided Endo "something with future commercial potential, accepting all of the risk associated with developing any drug, and also that it was consistent with [Endo's] sales footprint with the pain sales force as it existed at the time." (Cobuzzi, Tr. 2562).

431. That sales force was focused on primary care physicians that prescribed neurological medications like Parkinson's treatments. (Nestor, Tr. 2948-49).

432. Endo also analyzed the net present value of its initial investment under the DCA. Endo generally requires a 10 percent rate of return on its investment before agreeing to a development and co-promotion deal. (Cobuzzi, Tr. 2561).

433. In the case of IPX-203, Endo determined that the DCA and IPX-203 had a "good" and "very reasonable rate of return" [redacted] (Cobuzzi, Tr. 2560; CX1209-018 [redacted]; RX-080.0017).

434. [redacted] (Cobuzzi, Tr. 2622-23).

435. [redacted] (Cobuzzi, Tr. 2536-37).

436. [redacted] (Cobuzzi, Tr. 2623).

437. Endo's commercial valuations of the DCA were reached without any consideration of the separate SLA. Mark Bradley, Endo's Senior Director of Corporate Finance and the person responsible for performing valuations of corporate development activities at the time of settlement, explained that the settlement agreement played no role in his valuation of IPX-203. (CX4031 (Bradley, Dep. at 196)).

438. Dr. Cobuzzi, who led Endo's assessment of the DCA, had no role in negotiating or drafting the separate SLA, nor was he kept abreast of those negotiations as they occurred. (Cobuzzi, Tr. 2513).

b. Endo Concluded that IPX-203 Would Improve Parkinson's Treatments

439. The opportunity evaluation worksheet Dr. Cobuzzi sent to Endo's Board of Directors noted that [redacted] (CX1209-011).

440. IPX-203 was intended to address the second exception. Specifically, it would extend the period of time over which the drug is absorbed, which would allow doctors to lower the doses needed for effective treatment. (Cobuzzi, Tr. 2555; *see* Nestor, Tr. 2935 ("the whole idea behind this product . . . is to be able to even extend more the effective time that a patient is

on IPX-203, meaning that they have a longer period of time when their motor control symptoms are under control")).

441. Over time, lower doses would also prevent the drug from losing effectiveness in patients. (Cobuzzi, Tr. 2555).

442. The OEW further explained that [redacted] (CX1209-012).

443. Taking the drug less frequently would be particularly beneficial for Parkinson's patients, who can have trouble "even picking up the pill." (Cobuzzi, Tr. 2557).

444. Taken together, the Endo diligence team concluded that these attributes would make IPX-203 a "greater improvement in disease control and ease of use relative to" IPX-066. (RX-080.0011).

445. Indeed, the IPX-203 product concept addressed shortcomings in existing Parkinson's treatment already on the market and "had the potential to meaningfully enhance the efficacy" of Parkinson's disease treatments. (CX4017 (Levin, Dep. at 166-67); *see* Cobuzzi, Tr. 2536; CX2748-003).

c. Endo Concluded that IPX-203 Would Likely Move Quickly Through Development

446. Endo's due diligence team further concluded that IPX-203 "had the opportunity to move very quickly through development" and "was an exciting compound in that it was made up

of . . . two compounds that have already been approved by the FDA." (CX4017 (Levin, Dep. at 166-67)).

447. In particular Endo's OEW explained that [redacted] (CX1209-007).

448. This meant that while IPX-203 was "slightly different" than IPX-066, it contained the same elements and had supporting clinical studies to help its development progress. (Cobuzzi, Tr. 2551).

449. And while "every drug that is developed has inherent risk in the development program," IPX-203 had a "risk profile that [Endo] understood, which I think is the best that we could ask for a drug in development." (Cobuzzi, Tr. 2553).

d. Endo Concluded that IPX-203 Could Likely Secure Regulatory Approval

450. [redacted] (Cobuzzi, Tr. 2537-38).

451. Dr. Cobuzzi testified [redacted] (Cobuzzi, Tr. 2537).

452. Dr. Cobuzzi consequently believed IPX-203 had a path to approval that would successfully bring IPX-203 to the market. (Cobuzzi, Tr. 2552).

e. Endo Concluded that the DCA Favorably Mitigated Endo's Risks

453. Endo's OEW for IPX-203 explained to Endo's Board of Directors that [redacted] (CX1209-003).

454. Dr. Cobuzzi testified to the same effect, noting that most of the risk under the DCA was borne by Impax. (Cobuzzi, Tr. 2543).

455. First, Endo had to make a single contribution to Impax's development work and would make additional payments only if the "risk associated with proving the concept would have been retired" through successful completion of development milestones like Phase II clinical trials. (Cobuzzi, Tr. 2543-44, 2558; *see* CX1209-003).

456. That arrangement mitigated the risk to Endo, even in the face of the early stage of IPX-203's development, because Endo knew its maximum development costs up front even though "[d]rug development is extremely expensive." (Cobuzzi, Tr. 2558).

457. To that end, Endo believed that Impax would have to spend more money on IPX-203 than Endo. (Cobuzzi, Tr. 2628).

458. Second, the DCA did not require Endo to perform any development work or otherwise expend internal resources. As a result, Endo did not have to record its investment under the DCA when accounting for profits and losses. (Cobuzzi, Tr. 2558-59, 2627-28).

459. Third, Endo retained the same profit-sharing rights no matter how much time or money Impax expended on IPX-203's development. (Cobuzzi, Tr. 2564, 2627-28).

460. Together, these factors left Endo "comfortable" with the collaboration from the perspective of risk. (Cobuzzi, Tr. 2543-44).

461. This was not always the case for Endo when evaluating development deals. In other early-stage collaboration deals, Endo was forced to perform development work itself and

did not know its maximum development costs up front, which "hurt [Endo] from an accounting standpoint as well as from a risk standpoint." (Cobuzzi, Tr. 2629).

462. And some of those early-stage co-development arrangements carried "a lot of risk inherent in the biology, the chemistry, and other pieces" because they targeted novel products. (Cobuzzi, Tr. 2629).

463. The DCA, by comparison, focused on easily understood carbidopa and levodopa. (Cobuzzi, Tr. 2629).

3. Impax Valued the DCA and IPX-203

a. Impax Considered IPX-203 Valuable

464. Like Endo, Impax expected IPX-203 to perform well commercially. (RX-371.0009 (IPX-203 had [redacted]).

465. The product was also strategically "very important in terms of ensuring that [Impax] had a longer term business foundation established." (Nestor, Tr. 2939).

466. Dr. Michael Nestor, President of Impax's brand division, noted in 2010 that he "would hate to have to sell" IPX-203 since the product was envisioned as a better product than, and "a potential franchise extender for," IPX-066. (RX-387.0001).

467. In fact, Impax initially wanted to retain any profits flowing from prescriptions written by high-prescribing non-neurologists—which were the profits Endo sought under the DCA—because of the "significant" amount of money those prescriptions represented. (RX-405.0001; *see* CX4033 (Nestor, Dep. at 123) ("I wanted to keep [high-prescribing non-neurologists]."); CX1009-008 (non-neurologists "manage about 40%" of Parkinson's patients)).

468. Impax knew that there were at least "a couple of thousand physicians who were primary care physicians that prescribed Parkinson's patients, somewhat like a neurologist. So that was the audience that we had envisioned promoting IPX-203 to." (Nestor, Tr. 2948).

b. Impax Wanted a Partner to Share the Risks and Potential Rewards Associated with IPX-203's Development

469. In proposing the IPX-203 partnership, Impax "got a partner who would fund some of the costs to get [IPX-203] approved." (Koch, Tr. 321).

470. Impax could not fund the IPX-203 project internally. (Nestor, Tr. 3052-53).

471. This was because shareholders of a generic pharmaceutical company like Impax "are not accustomed to the kind of spending for research and development that you do with a brand product," often seeing brand drug development work as a "sinkhole." (Nestor, Tr. 2940).

472. Investors did not "want to see large sums of money being spent over an extended time period on a single product. They were accustomed to R&D investments being made on many individual products that you bring to market as a generic." (Nestor, Tr. 3053).

473. Impax consequently needed external funding to move the IPX-203 product forward in development. (Nestor, Tr. 3052-53).

474. Impax explored a number of possible funding approaches, including seeking money from venture capital firms, because Impax was "quite intent on being able to begin work on IPX-203." (Nestor, Tr. 2941).

475. When the DCA with Endo became a possibility, Impax's brand drug development team was "very excited about that." (Nestor, Tr. 2941).

476. If Impax had waited until the drug was at a later stage of development before seeking a partner, IPX-203 would never have moved forward at all. (Nestor, Tr. 3053).

c. Impax Exerted Substantial Efforts to Develop IPX-203 Before and After the Parties Terminated the DCA

477. [redacted] (Nestor, Tr. 2952-53; RX-247).

478. [redacted] (Nestor, Tr. 2953; RX-247 [redacted]).

479. [redacted] (Nestor, Tr. 2970-71, RX-241 [redacted]).

480. In 2010, Impax commissioned preclinical pharmacokinetic studies testing several relevant compounds and began laboratory research. (RX-241 [redacted]; RX-242 (listing IPX-203 projects)).

481. [redacted] (Nestor, Tr. 2957; RX-157.0020).

482. [redacted] (RX-157.0020).

483. Further development work on IPX-203 temporarily was delayed after Impax experienced delays in the development of IPX-066, the brand drug IPX-203 was intended to extend and improve upon. (Reasons, Tr. 1237-38; CX4021 (Ben-Maimon, Dep. at 145) (IPX-066 development was delayed for a "[c]ouple years"); CX4033 (Nestor, Dep. at 135-36)).

484. Bryan Reasons, Impax's current Chief Financial Officer, explained that when IPX-066 was delayed, "resources were put to focus on the approval of Rytary [IPX-066] so that we could get that to market, grow that . . . commercially, and it would also be beneficial to [] when we launched the next generation of [IPX]-203." (Reasons, Tr. 1237-38).

485. Impax believed that getting IPX-066 approved "would help from a regulatory perspective in getting IPX-203 approved as well." (Reasons, Tr. 1237-38).

486. Additionally, [redacted] (Nestor, Tr. 2968).

487. Impax's research and development team "worked to help remediate" any issues identified by the FDA and to prepare for "the FDA to come in and do their re-inspection," which meant that "nothing was going to go forward until such time as we got over that hurdle." (Nestor, Tr. 2986-88).

488. Impax's remediation efforts were successful but ultimately delayed IPX-066 and IPX-203 development work. (Nestor, Tr. 2986, 2989).

489. [redacted] (Nestor, Tr. 2970).

490. In fact, IPX-203 is now Impax's "lead compound on the brand side of our R&D program. It's really our strategy to continue to grow and extend the duration of our Parkinson's franchise." (Reasons, Tr. 1238).

491. Impax has completed Phase II clinical trials for IPX-203 and will begin Phase III trials at the beginning of 2018. (Nestor, Tr. 2978; Reasons, Tr. 1238; Snowden, Tr. 458).

492. Phase II clinical trials of IPX-203 revealed a statistically significant improvement in treatment over IPX-066 and other existing treatments, reducing the amount of time Parkinson's patients are without control over their motor symptoms. (Nestor, Tr. 2978).

493. The studies suggest that IPX-203 will offer an improvement of over two hours in motor symptom control when compared to immediate-release carbidopa-levodopa treatments and one hour of improvement over IPX-066. (Nestor, Tr. 2984-85; *see also* RX-208.0015-16).

494. Such improvements over existing medications are "terrific result[s]" that are "highly statistically significant" and "clinically meaningful." (Nestor, Tr. 2978, 2984-85).

495. Indeed, an improvement of 2.3 hours of symptom control—as IPX-203 has shown in Phase II clinical trials—represents a "wow" result. (Nestor, Tr. 2978-79).

496. The results suggest that Parkinson's patients will have "their symptoms . . . under control for a longer time period," which is "a very important thing" for patients. (Nestor, Tr. 2937, 2966).

497. Impax also sought, and the FDA granted, special protocol assessment for further clinical trials of IPX-203. (Nestor, Tr. 3001).

498. A special protocol assessment is an agreement between a pharmaceutical company and the FDA regarding the design of clinical trials. When a special protocol assessment is in place, the FDA will not question the trial designs in Phase III clinical trials. (Nestor, Tr. 3001).

499. Having a special protocol assessment "takes an element of risk out of a new drug application review." (Nestor, Tr. 3001).

500. Such special protocol assessments do "not happen all the time." (Nestor, Tr. 3001-02).

4. The Criticisms of the DCA by Complaint Counsel's Expert, Dr. Geltosky, are Baseless

501. Complaint Counsel proffered Dr. John Geltosky as an expert in pharmaceutical business development agreements. (Geltosky, Tr. 1057-58).

a. Size of Payment

502. Dr. Geltosky opined that a payment of $10 million under a development and co-promotion agreement was "very large" for "an early-stage compound of this sort, in this therapeutic area, with the eventual fairly small market it was going to be addressing." (Geltosky, Tr. 1072-73).

503. Dr. Geltosky, however, did not conduct any valuation analysis of the DCA at issue in this case. (Geltosky, Tr. 1125).

504. Dr. Geltosky did not calculate a net present value of the DCA at the time it was executed. (Geltosky, Tr. 1125).

505. Dr. Geltosky did not conduct a sensitivity analysis regarding the DCA. (Geltosky, Tr. 1125).

506. Nor did Dr. Geltosky conduct any other form of empirical analysis regarding the DCA. (Geltosky, Tr. 1133).

507. In fact, Dr. Geltosky has never actually performed a financial valuation of a pharmaceutical collaboration. (Geltosky, Tr. 1179-80).

508. And he is not sure whether he ever calculated net present value for products involved in early-stage co-development deals. (Geltosky, Tr. 1145).

509. Dr. Geltosky consequently does not offer any opinion about the actual value of the DCA to Endo. (Geltosky, Tr. 1125).

510. Instead, Dr. Geltosky bases his opinion regarding the size of the DCA payment on his "recollections of the agreements that [he] was involved in." (Geltosky, Tr. 1140). He used "common sense, just looking at it, and came up with [his] conclusion." (Geltosky, Tr. 1133).

511. Dr. Geltosky did not even review other development and co-promotion agreements, and he consequently did not compare the payment terms in the DCA to actual payment terms in any other development and co-promotion agreement. (Geltosky, Tr. 1140).

512. In fact, Dr. Geltosky deemed it a waste of time to review other development and co-promotion agreements when assessing the size of the payment in the Endo-Impax DCA. (Geltosky, Tr. 1141).

513. Importantly and as noted above, Dr. Cobuzzi, Endo's head of corporate development and the individual in charge of assessing every collaboration agreement at Endo, testified that the $10 million investment to buy into IPX-203 was not a lot of money for Endo. (Cobuzzi, Tr. 2559).

514. Compared to other collaboration agreements, Endo's $10 million payment was "not an uncharacteristically large amount of money." (Cobuzzi, Tr. 2559).

b. Dr. Geltosky Concedes or Ignores Justifications for the DCA Payment

(1) Bona Fide Scientific Collaboration

515. Dr. Geltosky does not dispute that the DCA was a bona fide scientific collaboration. (Geltosky, Tr. 1127-28).

516. Dr. Geltosky offers no opinion about whether Endo should have entered the DCA. (Geltosky, Tr. 1125-26).

517. Dr. Geltosky offers no opinion about whether Endo exercised sound business judgment in entering the DCA. (Geltosky, Tr. 1126).

518. And Dr. Geltosky has no criticism of Impax's behavior with respect to the DCA. (Geltosky, Tr. 1183).

(2) **Profit-Sharing Rights**

519. What is more, Dr. Geltosky does not offer any opinion regarding the profit-sharing rights that Endo received under the DCA. (Geltosky, Tr. 1124).

520. He does not, for instance, address the actual value of the profit-sharing rights acquired by Endo. (Geltosky, Tr. 1124-25).

521. Nor does he address whether Endo's profit-sharing rights justified its DCA payment obligations. (Geltosky, Tr. 1124).

522. Dr. Geltosky does not even offer an opinion regarding whether the profit-sharing provisions in the DCA favored Impax or Endo, although he concedes that Endo's profit-sharing rights remained the same regardless of the development costs incurred by Impax. (Geltosky, Tr. 1137-38).

523. Once again, Dr. Geltosky's opinions ignore the testimony of Endo employees. Dr. Cobuzzi testified that the profit-sharing rights in the DCA justified Endo's payment obligations at the time the agreement was executed. (Cobuzzi, Tr. 2564).

524. Dr. Geltosky's opinions also ignore Complaint Counsel's economic expert, Professor Roger Noll. Professor Noll testified that if a payment from a brand company to a generic company is used to purchase a bundle of rights at fair market price, the payment is justified. (Noll, Tr. 1620).

525. Professor Noll did not independently analyze the DCA to determine whether it was justified, had value to either party, or represented an overpayment. (Noll, Tr. 1456, 1581-82).

526. Professor Noll instead relies on Dr. Geltosky for a "detailed analysis of the degree to which the $10 million payment and co-development deal represented the acquisition of an asset that was approximately valued at a $10 million price." (Noll, Tr. 1582).

527. Professor Noll concedes, however, that if Dr. Geltosky does not offer an opinion regarding the actual value of the DCA to Endo at the time it was executed, then "I would not include the $10 million as part of the large payment that was unjustified." (Noll, Tr. 1585-86).

528. At bottom, Dr. Geltosky's failures to empirically analyze the value of the DCA or whether its profit-sharing terms justified any payments thereunder reflect his larger failure to measure whether any competitive effects arise from the DCA or SLA. (*See* CX5003 (Geltosky Report); CX4042 (Geltosky, Dep. at 73) (noting all opinions are contained in report)).

(3) **A Means to Share Risks and Costs**

529. The development of any pharmaceutical product carries risk at every stage of the development process. (Geltosky, Tr. 1134).

530. Dr. Geltosky acknowledges that the DCA was a way for Impax and Endo to share both risks and costs associated with developing IPX-203. (Geltosky, Tr. 1135).

531. Dr. Geltosky does not, however, offer an opinion regarding whether Endo or Impax bore more of the risk under the DCA. (Geltosky, Tr. 1138).

532. And Dr. Geltosky did not quantify any risk related to the DCA or what the appropriate payment would be to reflect that risk, even though he criticizes the DCA payment for failing to account for risk. (Geltosky, Tr. 1083, 1147).

533. Dr. Geltosky, moreover, conceded that estimated costs for the development of IPX-203 were between $80 and $100 million at the time of settlement. (Geltosky, Tr. 1138).

534. And while Endo only agreed to take on some of those development costs, with a cap on its contributions based on accomplished milestones, Impax was responsible for all IPX-203 development work. (Geltosky, Tr. 1135).

535. Impax had to cover all development costs in excess of Endo's specified milestone contributions, no matter how much the development work cost. (Geltosky, Tr. 1136-37).

536. For this reason, Dr. Cobuzzi and Endo believed that the DCA favorably mitigated risks by capping Endo's costs and putting the development burden on Impax. (Cobuzzi, Tr. 2558-59, 2627-28).

c. Strategic Fit of the DCA

537. Dr. Geltosky opined that the DCA was not a strategic fit for Endo because certain documents provided to him by Complaint Counsel did not mention the words "Parkinson's disease." (Geltosky, Tr. 1071, 1160).

538. Dr. Geltosky further opined that a handful of documents provided to him by Complaint Counsel suggested Endo was interested in late-stage assets close to launch. (Geltosky, Tr. 1071, 1160).

539. Nothing else informed Dr. Geltosky's opinions regarding strategic fit. (Geltosky, Tr. 1160).

(1) **Early-Stage Development Partnerships**

540. Dr. Geltosky's admits that Endo has entered into very-early, discovery-stage pharmaceutical partnership deals. (Geltosky, Tr. 1145).

541. In fact, pharmaceutical companies enter early-stage development deals "all the time." (Geltosky, Tr. 1146).

542. Dr. Geltosky's opinions regarding strategic fit are not actually based on a review of any partnership deals Endo contemplated or entered. (Geltosky, Tr. 1160-61).

543. His opinions are based instead on his review of the business documents provided to him by Complaint Counsel. (Geltosky, Tr. 1131-32).

544. But Dr. Geltosky has never worked for Endo. (Geltosky, Tr. 1129). Nor has he had contact with the individuals involved in negotiating and approving the DCA. (Geltosky, Tr. 1129).

545. Those employees testified that Endo's collaboration agreements regularly include early-stage development agreements. Because Endo has "no discovery pipeline ourselves in place," Endo must enter "very early, very speculative agreements" for promising drugs. (Cobuzzi, Tr. 2516).

546. [redacted] (Cobuzzi, Tr. 2532-33).

547. [redacted] (Cobuzzi, Tr. 2532-33).

548. [redacted] (Cobuzzi, Tr. 2533).

549. [redacted] (Cobuzzi, Tr. 2533).

550. By comparison, Dr. Geltosky has only worked on a handful of development deals in their early stages. (Geltosky, Tr. 1144-45).

551. And he has never negotiated a development and co-promotion agreement like the one at issue here. (Geltosky, Tr. 1142). In fact, in Dr. Geltosky's roughly ten years as a consultant, he has been involved in only two deals that actually resulted in executed agreements. (Geltosky, Tr. 1181-83).

552. Additionally, the majority of Dr. Geltosky's experience with pharmaceutical collaboration agreements relate to his employment at big pharmaceutical companies SmithKline Beecham and Bristol-Meyers Squibb. (Geltosky, Tr. 1141).

553. Except for his time at these multi-billion dollar companies, Dr. Geltosky's experience generally has been on behalf of "net sellers," which are the companies selling a drug and not actually conducting due diligence. (Geltosky, Tr. 1177).

554. Dr. Geltosky consequently cannot speak to how the universe of small or mid-sized pharmaceutical companies approach partnerships for early-stage products. (Geltosky, Tr. 1143).

(2) **Endo's Focus on Central Nervous System Drugs**

555. At the time of settlement, Dr. Cobuzzi, Endo's Senior Vice President of Corporate Development, considered the DCA's focus on Parkinson's treatment "an exciting opportunity for Endo as it further builds our product pipeline for the future with a drug candidate that fits with our commercial footprint." (CX1209-001; *see* Geltosky, Tr. 1162).

556. Dr. Geltosky acknowledges that Endo's Senior Vice President of Corporate Development is better qualified to assess the strategic fit of the DCA than he is. (Geltosky, Tr. 1163).

557. Indeed, when Dr. Geltosky approached Endo in his role as a consultant to propose an investment opportunity he believed was a strategic fit for Endo, Endo rejected his overture because "[t]hey were not interested enough to execute an agreement." (Geltosky, Tr. 1172-73).

558. Moreover, Dr. Geltosky did not review Endo's opportunity evaluation worksheets—which assessed possible collaborations with other companies to develop drugs—to see whether they reflected Endo's strategic business goals. (Geltosky, Tr. 1165).

559. Yet Dr. Geltosky conceded that Endo's opportunity evaluation worksheets actually noted that drugs targeted at the central nervous system were a "fit" for Endo because they overlapped with Endo's neurology call points. (Geltosky, Tr. 1168-69; *see* CX1209-003).

d. Due Diligence

560. Dr. Geltosky also opined that Endo's due diligence review of the DCA was not consistent with its usual processes. (Geltosky, Tr. 1158-59).

561. Dr. Geltosky's opinion regarding Endo's due diligence practices is based on a single document provided to him by Complaint Counsel. (Geltosky, Tr. 1159).

562. It is perhaps for this reason that Dr. Geltosky does not offer an opinion about whether Endo exercised good business judgment in its due diligence. (Geltosky, Tr. 1128).

563. Dr. Geltosky admits, moreover, that key variables surrounding IPX-203 were informed by information about IPX-066, both because IPX-203 was a follow-on drug and because the two products could compete. (Geltosky, Tr. 1153, 1155-56).

564. Those variables included the parameters of the project and the burdens associated with it. (Geltosky, Tr. 1153).

565. In modeling how IPX-203 might perform in the market, Dr. Geltosky conceded that Impax and Endo needed to use IPX-066 as a benchmark. (Geltosky, Tr. 1153-54).

566. And Dr. Geltosky admits that Impax provided Endo with comprehensive information regarding IPX-066, including clinical information regarding safety and efficacy, intellectual property, technical due diligence, and financial analysis. (Geltosky, Tr. 1156-58; RX-272.0005-08).

567. Impax never refused to provide Endo with requested due diligence information. (Geltosky, Tr. 1149). And Dr. Geltosky does not criticize Impax's due diligence efforts. (Geltosky, Tr. 1183).

B. The SLA Did Not Include a Large or Unjustified Payment

568. The SLA's terms were of uncertain value at the time of settlement. Their value hinged on unknown future events that were entirely outside of Impax's control. (Cuca, Tr. 629; Snowden, Tr. 437).

569. Depending on how market events unfolded, the SLA's supposed payment terms—the Endo Credit and No-Authorized Generic provision—could have resulted in zero value to Impax. (Cuca, Tr. 628-29; Reasons, Tr. 1219).

570. But Complaint Counsel did not offer any evidence regarding the value of the supposed payment terms in light of their contingent nature. Nor did it present any evidence that those terms carried a large expected value. (Noll, Tr. 1613; Addanki, Tr. 2384).

571. Finally, the evidence is clear that there was no link between either the Endo Credit or the No-Authorized Generic and Impax's license date. Neither was exchanged for delay. (Mengler, Tr. 567; Cuca, Tr. 666).

1. The Endo Credit Provision

a. How Much Either Party Would Pay Under the Endo Credit and Royalty Provisions, and Whether Any Payment Would be Triggered, Was Uncertain at the Time of Settlement

572. Whether and how much Endo would be required to pay under the Endo Credit depended on Endo's actions and external market forces beyond either party's control, including peak quarterly sales of Opana ER after settlement and sales immediately before Impax's January 2013 launch. (Cuca, Tr. 629).

573. In fact, the prospect of a payment from Endo to Impax could only be assessed by (1) determining Endo's quarterly peak sales between July 2010 and September 2012; (2) determining the pre-Impax amount of Opana ER sales, "which is the sales of Opana ER in the fourth quarter of 2012, the sales right before Impax was to launch its generic product"; (3) comparing the quarterly peak number to the pre-Impax amount, and if the pre-Impax amount is less than 50 percent, then the payment obligation is triggered; and (4) only then multiplying the difference between the quarterly peak number and the pre-Impax number by a specified amount to calculate the final sum due. (Snowden, Tr. 437; *see* CX2626-006; Engle, Tr. 1749-50).

574. None of these factors were known at the time of settlement and could not be ascertained until years later. (Snowden, Tr. 437-38).

575. If Endo preserved or even enhanced Impax's opportunity for original Opana ER, Endo was not required to pay anything, but Impax might be obligated to pay Endo a royalty. (CX2626-012).

576. Impax was aware at the time of settlement that the Endo Credit could result in zero value to Impax. (CX4032 (Snowden, Dep. at 204-06); CX4002 (Smolenski, IHT at 128-30)).

577. Indeed, this was Impax's preferred outcome. Bryan Reasons, Impax's Chief Financial Officer, testified that Impax wanted to launch a generic product "into a robust, large market and pay a royalty and have larger ongoing revenue streams than have a one-time cash payment that we would pull out of our [financial] results when we report to the investors." (Reasons, Tr. 1226).

578. Investors want the same thing, discounting one-time payments when evaluating company financials and placing an emphasis on forward-looking revenues. (Reasons, Tr. 1226).

579. Impax's Chief Executive Officer at the time of the settlement, Larry Hsu, also emphasized Impax's desire for a sustainable revenue source rather than a one-time lump-sum payment. (CX4014 (Hsu, IHT at 89, 165-66)).

580. Impax's Director of Market Planning, Ted Smolenski, similarly testified that "we would make more money in the long run" by launching oxymorphone ER rather than receiving a payment under the Endo Credit. (CX4002 (Smolenski, IHT at 204-05)).

581. And the Impax employees who negotiated the SLA and its Endo Credit provision had no expectation that Endo would pay Impax anything pursuant to the Endo Credit. (Snowden, Tr. 439).

582. Impax simply did not view the Endo Credit as a means to generate income; it was instead meant to ensure Impax had a generic opportunity. (Mengler, Tr. 582-83).

583. Given this perspective and the uncertainty regarding a payment under the Endo Credit, Impax never analyzed or forecasted whether it would receive a payment under the Endo Credit. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88)).

584. And Impax never expressed an expectation to Endo that Endo would make a payment under the Endo Credit. (CX4017 (Levin, Dep. at 128)).

585. Endo similarly did not forecast any payment under the Endo Credit at the time of settlement. It instead conducted "about five minutes of work with maybe one or two sets of numbers . . . to make sure the provision worked, and once [it] was satisfied with that, that would have been the end of it." (Cuca, Tr. 629-31 (ensuring formula "produced a sensible result"); *see* CX4017 (Levin, Dep. at 96-98); Noll, Tr. 1649 (neither Endo nor Impax forecast or planned for a payment under the settlement)).

586. Although Endo analyzed how the Endo Credit was supposed to work, it never discussed internally or with Impax what could prompt an obligation to pay. (Cuca, Tr. 631, 673).

587. And Endo acknowledged at the time of settlement that the Endo Credit could result in no value to Impax. (Cuca, Tr. 628-29; CX4017 (Levin, Dep. at 143-44)).

588. As Mr. Cuca testified, he did not assume that there would be a payment under the Endo Credit when he drafted the provision, and he knew that the term could result in zero payment. (Cuca, Tr. 625-26; *see* Noll, Tr. 1649-50 ("I'm not aware of a document that estimates the expected value of any provision of the settlement agreement or the overall expected value of the settlement agreement to either party.")).

589. No one else at Endo expressed any view about the likelihood or size of payment under the Endo Credit. (Cuca, Tr. 665-66).

590. In fact, "it was not [Endo's] expectation that a payment would have to be made." (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")).

591. Endo did not even book a reserve of any sort for a payment under the Endo Credit because under "generally accepted accounting principles, which is what would have governed

the booking of that [reserve], you wouldn't book that reserve unless the event was probable and the amount of the reserve was estimable, and so we would not have concluded that it was both probable and estimable at" the time of settlement. (Cuca, Tr. 664-65; CX4017 (Levin, Dep. at 125-26)).

592. Indeed, because Endo "did not expect to make a payment to Impax," it did not accrue a liability in its financial statements for the Endo Credit. (CX4017 (Levin, Dep. at 126)).

b. The Actual Endo Credit Payment Was Caused by Unforeseeable Events

593. The fact and size of the Endo Credit payment were the result of post-settlement events outside the control of Impax, including (1) Opana ER sales and (2) the Novartis supply chain disruption that accelerated Endo's complete withdrawal of original Opana ER. (Addanki, Tr. 2354-56; Noll, Tr. 1612; Bazerman, Tr. 923 ("I can't come up with an answer to how [Impax] would have an impact" on any Endo Credit payment)).

594. But Dr. Bazerman, one of Complaint Counsel's own experts, admits that the FDA's actions shutting down Novartis' plant even "took matters out of [Endo's] hands" with respect to the Endo Credit and any payments thereunder. (Bazerman, Tr. 923-24).

595. Endo, moreover, generated $300 million in sales of Opana products in 2010. (RX-128.0002; CX4017 (Levin, Dep. at 151)).

596. Endo expected to generate roughly $350 million in sales of Opana products in 2011, an increase of less than 20 percent. (RX-128.0002; CX4017 (Levin, Dep. at 151)).

597. Some industry analysts forecasted that sales of Opana products could grow by as much as 35 percent on an annual basis. (*See, e.g.*, RX-419 (not admitted or cited for the truth of matters asserted therein); RX-422 (not admitted or cited for the truth of the matters asserted therein)).

598. Other industry analysts projected a decline in Opana sales. (*See, e.g.*, RX-417 (not admitted or cited for the truth of the matters asserted therein); RX-421 (not admitted or cited for the truth of the matters asserted therein)).

599. [redacted] (RX-414).

600. That growth resulted in $186 million in sales of Opana ER in the fourth quarter of 2011 alone. (CX4017 (Levin, Dep. at 149); RX-108.0002 at 10).

601. From that unexpected high, sales of original Opana ER ceased altogether in early-2012 when the FDA forced Endo to stop selling the original formulation. (CX4017 (Levin, Dep. at 138-39, 155); RX-100.0001; RX-094.0004; RX-108.0002 at 10).

c. Impax and Endo Could Only Determine that Endo Would Make a Payment Under the Endo Credit Term in April 2012

602. Only after these events—the Novartis supply disruption in early 2012, the need to launch reformulated Opana ER earlier than expected in March 2012, and the FDA's subsequent order to stop selling original Opana ER—could Endo determine that it owed a payment under the Endo Credit. (Cuca, Tr. 665; Reasons, Tr. 1203, 1229; RX-039 (Endo Credit liability discovered in April 2012)).

603. Indeed, the first time that Endo knew its sales would be zero in the last quarter of 2012 was after the Novartis plant shutdown and resulting supply interruption. (Cuca, Tr. 677; RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)).

604. As Mr. Cuca explained, "One of the components of the [Endo Credit] formula is the sales of Opana in the last quarter immediately before Impax's launch. When the Novartis

supply disruption took place, we know that sales in that quarter were likely to be close to zero." (Cuca, Tr. 671).

605. No one at Endo expected or discussed the possibility of a supply disruption at the time of settlement. (Cuca, Tr. 671).

606. Accordingly, Endo did not report a liability under the Endo Credit until May 2012. (RX-494.0007 (Endo Form 8-K from May 1, 2012); CX4017 (Levin, Dep. at 140-41)).

607. The first time Impax learned it was likely to receive any payment under the Endo Credit was May 2012, when Endo publicly disclosed that it had accrued the liability. (Reasons, Tr. 1228).

608. Impax did not even attempt to calculate the size of any payment until the third quarter of 2012. (Engle, Tr. 1765-66).

d. There is No Link Between the Endo Credit and Impax's License Date

609. During settlement discussions, the parties never discussed Impax accepting the Endo Credit for a later license date. (Mengler Tr. 567).

610. Impax did not accept a later entry date in exchange for the Endo Credit. (Mengler, Tr. 567).

611. Endo similarly did not believe it was giving Impax any settlement provision in exchange for a later entry date. (CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)).

612. And Endo did not plan to pay Impax a large sum of money in return for Impax delaying a launch of its oxymorphone ER product. (Cuca, Tr. 666).

613. Indeed, by the time the Endo Credit was introduced, the parties had already negotiated entry dates for some time. (RX-333 (Endo's initial term sheet with no Endo Credit

provision); CX4017 (Levin, Dep. at 117) (Endo's initial offer included March 2013 entry but no Endo Credit); RX-386).

614. Adding the Endo Credit to the proposed settlement did not lead to a later license date, just the opposite. The SLA hastened Impax's license date to January 1, 2013. (CX2626 (executed settlement agreement including Endo Credit and January 1, 2013 license date); CX4017 (Levin, Dep. at 121)).

615. At bottom, Impax "ended up with the earliest possible entry date and with a protection in the event that the market conditions became adverse to Impax." (Mengler, Tr. 536).

2. The No-Authorized Generic Term

a. Endo Did Not Plan to Launch an Authorized Generic

616. Demir Bingol, Endo's Senior Director of Marketing for the Oral Analgesics business and the person responsible for marketing Endo's Opana ER products, testified that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea." (Bingol, Tr. 1338-39; *see* Bingol, Tr. 1337 ("I don't recall specific forecasts about an authorized generic.")).

617. Brian Lortie, Endo's Senior Vice President for Pain Solutions at the time of settlement, similarly explained that "we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to." (CX4019 (Lortie, Dep. at 118-19)).

618. And Mark Bradly, Endo's Senior Director of Corporate Finance at the time of settlement, testified, "I don't recall having any conversation with any colleagues regarding the launch of an authorized generic." (CX4031 (Bradly, Dep. at 198)).

619. Despite Endo's forecasting of various scenarios impacting original and reformulated Opana ER, including the theoretical ability to market drug claims that had not been approved by the FDA, Endo often did not forecast an authorized generic launch. (Bingol, Tr. 1338-39).

620. And given Endo's plans to launch a reformulated version of Opana ER, it had no intention of launching both an authorized generic and a reformulated version of Opana ER. (Bingol, Tr. 1338).

621. Mr. Lortie explained that Endo "intended to replace one product with the other, and that would be the only product that we had on the market." (CX4019 (Lortie, Dep. at 117-18)).

622. Mr. Lortie noted it would be "morally very difficult to justify at the same time having a crushable authorized generic product" and a non-crushable branded product. (CX4019 (Lortie, Dep. at 117-18)).

623. Endo's reluctance to launch an authorized generic is not unusual. Brand companies launch authorized generics "from time to time," but do not always utilize authorized generics. (Koch, Tr. 233).

b. Impax Valued a Robust Opportunity, Not the Absence of an Authorized Generic

624. Impax did not know whether Endo would launch an authorized generic of Opana ER. (Engle, Tr. 1773).

625. Impax, however, did not view the No-Authorized Generic provision as particularly valuable. Chris Mengler explained that Impax derives value "by selling the drug [] with or without an" authorized generic. (Mengler, Tr. 528-29).

626. Dr. Hsu, Impax's CEO at the time of settlement, similarly explained that getting on the market as early as possible is what matters. Impax did not value the absence of an authorized generic if it meant delaying its own product. (CX4030 (Hsu, Dep. at 76-77)).

627. In any event, if Endo pulled its original version of Opana ER and moved to a different product, the No-AG term would have absolutely no value since there would be no automatic substitution. (Reasons, Tr. 1230-31; *see* Mengler, Tr. 529-30 ("The value I get is selling my drug with whatever market conditions exist, so if there's no market, then an AG is not a relevant issue")).

c. There Was No Link Between the No-Authorized Generic Term and Impax's License Date

628. As with the Endo Credit, the negotiation history indicates that there was no connection between the No-AG provision and Impax's license date. After Endo proposed the No-Authorized Generic term, Impax's license date only got earlier, moving from March 2013 to January 1, 2013. (RX-333 (initial term sheet including No-AG provision and March 2013 license date); CX2626 (executed settlement agreement with same No-AG provision and January 1, 2013, license date)).

629. At no point during the parties' settlement discussion did the parties discuss Impax accepting the No-Authorized Generic provision for a later license date. (Mengler, Tr. 567).

630. In fact, Alan Levin, one of Endo's lead negotiators, does not recall any discussion about the No-Authorized Generic term, or any link between the term and comment date. (CX4017 (Levin, Dep. at 156-57); *see also* CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)).

631. And Impax did not accept a later license date in exchange for the No-Authorized Generic provision. (Mengler, Tr. 567).

3. The Relationship Between the Endo Credit and the No-Authorized Generic Term Did Not Guarantee a Payment

632. Impax was not guaranteed to receive a payment through the combination of the Endo Credit and the No-Authorized Generic provision. Ted Smolenski, Impax's Director of Market Planning, told his colleagues at the time of settlement that "even in the event that the market degraded below the contractual trigger, even with the language that was ultimately put in the contract, there was still a real chance that there would be no payment." (CX4002 (Smolenski, IHT at 129); *see* CX4002 (Smolenski, IHT at 50-51, 187-88); CX0219-001).

633. This possibility was inherent in the Endo Credit formula. If Endo launched reformulated Opana ER late in 2012 but continued to sell original Opana ER into the fourth quarter of that year, Endo "could have moved the market down so in the last quarter it would be down less than 50 percent and they would not have had to pay the credit." (Reasons, Tr. 1228; *see* CX4032 (Snowden, Dep. at 205-06)).

634. If that occurred, Impax would have a much reduced opportunity for its generic version of the original Opana ER, but would not receive any payment. (Mengler, Tr. 583; CX4037 (Smolenski, Dep. at 251-52); CX0219-001).

635. Mr. Mengler considered it "entirely plausible" that Endo could employ a late switch in products such that there was a reduced generic opportunity for Impax but no Endo Credit payment. (Mengler, Tr. 589-90).

636. Endo, for its part, intended to transition to a reformulated version of Opana ER at the very end of 2012 while continuing to sell original Opana ER into the fourth quarter of that year. (CX4017 (Levin, Dep. at 131); RX-094).

637. Endo's original budget for 2012 consequently projected original Opana ER sales extending into the fourth quarter of 2012. (RX-108.0002 at 10).

638. As Endo's internal documents explained, "prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012." (RX-094.0006).

4. Complaint Counsel's Economic Expert Offers No Evidence Regarding the Expected Value of Any Settlement Term

639. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA. (Noll, Tr. 1613, 1651-52).

a. The Endo Credit Provision

640. Professor Noll did not calculate the expected value of the Endo Credit. (Noll, Tr. 1613).

641. Professor Noll similarly did not calculate the expected value of the Endo Credit when considered in combination with the No-Authorized Generic provision. (Noll, Tr. 1613; Addanki, Tr. 2384).

642. Professor Noll also testified that he is not aware of any attempt by Impax or Endo to calculate the value of the Endo Credit at the time of settlement or at any other point before 2012. (Noll, Tr. 1610-11).

643. Only in 2012 were "a lot the contingences . . . resolved" such that the parties could estimate an expected liability. (Noll, Tr. 1610-11, 1614).

644. Professor Noll also explained that there was a possibility that the Endo Credit and the no-Authorized Generic provision could result in no value to Impax. (Noll, Tr. 1611-12). The terms' value ultimately depended on contingent events. (Noll, Tr. 1612).

b. The No-Authorized Generic Provision

645. Professor Noll similarly did not calculate an expected value to Impax of the No-Authorized Generic provision. (Noll, Tr. 1591).

646. What is more, Professor Noll concedes that Endo did not plan on launching an authorized generic if Impax did not launch a product of its own. (Noll, Tr. 1588).

647. He offers no opinion, however, about whether Endo actually would have launched an authorized generic if Impax launched a generic oxymorphone ER product. (Noll, Tr. 1589).

648. Nor does Professor Noll calculate any probabilities of Endo launching an authorized generic, even though expected values depend on the probabilities of relevant events actually occurring. (Noll, Tr. 1478, 1591).

649. In fact, Professor Noll "didn't attach probabilities" to any potential outcomes. (Noll, Tr. 1613; *see* Noll, Tr. 1650-51 ("Q. You didn't calculate the probability of any of these scenarios occurring right? A. I did not calculate the probability of any of these or any of the others that are in the report.")).

650. Instead, Professor Noll merely applied a discount rate to estimate the "present" value of potential outcomes in June 2010. (CX5000-169).

651. In any event, Professor Noll admits that at the time of settlement Endo planned to launch a reformulated version of Opana ER and would not have launched an authorized generic if their reformulated product was on the market. (Noll, Tr. 1588-89).

652. Finally, Professor Noll concedes that Impax never assigned a numeric value to the No-Authorized Generic provision. (Noll, Tr. 1593-94).

c. The Royalty Provision

653. Professor Noll did not estimate the value of the royalty provision. (Noll, Tr. 1647).

d. The Broad Patent License

654. Professor Noll did not consider the value of the patent license rights Impax received under the SLA. (Noll, Tr. 1648).

655. In fact, the broad patent rights played no role in Professor Noll's analysis, even though he admits it is important to take agreements as a whole. (Noll, Tr. 1645-46).

656. Professor Noll consequently did not consider whether the broad patent rights Impax received had any impact on the SLA or consumer welfare. (Noll, Tr. 1647).

IX. THERE IS NO DIRECT EVIDENCE OF MONOPOLY POWER

657. In assessing the competitive impact of a settlement agreement from an economic perspective, one must consider all facts surrounding the settlement and whether consumers actually are worse off with the settlement than they would have been without it. (Addanki, Tr. 2205).

658. From an economic standpoint, the first step when evaluating a settlement agreement is to assess whether the patentee possessed monopoly power. Settlements are only anticompetitive if they preserve, enhance, or create monopoly power. (Addanki, Tr. 2206).

659. Absent monopoly power, a settlement cannot be anticompetitive from an economic standpoint. (Addanki, Tr. 2206).

660. There is no direct evidence in the record suggesting that Endo possessed monopoly power.

A. <u>There is No Evidence of Reduced Output</u>

661. Monopolists do not face competitive constrains. They are able to restrict output and thereby charge monopoly prices. (Addanki, Tr. 2349).

662. From an economic standpoint, this means that "consumer harm comes about because of a reduction in output brought about by a monopolist." (Addanki, Tr. 2372).

663. Economists consequently expect to see an increase in output when a generic enters a monopolized market, undoing the consumer harm that was inflicted by the prior exercise of monopoly power. (Addanki, Tr. 2349; RX-547.0051; RX-547.0135).

664. The ability to assess whether output expands after generic entry is a "natural experiment" that indicates whether the brand pharmaceutical company actually exercised monopoly power before generic entry. (Addanki, Tr. 2348).

665. "[W]hen we see monopoly power being dissipated, we see an expansion in output." (Addanki, Tr. 2372). As Impax's economic expert, Dr. Sumanth Addanki, testified, "[o]utput actually lets you measure something real." (Addanki, Tr. 2350).

666. If, however, a generic product enters the market and economists do not see an expansion in output—the amount of product being sold—they "can safely infer that there wasn't any monopoly power being exercised before the fact." (Addanki, Tr. 2349).

667. In the case of oxymorphone ER, Impax's introduction of a generic product did not expand output. (Addanki, Tr. 2349).

668. There was no increase in the combined number of Opana ER and generic oxymorphone ER prescriptions when compared to the total number Opana ER prescriptions before Impax's entry. (Addanki, Tr. 2350; *see* RX-547.0051; RX-547.0135).

669. Indeed, in April 2013, after Impax had launched its generic oxymorphone ER product and Endo had launched reformulated Opana ER, the extended-release opioid market was "flat," with "significant competitors." (RX-073 at 39).

670. By comparison, when generic OxyContin entered the market in 2004, there was an expansion in output. (Addanki, Tr. 2350).

671. Similarly, when a generic version of Zocor, a cholesterol drug, launched around 2007, there was a substantial increase in output. (Addanki, Tr. 2351).

B. Complaint Counsel's Economic Expert, Professor Noll, Has Not Advanced Direct Evidence of Monopoly Power

672. Professor Noll observed two purportedly direct indicators of market power: (1) Endo's alleged ability to profitably set prices above a competitive level, as measured by the Lerner Index; and (2) Endo's alleged ability to exclude competitors. (Noll, Tr. 1412-14).

1. Gross Margins Do Not Reflect Monopoly Power

673. The Lerner Index is a means to track gross margins. (Addanki, Tr. 2340-41; Noll, Tr. 1413 (Lerner Index is the "markup of price over some estimate of marginal cost"); CX5000-095).

674. Professor Noll used the Lerner Index to estimate that Endo's gross profit margins were between 70 and 90 percent, depending on time period. (Noll, Tr. 1417; *see* CX5000-100 [redacted]).

675. Professor Noll concluded that such profit margins allow Endo to "profitably set prices above a competitive level." (Noll, Tr. 1412-13; *see* CX5000-096 (high values purportedly indicate presence of market power)).

676. But a high Lerner Index (high gross margins) is not indicative of monopoly power. Indeed, "high gross margins or high Lerner Indexes actually tell you nothing at all about monopoly power." (Addanki, Tr. 2341).

677. Indeed, Professor Noll acknowledged that a high Lerner Index "doesn't necessarily mean" that firm has monopoly power. (Noll, Tr. 1415-16 (high Lerner Index indicates that a firm can "sustain price above marginal cost," but "[w]hether they have monopoly power depends on other things")).

678. This is because there are many industries in which most costs are fixed. In those industries, the costs of developing a product are upfront and the marginal or variable cost of selling another unit is essentially zero. (Addanki, Tr. 2341). When that is the case, one expects to find "astronomical Lerner Indexes." (Addanki, Tr. 2341; *see* Noll, Tr. 1415 (noting software developers have a "very high Lerner Index")).

679. Accordingly, economists have long recognized that marginal costs do not represent "competitive benchmark price" in the many real-world industries with substantial fixed costs. (Addanki, Tr. 2341-42).

680. Marginal costs just as easily may reflect large fixed costs that need to be covered in order to remain in business. (Addanki, Tr. 2339).

681. This is particularly true in the pharmaceutical industry, where a higher Lerner Index is a "normal market outcome" because the cost structure is front-loaded—with high fixed costs and low marginal costs—and marginal cost pricing is not feasible. (Noll, Tr. 1416; *see* RX-547.0055-56).

682. As a result, gross margins for branded drugs generally are much higher than gross margins for generic drugs, not because of monopoly power, but because the generic is nothing but a copy of the brand-name product. (RX-547.0057).

683. This means the generic's prices do not reflect the long-run costs that the brand company incurred to research, develop, and promote the drug in the first instance. (RX-547.0057).

684. Any other approach would mean that every brand pharmaceutical manufacturer or software developer would be a monopolist given their gross margins. (Addanki, Tr. 2341-42).

2. Patent Rights Do Not Signify Monopoly Power

685. Professor Noll also testified that Endo had monopoly power because it "was able to exclude people from the market" through "enforcement of patent rights." (Noll, Tr. 1412; *see* CX5000-088-89).

686. From an economic perspective, patents do not confer monopoly power. All a patent does is give the owner the right to exclude someone from making a direct copy of what the owner makes. (Addanki, Tr. 2343).

687. In the case of Opana ER, this mean that Endo's patents merely "prevent[ed] competitors from making direct copies of Opana ER." (Addanki, Tr. 2343).

688. But "to the extent that other long-acting opioids competed with Opana ER, the patents had no ability to block them." (Addanki, Tr. 2343).

3. Differences in Price Between Generic and Brand Drugs Do Not Suggest the Brand Has Monopoly Power

689. Generic products, from aspirin to bread, are sold for less than brand name products. (Addanki, Tr. 2343-44).

690. In the case of pharmaceutical products, a generic "has to be offered at a discount from the brand price. And that's just institutional. For it to be listed as a generic, it has to be offered at a selling price below the brand price." (Addanki, Tr. 2346).

691. This means that anytime one compares brand drug prices to generic drug prices, "you're going to have a price difference . . . no matter whether the brand has a hundred equally good therapeutic substitutes or none." (Addanki, Tr. 2346).

692. Put differently, whether the brand drug has monopoly power or not, generic equivalents will be listed for a lower price by virtue of being generic products. (Addanki, Tr. 2347).

X. THE RELEVANT MARKET INCLUDES ALL EXTENDED-RELEASE OPIOIDS

693. The relevant geographic market for purposes of this litigation is the United States. (JX-001-002 (¶ 10) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

694. The foundational consideration when determining the relevant product market is "what the set of products is to which customers of Opana ER could and realistically would turn in the event of a price increase." (Addanki, Tr. 2239).

695. From an economic perspective, it is "very clear that the evidence . . . points to the relevant market being no smaller than the market for long-acting opioids in the United States." (Addanki, Tr. 2328).

696. That market includes, at a minimum, extended-release oxycodone, morphine, hydromorphone, tapentadol, hydrocodone, oxymorphone, and fentanyl. (RX-547.0047).

697. Indeed, the evidence at trial demonstrated that all extended-release opioids are interchangeable for the vast majority of patients, and that extended-release opioids compete vigorously on price. (*See, e.g.*, Michna, Tr. 2107; Bingol, Tr. 1324-25; Addanki, Tr. 2291).

A. All Extended-Release Opioids are Equally Safe and Effective for the Vast Majority of Patients

698. All extended-release opioids are proven to relieve chronic pain. (Michna, Tr. 2107).

699. And all extended-release opioids are equally safe and effective in relieving pain in the vast majority of patients. (Michna, Tr. 2107).

700. Indeed, there are no clinical trials or head-to-head medical studies showing that one extended-release opioid is more effective than any other extended-release opioid in treating any particular group of patients. (Michna, Tr. 2107-08).

701. Nor are there any documented studies showing that one extended-release opioid is more effective than another in in treating pain from any particular disease or injury. (Michna, Tr. 2107-08).

702. There is no medical condition for which oxymorphone ER or any other extended-release opioid is the only safe and effective option to treat pain. (Michna, Tr. 2149; RX-547.0105; Addanki, Tr. 2248 ("there's no indication for which oxymorphone had any significant use for which there isn't at least one other long-acting opioid available that was also used for the same indication")).

703. And there are no comorbid medical conditions—additional conditions on top of the condition causing pain—that prohibit a patient from having multiple extended-release opioid options to treat chronic pain. (Michna, Tr. 2112).

704. As Complaint Counsel's medical expert, Dr. Seddon Savage, testified, no opioid is superior to any other opioid. (Savage, Tr. 743-44, 791-92).

705. Professor Noll, Complaint Counsel's economic expert, similarly concedes that no extended-release opioid is superior to any other extended-release opioid for any new patient. (Noll, Tr. 1504-05).

706. Chronic-pain sufferers consequently have numerous equally safe and effective extended-release opioid options available to them, including oxymorphone, fentanyl, morphine sulfate, methadone HC1, oxycodone HC1, tapentadol HC1, hydrocodone, and hydromorphone HC1. (Michna, Tr. 2176-77).

707. And physicians can choose among these extended-release opioids when deciding which medication to prescribe a patient with chronic pain. (Noll, Tr. 1504).

708. Even for patients with unique medical conditions that prevent the use of certain extended-release opioids, there are always multiple opioid options available that would be equally safe and effective for the treatment of chronic pain. (Michna, Tr. 2148; Noll, Tr. 1548).

709. But to the extent any patients exist for whom oxymorphone ER or any other extended-release opioid is the most effective option, such patients could not be identified in advance of treatment. (Michna, Tr. 2148-49).

710. This means that there is no identifiable group of patients for which oxymorphone ER or any other extended-release opioid is the only treatment option. (Michna, Tr. 2148-49; Noll, Tr. 1508-09; CX4041 (Savage, Dep. at 60)).

B. Clinical Guidelines Treat All Extended-Release Opioids Identically

711. The FDA has approved all extended-release opioids, including generic and branded Opana ER, for the exact same indication: Treating "pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." (RX-549.0010-11; *see* Michna, Tr. 2107; RX-230.0001 (oxymorphone label); RX-030.0001 (Opana ER label)).

712. For this reason, the labels for all extended-release opioids are standardized to contain identical language. (Addanki, Tr. 2240-42).

713. When the FDA modifies the indication for opioids, it does so on a class-wide basis for all relevant drugs. (Michna, Tr. 2107).

714. The FDA also requires that all extended-release opioids utilize a single Risk Evaluation and Mitigation Strategy ("REMS"). (Michna, Tr. 2111; Savage, Tr. 745-46; Addanki, Tr. 2251-52).

715. REMS programs are required by the FDA to ensure that the benefits of a particular medication outweigh the medication's risks. (Michna, Tr. 2110). Such programs

allow the FDA to identify potential problems with prescription drugs and institute actions to address those problems. (Michna, Tr. 2110).

716. By requiring a single REMS program, the FDA assesses the risks and benefits of extended-release opioids collectively across the entire class of such products, even though individual patients may react differently to individual opioids. (Michna, Tr. 2111).

717. This matters because when products are used for similar therapeutic purposes, but have different risk profiles, they may not be good substitutes for one another. (Addanki, Tr. 2250). In the case of extended-release opioids, the use of a single REMS program and the absence of any differences in risk profiles suggests substitutability. (Addanki, Tr. 2250-51).

718. Like the FDA, the DEA treats all extended-release opioids identically. All extended-release opioids are listed on the same schedule of controlled substances—Schedule II. (Addanki, Tr. 2250-51).

719. The World Health Organization similarly views extended-release opioids as equivalents. The WHO publishes an analgesic ladder which lists treatment options for pain depending on the severity and nature of the pain. That analgesic ladder classifies all extended-release opioids as undifferentiated treatments for moderate to severe pain. (Addanki, Tr. 2243-44).

C. Physicians and Insurance Companies Treat Extended-Release Opioids as Interchangeable

720. Doctors use every extended-release opioid to treat the same medical conditions, including post-operation pain, lumbago, and chronic pain syndrome. (RX-547.0105; Addanki, Tr. 2245-47).

721. Indeed, it is "rare to find an indication for which there's no use at all of one of these [extended-release opioid] products." (Addanki, Tr. 2247; *see* RX-547.0105).

722. This means that whenever an extended-release opioid product is being used to treat a medical condition, other extended-release opioids can and are used to treat the same condition as well. (RX-547.0105; Addanki, Tr. 2247).

723. When a patient seeks treatment for chronic pain in the first instance, doctors can prescribe any extended-release opioid. (Savage, Tr. 732).

724. The factors taken into account when prescribing extended-release opioids in the first instance include the individual patient's prior experiences, including any opioid medications the patient has tolerated in the past and those that they have not; patient preferences; the doctor's own familiarity with a particular opioid; and whether the medication is covered by the patient's insurance plan. (Michna, Tr. 2119, 2121).

725. Most doctors are familiar and comfortable with certain opioids and tend to prescribe those opioids first, despite having multiple options from which to prescribe. (Michna, Tr. 2119).

726. As Professor Noll put it, which extended-release opioid is prescribed in the first instance is a matter of physician preference. (Noll, Tr. 1529).

727. Doctors will then assess the efficacy of the drug and any side effects experienced by the patient to determine future treatment or the need to try a different extended-release opioid. (Michna, Tr. 2109-10).

728. This clinical interchangeability indicates that "there doesn't appear to be any reason why [extended-release opioid] products would not be interchangeable for one another, because they are being used for many of the same things or virtually all of the same things. (Addanki, Tr. 2248).

1. Physicians Frequently Switch Patients Between Extended-Release Opioids

729. Doctors routinely switch patients from one extended-release opioid to another. (Savage, Tr. 693-94 ("it's frequently necessary or advisable to switch patients")).

730. In fact, Dr. Michna, Impax's medical expert, estimated that switching between extended-release opioids is "probably done thousands of times each day." (Michna, Tr. 2124).

731. Switching can and frequently does occur for wholly non-medical reasons, including a change in insurance coverage. (Michna, Tr. 2125).

732. Switching between extended-release opioids can also occur because of a patient's response to a particular opioid, either in terms of tolerance or pain relief. (Michna, Tr. 2124-25).

733. Individual patients may react better to one extended-release opioid than another because all humans are "different physiologically in the way we tolerate medications. Some people have very high tolerance. Some people have side effects. There's a lot of variability." (Michna, Tr. 2108-09).

734. Switching a patient between one extended-release opioid to another is not a complex process, however. (Michna, Tr. 2127; Savage, Tr. 762 (switching patients between extended-release opioids can be "simple")).

735. Especially when patients are on "low dose[s] of an opioid, they can switch easily to something else." (Savage, Tr. 762).

736. Dr. Michna testified that if "a patient is on a relatively low dose of medication, we'll directly switch from one medication to another . . . by consult[ing] conversion tables that show relative equivalency of the two medications, and then typically we'll cut that dose in half or more just to err on the safe side in terms of how patients react to it." (Michna, Tr. 2126-27).

737. Dr. Savage, Complaint Counsel's medical expert, agreed, explaining that "if you're taking two Percocet today and you want to switch to a couple of hydrocodone, that's not going to be a complicated switch." (Savage, Tr. 765-66, 768-69).

738. But even for patients on high doses of multiple opioids, it is only "a bit more complicated" to switch between extended-release opioids. (Savage, Tr. 762).

739. In fact, Dr. Savage has never been unable to switch a patient between extended-release opioids. (Savage, Tr. 793-94).

740. Nor has Dr. Michna ever heard of any instance when a switch between extended-release opioids was not accomplished safely and effectively. (Michna, Tr. 2126).

741. Switching regularly plays out in practice. The most commonly used opioids in emergency rooms and other inpatient settings are hydromorphone, fentanyl, and morphine. (Savage, Tr. 787).

742. The most commonly prescribed opioids in outpatient settings are oxycodone, hydrocodone, and morphine. (Savage, Tr. 786).

743. When patients are released from the hospital they are almost always switched from one opioid to an entirely different opioid for outpatient purposes. (Savage, Tr. 798-801).

744. This means that even when a patient is shown to tolerate an opioid in the hospital, physicians "very often switch which molecule is used when the patient leaves the hospital." (Noll, Tr. 1530).

745. Similarly, patients who take both extended-release and immediate-release opioids at the same time—used simultaneously to treat chronic pain and short-lived "breakthrough" pain—often take different opioid molecules in order to achieve better pain response. (Michna, Tr. 2115-16).

746. Endo's internal documents also highlight real-world switching patterns between Opana ER and other extended-release opioid products, including drugs containing fentanyl, oxycodone, and morphine. (RX-083.0003 at 35; *see* RX-073.0002 at 13, 16 (tracking switching prescriptions for various extended-release opioids and noting Endo "must accelerate the gain of switches from Oxycontin")).

747. Endo tracked switching patterns between extended-release opioids on a month-by-month basis. The analysis indicates that Endo saw more patients switched from Opana ER than switched to it, with Morphine Sulfate and OxyContin accounting for 29 and 27 percent of all Opana ER switches, respectively. Hundreds of additional patients were switched from Opana ER to still other extended-release opioids. (RX-060.0002 at 25).

748. In general, Morphine Sulfate, OxyContin, and fentanyl each captured roughly 20 percent of all patients being switched between extended-release opioids. Opana ER, in comparison, received only 8 percent of switching patients. (RX-060.0002 at 28).

749. All told, thousands of patients switched from Opana ER to other extended-release opioids—and from other extended-release opioids to Opana ER—every month. (RX-073.0002 at 16).

2. Switching for Economic Reasons

750. Switches between extended-release opioids are often driven by economic factors, including changes in insurance coverage. (Michna, Tr. 2125).

751. Formularies change at least once a year, but often more frequently than that, including any time the insurance company receives a rebate or other change in their pricing. (Michna, Tr. 2136).

752. When the formulary status of an extended-release opioid changes, prescribers frequently switch patients from one extended-release opioid to another. (Michna, Tr. 2148).

753. Indeed, formulary changes can mean that a drug that was previously covered by an insurance plan is no longer covered or no longer covered to the same extent. This forces doctors to rotate patients to alternative medications to avoid high out-of-pocket expenses. (Michna, Tr. 2125).

754. When a formulary change occurs, the insurance company will inform doctors about substitute medications that are covered. (Michna, Tr. 2148).

755. For example, when an insurance company decided that it would no longer cover OxyContin, it informed doctors that patients could transition to oxymorphone ER because it was still covered. (Michna, Tr. 2148).

756. Dr. Michna consequently switched patients from oxycodone ER to oxymorphone ER several times as a result of insurance changes. (Michna, Tr. 2148; *see* RX-549.0007 (Dr. Michna has conducted hundreds of switches)).

757. Prescribers also have access to electronic records that identify whether any medication, including an extended-release opioid, is covered by a particular patient's insurance plan. (Michna, Tr. 2121-22). Those electronic records detail the co-pay cost to the patient. (Michna, Tr. 2121-22).

758. Doctors can then make prescribing decisions based on price and where a medication is located on an insurance company's formulary in order to avoid high out-of-pocket costs for patients. (CX4044 (Addanki, Dep. at 148); CX4046 (Michna, Dep. at 115-16); Noll, Tr. 1505-06).

759. Dr. Michna testified that when he puts a "drug order in the system, as I'm ready to print it or electronically send the prescription to the pharmacy, I will get an immediate feedback

as to whether that's a covered medication for that insurance company, also what level of additional pay that the patient has to pay at the pharmacy." (Michna, Tr. 2122).

760. Before the widespread adoption of electronic medical and formulary records, doctors still were aware of insurance coverage, costs to patients, and any changes therein. (Michna, Tr. 2123). Doctors would receive feedback directly from patients regarding cost and would receive requests to prescribe a lower-cost opioid. (Michna, Tr. 2123).

761. Doctors would also receive feedback from pharmacists who "would immediately call us and say, This is not a drug that this patient can receive without a prior authorization from the insurance company." (Michna, Tr. 2123).

762. And doctors would receive information directly from representatives of drug manufacturers, including which drugs are covered by which insurance plans and at what level. (Michna, Tr. 2123).

763. Switching for economic reasons plays out in practice. When the University of Pittsburgh Medical Center ("UPMC") instituted a formulary change that took OxyContin off UPMC formularies and replaced it with Opana ER as the only branded extended-release opioid, the vast majority of OxyContin patients—roughly 70 percent of them—transitioned to an alternative extended-release opioid. (RX-087; *see* Noll, Tr. 1561; Addanki, Tr. 2305).

764. In fact, of 1,639 UPMC patients who had a paid claim for OxyContin prior to the formulary changes, 1,142 switched to another extended-release opioid. (RX-087; *see* Noll, Tr. 1561; Addanki, Tr. 2306).

765. Of those who switched, roughly 29 percent switched to Opana ER. (RX-087; *see* Noll, Tr. 1562). Prior to UPMC's formulary change, Opana ER only received 1.62 percent of extended-release opioid prescriptions. (RX-087; Addanki, Tr. 2307).

766. Only 329 patients, roughly 20 percent, remained on OxyContin post-formulary change. (RX-087; *see* Noll, Tr. 1561).

767. By making the formulary change, UPMC created a change in relative price from the perspective of both the insurer and the patient. (Addanki, Tr. 2502-03). Specifically, UPMC was able to reduce both prescription drug costs and medical costs. (RX-087; Addanki, Tr. 2308-09).

768. UPMC concluded that there were no adverse cost increases as a result of its efforts to shape prescribing habits. (RX-087; *see* Noll, Tr. 1562, 1563-64).

769. UPMC's results are consistent with Dr. Savage's own experiences as a pain specialist. Dr. Savage noted that doctors can "do our best with whatever opioids are available" after insurance coverage changes. (Savage, Tr. 761-62).

770. If oxymorphone ER were no longer available in any form, doctors could rotate patients to other opioids. (Savage, Tr. 817).

771. Indeed, Dr. Savage admits that "most" people can get equally effective and safe pain relief from numerous extended-release opioids. (CX4041 (Savage, Dep. at 66-67)). And at least 50 percent of patients taking oxymorphone ER could achieve the same results from oxycodone ER. (Savage, Tr. 792-93).

772. Before Endo introduced Opana ER in 2006, Dr. Savage was able successfully to treat patients with chronic pain. (Savage, Tr. 818).

3. Switching Through Opioid Rotation Therapy

773. Some doctors employ "opioid rotation" therapy. (Savage, Tr. 760-61).

774. Opioid rotation is a process whereby doctors rotate a patient between different extended-release opioids to avoid tolerance to any one medication and regain pain relief at lower

doses. (Michna, Tr. 2146-47). It is a "very important clinical tool" in the avoidance of tolerance and side effects in patients. (Savage, Tr. 760-61).

775. Rotating from one extended-release opioid to another does not involve any risks or inordinate difficulties, assuming the physician supervising the switch understands the medications she is prescribing. (Michna, Tr. 2126; Savage, Tr. 782-83).

776. Indeed, Endo's Opana ER Business Review from April 2013 indicates that "Opioid rotation/switching is common in this therapeutic category." (RX-073.0002 at 45).

777. And Dr. Michna has always been able to find effective extended-release opioids through rotation therapy. (Michna, Tr. 2147).

4. Switching Costs are Insignificant

778. Switching from one extended-release opioid to another requires physician monitoring. (Michna, Tr. 2127).

779. This includes follow-up visits with the doctor in order to assess whether the patient is getting adequate pain relief. (Michna, Tr. 2127).

780. Physician monitoring can also include telephone conversations between doctor and patient. (Michna, Tr. 2127).

781. Because switching between extended-release opioids is often driven by insurance companies and their formulary changes, follow-up visits to monitor new opioids after a switch are "not well compensated" with "fairly low reimbursement." (Michna, Tr. 2127-29).

782. In any event, insurance companies calculate the savings achieved by their formulary changes and believe that "savings they have on the medication front more than make[] up for the additional cost of the follow-up visit." (Michna, Tr. 2129).

783. In the case of UPMC's formulary change, UPMC modified which extended-release opioids were covered by its plans and UPMC was able to switch nearly 70 percent of

OxyContin patients to other extended-release opioids without any adverse cost increases. (RX-087; *see* Noll, Tr. 1562-64).

784. Patients, for their part, generally do not mind extra doctor visits in order to treat their pain effectively. (Michna, Tr. 2128). In fact, there is some medical research that suggests that the more often patients suffering from pain see doctors, the less pain they experience overall. (Michna, Tr. 2128-29).

*** * ***

785. Taken together, this clinical evidence indicates that all extended-release opioids (1) "are indicated for similar use for the treatment of chronic, severe pain that won't respond to other things"; (2) "they are actually used for very much the same set of indications, and it's a huge set; and (3) "there's nothing about their risk profiles that suggest that there would be any impediment to interchanging one for the other except from a therapeutic standpoint." (Addanki, Tr. 2252).

786. In fact, all patients have multiple opioid options available that are equally safe and effective for the treatment of chronic pain, and there is no identifiable group for which any particular extended-release opioid is the only treatment option. (Michna, Tr. 2148-49; Noll, Tr. 1508-09, 1548).

787. This means that there is "no clinical impediment . . . for all of these [extended-release opioids] to be regarded as being in the same relevant economic market." (Addanki, Tr. 2252).

D. Drug Manufacturers View Extended-Release Opioids as Directly Competing Products

788. Demir Bingol, Endo's Senior Director of Marketing and the Endo employee responsible for knowing with whom Opana ER competed, considered "all long-acting opioid

formulations," even those not actively marketed, to be direct competitors of Opana ER at the time of settlement. (Bingol, Tr. 1271, 1313; CX2610-024; *see* Noll, Tr. 1512 (conceding that Endo regarded itself as competing against other extended-release opioids)).

789. Alan Levin, Endo's CFO at the time of settlement, similarly viewed Opana ER as competing in a long-acting opioid market. (CX4017 (Levin, Dep. at 172-73)).

790. This included, OxyContin, Avinza, Kadian, generic long-acting morphine, Exalgo, and any "number of other long-acting opioids that a clinician can choose from." (Bingol, Tr. 1271; *see* CX2610-024 (2010 Endo document listing oxycodone, morphine, tapentadol, hydromorphone, fentanyl, buprenorphine, and duloxetine as competitors)).

791. With respect to generic products, Mr. Bingol explained that "we would still compete" against them since "we were competing against the[] intrinsic value of their molecule." (Bingol, Tr. 1278-79).

792. Endo was able to compete for market share against other long-acting opioids by, among other things, "effective targeting of your messaging to your clinicians," "rebates that you offer payers in order to ensure that you have a competitive place on formularies," and "certain competitors coming and going that your product becomes a natural next choice." (Bingol, Tr. 1284).

793. Mr. Bingol made the same points in March 2010, when he stated in the court proceedings between Endo and Impax that "the LAO [long-acting opioid] market was a well-established and competitive market that consisted of many products that had been on the market for years." (CX3273-003).

794. Such broad competition among extended-release opioids was the same for both original and reformulated Opana ER. (Bingol, Tr. 1314-15).

795. Endo's internal documents confirm that Endo believed Opana ER competed against all other extended-release opioids. (*See, e.g.*, RX-085; RX-060; RX-112).

796. Indeed, those documents [redacted] (Addanki, Tr. 2259).

797. In June 2007, for example, [redacted] (RX-085 at 57).

798. [redacted] (RX-085 at 57). [redacted] (RX-085 at 59).

799. [redacted] (RX-112 at 5, 16; Addanki, Tr. 2260).

800. [redacted]

(RX-112 at 13-14). [redacted] (RX-112 at 14).

801. [redacted] **(**RX-026.0005). [redacted] (RX-026.0006-08).

802. In December 2010, Endo identified "direct competitors" of reformulated Opana ER to include all drugs containing oxycodone, morphine, tapentadol, and hydromorphone, while indirect competitors included drugs containing fentanyl, buprenorphine, and duloxetine. (RX-078 at 23; Addanki, Tr. 2261-62 ("the competitive set" is "long-acting opioids" generally, not Opana ER alone)).

803. Again in 2011 and 2012, Endo identified a broad class of direct and indirect competitors. (RX-115 at 7; RX-111.0003 at 25, 45; RX-060.0002 at 5, 24, 39).

804. In 2012, for example, Endo estimated that OxyContin, fentanyl, and morphine all possessed over 25 percent of the extended-release opioid market, while Opana ER held roughly 4 percent. (RX-060.0002 at 24).

805. Endo sought to switch greater volume from OxyContin and Morphine Sulfate to Opana ER, and to capture prescriptions for new patients away from those drugs in first instance, which it considered" the biggest opportunity in the market." (RX-060.0002 at 29).

806. In April 2013, [redacted]

[redacted] (RX-073.0002 at 7; Addanki, Tr. 2262-63).

807. [redacted] (RX-073.0002 at 39; Addanki, Tr. 2264).

808. At the same time, [redacted] (RX-073.0002 at 38; Addanki, Tr. 2263-64).

809. [redacted] (Addanki, Tr. 2264-65).

810. [redacted] (Addanki, Tr. 2266-67).

811. [redacted]

812. [redacted]

813. [redacted] (Addanki, Tr. 2266-67).

814. [redacted]

E. Extended-Release Opioids Compete on Price

815. The manufacturers of extended-release opioids compete on price in a variety of ways. (Bingol, Tr. 1327).

816. There are multiple layers of competition in the pharmaceutical industry. Unlike traditional industries in which competitive efforts are targeted at individual consumers, who decide which products to purchase and then personally pay for and consume those products, the pharmaceutical industry is disjointed. Physicians are the decision makers in terms of which drug is prescribed. Insurance companies pay the bulk of any drugs cost. And individual patients consume the drug and generally pay a small portion of the drug price. (Addanki, Tr. 2212-15).

817. As a result, it is necessary to analyze different layers of competition, including competition at the insurer level, physician level, and patient level. (Addanki, Tr. 2215). The evidence is plain that extended-release opioid manufacturers compete vigorously on price at each level of competition.

1. Price Competition for Formulary Placement at the Insurer Level

818. Because third-party payors are often responsible for most of a drug's cost, competition between pharmaceutical companies regularly takes place at the insurer level. (Bingol, Tr. 1324).

819. Insurers typically invite drug manufacturers to submit pricing bids on an annual basis. Those bids can then lead to negotiations about overall price, rebates, and formulary placement. (Addanki, Tr. 2224).

820. With respect to extended-release opioids, manufacturers compete directly on price in the form of rebates and discounts in order to secure favorable formulary placement vis-à-vis competitors. (Bingol, Tr. 1324-25).

821. Demir Bingol, Endo's Senior Director of Marketing, testified that insurance companies have "a choice . . . amongst multiple products" and manufacturers must "create a financial position for the payer that is justifying their putting you on [a] tier." (Bingol, Tr. 1325).

822. Even for government insurance plans like those through the Department of Veterans Affairs, there are preferred drug lists for which pharmaceutical companies must compete on price. (Noll, Tr. 1507-08).

823. As Complaint Counsel's economic expert, Professor Roger Noll, testified, drugs do not appear on any formulary tier "by accident." Manufacturers must affirmatively secure better positions vis-à-vis other extended-release opioids by offering lower prices. (Noll, Tr. 1545-46).

824. Depending on the specific pricing and discounts offered, different insurance companies will list the same extended-release opioid on different tiers. (Michna, Tr. 2136).

825. It is also possible for one manufacturer's drug to appear on some formularies but not appear in any manner on other formularies. (Noll, Tr. 1509).

826. In general, however, drugs will move higher on a formulary when the pharmaceutical company gives a better rebate to the insurance company, "meaning they'll give them a discount on the medication." (Michna, Tr. 2130-31).

827. This includes rebates by brand companies in order to compete with generic products on price. (Bingol, Tr. 1327; Engle, Tr. 1718; CX4037 (Smolenski, Dep. at 155); *but see* Hoxie, Tr. 2795 (claiming generics do not always sell at a discount to the brand)).

828. Taken together, the use of rebates and discounts is competition related to the net price of drugs—rebates reduce the net prices paid by insurers and thereby secure favorable formulary coverage and drive substitution among products. (Addanki, Tr. 2226, 2289-90).

829. Such net-price competition at the formulary level "happens all the time" and "is a fact of life in the pharmaceutical industry." (Addanki, Tr. 2220).

830. Such net price competition at the formulary level is also effective. [redacted] (Addanki, Tr. 2290; *see* RX-547.0053-54; Noll, Tr. 1681-83).

831. [redacted] (RX-547.0053-54; Noll, Tr. 1681-83).

832. Professor Noll consequently is wrong in stating that that competition for formulary placement had "not been successful in preventing drug prices from going up more rapidly than the rate of inflation by a substantial amount." (Noll, Tr. 1523-24).

833. Indeed, Professor Noll's statement is premised on list prices. (CX5000-090-95 (discussing documents related to list prices)).

834. [redacted] (Addanki, Tr. 2290).

835. [redacted] (Noll, Tr. 1684-85). [redacted] (Noll, Tr. 1681).

a. Contemporaneous Evidence of Endo's Price Competition

836. Endo's contemporaneous business documents indicate [redacted] (Addanki, Tr. 2291).

837. In 2009, many doctors believed that Opana ER did not have sufficient coverage on insurance plans. (CX1106-009).

838. In response, Endo sought to improve Opana ER placement on insurance plans in order to secure more prescriptions for Opana ER. (CX1106-009; *see* Addanki, Tr. 2292-93).

839. Endo specifically acknowledged "that managed care access is important in the LAO market" and developed "a series of managed care growth strategies," including efforts to secure a "number of plans where we have preferred access, or some other leg up on the competition." (RX-023.0003).

840. [redacted] (Addanki, Tr. 2293).

841. [redacted] (RX-558.0003). [redacted] (RX-558.0003).

842. In 2011, [redacted] (RX-014.0002; Addanki, Tr. 2294-95).

843. Endo previously executed a Medicare agreement with Prime Therapeutics in 2009, but could not secure placement of Opana ER on Prime Therapeutics national formulary. (RX-014.0002). As a result, Opana ER sales had been "negligible" on Prime Therapeutics' plans. (RX-014.0002).

844. [redacted] (Addanki, Tr. 2295).

845. Also in 2011, [redacted] (RX-021.0005; Addanki, Tr. 2296). [redacted] (RX-021.0005).

846. [redacted] (RX-021.0005; Addanki, Tr. 2298). [redacted] (RX-021.0005; Addanki, Tr. 2298-99).

847. [redacted] (RX-021.0007).

848. In 2012, [redacted]

[redacted]

(RX-022.0004; Addanki, Tr. 2300-01). [redacted] (Addanki, Tr. 2301).

849. Such increases in rebates are on the order of magnitude of a small but significant increase in price ("SSNIP"), indicating that "even small price changes were competitively potentially significant." (Addanki, Tr. 2500).

850. Also in 2012, [redacted] (CX3206-002).

851. Endo negotiated exclusive placement agreements with other health care plans as well. For example, Endo secured exclusive formulary status for Opana ER on Wellcare's Medicare Part D plans, with a block on OxyContin and other branded extended-release opioids. (RX-017.0002 at 12). OxyContin had previously received 84 percent of Wellcare's extended-release opioid prescriptions. (RX-017.0002 at 12).

852. Endo also negotiated deals with Humana, Optum, and UPMC to list Opana ER on their formularies at the express exclusion of other brand extended-release opioids like OxyContin. (RX-017.0001; RX-017.0002 at 11).

853. And as noted above, UPMC modified its formulary to exclude OxyContin and list Opana ER as the only branded extended-release opioid. (RX-087). In so doing, UPMC was able to reduce total medical costs. (RX-087; Addanki, Tr. 2308-09).

854. UPMC's experience indicates that there "was economic substitution going on because there was competition via pricing, the rebates, to the payer layer of this market, the

industry, and that competition for formulary coverage was in fact economic substitution. And this is another instance of an insurer describing its experience with implementing a formulary change and tracing through the consequences and effects." (Addanki, Tr. 2309).

855. UPMC's formulary change (and others like it) had a direct impact on Endo, which experienced significant increases in sales of Opana ER, including gains of roughly 3 and 7 percent on different formulary plans. (RX-110.0002 at 33).

856. Put differently, price changes at the formulary level lead to volume changes in sales and prescriptions of extended-release opioids. (Addanki, Tr. 2502-03).

857. Price competition can also result in branded products appearing on higher, more preferred tiers than generic versions of the same drug. (Michna, Tr. 2135).

858. UnitedHealth, for instance, listed Opana ER on tier two of its formulary while no generic version of oxymorphone ER appeared on the formulary. (Noll, Tr. 1546).

859. Similarly, Endo secured favorable placement of Opana ER on Humana and Caremark formularies with blocks against generic versions of oxymorphone and oxycodone, including Impax's product. (RX-017.0001; RX-017.0002 at 11).

860. Taken together, such evidence is contrary to Professor Noll's testimony that Endo "rarely considered the prices of other drugs." (Noll, Tr. 1392-94).

b. Formulary Data Indicates Price Competition

861. Managed Market Insights, a data syndication company, tracks the formulary treatment of pharmaceutical products by most commercial and Medicare insurers in the United States. (Addanki, Tr. 2310-11).

862. That data can be used to compare how different extended-release opioids are treated across formularies. The data indicates that branded extended-release opioids are "treated

differently by different plans, and so there's a lot of diversity in the outcomes that you see from the formulary competition" based on economic factors. (Addanki, Tr. 2315-16).

863. OxyContin, for example, was often the most preferred branded extended-release opioid product on commercial formularies at the time of settlement. (RX-547.0114; Addanki, Tr. 2316).

864. [redacted] (RX-547.0039-40).

865. [redacted] (RX-547.0114; Addanki, Tr. 2316).

866. Each branded extended-release opioid, however, was the most preferred drug to the exclusion of other products on at least some commercial formularies. (RX-547.0114; Addanki, Tr. 2316). And each branded extended-release opioid was not covered on at least some commercial formularies. (RX-547.0114).

867. Similar variation existed on Medicare Plans at the time of settlement, [redacted] (RX-547.0115; Addanki, Tr. 2317; *see* RX-547.0116-17 (Opana ER placement varied in comparison to other branded extended-release opioids at time of settlement, with no opioid systematically favored over any other)).

868. Opana ER, for its part, secured a "mild preference" over OxyContin, [redacted] (Addanki, Tr. 2317; RX-547.0039-40).

869. Over time, these formulary placements would change. In fact, from year to year, some extended-release opioids would become more preferred on formulary plans relative to other extended-release opioids, while others would become less preferred. (Addanki, Tr. 2318).

870. [redacted] (RX-547.0126; Addanki, Tr. 2318).

871. Similar formulary changes happened every year, with large changes occurring in Opana ER's favor in 2011 and large changes occurring in the favor of other extended-release opioids in 2012. (RX-547.0126; Addanki, Tr. 2318-19).

872. Changes occurred on a yearly basis for Medicare plans as well, with significant shifts in Opana ER's favor in 2009 and equally significant shifts in the favor of other extended-release opioids in 2012. (RX-547.0127; Addanki, Tr. 2320).

873. OxyContin, similarly, experienced changes in formulary placement from year to year, becoming less preferred on commercial plans vis-a-vis other extended-release opioids in 2010 and 2012. (RX-547.0130; Addanki, Tr. 2320-21).

874. Together, this movement in formulary placement is the result of competition, "not just Endo's competitive efforts but all the other LAO suppliers' competitive efforts." (Addanki, Tr. 2319).

875. In general, "there is churn" in formulary place because "there are differences in the way these formulary competitions play out in terms of the formulary positioning that's given by different plans, which is entirely consistent with there being . . . competition at the formulary stage at the payer level." (Addanki, Tr. 2328; *see* RX-547.0040 ("churn is consistent with . . .

compet[ition] for favorable insurance coverage and there being various 'winners' in that competitive process across formularies and within the same formulary over time")).

*** * ***

876. This competition indicates that (1) extended-release opioids are in fact regarded as good therapeutic substitutes, and (2) economic substitutability is actually happening as insurers adjust their formularies. (Addanki, Tr. 2225-26).

877. Such substitution in response to price competition is "exactly the kind of competition we're talking about when we're analyzing . . . relevant markets." (Addanki, Tr. 2232-33).

2. Price Competition for Prescriptions at the Physician Level

878. Manufacturers of extended-release opioids use journal advertisements, direct-to-physician detailing, office visits, and other promotional strategies to compete for prescriptions written by physicians. (Bingol, Tr. 1284-85; *see* Addanki, Tr. 2268).

879. These efforts are aimed at switching prescriptions from one extended-release opioid to another. [redacted] (RX-040.0008; Addanki, Tr. 2269).

880. [redacted] (Addanki, Tr. 2270; *see* RX-085 at 21).

881. In 2007, for example, [redacted]

[redacted] (RX-085 at 22; Addanki, Tr. 2274).

882. [redacted] (RX-085 at 21).

883. [redacted] (RX-085 at 22).

884. [redacted] (RX-023.0002-03; Addanki, Tr. 2275).

885. [redacted] (RX-547.0110-11; Addanki, Tr. 2277-78).

886. In 2007, for instance, [redacted] (RX-547.0110; Addanki, Tr. 2277).

887. In 2008, [redacted] (RX-

547.0110; RX-040.0008 (detailing tens of thousands of doctor visits per month); Addanki, Tr. 2277).

888. In total, [redacted] (RX-547.0038, 112; Addanki, Tr. 2279).

889. [redacted] (Addanki, Tr. 2279).

890. Other manufacturers also viewed competition at the physician level as important. Impax, for instance, specifically targeted OxyContin prescribers with its promotional efforts after it launched its oxymorphone ER product. (CX4004 (Engle, IHT at 210-11); RX-394.0001).

891. [redacted] (RX-111.0003 at 48).

892. [redacted]

893. [redacted]

894. This competition for physician prescriptions is a form of price competition. The price information that matters to physicians is embodied in formulary placement—the last thing

a doctor wants is for a patient to not fill a prescription (or for a pharmacy to be unable to fill a prescription) due to lack of coverage. (CX4044 (Addanki, Dep. at 148); *see* CX4046 (Michna, Dep. at 115-16)).

895. Using medications on preferred formulary tiers also reduces administrative burdens for prescribers because disfavored or off-formulary drugs will require the prescriber to spend additional time and resources coordinating with the pharmacy. (Addanki, Tr. 2230; CX4044 (Addanki, Dep. at 148); CX4046 (Michna, Dep. at 116)).

896. Extended-release opioid manufacturers consequently seek to educate physicians about favorable formulary placement, which entails lower out-of-pocket costs to patients. (CX4044 (Addanki, Dep. at 130)).

897. Endo [redacted], for example, each pursued marketing strategies to inform prescribers of their products' formulary coverage. (RX-016.0002 at 96-97; RX-445.0020-22).

898. And drug companies routinely informed Dr. Michna of their products' formulary status. (CX4046 (Michna, Dep. at 148-49)).

3. Price Competition at the Patient Level

899. Manufacturers of extended-release opioids also compete at the patient level by subsidizing patients' co-payments or coinsurance, thus making their products relatively less expensive and reducing the net price received by the manufacturer. (Bingol, Tr. 1325; *see* Addanki, Tr. 2280, 2284).

900. Manufacturers do this by offering coupons directly to consumers. (Bingol, Tr. 1325-26; *see* Addanki, Tr. 2280).

901. When a patient presents a coupon at the pharmacy, the drug company will remit to the pharmacy a specified sum of money that effectively lowers the patient's co-pay. (Addanki, Tr. 2234-35).

902. Coupons can greatly reduce a patients out-of-pocket expenses, in some cases eliminating them completely, regardless of the formulary tier on which the prescribed extended-release opioid appears. (Bingol, Tr. 1325; Addanki, Tr. 2284 [redacted]).

903. Put differently, manufacturers can use consumer rebates to compete with other extended-release opioids that have more favorable formulary placement. (Addanki, Tr. 2234-36).

904. [redacted] (RX-028.0011 [redacted]).

905. [redacted] (RX-028.0011; Addanki, Tr. 2281).

906. In response to such [redacted] (RX-028.0011).

907. Between 2009 and mid-2010, Endo continued to offer co-pay assistance. Over that period, Endo offset a portion of nearly 90,000 prescriptions for Opana ER. (RX-066.0003).

908. In 2011, [redacted] (RX-123.0006; Addanki, Tr. 2285).

909. And in 2012, [redacted] (RX-119.0002; Addanki, Tr. 2286).

910. [redacted]

911. In 2013, [redacted]

912. [redacted]

913. [redacted]

914. Such aggressive price discounting indicates that Opana ER competed against all other extended-release opioids. (Addanki, Tr. 2236-37).

915. Importantly, patient rebates like those employed by Endo, Purdue, and King Pharmaceutical would not occur in monopolized markets: "JUDGE CHAPPELL: Let me ask another way. Have you ever seen a rebate being used like this when there's only one brand on

the market with no competition? THE WITNESS: No. No. It is the hallmark of when there's actually competition." (Addanki, Tr. 2236-37).

F. Testimony from Complaint Counsel's Medical Expert, Dr. Savage, Does Not Support a Narrow Market

916. Complaint Counsel's economic expert, Professor Noll, relies on Complaint Counsel's medical expert, Dr. Seddon Savage, to support his opinion that the relevant product market is limited to oxymorphone ER. (CX4039 (Noll, Dep. at 10-11, 13) (testifying that he relies on Dr. Savage's "opinions about whether or not two drugs are clinically close substitutes," which is "sort of a necessary but not sufficient condition to make things economic substitutes")).

917. Dr. Noll similarly defers to Dr. Savage with respect to the therapeutic differences between extended-release opioids. (Noll, Tr. 1494-95). But Dr. Savage's own testimony makes clear that a narrow market is not appropriate:

1. Patient Preferences

918. Dr. Savage testified that some patients have preferences for one extended-release opioid over another. (Savage, Tr. 822).

919. She explained that "a patient" may "prefer" oxymorphone ER over fentanyl, an extended-release opioid that is applied through a patch on the skin, if the patient wants to "sit in a hot bath, to raise [their] body temperature through very vigorous exercise, or otherwise expose the patch to intermittent heat." (Savage, Tr. 741).

920. Other patients prefer fentanyl if they have difficulty swallowing or absorbing oral medications. (Savage, Tr. 740-41).

921. Still other patients may want to take a different extended-release opioid that requires more pills so that they have a sense of control over their treatment. (Savage, Tr. 742).

922. Dr. Savage, however, does not offer any opinion regarding whether the patients who prefer or react best to oxymorphone ER (or any other opioid) are significant in number. (CX4041 (Savage, Dep. at 61-62)).

923. Dr. Savage instead admits that "most" people can get equally effective and safe pain relief from numerous extended-release opioids, and she acknowledges that such individuals cannot be identified in advance of treatment. (CX4041 (Savage, Dep. at 60, 66-67)).

924. For example, at least 50 percent of patients taking oxymorphone ER could achieve the same results from oxycodone ER. (Savage, Tr. 792-93).

925. In any event, patient preferences do not diminish the therapeutic equivalence of extended-release opioids. (Michna, Tr. 2126). Patient preferences may instead reflect a patient's anxiety about leaving a known medication that provides good pain relief for a medication for which they do not know if it will provide the same results. (Michna, Tr. 2126).

2. Patients for Whom Oxymorphone ER May Be the Best Option

926. No doctor can predict prospectively how any particular patient will respond to any extended-release opioid. (Savage, Tr. 710-11; *see* Michna, Tr. 2148-49; CX4041 (Savage, Dep. at 38)).

927. Doctors do not have a way to match patients to the best possible opioid in advance of treatment. (Savage, Tr. 794; Michna, Tr. 2148-49).

928. They instead match patients to opioids through trial and error. (Michna, Tr. 2168-69; CX4041 (Savage, Dep. at 38-40)).

929. Sometimes doctors find the right treatment on the first try. (Savage, Tr. 790).

930. Many times doctors "try two, three, or four different opioids before they arrive at one that's both effective for them with minimal side effects." (Savage, Tr. 711).

931. If a patient has never taken opioids before, doctors usually start with whatever medication the prescribing doctor is familiar with. (Savage, Tr. 789; Michna, Tr. 2119).

932. And familiarity with specific medications will vary among doctors because medical practice is regionalized, with practices in one hospital differing from practices in another hospital, and because individual doctors are influenced by a range of issues, including knowledge of medical literature, the practices of colleagues, marketing materials, and the doctor's own experiences with patients generally. (Savage, Tr. 787-88).

933. Accordingly, no one extended-release opioid is superior to any other extended-release opioid across broad populations of patients. (Savage, Tr. 790-91; Michna, Tr. 2149).

934. No extended-release opioid is better, for example, for men than for women. (Savage, Tr. 791).

935. And no medical conditions produce pain for which oxymorphone ER or any other opioid mediation is the only extended-release opioid option. (Savage, Tr. 791; Michna, Tr. 2149).

936. The only differences in extended-release opioid treatments occur among "individual patients with specific types of pain in specific contexts" that render particular opioid treatments "superior choices for individuals in particular contexts." (Savage, Tr. 743-44, 788-89).

937. As Dr. Savage testified, "We are all biologically and genetically somewhat different. . . . [S]o somebody may respond better to oxycodone than to hydromorphone than to morphine. They may not only experience different levels of analgesia in response to the drug but different side effects. Most people who have taken opioids have expressed different effects of different opioids." (Savage, Tr. 691-92).

938. Other individualized differences can include a personal history of negative reactions to a particular medication or unique habits like taking "all their medications at breakfast and at dinnertime" as opposed to taking them "after exercising, before dinner." (Savage, Tr. 729-31).

939. Taken together, the inability to identify individuals or patient groups for whom oxymorphone ER may be the best treatment means that Endo and any other drug manufacturer would have no means to price discriminate against those patients. (CX4039 (Noll, Dep. at 171-72)).

3. Unique Characteristics of Oxymorphone ER

a. CYP 450 Metabolism

940. Oxymorphone is metabolized in the liver. (Savage, Tr. 715-16).

941. Other extended-release opioids are metabolized via a pathway known as CYP 450. (Michna, Tr. 2151; Savage, 715-16).

942. The CYP 450 pathway is utilized by a majority of medications prescribed generally. (Michna, Tr. 2151).

943. It is "possible" that the use of the CYP 450 pathway "may" require doctors "to adjust the dose of the opioid that you're using" so that the patient will not have "a higher level of the opioid in their body because it's not being broken down as rapidly" when compared to other metabolic pathways. (Savage, Tr. 716-17; *see* Michna, Tr. 2151).

944. But a patient's reaction to CYP 450 metabolism is not a clinically relevant factor when physicians are prescribing extended-release opioids. (Michna, Tr. 2151-52).

945. When doctors prescribe an extended-release opioid, they start at low doses and then build up to assess reaction and side effects. (Michna, Tr. 2152).

946. Accordingly, even if a patient has trouble metabolizing via the CYP 450 pathway, it would simply mean that the patient would achieve pain relief "at a much earlier point" in the buildup of dosing than if the patient had more rapid metabolism. (Michna, Tr. 2152).

947. Indeed, Dr. Savage concedes that patients who do not respond well to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796).

948. In any event, patients have several extended-release opioid options that do not raise any CYP 450 issues. Neither morphine nor hydromorphone utilize the CYP 450 pathway. (Savage, Tr. 795-96).

949. And while there is a test to assess how a patient will metabolize drugs through the CYP 450 pathway, Dr. Michna has never performed it and has never seen any other doctor do so. (Michna, Tr. 2152).

b. Injectable and Tablet Forms

950. Dr. Savage opined that oxymorphone is available in both tablet form and in injectable form, giving it an advantage over other drugs in the hospital setting. (Savage, Tr. 798).

951. But the availability of oxymorphone ER in both injectable and tablet form is not a clinically relevant factor. (Michna, Tr. 2149-50).

952. Dr. Michna explained that he has never seen oxymorphone stocked in any form in a hospital. (Michna, Tr. 2149-50).

953. Indeed, the most commonly used opioids in emergency rooms and other inpatient settings are hydromorphone, fentanyl, and morphine. (Savage, Tr. 787).

954. The most commonly prescribed opioids in outpatient settings are oxycodone, hydrocodone, and morphine. (Savage, Tr. 786; Michna, Tr. 2150).

955. When patients are released from the hospital they are almost always switched from one opioid to an entirely different opioid for outpatient purposes. (Savage, Tr. 798, 799-800; Michna, Tr. 2149-50).

c. Frequency of Dosing

956. Dr. Savage also opined that oxymorphone is unique because she has observed patients taking Opana ER on a twelve-hour dosing schedule while she has "encountered patients taking OxyContin . . . more frequently than every twelve hours." (Savage, Tr. 723-24).

957. But this characteristic would actually remove Opana ER as a potential option for certain patients. (CX4041 (Savage, Dep. at 121)).

958. Some patients want to take extended-release opioids that requires more pills so that they have a greater sense of control over their treatment. (Savage, Tr. 742).

959. Others patients prefer even less dosing if they have difficulty swallowing or absorbing oral medications, and therefore may opt for extended-release opioids that are absorbed through patches on the skin. (Savage, Tr. 740-41).

d. The Identified Differences Among Extended-Release Opioids are Used for Marketing Purposes

960. All of the differences Dr. Savage identified between oxymorphone ER and other extended-release opioids are used by pharmaceutical companies for marketing purposes. (Bingol, Tr. 1314; Michna, Tr. 2152-53).

961. Demir Bingol, Endo's Senior Director of Marketing, testified that claims of differentiation are a way to "simplify and distill down to kind of the essence of how you're going to compete against" other extended-release opioids. (Bingol, Tr. 1314).

962. Issues like frequency of dosing and metabolic pathways represented Endo's "best opportunity to compete against those [other extended-release opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314).

963. Indeed, Endo used the differences found in the oxymorphone molecule as a means to differentiate the "intrinsic qualities" of Opana ER from branded and generic drugs that incorporate different molecules. (Bingol, Tr. 1278-79).

964. Endo would send communications highlighting these issues to "constituents in the value chain," including wholesalers, pharmacies, physicians, and patients, in an effort to increase sales. (Bingol, Tr. 1265-66).

965. Endo also held meeting in which Endo marketing personal explained to doctors Opana ER's metabolic characteristics to assess whether the difference "would resonate with clinicians." (Michna, Tr. 2154-55).

966. The clinicians "universally . . . said no because it's really not clinically relevant." (Michna, Tr. 2154-55).

967. At bottom, the variations among extended-release opioids are no different than those found in over-the-counter pain relievers like Advil, Tylenol, Aleve, and aspirin. All have different mechanisms of action, different dosage frequencies, and different toxicity profiles. (Savage, Tr. 812-14). And each over-the-counter pain reliever will act differently in different individuals. (Savage, Tr. 813-14).

968. Yet Dr. Savage admits that each over-the-counter pain reliever can be used for the same problems. (Savage, Tr. 814-15).

969. And Dr. Savage admits that each over-the-counter pain reliever competes for the same consumers. (Savage, Tr. 815-16).

970. In the same fashion, extended-release opioids compete for the same consumers, even if they treat pain differently. (Savage, Tr. 816).

4. Difficulty Switching

971. Dr. Savage "prefer[s]" to keep a patient on a well-tolerated medication because a switch may require adjusting the dose or otherwise create complexities. (Savage, Tr. 744, 758-59).

972. Yet Dr. Savage admits that in her own practice she has switched patients from oxymorphone to other extended-release opioids. (Savage, Tr. 793-94).

973. In fact, Dr. Savage has never been unable to switch a patient between extended-release opioids. (Savage, Tr. 793-94).

974. Dr. Savage also admits that doctors frequently switch patients from one extended-release opioid to another. (Savage, Tr. 762).

975. "[M]ost [opioids] are interchangeable if attention is paid to relative potencies and onset and duration of action." (Savage, Tr. 782-83).

976. And to the extent patients develop side effects, those side effects can be treated with additional medications. (Savage, Tr. 785).

G. Testimony from Complaint Counsel's Economic Expert, Professor Noll, Does Not Support a Narrow Market

977. Professor Noll primarily employed an "indirect" method of proving monopoly power, which centers on the degree of concentration in the relevant market. (Noll, Tr. 1405-06).

978. In so doing, Professor Noll opined that the relevant product market is limited to extended-release oxymorphone ER and nothing else. (Noll, Tr. 1372-73).

979. Professor Noll explained that one can determine which products are economic substitutes—and therefore part of the same relevant market—by either (1) performing an

analysis to determine whether a small but significant increase in price—known as a "SSNIP" test—would cause consumers to switch products, or (2) assess whether events impacting one product influence prices or quantities of other products. (Noll, Tr. 1374-75). Professor Noll failed in both respects.

1. Professor Noll Did Not Conduct Relevant Statistical Analysis

980. Dr. Noll opined that the relevant market is limited to oxymorphone ER because while generic oxymorphone ER products drew share from Endo's branded Opana ER, the launch of generic versions of other opioids did not. (Noll, Tr. 1377-87).

981. Professor Noll admits, however, that he did not conduct a SSNIP test. (Noll, Tr. 1514).

982. Nor did Professor Noll analyze whether demand for oxymorphone ER is price elastic, preferring instead to "just infer[] it from facts about market events." (Noll, Tr. 1509-10).

983. And while Professor Noll faults Endo for "not attempt[ing] to estimate . . . the cross-elasticity of demand between Opana ER and OxyContin" in certain instances, (CX5000-068-69), Professor Noll himself did not calculate cross-elasticity of demand for oxymorphone ER or any other extended-release opioid. (Noll, Tr. 1517).

984. In fact, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331).

985. Professor Noll merely scanned for any "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384).

986. Finally, Professor Noll failed to advance any empirical analysis of switching costs and cannot quantify whether the cost of switching between extended-release opioids is high. (Noll, Tr. 1552-53).

987. Instead, Professor Noll argues only that switching is costly because patients have to taper off of the first drug and gradually titrate up on the second, all under supervision of a physician. (Noll, Tr. 1389-90).

2. Professor Noll Deliberately Ignores Real World Events

988. Professor Noll opined that products that are functionally similar may not be economic substitutes because "of consumer preferences, because of brand reputations, brand loyalties, behavior . . . being stuck in the mud and, you know, inflexible in behavior, or simply switching costs." (Noll, Tr. 1373-74; *see* Noll, Tr. 1388).

989. None of these factors support a narrow market definition. Indeed, Professor Noll did not analyze how frequently patients are successfully switched from one extended-release opioid to another extended-release opioid. (Noll, Tr. 1525).

990. Although Professor Noll concedes that there is evidence of switching between extended-release opioids in response to price changes, Professor Noll dismisses such price-based switching as irrelevant because he claims "there's no evidence of a quantity effect of . . . any significance." (Noll, Tr. 1518-19).

991. Professor Noll similarly dismisses as irrelevant evidence that demand for oxymorphone ER increased after Impax's generic entry, with patients switching from other extended-release opioids to oxymorphone ER. (Noll, Tr. 1525).

992. And Professor Noll dismisses evidence that Opana ER experienced its highest loss rates in 2012 in part because physicians switched their patients to other extended-release opioids. Professor Noll claims instead that patients leaving Opana ER switched to heroin or other illegal drugs instead. (Noll, Tr. 1525-26).

993. The actual evidence of switching between oxymorphone ER and other extended-release opioids, however, is "very substantial evidence of switching, of competition, price-based

competition that leads to switching through formulary coverage." (Addanki, Tr. 2332). Indeed, Professor Noll's claims of no price competition among extended-release opioids is "entirely contradicted by the evidence" of competition "at the patient level and at the payer level," both of which are price competition. (Addanki, Tr. 2332).

994. For these reasons, Dr. Addanki testified that "it seems to me that when I look at the weight of the evidence, I don't see any compelling evidence that there was any lack of competition between Opana ER and any of the other LAOs." (Addanki, Tr. 2332).

995. With respect to switching costs, such costs do not apply to new patients starting opioid therapy in the first instance. (Addanki, Tr. 2330). But even for patients already on extended-release opioids, switching occurs frequently and without significant costs, as UPMC made plain. (Addanki, Tr. 2330; RX-087.0001).

996. If switching costs actually were prohibitive, "you wouldn't see the efforts by managed care and the manufactures responding to managed care to be getting the best terms possible for the most favorable position on the formulary because . . . when you see that happening, that underscores that economic substitution is in fact taking place, so whatever the switching costs were, they were not an impediment to economic substitution." (Addanki, Tr. 2330-31).

997. Professor Noll also opined that manufacturers promotional efforts "focused primarily on product differentiation," which argues against a broad product market. (Noll, Tr. 1394).

998. He argued in particular that differentiation efforts can have the effect of "undermining, rather than enhancing, price competition, and in so doing reduce[] . . . the likelihood that two products are in the same relevant market." (CX5004-027).

999. But as noted, Endo acknowledged that extended-release opioid "[p]roducts are not very differentiated," forcing Endo to emphasize Opana ER's purported advantages over other opioids, including its "12 hour dosing." (RX-023.0002).

1000. Finally, Professor Noll's opinion that clinical differences among extended-release opioids—different half-lives, side effects, interactions, or modes of metabolism—prevents them from acting as economic substitutes is not supported by evidence. (Noll, Tr. 1388; CX5000-064-66). To the extent any clinical differences exit, they did not prevent effective economic competition among extended-release opioids. (Addanki, Tr. 2329).

1001. Moreover, to the extent any clinical differences exist among extended-release opioids, they would not allow Endo or any other manufacturer "to price-discriminate among patients on the basis of their conditions," since there is no way to tell which opioid will work best in advance of treatment. (CX4039 (Noll, Dep. at 171-72); *see* Savage, Tr. 710-11; Michna, Tr. 2148-49).

XI. ENDO DID NOT POSSESS A SUBSTANTIAL SHARE OF THE EXTENDED-RELEASE OPIOID MARKET

1002. Opana ER accounted for less than 10 percent of the extended-release opioid market between 2009 and 2013. (Addanki, Tr. 2333; RX-547.0132).

1003. Dr. Addanki explained that he assessed market shares between 2009 and 2013 because that period captured the state of the market at the time of settlement as well as at the date of Impax's entry, which allows one to assess whether Endo had monopoly power at the time of settlement and whether the settlement agreement maintained monopoly power. (Addanki, Tr. 2336-37).

1004. By its own estimate, Endo held only 3.4 percent of the long-acting opioid market in March 2010, noting that it was a "well-established and competitive market that consisted of

many products that had been on the market for years." (CX3273-003 (market "comprises controlled release opioid products"); Bingol, Tr. 1315-16; *see* Noll, Tr. 1512-13 (conceding that Endo believed it held less than 10 percent of the extended-release opioid market)).

1005. [redacted] (RX-558.0001).

1006. If Impax had launched a generic version of Opana ER in 2010, Endo would have lost some of its roughly 3.5 percent market share. (Bingol, Tr. 1318-19).

1007. In 2012, Endo again estimated that it was "currently hovering around the 4% mark" of the "long acting opioid market." (RX-139.0001).

1008. As a matter of economics, it is "[a]bsolutely not" possible to exercise monopoly power if a firm holds less than 10 percent of a relevant market. (Addanki, Tr. 2334-35). "With less than 10 percent market shares, it's simply inconceivable that a product could command monopoly power. It just can't happen." (Addanki, Tr. 2333).

1009. And because Endo possessed such a small share of the extended-release opioid market, Endo never possessed monopoly power. (Addanki, Tr. 2333).

XII. THE SLA HAD NO ANTICOMPETITIVE EFFECTS

1010. Assuming that Endo actually had monopoly power, one must consider the "but-for world, what would happen but for the settlement." (Addanki, Tr. 2358-59).

1011. That analysis is a "test of consumer benefits in two worlds, the world that we actually have with the settlement that took place and a but-for world where no settlement happened." (Addanki, Tr. 2373).

1012. Put differently, the relevant question regarding anticompetitive impact is whether entry would have occurred sooner or later if not for the settlement in question. (Addanki, Tr. 2208).

1013. In this case, Impax had two options absent the settlement: (1) abandon any effort to challenge Endo's patents, or (2) continue to litigate with Endo. (Noll, Tr. 1596; *see* Addanki, Tr. 2359-60).

1014. Complaint Counsel's economic expert admits that Impax abandoning its patent challenge would have been bad for consumers. (Noll, Tr. 1667).

1015. Had Impax continued to litigate against Endo and lost, that too would have made consumers worse off. (Noll, Tr. 1667).

A. Impax Would Not Have Launched Generic Opana ER Before January 2013 If It Had Continued to Litigate Against Endo

1016. The record indicates that had Impax continued to fight Endo's patents in court, it would have been mired in litigation long past January 1, 2013, and likely would be enjoined from selling oxymorphone ER today. (Addanki, Tr. 2360; Figg, Tr. 1870-72).

1017. Indeed, even if Impax prevailed in patent litigation against Endo, the very "process of being involved in litigation" would have kept Impax from launching oxymorphone ER free from patent risk any time before January 1, 2013. (Addanki, Tr. 2497).

1. Impax Was More Likely Than Not to Lose its Patent Suit Against Endo

1018. The evidence at trial made clear that Impax was more likely than not to lose its patent suit against Endo. As discussed below, the District Court ruled in Endo's favor on all matters of claim construction, which made it more likely that Endo could prevail on the merits. (Figg, Tr. 1870). Endo also had the stronger position on the issue of validity and likely would have proved infringement. (Figg, Tr. 1884, 1904).

1019. Complaint Counsel offered no evidence regarding who would have won the underlying patent litigation between Endo and Impax, and provides no reason to find that Impax would have prevailed had it continued to litigate.

a. The District Court Rejected Impax's Construction of the Relevant Patents

1020. Every patent has clauses at the end of the patent that are called patent claims. (Figg, Tr. 1861).

1021. Patent claims define the scope of a patent holder's right to exclude others on the patent. (Figg, Tr. 1861-62).

1022. Because patent claims contain very technical terms, courts often have to rule on what the terms in those claims mean. (Figg, Tr. 1862).

1023. Court hearings in which patent claims are interpreted (or "constructed") are known as "Markman" hearings, and can involve briefs and expert testimony. (Figg, Tr. 1862).

1024. Each party advocates for the claim construction that will be most advantageous for their case going forward and, depending on the claim construction ruling, can influence how the parties present their case at trial. (Hoxie, Tr. 2833).

1025. A claim construction hearing is a "very important part of most patent litigation." (Figg, Tr. 1862-63). It can even be dispositive to the patent litigation. (Hoxie, Tr. 2671).

1026. Indeed, rulings in claim construction hearings are "oftentimes" dispositive because the defendant's non-infringement position will be undermined by how the court has construed the relevant claims. (Figg, Tr. 1863).

1027. On December 21, 2009, and March 19, 2010, the District Court presiding over the Endo-Impax litigation held claim construction hearings. (JX-003-004 (¶ 18) (Second Set of Joint Stipulations); RX-484.0002 (not admitted or cited for the truth of the matters asserted therein)).

1028. One term contested by the parties in the claim construction hearing was "hydrophobic material," which in general terms related to the hydration of an Opana ER gelling agent. (Figg, Tr. 1865-66; *see* RX-464.0011 (not admitted or cited for the truth of the matters

asserted therein); RX-465.0010 (not admitted or cited for the truth of the matters asserted therein)).

1029. The District Court adopted Endo's construction of "hydrophobic material" verbatim. (JX-003-004 (¶ 19) (Second Set of Joint Stipulations); *compare* RX-465.0028 (not admitted or cited for the truth of the matters asserted therein), *with* RX-483.0003 (not admitted or cited for the truth of the matters asserted therein) *and* RX-484.0003 (not admitted or cited for the truth of the matters asserted therein); *see* Figg, Tr. 1867; Hoxie, Tr. 2836).

1030. A second term contested by the parties at the claim construction hearing was "sustained release," which in general terms related to how the active medication was released. (Figg, Tr. 1867-68; *see* RX-464.0008 (not admitted or cited for the truth of the matters asserted therein); RX-465.0010-11 (not admitted or cited for the truth of the matters asserted therein)).

1031. Again, the District Court adopted Endo's construction of "sustained release" verbatim. (JX-003-004 (¶ 19) (Second Set of Joint Stipulations); *compare* RX-465.0015 (not admitted or cited for the truth of the matters asserted therein), *with* RX-483.0003 (not admitted or cited for the truth of the matters asserted therein) *and* RX-484.0003 (not admitted or cited for the truth of the matters asserted therein); *see* Figg, Tr. 1868; Hoxie, Tr. 2836).

1032. E. Anthony Figg, Impax's patent expert, testified that the District Court's wholesale adoption of Endo's constructions meant that Endo won the claim construction phase of the litigation. (Figg, Tr. 1869; *see* Hoxie, Tr. 2671).

1033. Mr. Figg further explained that a reasonable litigant in Impax's position would have viewed the claim construction order as a significant setback because the constructions negatively affected Impax's positions with respect to non-infringement and invalidity. (Figg, Tr. 1869-70).

1034. In fact, Mr. Figg opined that once the District Court issued its claim construction order, "a reasonable party in Impax's position would have concluded that it was less likely to . . . prevail ultimately in the patent trial." (Figg, Tr. 1870).

b. Endo Likely Would Have Proven Infringement

1035. Because ANDA filers must demonstrate that their products are therapeutically equivalent to an already-approved drug, ANDA filers must copy aspects of the brand drug and the brand label. This makes it more difficult for ANDA filers to design their products in ways that avoid the relevant patents. (Figg, Tr. 1854-55).

1036. Accordingly, brand companies win Hatch-Waxman cases more often than not and have "somewhat of an edge in these cases." (Figg, Tr. 1855). In fact, brands prevail roughly 52 percent of the time in Hatch-Waxman litigation. (Figg, Tr. 1856).

1037. Brand companies must prove a patent is infringed by a "preponderance of the evidence." (Figg, Tr. 1851; Hoxie, Tr. 2831).

1038. In the Endo-Impax litigation, Impax focused its defense on non-infringement, which was better developed in its pretrial brief than its invalidity defense. (Figg, Tr. 1872; *see* RX-260.0009 (not admitted or cited for the truth of the matters asserted therein)).

1039. Even so, Mr. Figg opined that Endo had the stronger position on the issue and likely would have proved infringement. (Figg, Tr. 1884).

1040. With respect to the "hydrophobic material" at issue, the District Court's claim construction ruling necessarily called for evidence regarding the manner in which Impax's material inhibited (or not) water uptake. (Figg, Tr. 1874-75).

1041. Indeed, Endo's "functional" definition of "hydrophobic material," which the District Court adopted, "would have required some kind of testing" to meet. (Hoxie, Tr. 2836;

see Figg, Tr. 1874-75). Impax's rejected construction of "hydrophobic material," by comparison, "described what the material is [and] what it does" only. (Figg, Tr. 1865-66).

1042. The result was a battle of the experts between Endo and Impax experts. (Hoxie, Tr. 2840).

1043. Endo had experts supervise tests in which water uptake in Impax tablets was measured. Endo contended that those tests demonstrated that Impax's tablets inhibited water uptake in a way similar to the materials in Endo tablets. (Figg, Tr. 1874; *see* RX-261.0015-18 (not admitted or cited for the truth of the matters asserted therein); RX-469.0019-23 (not admitted or cited for the truth of the matters asserted therein)).

1044. Impax, on the other hand, did not conduct any tests regarding water uptake in its hydrophobic materials, it simply criticized the testing done by Endo. (RX-261.0017 (not admitted or cited for the truth of the matters asserted therein); *see* RX-260 (not admitted or cited for the truth of the matters asserted therein); Figg, Tr. 1874; Hoxie, Tr. 2839).

1045. Accordingly, Mr. Figg testified that Endo likely would have established infringement of its hydrophobic material. (Figg, Tr. 1875).

1046. As to the "sustained release" technology at issue, Endo's experts presented evidence of how Impax's product compared to Endo's product. (RX-261.0013-15 (not admitted or cited for the truth of the matters asserted therein); Figg, Tr. 1876).

1047. Indeed, because Impax's product had to be bioequivalent to Endo's product to secure ANDA approval, Impax itself had to show the FDA (1) that its product released the oxymorphone drug in a way similar to Endo's product and (2) achieved the same maximum blood concentration and the same extent of delivery of the drug. (Figg, Tr. 1876-77).

1048. Endo's experts consequently used the pharmacokinetic data Impax submitted to the FDA to contend that Impax's product released oxymorphone nearly identically to Endo's product. (Figg, Tr. 1877; *see* RX-261.0013-15 (not admitted or cited for the truth of the matters asserted therein)).

1049. Impax presented no expert testimony regarding the "sustained release" technology. (RX-260.0017-18 (not admitted or cited for the truth of the matters asserted therein); RX-261.0013-15 (not admitted or cited for the truth of the matters asserted therein); Figg, Tr. 1875-76).

1050. Mr. Figg testified that Endo consequently had the stronger position on "sustained release" infringement. (Figg, Tr. 1880-81).

1051. A third infringement issue related to "homopolysaccharide gum," a component necessary to form a gel in the finished product. (Figg, Tr. 1881; *see* RX-261.0019 (not admitted or cited for the truth of the matters asserted therein)).

1052. Endo's experts contended that the relevant component in Impax's oxymorphone ER product was actually described in Endo's patent. (RX-473.0005-06 (not admitted or cited for the truth of the matters asserted therein)).

1053. As a result, Mr. Figg opined that Endo was likely to prove infringement of the homopolysaccharide gum technology as well. (Figg, Tr. 1883-84).

c. Endo Likely Would Have Demonstrated its Patents Were Valid

1054. In Hatch-Waxman litigation, generic companies must prove a patent is invalid by "clear and convincing" evidence. (Figg, Tr. 1885; Hoxie, Tr. 2845).

1055. Impax raised three arguments claiming that Endo's patents were invalid: (1) the claims were anticipated; (2) the claims were obvious; and (3) the claims were not supported by

an adequate written description. (RX-260.0021-38 (not admitted or cited for the truth of the matters asserted therein); Figg, Tr. 1889).

1056. Anticipation may invalidate a patent claim if there is an already-existing, publicly-available description of the elements of the challenged patent claim, arranged in the same way. (Figg, Tr. 1889-90).

1057. Endo argued that to prove the hydrophobic material was anticipated, Impax had to prove that a substance in the public domain inhibited water uptake in the same way as Endo's patent claim. But Impax did not test any of the formulations in the public domain to demonstrate whether they inhibited water uptake. (Figg, Tr. 1895-96; Hoxie, Tr. 2846; *see* RX-261.0026-29 (not admitted or cited for the truth of the matters asserted therein)).

1058. Mr. Figg consequently testified that Endo was likely to rebut claims of invalidity by means of anticipation. (Figg, Tr. 1896).

1059. The second invalidity issue, obviousness, prohibits a patentee from taking something away from the public that, while not yet existing in literal form, would have been obvious based on existing patents. (Figg, Tr. 1897).

1060. Endo argued that Impax failed to advance evidence establishing that existing patents described hydrophobic material and sustained release in a way similar to Endo's patents. (RX-261.0030-32 (not admitted or cited for the truth of the matters asserted therein)).

1061. Endo also argued that Opana ER had been a commercial success and met unfulfilled needs, indicating that it was not obvious before Endo's actions. (RX-261.0032-34 (not admitted or cited for the truth of the matters asserted therein)).

1062. On the basis of these arguments, Mr. Figg opined that Endo was likely to prevail on the obviousness issue. (Figg, Tr. 1898-99, 1900-01).

1063. The third invalidity issue, an adequate written description, relates to a patentee's obligation to provide full disclosure of its invention. (Figg, Tr. 1902).

1064. Impax challenged Endo's written description of how long it would take from ingestion of a tablet until there is maximum blood plasma concentration. (RX-260.0036-38 (not admitted or cited for the truth of the matters asserted therein); RX-261.0035-36 (not admitted or cited for the truth of the matters asserted therein)).

1065. Endo argued that the range of time for maximum blood plasma concentration was expressly disclosed in its patent application. (RX-261.0036 (not admitted or cited for the truth of the matters asserted therein)).

1066. For this reason, Mr. Figg opinioned that Endo was likely to prevail on the written description issue of patent validity. (Figg, Tr. 1903-04).

*** * ***

1067. If Endo prevailed on just one of the infringement and validity claims, the District Court would have issued an injunction preventing Impax from marketing its product until Endo's patents expired in September 2013. (Figg, Tr. 1871, 1904-05).

1068. But Endo was more likely than not to prevail on every claim. (Figg, Tr. 1884, 1904).

1069. Mr. Figg consequently testified that "[g]iven everything I've seen and factoring in my evaluation or my assessment of how that patent litigation was likely to come out . . . I think this was a very reasonable [settlement license] date for Impax to agree to. It allowed them to get on the market eight months before these patents would expire." (Figg, Tr. 1927-28).

1070. The SLA's January 1, 2013, entry date did not represent a "delay of entry compared to the date Impax could have reasonably expected to enter had it not settled." (Figg, Tr. 1928).

d. All Other ANDA Filers Settled Similar Litigation

1071. As discussed above, Endo also sued Actavis and all other Opana ER ANDA filers, alleging patent infringement of the '456 and '933 patents. (Snowden, Tr. 440).

1072. Those ANDA filers—Actavis, Barr, Sandoz, Watson Labs, and Roxane Labs—were all large sophisticated companies accustomed to patent litigation. (Figg, Tr. 1944-45).

1073. Yet each ANDA filer settled its suit against Impax. (Snowden, Tr. 440; RX-441; RX-442; RX-443; CX3192).

1074. The fact that each company decided to settle Endo's '456 and '933 patent infringement claims "reinforces the notion that it was probably a prudent decision for Impax to settle." (Figg, Tr. 1944-45).

2. Even if Impax Prevailed in its Initial Litigation Against Endo, Impax Could Not Have Launched Risk-Free Earlier than January 1, 2013

1075. If Impax had not settled with Endo and kept litigating the underlying patent suit, it likely would have been tied up in litigation until 2013, even if it ultimately prevailed. Indeed, following a trial, the parties would have had to wait for the District Court to issue findings of fact, conclusions of law, and an order. Mr. Figg testified that it would take four to five months after the trial concluded to receive the District Court's decision. (Figg, Tr. 1906-07).

1076. This means that the earliest the parties could have expected a District Court decision was November 2010. (Figg, Tr. 2027-28).

1077. But as Mr. Hoxie explained, judges can take "their own sweet time" in releasing opinions in patent infringement cases. (Hoxie, Tr. 2860).

1078. For instance, in one of Endo's subsequent patent suits against Opana ER ANDA filers, it took the district court nearly twelve months to issue a decision after trial. (Hoxie, Tr. 2867-68).

1079. Whenever the District Court would have issued its decision in the Endo-Impax litigation, an appeal was likely, and would take thirty days to docket in the Federal Circuit. (Figg, Tr. 1908).

1080. The earliest the parties could have expected a decision from the Federal Circuit was November 2011. (Figg, Tr. 1908-09).

1081. That estimate, however, is "very conservative" since the median time from docketing to final decision was approximately 11 months in 2010 and 2011, and that takes into account settlements and summary affirmances. (Figg, Tr. 1908-09).

1082. Indeed, the Federal Circuit is generous with briefing extensions, which increases the time it takes to receive a decision. (Figg, Tr. 1909-10).

1083. It was possible that the Federal Circuit would not have issued a decision until long after November 2011. (Figg, Tr. 1908-09; Hoxie, Tr. 2865).

1084. But the earliest Impax could theoretically have launched free from risk would have been some point in November 2011. (Figg, Tr. 1911).

1085. If Impax had lost at the trial level, the Federal Circuit appeal likely would have focused on the trial court's claim construction ruling, in part because Impax would have had "substantial arguments" regarding that ruling on appeal. (Hoxie, Tr. 2694; *see* Figg, Tr. 1911-12).

1086. This means that even if Impax prevailed on appeal, the Federal Circuit likely would have remanded the case to the trial court. (Figg, Tr. 1911-12).

1087. As Mr. Figg explained, a remand would have been highly likely if Impax prevailed on appeal because the parties would need to dispute infringement and validity under Impax's construction of the claims. Given the trial court's claim construction ruling in favor Endo, Endo never developed a record that Impax infringed its patents under Impax's construction of the claims. And absent a record on the issue of infringement and validity, the Federal Circuit would not decide the issue in the first instance, leaving that task to the trial court. (Figg, Tr. 1912-13).

1088. The need for remand proceedings would have further delayed a risk-free launch between six and eighteen months, with remand proceedings likely taking close to eighteen months. (Figg, Tr. 1914-15).

1089. Mr. Figg consequently concluded that even if Impax could have prevailed against Endo in the underlying patent litigation, it would not have done so until after January 1, 2013, the date the parties agreed to in their settlement agreement. (Figg, Tr. 1927, 1973).

1090. If Impax had lost at the Federal Circuit, however, it would be enjoined and would not have been able to launch its oxymorphone ER product until September 2013 at the earliest. (Figg, Tr. 1973).

1091. Taken together, Mr. Figg explained that Impax's decision to settle with Endo for a January 1, 2013, entry date was "a very reasonable and prudent decision" because it "got them on the market eight months before the patent[s] expired," Impax "avoided the uncertainty that remained in the patent litigation," and Impax was able to launch at roughly the same time they would have "if they had prevailed in everything" in the initial litigation. (Figg, Tr. 1976; *see* Hoxie, Tr. 2665, 2753 (patent litigation is uncertain)).

3. Even if Impax Prevailed in its Initial Litigation Against Endo, Impax Would Now be Enjoined from Selling Oxymorphone ER

1092. As noted above, after entering the Settlement and License Agreement, Endo obtained additional patents and patent licenses that it has asserted cover both original and reformulated Opana ER. (JX-001-012 (¶ 55) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

1093. This real world behavior demonstrates that Endo had economic incentives to be "very assiduous about acquiring and asserting more patents against all the ANDA filers on original and reformulated Opana ER. It got its own patents as well as acquired patents from others and asserted them against the generic companies." (Addanki, Tr. 2360; *see also* Addanki, Tr. 2374).

1094. Indeed, even if Impax had won the initial litigation in November 2011, Impax likely would not have been able to launch risk-free because (1) the Johnson Matthey patent that was later acquired by Endo had issued at the end of 2010; (2) Endo was on notice of that patent as early as 2009; and (3) Endo would have had incentive to acquire the Johnson Matthey patent earlier in the but-for world than it did in the actual world. (Addanki, Tr. 2362-63, 2374-75; RX-102.0003).

1095. Additionally, in August 2015, the U.S. District Court for the Southern District of New York held that Endo's later-acquired '122 and '216 patents were not invalid and were infringed by other companies' generic versions of original Opana ER, but not by Impax's product, and by generic versions of reformulated Opana ER, including Impax's. (JX-001-013 (¶ 62) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 441, 445-46).

1096. The court issued an injunction barring all defendants except Impax from selling their generic versions of original Opana ER until 2023. The ruling is currently on appeal to the

Federal Circuit. (JX-001-013 (¶ 62) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

1097. In October 2016, the U.S. District Court for the District of Delaware held that Endo's later-acquired '779 patent was not invalid and was infringed by a generic version of reformulated Opana ER. The ruling is currently on appeal to the Federal Circuit. (JX-001-013 (¶ 64) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); *see* Snowden, Tr. 441-42).

1098. In fact, the defendants in the District of Delaware litigation stipulated that their generic versions of Opana ER infringed the '779 patent. (Figg, Tr. 1965).

1099. The '779 patent expires in 2029, which means that no generic ANDA filer can sell their generic Opana ER products until 2029. (Snowden, Tr. 451; Figg, Tr. 1965-66; *see* CX3255).

1100. Thus, even in an alternative "but-for" world in which Impax prevailed in its initial patent suit against Endo, it would have needed to prevail against Endo's additional patent claims in order to launch and continue selling oxymorphone ER risk free. (Figg, Tr. 1951, 1963-64).

1101. But no generic manufacturer has been able to overcome Endo's patent portfolio. This indicates that absent the broad patent license found in the SLA, Impax's oxymorphone ER product likely would be enjoined today like every other generic oxymorphone ER product. (Figg, Tr. 1975-76).

1102. As Mr. Figg explained, had Impax continued to litigate against Endo, "Impax wouldn't be on the market in the foreseeable future" because multiple court decisions have enjoined all other ANDA filers until 2023 and 2029. (Figg, Tr. 1972).

1103. But even if Impax could have prevailed in each of Endo's many subsequent patent suits, Impax would still have needed to litigate against Endo for years (including until today). (Addanki, Tr. 2360; Figg, Tr. 1951, 1963-64).

1104. "Endo and Impax would have been embroiled in continuing patent litigation" until well beyond January 2013 absent the settlement. (Addanki, Tr. 2376-77).

1105. That years-long involvement in high-stakes litigation is itself relevant. As Dr. Addanki testified, "regardless of who would have won the litigation ultimately, it was the process of being involved in the litigation and having to consider launching at risk" that was relevant in keeping Impax from launching risk-free any time before January 1, 2013. (Addanki, Tr. 2497).

4. Complaint Counsel's Patent Expert Offers No Evidence that Impax Would Have Launched Before January 2013 Had Impax Continued to Litigate

a. No Opinions Regarding Likely Litigation Outcomes

1106. Complaint Counsel's patent expert, Thomas Hoxie, does not offer any opinion on the ultimate outcome of the Endo-Impax litigation. (Hoxie, Tr. 2751-52).

1107. Mr. Hoxie does not offer any opinion on the strength of either party's litigation positions before the claim construction hearing. (Hoxie, Tr. 2835).

1108. With respect to litigation after the District Court issued its claim construction ruling, Mr. Hoxie did not calculate the probability that Endo would have won the patent litigation. (Hoxie, Tr. 2752-53).

1109. Nor did Mr. Hoxie opine that Impax would have won the patent litigation against Endo. (Hoxie, Tr. 2693).

1110. Mr. Hoxie does not offer an opinion regarding which party would have prevailed on issues of infringement. (Hoxie, Tr. 2841).

1111. Mr. Hoxie does not offer an opinion about which party would have prevailed on the issue of invalidity. He opined only that Impax's arguments could have made it more difficult for Endo to prevail. (Hoxie, Tr. 2845).

1112. Mr. Hoxie does not offer any opinions about whether the claims in the patents were obvious or how a court was likely to resolve the issue of invalidity by means of written description. (Hoxie, Tr. 2852).

1113. With respect to an appeal to the Federal Circuit, Mr. Hoxie again offered no opinion with respect to how the Federal Circuit would have ruled. (Hoxie, Tr. 2694).

1114. Mr. Hoxie conceded, however, that for Impax to avoid an injunction, Impax would have needed to prevail against every claim at issue at every stage of litigation. (Hoxie, Tr. 2835).

b. Mr. Hoxie Generally Accepts the Timing of Patent Litigation

1115. Mr. Hoxie testified that he did not "have any dispute" with the estimates advanced by Mr. Figg regarding the timing of patent litigation because "each of those individual steps are, you know, fair, reasonable, conservative average estimates." (Hoxie, Tr. 2860-61).

1116. Mr. Hoxie, agreed, for instance, that the time between docketing of an appeal and receiving a decision from the Federal Circuit would take roughly one year, but could take longer. (Hoxie, Tr. 2865).

1117. Mr. Hoxie also agreed that district court opinions can take even longer than the estimates advanced by Mr. Figg. (Hoxie, Tr. 2868).

1118. Mr. Hoxie's sole disagreement on the likely timing of the Endo-Impax litigation is whether a remand would be necessary. (Hoxie, Tr. 2864).

1119. Mr. Hoxie admitted, however, that a remand "was a possibility." (Hoxie, Tr. 2864).

1120. He also admitted that a remand is appropriate when there is a need for further findings of fact. (Hoxie, Tr. 2874). And Mr. Hoxie noted that claim construction rulings can change how parties present their case, keeping them from advancing certain arguments based on the claim construction rulings. (Hoxie, Tr. 2874-75).

c. Mr. Hoxie Lacks Experience With Hatch-Waxman Litigation

1121. Despite opining on the Hatch-Waxman litigation between Endo and Impax, Mr. Hoxie has never represented ANDA filers in court. (Hoxie, Tr. 2743).

1122. In fact, in the last thirteen years, Mr. Hoxie has never set foot in a courtroom on behalf of a generic pharmaceutical company in Hatch-Waxman litigation. (Hoxie, Tr. 2757).

1123. Mr. Hoxie has never argued in a claim construction hearing. (Hoxie, Tr. 2744).

1124. Mr. Hoxie has only been involved with a single at-risk launch in any capacity. (Hoxie, Tr. 2761-63).

1125. And Mr. Hoxie has no experience litigating in front of the judge who presided over the Endo-Impax patent litigation. (Hoxie, Tr. 2871).

B. Impax Would Not Have Launched At Risk

1126. Absent the settlement, the only possibility of a pre-2013 launch by Impax would have been an at-risk launch. (Addanki, Tr. 2363, 2378-79).

1127. There is no evidence that Impax was planning to launch at risk or that it would have launched generic Opana ER at risk absent the settlement with Endo.

1. At-Risk Launches Generally

1128. Launching a generic product before a non-appealable decision in a relevant patent challenge is commonly known as an "at-risk launch." (JX-001-008 (¶ 23) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); *see* Koch, Tr. 246; Bingol, Tr. 1282; Hoxie, Tr. 2831).

1129. An at-risk launch is a "very serious risk." (Koch, Tr. 286-87; *see* Hoxie, Tr. 2810, 2830 (when "you're in litigation, of course, [the risks of a launch] are relatively high" and represent "a high-risk" action)).

1130. If a generic company launches a product before a non-appealable court decision or patent expiration, brand companies can seek damages measured by their own lost profits rather than the generic's earned profits. (Koch, Tr. 286-87; CX4030 (Hsu, Dep. at 48-49)).

1131. Lost profits are measured by the profits the patent owner would have made on sales of its branded product but for the launch of the generic product. (Figg, Tr. 1921-22; Hoxie, Tr. 2782).

1132. Those damages can be trebled if the infringement is found to be willful, for instance, launching before a district court rules on the patent dispute. (Figg, Tr. 1923; Hoxie, Tr. 2782).

1133. In fact, if a generic company launches it product before the district court rules on the patent challenge, the case generally shifts from one seeking an injunction in a bench trial to a case in which damages are tried to a jury. (Figg, Tr. 1918).

1134. Mr. Figg testified that jury trials are more beneficial to patent owners because if "a jury is confused and doesn't understand these arguments, then basically [the jury] is left with saying I haven't been clearly and convincingly persuaded that the challenger has won its case." (Figg, Tr. 1919-20).

1135. Generic companies consequently risk far more in infringement liability than they earn from each sale when launching at risk. (Koch, Tr. 286-87; CX4039 (Noll, Dep. at 74); CX4021 (Ben-Maimon, Dep. at 159) (at-risk launches could result in generic "pay[ing] more to the brand company than [generic] made")).

1136. Indeed, given the differences in generic and branded pricing, the "ratio of [generic] profits to [damages] risk could be something like one to ten." (CX4002 (Smolenski, IHT at 18-19); *see* CX4037 (Smolenski, Dep. at 69)).

1137. Such damages represent "bet-the-company" stakes and can "take the solvency of the company entirely." (Koch, Tr. 287; *see* CX4030 (Hsu, Dep. at 43) ("the risk can be huge depending on the size of the product and depending on whether we're first to file")).

1138. Damages can be in the billions of dollars if the sales of the branded drug are high enough. (Hoxie, Tr. 2782).

1139. Mr. Figg testified that he could not "think of any situation where it would" be profitable for a generic company to pay lost-profit damages since "the profits that the brand company loses would almost always be greater than the total revenues that the generic company receives." (Figg, Tr. 1922-23; *see* Addanki, Tr. 2379-80).

1140. An at-risk launch also jeopardizes a first-filer's 180-day exclusivity period, which is "extremely valuable." (Hoxie, Tr. 2754, 2778-79; *see* Snowden, Tr. 503-04; Figg, Tr. 1923; Noll, Tr. 1606; CX4021 (Ben-Maimon, Dep. at 164-65)).

1141. Indeed, the 180-day exclusivity period is an "important carrot[] that helps induce generic companies to file ANDAs." (Addanki, Tr. 2381).

1142. If a patentee successfully moves for an injunction following an at-risk launch, the infringer forfeits its generic exclusivity because the 180-day clock would continue to run during the period the infringer is enjoined from making sales. (Snowden, Tr. 503-04; Figg, Tr. 1923; CX4039 (Noll, Dep. at 234-35)).

1143. Even if the injunction was eventually lifted or the infringer prevailed in the underlying patent litigation, the infringer could never recover its 180-day exclusivity. (Snowden, Tr. 503-04; Figg, Tr. 1924; Hoxie, Tr. 2780).

1144. Courts can also award attorney's fees to the brand company if the generic's actions are deemed "exceptional." (Figg, Tr. 1924).

1145. At-risk launches consequently are rare across the entire pharmaceutical industry. (Figg, Tr. 1924-26; *see* Hoxie, Tr. 2827-28 (agreeing that at-risk launches between 2003 and 2009 were "fairly uncommon")).

1146. At-risk launches are "most common" when there are multiple ANDA filers who have received approval from the FDA, no ANDA filer has exclusivity, and there subsequently is a race to the market. (Hoxie, Tr. 2704-05).

1147. And when at-risk launches do occur, they generally are undertaken by large pharmaceutical companies that can absorb significant financial risk in the event they are found to infringe. (Figg, Tr. 1925).

1148. Over a fifteen year period, Professor Noll identified only forty-eight at-risk launches. (Noll, Tr. 1606-07).

1149. Twenty-one of those forty-eight at-risk launches were conducted by Teva, which Professor Noll explains "is by far the most likely company to do at-risk launches." (Noll, Tr. 1608-09).

1150. Teva is a "very large pharmaceutical company" and, as a result, can undertake at-risk launches more regularly. (Figg, Tr. 1925).

1151. Mr. Hoxie noted that Teva has "a high willingness to take risks" and "a greater appetite for risk than others." (Hoxie, Tr. 2820).

1152. Only four at-risk launches in Professor Noll's fifteen-year analysis were conducted by companies with less than $1 billion in revenue. (Noll, Tr. 1609).

1153. And Professor Noll does not know if any of the at-risk launches he identified involved a first-to-file company, or how forty-eight launches over a period of fifteen years compares to the number of Hatch-Waxman cases brought during the same period. (Noll, Tr. 1607-08).

1154. Mr. Hoxie similarly has not done any empirical work to quantify how many at-risk launches occur relative to the number of Hatch-Waxman cases filed. (Hoxie, Tr. 2822).

1155. But Mr. Hoxie agrees with industry analysts who empirically analyzed at-risk launches between 2003 and 2009 that "at-risk launches are fairly uncommon." (Hoxie, Tr. 2827-28).

1156. Indeed, in comparison to the forty-eight at-risk launches that occurred over a fifteen year period, hundreds of Hatch-Waxman claims are filed every year. (Hoxie, Tr. 2824). Between 2009 and 2016, the lowest number of Hatch-Waxman cases filed in any single year was 236. (Hoxie, Tr. 2824). The highest number of Hatch-Waxman cases filed in a single year was 468. (Hoxie, Tr. 2824). All told, between 2009 and 2016 an average of 269 Hatch-Waxman cases were filed every year. (Hoxie, Tr. 2824-25).

2. Impax's Limited History of At-Risk Launches

1157. Impax is a small pharmaceutical company. (Koch, Tr. 275, 287; *see* Figg, Tr. 1925).

1158. Impax consequently is "incredibly conservative" with respect to at-risk launches. (CX4021 (Ben-Maimon, Dep. at 34); *see* Koch, Tr. 287).

1159. It "is very important for [Impax] to have a . . . risk-free launch" before it enters any market. (CX4014 (Hsu, IHT at 117)).

1160. Impax does not "want to risk [its] business on any one particular situation, product, lawsuit, and we were very careful." (Koch, Tr. 287).

1161. Arthur Koch, Impax's Chief Financial Officer at the time of settlement, explained that "being a small company" Impax "could not bet the company on any one product." (Koch, Tr. 275; *see* CX4018 (Koch, Dep. at 97) (describing risks as "huge")).

1162. Mr. Hoxie, Complaint Counsel's patent expert, agreed, noting that "a smaller company like Impax [] maybe doesn't have the resources to spend money willy-nilly." (Hoxie, Tr. 2772; *see* CX4026 (Nguyen, Dep. at 127) ("given Impax's bank account, it should be and it was risk adverse")).

1163. Accordingly, Impax only "infrequently" considers the possibility of an at-risk launch. (Koch, Tr. 246-47).

1164. During Mr. Koch's tenure as Impax CFO between 2005 and 2012, for example, Impax launched a product at risk only once. (Koch, Tr. 274).

1165. That launch involved a generic version of oxycodone. (Koch, Tr. 274).

1166. But Impax launched the product only after it received a favorable district court decision holding the relevant patents unenforceable. (Snowden, Tr. 425-26; Koch, Tr. 275). And Impax launched the product in only one dosage strength. (Snowden, Tr. 425).

1167. Impax launched that single dosage strength only after Teva, the first ANDA filer for the relevant dosage, had launched at risk six months earlier. (Snowden, Tr. 425; *see* Noll, Tr. 1609-10).

1168. And Impax limited its risk of damages by capping its potential sales at $25 million. (Koch, Tr. 275).

1169. The risks to a second generic company launching at risk are much lower than an initial at-risk launch because (1) they do not have first-filer exclusivity at stake, and (2) the patent holder may have a harder time arguing that damages are the result of a particular generic's sales. (Hoxie, Tr. 2817).

1170. Apart from the limited oxycodone launch, Impax had not pursued any other at-risk launches at the time of Endo-Impax settlement. (Snowden, Tr. 424, 426).

1171. After the settlement in 2010, Impax has considered just three possible at-risk launches. (CX2927-014-19). Only one of those launches occurred, and only in a very limited fashion. (Snowden, Tr. 466-67).

1172. Impax's post-settlement launch involved a drug called azelastine, a nasal spray antihistamine. (Snowden, Tr. 462).

1173. Impax and Perrigo, the ANDA holder and marketer of azelastine, entered a partnership agreement in which Impax would share development costs and litigation expenses in return for a share of the drug's profits. (Snowden, Tr. 462; CX4021 (Ben-Maimon, Dep. at 153)).

1174. In 2014, Perrigo notified Impax that it intended to launch azelastine at risk. (Snowden, Tr. 462).

1175. Under the terms of the Impax-Perrigo partnership agreement, Impax could participate in the launch and earn a share of the profits or not participate, in which case Perrigo would receive all azelastine profits. (Snowden, Tr. 462).

1176. Impax participated in Perrigo's at-risk launch, but again limited its exposure to potential damages by capping its participation at 150,000 units. (Snowden, Tr. 464-65; CX4021 (Ben-Maimon, Dep. at 37-39); CX2689 (minutes of special meeting of Impax Board)).

1177. The azelastine launch lasted only a few days because Perrigo and Impax negotiated a settlement agreement with the brand company. (Snowden, Tr. 466-67; CX4021 (Ben-Maimon, Dep. at 39-40)).

1178. Margaret Snowden, Impax's in-house attorney responsible for Intellectual Property and the highest ranking lawyer at Impax at the time of the settlement, has never been asked to give a recommendation to the Board of Directors on whether or not Impax should launch a product at risk where Impax held first-to-file exclusivity. (JX-003-011 (¶ 71) (Second Set of Joint Stipulations); Snowden, Tr. 507-11).

3. Impax's Board of Directors Must Approve Every At-Risk Launch

1179. It is an absolute prerequisite for Impax's Board of Directors to formally approve any at-risk launch. (Koch, Tr. 276-77 ("every at-risk launch is a board-level decision"); Snowden, Tr. 426; CX4030 (Hsu, Dep. at 128); CX4021 (Ben-Maimon, Dep. at 160)).

1180. Carole Ben-Maimon, the former President of Impax's Generics Division, explained that "[i]f there was any kind of liability at all, it went to the Board. Impax is incredibly conservative." (CX4021 (Ben-Maimon, Dep. at 34).

1181. Impax has "to have sign off from the Board, because we're such a small company, and a launch at risk would . . . potentially cause our company problems if we were hit with damages, big damages." (CX4026 (Nguyen, Dep. at 55-56)).

1182. Put differently, Impax is "a very small company, and we didn't have a lot of money, and so launches at-risk would be a big thing." (CX4026 (Nguyen, Dep. at 121)).

1183. But even for large pharmaceutical companies, board approval of at-risk launches is common. At Novartis, one of the largest pharmaceutical companies in the world, at-risk launches are board-level decisions. (Hoxie, Tr. 2770-71).

1184. Still, Impax's process for deciding whether to launch at risk is "the most significant effort" undertaken by the company. (Koch, Tr. 276).

1185. And while every product evaluation is unique, the process of evaluating possible at-risk launch starts with Impax's New Product Committee evaluating the science, marketing opportunity, and legal issues related to the drug. (Koch, Tr. 276).

1186. If the New Product Committee recommends an at-risk launch, Impax's Research and Development team conducts further due diligence regarding the potential product. (Koch, Tr. 276).

1187. Impax's in-house legal team also conducts further analysis regarding the specifics of the patent litigation between Impax and the brand company, as well as the strength of the underlying patents. (Koch, Tr. 276; CX4021 (Ben-Maimon, Dep. at 166)).

1188. Impax's division heads, including those from the legal department, marketing, operations, and the generics division, then meet with Impax's CFO to formulate a risk analysis profile regarding a potential launch. (Koch, Tr. 276).

1189. The CFO then presents the risk analysis profile to Impax's Executive Committee which has to approve any at-risk launch. (Koch, Tr. 276-77).

1190. Impax's Chief Executive Officer must also approve any decision to launch at risk. (CX4030 (Hsu, Dep. at 127); CX4021 (Ben-Maimon, Dep. at 167-68)).

1191. If the CEO and Executive Committee approve a possible at-risk launch, Impax senior management then makes a "very formal presentation" to Impax's Board of Directors regarding the recommendation to launch at risk. (Koch, Tr. 277; *see* CX2689 (minutes of special meeting of Impax Board); CX3223 (same)).

1192. The presentation is made by Impax's CFO, the legal department, president of the generics division, and the manufacturing department. (Koch, Tr. 277).

1193. The Board presentation includes background on the product, the basis for the Executive Committee's decision to propose an at-risk launch, and a formal resolution seeking the Board's vote on the matter. (Koch, Tr. 277).

1194. The Board presentation would also include any recommendations about limitations on at-risk sales in order to mitigate potential damages. (Koch, Tr. 278).

1195. Such limitations on sales are formulated "[t]hrough a deliberation among the executive committee" in which it decides "how much of the capital of the company we felt we could put at risk in this type of launch scenario, and based on that, we would do a calculation" on what the company could absorb. (Koch, Tr. 278).

1196. Mr. Koch testified that when he was CFO of Impax, the Board "would often drill us on whatever interests or questions they had" following the formal presentation. (Koch, Tr. 285).

1197. In those instances, the Executive Committee would ask the Board to "appoint a special committee so that we could have time to collect the answers to their questions and report back to the board those answers and use the special committee as a tool during the evaluation by the board." (Koch, Tr. 285-86).

1198. Once all of the Board's questions and concerns are addressed, the Executive Committee returns to the Board of Directors for a full vote on a resolution approving an at-risk launch. (Koch, Tr. 277, 285-86 (Mr. Koch personally would "draft a resolution seeking [the Board's] vote")).

1199. If the Board formally authorizes an at-risk launch, the approval is recorded in the Board of Director's Minute Book. (Koch, Tr. 286).

1200. In the case of azelastine, the nasal spray antihistamine, Impax senior management, including the president of Impax's generics business, Impax's General Counsel, and Margaret Snowden, Impax's in-house attorney responsible for Intellectual Property, made a formal presentation and recommendation regarding a limited at-risk launch at a special Board of Directors meeting. (Snowden, Tr. 463-64; CX4021 (Ben-Maimon, Dep. at 153-54); CX2689 (minutes of special meeting of Impax Board regarding azelastine)).

1201. A formal resolution was then placed before the board, and the board formally voted to approve the resolution. (Snowden, Tr. 466).

1202. But even with Board authorization, Impax may not launch at-risk given the dynamics in underlying patent litigation and the market, or the limitations placed on the launch. (Koch, Tr. 286; CX4026 (Nguyen, Dep. at 56) ("even after Board approval, senior management still has the decision to pull the trigger or not")).

1203. Impax, for instance, considered an at-risk launch of dutasteride, a medicine used to treat conditions of the prostate. (Snowden, Tr. 467; CX4021 (Ben-Maimon, Dep. at 156)).

1204. The Impax Board formally approved an at-risk launch after a formal recommendation from senior management, with the limitation that no launch could occur unless and until the district court hearing an underlying patent suit between Impax and the brand company issued a favorable decision. (Snowden, Tr. 467-69; CX4021 (Ben-Maimon, Dep. at 156-58); CX3223 (minutes of special meeting of Impax Board regarding dutasteride)).

1205. Impax never launched dutasteride because the district court ruled against Impax. (Snowden, Tr. 470; CX4021 (Ben-Maimon, Dep. at 157)).

4. Impax Management Never Sought or Obtained Board Approval to Launch Oxymorphone ER At Risk

1206. Impax would never launch a product at-risk absent Board approval. (Snowden, Tr. 470).

1207. And as described below, Impax senior management never decided to pursue an at-risk launch or requested Board approval for an at-risk launch. (Koch, Tr. 299, 324-25; Snowden, Tr. 470-71).

a. Senior Management Never Decided to Pursue an At-Risk Launch

1208. Impax's senior management never decided to pursue an at-risk launch of generic Opana ER. (Mengler, Tr. 547-48, 584; CX4002 (Smolenski, IHT at 99) ("there was never a 'final decision' to launch")).

1209. In fact, Impax senior management did not believe a limited at-risk launch was a good business strategy for generic Opana ER. (Snowden, Tr. 503-04).

1210. Impax was the first ANDA filer for most dosage strengths and "when a generic launches at risk, being enjoined is quite [] possible, and so if you launch at risk and then you get enjoined, the 180-day clock will keep ticking . . . and so the generic company loses the value of the 180-day exclusivity period." (Snowden, Tr. 503-04).

1211. Mylan, another pharmaceutical company, faced that exact scenario. It launched at risk following a favorable district court ruling. The same district court, however, enjoined Mylan from making any sales, which resulted in its loss of the 180-day exclusivity period. (Snowden, Tr. 505-06).

1212. Impax's CFO at the time of settlement was unequivocal that Impax never intended to launch an oxymorphone ER product at risk:

> JUDGE CHAPPELL: Are you a hundred percent certain you would be aware of whether or not Impax planned an at-risk launch of Opana ER? WITNESS: Absolutely. I would have a key role in that. JUDGE CHAPPELL: Do you know in fact whether Impax intended an at-risk launch of Opana ER? . . . THE WITNESS: I do know. JUDGE CHAPPELL: Did they intend to do an at-risk launch of Opana ER? THE WITNESS: No.

(Koch, Tr. 324-25).

1213. Indeed, when Impax's ANDA received tentative FDA approval in May 2010, Impax's CEO, Larry Hsu, informed Arthur Koch, Impax's CFO, that "it's unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reason[s])." (RX-297.0002).

1214. Dr. Hsu further explained that that "mostly likely we will make launch decision based on court decision on the PI." (CX2929-001).

1215. This meant that the earliest Impax would even consider an at-risk launch was after a favorable court ruling regarding the Endo patent suit. (Koch, Tr. 310; Hoxie, Tr. 2770; *see* CX0008-002 (May 2010 email from Larry Hu stating that a "special Board conference call" would be necessary)).

1216. When customers inquired about the status of Impax's Opana ER product, Impax sales team consequently noted that "[a] launch decision has not been made yet. There is nothing we can tell the customers yet." (RX-323.0001).

1217. Impax also told the court presiding over the Endo-Impax patent litigation that Impax would not launch at-risk during trial. (Snowden, Tr. 471-72; RX-251 (letter to court)).

b. Senior Management Never Recommended an At-Risk Launch

1218. Impax's senior management never made a presentation to the Impax Board of Directors recommending an at-risk launch of oxymorphone ER. (Koch, Tr. 299; Snowden, Tr. 470-71; CX4030 (Hsu, Dep. at 85)).

1219. Had Impax actually contemplated an at-risk launch, it would have sought Board approval well before tentative FDA approval of its ANDA. (Koch, Tr. 333-34).

1220. Mr. Koch explained that because "the date of approval is pretty well predictable, we would want to be ready . . . on the date of that approval to make such a launch, so we would never wait for [FDA] approval to seek the board's approval to pursue an at-risk launch, we would do it well in advance so that we could accomplish the tasks necessary to prepare." (Koch, Tr. 341).

1221. Tentative FDA approval is effectively the last step in an ANDA filer's approval efforts since "it's pretty routine and rubber stamp from the time of a tentative approval to final approval." (Koch, Tr. 340-41; *see* Snowden, Tr. 417-18 (tentative approval from FDA "suggest[s] that Impax was almost certain to get final approval at the conclusion of the 30-month stay")).

1222. [redacted] (CX2662-012).

1223. The discussion occurred at a regular board meeting on May 25-26, 2010, after the FDA granted tentative approval to Impax's oxymorphone ER product. (Mengler, Tr. 548; CX2662).

1224. Senior management did not make a recommendation for an at-risk launch, did not discuss the risk or benefits of an at-risk launch, and did not ask the Board to approve an at-risk launch at that meeting. (Koch, Tr. 295; Mengler, Tr. 584-85).

1225. In fact, there was no substantive discussion of an at-risk launch at all. (Koch, Tr. 295; Mengler, Tr. 584).

1226. The discussion about oxymorphone ER was instead used to put oxymorphone ER "on the radar" of the Board. (Mengler, Tr. 548).

1227. Specifically, the senior management mentioned oxymorphone ER at the Board meeting to "alert the board as to the product being out there that might get to the point of an at-risk launch, so that was it." (Mengler, Tr. 584).

1228. Larry Hsu, Impax's CEO at the time, explained that senior management "want to alert the board that we are considering this is one of the scenario[s] so that if we do come up with a final recommendation to the board, there will be no surprise. . . . [T]his is very typical." (CX4030 (Hsu, Dep. at 82)).

1229. Indeed, the presentation was consistent with Impax's normal practices. Senior management annually updated the Board of Directors on various scenarios that could impact products in the company's pipeline, ensuring that the Board in not caught off guard regarding any future course. (Koch, Tr. 301).

1230. At the May 25-26, 2010, Board meeting, the President of the Generics Division, Chris Mengler, gave a presentation on Impax's recent past and the outlook ahead. (Koch, Tr. 290-91; *see* CX2662).

1231. Mr. Mengler updated the board on oxymorphone ER, including [redacted] (CX2662-013; Koch, Tr. 291, 293).

1232. Mr. Mengler told the Board that he thought oxymorphone "was a great market opportunity" because it was a "very rapidly growing product." (Koch, Tr. 294-95, 300-01). This

included a discussion of potential revenues from oxymorphone ER in the future. (Mengler, Tr. 584-85).

1233. Mr. Mengler's financial projections included the possibility of an at-risk launch scenario, but did not "imply or mean that any legal decision ha[d] been made to clear the way for a launch." (Mengler, Tr. 553).

1234. Impax merely tried to "look[] at different various scenarios" and attempt "very hard to . . . describe the possible outcomes under any number of different assumptions." (Koch, Tr. 299-300).

1235. Accordingly, as of June 8, 2010, the Impax Board of Directors had not been asked to vote on whether or not to launch generic oxymorphone ER at risk. (JX-001-009 (¶ 29) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Koch, Tr. 299; CX4030 (Hsu, Dep. at 85)).

1236. Mr. Koch, Impax's CFO and Secretary of the Impax Board at the time of settlement, explained that had a recommendation, discussion, or approval to launch at risk ever been made to or by the Board of Directors, it would have been "very carefully" recorded in Board meeting minutes. (Koch, Tr. 289-90).

1237. Indeed, any actual consideration of an at-risk launch for oxymorphone ER would have been reflected in detailed meeting minutes about the at-risk discussion, the resolution regarding the possible launch, a formal request for a vote, and the actual Board vote about the at-risk launch. No such meeting minutes exist. (Koch, Tr. 297-98 ("I would have written the resolution, and there was no resolution for oxymorphone")).

c. The Board of Directors Never Approved an At-Risk Launch

1238. The Board of Directors never voted on or approved an at-risk launch. (CX4030 (Hsu, Dep. at 85); Koch, Tr. 298-99).

5. Impax's Routine Launch Preparedness Efforts Do Not Reflect a Decision Regarding Launch Timing

a. Overview of Impax's General Preparedness Practices

1239. Impax strives to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)).

1240. In order to so, Impax uses an eighteen-month planning horizon. (Camargo, Tr. 952-53; CX4023 (Hildenbrand, Dep. at 79)).

1241. Any time a product is eighteen months away from its earliest theoretical launch, the Supply Chain Group—which is responsible for producing and packaging Impax's products—begins prelaunch preparation activities. (Camargo, Tr. 958; CX4023 (Hildenbrand, Dep. at 9-10)).

1242. The earliest theoretical launch date is often the date of anticipated FDA approval. (Camargo, Tr. 982; CX4028 (Camargo, Dep. at 59)).

1243. Every month the Impax Marketing Department provides the Supply Chain Group with a product forecast for the next eighteen months. (Camargo, Tr. 958).

1244. The Supply Chain Group uses those forecasts to begin routine launch planning. (Camargo, Tr. 958; CX4023 (Hildenbrand, Dep. at 79)).

1245. In particular, Impax uses a computer system called Enterprise Resource Planning ("ERP")—previously known as PRMS—to plan and track product production projects within the eighteen-month planning horizon. (Camargo, Tr. 959).

1246. The ERP system tracks the purchasing of materials, shop floor activities, financials associated with paying suppliers, and other planning activities based on projected batch sizes, necessary materials, and how the product is produced. (Camargo, Tr. 959-60).

1247. The Supply Chain Group also uses an excel spreadsheet called the product launch checklist to track launch-ready dates. (Camargo, Tr. 961).

1248. Once a product is uploaded into the ERP system, the Supply Chain Group undertakes certain tasks. (Camargo, Tr. 964).

1249. First, the Supply Chain Group requests a quota from the DEA to purchase any active pharmaceutical ingredients that are controlled substances. (Camargo, Tr. 965-66).

1250. Second, the Supply Chain Group purchases the active pharmaceutical ingredients and other unique materials necessary to produce the finished product. (Camargo, Tr. 964).

1251. Third, the Supply Chain Group conducts "process validation" to prove that Impax's manufacturing process is repeatable and makes the product in a satisfactory manner. (Camargo, Tr. 966-67).

1252. Finally, once the process validation process is completed and approved, the Supply Chain Group produces a "launch inventory build" to ensure that Impax has enough product to meet expected demand on the launchable date. (Camargo, Tr. 967-68).

1253. These preparation efforts are the same for all products, including products for which Impax is the first to file an ANDA. (CX4023 (Hildenbrand, Dep. at 30)).

1254. In conjunction with these tasks, the Supply Chain Group holds monthly meetings called "launch coordination meetings" to assess the status of any products in the eighteen-month planning horizon. (Camargo, Tr. 962-63).

1255. Impax's Vice President of Supply Chain chairs those meetings, which are attended by representatives of all departments who have responsibilities related to the planning of a product launch, including the marketing department, purchasing department, and regulatory department, among others. (Camargo, Tr. 962-63).

1256. But the Supply Chain Group does not decide if or when a product will actually launch. It only supports and provides information to other departments—"operations does not determine what to make or when to make it." (CX4023 (Hildenbrand, Dep. at 84-85); *see also* CX4023 (Hildenbrand, Dep. at 39-40)).

b. Process Validation

1257. Process validation is an FDA requirement imposed on all pharmaceutical manufacturers to prove that their manufacturing processes are satisfactory and repeatable. (Camargo, Tr. 966-67; Koch, Tr. 270).

1258. Manufacturers must demonstrate that the manufacturing steps necessary to produce small test batches of a product, can be used to create large, commercial volumes of the drug. (Koch, Tr. 269).

1259. Every product must undergo successful process validation before it can be launched. (Camargo, Tr. 966-67).

1260. Impax's business practice is to begin process validation six months before FDA approval of the relevant drug is expected, even if the product is the subject of active litigation. (Koch, Tr. 269-70).

1261. Impax publicly discloses this policy to investors in its annual 10-K report, in which it notes, "When the Company concludes FDA approval is expected within approximately six months, the Company will generally begin to schedule manufacturing process validation studies as required by the FDA to demonstrate the production process can be scaled up to manufacture commercial batches." (CX3278-101).

c. The Manufacture of Pre-Launch Quantities

1262. Impax may build pre-launch quantities of the products in its planning pipeline before either FDA approval is granted or a formal launch decision is made. (CX3278-101).

1263. It generally undertakes these pre-launch manufacturing activities because it takes months to build up launch inventory. (CX4030 (Hsu, Dep. at 42)).

1264. As Impax explains to investors in its annual 10-K reports, "the Company may build quantities of pre-launch inventories of certain products pending required final FDA approval and/or resolution of patent infringement litigation, when, in the company's assessment, such action is appropriate to increase the commercial opportunity, FDA approval is expected in the near term, and/or the litigation will be resolved in the company's favor." (CX3278-101).

1265. Impax considers its production of pre-launch quantities "routine" and consistent with industry practice. (Koch, Tr. 271; CX3278-101).

1266. Impax's production of launch quantities does not reflect any expectations regarding underlying patent litigation. (Koch, Tr. 271-72).

1267. Impax instead builds the products early because the manufacturing process involves long lead times and "it's much less expensive, in terms of the company's financial goals, to prepare a small cost item to be prepared for the launch into a large market." (Koch, Tr. 270-71).

1268. The cost of production for any pill is "very low relative to the market value of the products," making the pre-launch production "a small cost." (Koch, Tr. 271).

1269. This is true even when a product is subject to litigation, regulatory, or other risks. (Koch, Tr. 271-72; Camargo, Tr. 1007).

1270. By having pre-launch quantities ready, Impax is able to "increase the commercial opportunity" for its drugs. (RX-321.0002; *see* CX2685-003).

1271. It means that Impax is in a position to be ready to launch if appropriate competitive circumstances arise. (CX4023 (Hildenbrand, Dep. at 140)).

1272. If Impax does not take these predicate steps, it does not even have the option of launching once it receives FDA approval. (CX4030 (Hsu, Dep. at 86)).

1273. As Impax's CEO at the time of settlement explained, "in order to make sure whatever the discussion or the decision is meaningful, you have to have a supply ready. Then you can talk about [possible launches]. . . . [Y]ou have to have material ready. Then you decide which way you want to go." (CX4014 (Hsu, IHT at 86)).

d. The Regular Discarding of Products and Materials as a Result of Preparedness Efforts

1274. Because Impax's operations team prepares products for launch before FDA approval or a formal decision about launch timing, it is not unusual for Impax to discard and write off some of the products and raw materials in its inventory. (Camargo, Tr. 1020-21, 1033).

1275. In fact, Impax's standard accounting practices acknowledge the possibility of losses on unapproved products because of the risks that "FDA approval of product may not occur; approvals may require additional or different testing and/or specifications than used for unapproved inventory, and, in cases where the unapproved inventory is for a product subject to litigation, the litigation may not be resolved or settled in favor of the Company." (RX-321.0002).

1276. The same point is made in Impax's annual 10-K reports to investors, which also explains that if "any of these risks were to materialize and the launch of the unapproved product delayed or prevented, then the net carrying value of unapproved inventory may be partially or fully reserved," which means it would be written off. (CX3278-101; Koch, Tr. 272).

1277. Joseph Camargo, Impax's Vice President of Supply Chain, testified that the discarding of products or materials was "a matter of course pretty much every month." (Camargo, Tr. 1020-21, 1033).

1278. Impax's CFO at the time of settlement, Arthur Koch, similarly testified that writing off and destroying product is a routine and "small cost" of doing business in the generic industry. (Koch, Tr. 273).

1279. Impax, for example, discarded pre-launch methylphenidate products because Impax never received FDA approval. (CX4023 (Hildenbrand, Dep. at 95-96)).

1280. In April 2010, Impax wrote off over $1 million worth of non-oxymorphone products. (CX2905-003; Camargo, Tr. 1023).

1281. In June 2010, Impax wrote off roughly $560,000 worth of non-oxymorphone ER product. (CX2896-002-03; Camargo, Tr. 1023-24).

1282. In March 2011, Impax had over $2 million in non-oxymorphone raw materials and packaging at risk of destruction in a single location. (CX2922-003; Camargo, Tr. 1027-28). This included $618,000 of new bulk inventory at high-risk of destruction. (CX2922-007; Camargo, Tr. 1030). It also included $1.16 million in finished goods at risk of destruction. (CX2922-010; Camargo, Tr. 1032-33).

1283. And in 2017, Impax had to discard roughly $25 million in finished product. (Engle, Tr. 1786).

6. Impax's Specific Launch Preparedness Efforts For Oxymorphone ER Do Not Suggest Impax Was Likely to Launch At Risk

1284. As with all products, Impax's operations team sought to be ready to launch its generic Opana ER product at the expiration of the Hatch-Waxman Act's thirty-month stay. (Mengler, Tr. 558; Engle, Tr. 1769).

1285. In the case of generic Opana ER, that was June 14, 2010. (Mengler, Tr. 558).

1286. To meet the June 2010 "launchable" date, Impax began planning oxymorphone ER production in 2009. (Camargo, Tr. 969, 1004).

1287. The Supply Chain Group created master data for oxymorphone ER in its ERP system to manage production capacity and materials planning. (Camargo, Tr. 1006).

1288. The Supply Chain Group also put oxymorphone ER on its product launch checklist to coordinate all launch-related activities. (Camargo, Tr. 1006).

1289. Yet the Supply Chain Group acknowledged at the time that the "odds of launching [in June 2010] when the 30-month stay expires may be low." (RX-181.0001 (June 2009 email); *see* Camargo, Tr. 1009).

1290. Mr. Camargo explained that "it didn't seem likely to me that we would actually launch" in mid-2010 because the company "tended to shy away from" at-risk launches and oxymorphone ER would have been an at-risk launch given the ongoing litigation. (Camargo, Tr. 1009-10).

1291. Impax nevertheless undertook its normal launch preparations because the "upside [was] substantial and [] we may want to plan for" it. (RX-181.0001; *see* Camargo, Tr. 1007).

1292. The company sought to be prepared for a potentially "very lucrative" situation, even if the odds of an actual launch in June 2010 were low. (Camargo, Tr. 1010).

a. DEA Quota and API Purchases

1293. Impax requested a procurement quota from the DEA for oxymorphone, a necessary step before it could purchase oxymorphone API for any reason, including to conduct process validation of its oxymorphone ER product. (Camargo, Tr. 974, 1013).

1294. Impax made several requests for an oxymorphone quota in 2010 because its first request was denied by the DEA. (Camargo, Tr. 974-75).

1295. Impax was initially allotted 9.0 kg (of anhydrous base) of procurement quota of oxymorphone for 2010 by the Drug Enforcement Agency. (JX-001-008 (¶ 24) (Joint

Stipulations of Jurisdiction, Law, Fact, and Authenticity)). The initial allotment of oxymorphone quota was for product development manufacturing. (CX4027 (Anthony, Dep. at 145-48)).

1296. On January 18, 2010, Impax submitted a request for additional oxymorphone procurement quota to the DEA "to manufacture Product Validation Batches and to Build Product Launch Inventory." (JX-001-008 (¶ 25) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

1297. In response to Impax's January 2010 request, on March 3, 2010, the DEA increased Impax's 2010 oxymorphone procurement quota by 147.0 kg (of anhydrous base), for a total of 156.0 kg. The DEA stated: "It is understood that . . . [the] 147.0 kg will be used to support commercial manufacturing efforts (validation and launch)." (JX-001-008 (¶ 26) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

1298. Because of Impax's difficulties securing a quota to acquire necessary quantities of oxymorphone API, Impax revised its launch inventory build downward from twelve batches to eight batches. (*See* CX3063 (stating that Impax would need to manufacture twelve total batches of Oxymorphone ER after process validation to meet full launch requirements); RX-174 (stating that Impax would fall four lots short of full launch requirements due to insufficient quota); RX-186 (referring to "8-lot inventory build," which would "consume [Impax's] entire 2010 quota")).

1299. On April 15, 2010, Impax submitted another request for additional oxymorphone ER procurement quota to the DEA. (JX-001-008 (¶ 27) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

1300. On June 15, 2010, in response to Impax's April 2010 request, the DEA increased Impax's 2010 oxymorphone procurement quota by an additional 104.0 kg, for a total of 260.0 kg. (JX-001-009 (¶ 30) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

1301. In total, the DEA's quota decisions ensured Impax had enough oxymorphone quota to complete process validation. (Camargo, Tr. 975-76).

b. Process Validation

1302. Impax also conducted process validation for oxymorphone ER. (Camargo, Tr. 1011-12).

1303. Impax used a matrix approach for conducting process validation for its generic Opana ER product. (JX-001-009 (¶ 31) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

1304. A matrix approach to process validation takes less time, reduces the amount of product produced during the validation process, and ultimately reduces the costs incurred by Impax. (Camargo, Tr. 1012-13).

1305. But by utilizing a matrix approach, Impax also had less product at hand, requiring a more expansive launch inventory build at a later date. (Camargo, Tr. 1012-13; *see also* Camargo, Tr. 967-68 (even when process validation is successful, number of batches often insufficient to support a launch)).

1306. As of May 20, 2010, Impax had completed process validation for the 5 mg, 10 mg, 20 mg, and 40 mg dosages of generic oxymorphone ER. (JX-001-008 (¶ 28) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

c. Pre-Launch Quantities and Discarding Certain Products

1307. Prior to the settlement, Impax's inventory included finished goods of generic oxymorphone ER, including three lots of 10 mg, as well as bright stock of generic oxymorphone ER, including three lots of 5 mg, one lot of 20 mg, and two lots of 40 mg dosage strengths. (JX-001-009 (¶ 32) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

1308. Based on the cost of materials and labor, the total value of Impax's manufactured oxymorphone ER at the time of settlement was $1,387,883. (Camargo, Tr. 994-95).

1309. The specific value of Impax's manufactured oxymorphone ER is attributable in part to the "relatively expensive" cost of producing oxymorphone ER, which costs multiple dollars per pill, whereas other medications cost pennies per pill. (Engle, Tr. 1799).

1310. Following the Endo-Impax settlement in June 2010, Impax accounted for the oxymorphone ER product as likely to be rejected because the product could not be used. (Camargo, Tr. 998).

1311. The finished goods eventually were destroyed. (Koch, Tr. 273).

1312. But "[t]hrowing away product or discarding product in about a 1.5 million range happens frequently and it—it's not unusual." (Engle, Tr. 1785-86).

1313. In June 2010, Impax also possessed oxymorphone API that had not been incorporated into any finished products. (Camargo, Tr. 1022).

1314. Impax did not discard the API, and eventually used it to manufacture other finished products. (Camargo, Tr. 1022).

7. Impax Was Not Prepared to Launch Oxymorphone ER at the Time of Settlement

1315. Impax never actually completed a launch inventory build in support of an oxymorphone ER launch. (Camargo, Tr. 1020).

1316. As a general practice, after process validation is complete, the Impax operations team does not build launch inventory without management approval. (Camargo, Tr. 1015-16; RX-186.0004).

1317. In the case of oxymorphone ER, the Impax operations team never received instruction from senior management to begin a launch inventory build. (Camargo, Tr. 1020).

a. Additional Oxymorphone ER Necessary

1318. [redacted] (CX2662-013; *see* Engle, Tr. 1776, 1779).

1319. In fact, "the process validation batches weren't sufficient to meet the market demand for a full launch." (Koch, Tr. 292-93).

1320. The time required to produce the necessary amount of oxymorphone ER would have made a launch soon after FDA approval in mid-June 2010 impossible. (Engle, Tr. 1780).

1321. Nothing had changed by May 28, 2010. Impax's operations team had still not produced enough oxymorphone ER to support a launch. (CX0006-001; Engle, Tr. 1783).

1322. Todd Engle, Impax's Vice President of Sales and Marketing for the Generics Division, told the head of Impax's operations team that Impax would need at least one additional lot of 20 mg and three additional lots of 40 mg oxymorphone ER to meet sales estimates for even one month of sales. (Engle, Tr. 1783; CX0006-001).

1323. Having less than one month's worth of product would have prohibited a launch because Impax would "rapidly run out of product, and most likely [] would have started to incur penalties from [its] customers for not delivering on time." (Engle, Tr. 1784-85).

1324. It was for this reason that Mr. Engle previously requested that Impax produce twice as much oxymorphone ER as necessary to meet initial demand after any launch. (Engle, Tr. 1790; CX3348-003).

b. Operations Had Stopped Oxymorphone ER Preparation Efforts

1325. By May 2010, Impax's operations personnel had already stopped their oxymorphone ER preparation efforts and shifted capacity to other projects. (CX2904-001).

1326. On May 25, 2010, Impax's head of operations, Chuck Hildenbrand, had instructed Joe Camargo, his vice president, to shift manufacturing resources to another product, noting that "I don't see the OXM happening in June." (CX2904-001; Camargo, Tr. 1017-18).

1327. Mr. Camargo responded that he had already "advised the team that it was unlikely that we would make the Oxymorphone." (CX2904-001).

1328. Mr. Camargo testified that as of late May 2010, he and the operations team believed that oxymorphone ER "was not likely to be produced" and needed to be replaced with another product. (Camargo, Tr. 1019).

1329. Mr. Camargo believed that an actual launch of oxymorphone was unlikely "given the situation where it would have been a[n] at-risk launch, and we had no history of launching products at risk due to . . . what could happen if were to lose in the litigation, so . . . I had been given no direction at that point in time to actually execute the product launch, and it seemed unlikely to me that we would ever do that." (Camargo, Tr. 1020).

1330. Indeed, Impax's operations team had long noted that it "will not commence the launch inventory build until we receive direction to do so from senior mgmt." (CX2898-001).

1331. On May 7, 2010, for example, the Supply Chain Group had completed process validation but reported that they would not begin a launch inventory build until they were instructed by senior management. (RX-186.0004 ("We are then await [sic] management decision to proceed with 8-lot launch inventory build."); Camargo, Tr. 1016-17).

1332. By June 8, 2010, the date of the Endo-Impax settlement, launch inventory still had not been manufactured (much less tested or packaged). (CX2914-003; *see* CX4023 (Hildenbrand, Dep. at 207-09)).

1333. According to a June 8, 2010, planning document, the date on which Impax anticipated to be "Launch Ready" still remained "TBD." (CX2914-003; CX4023 (Hildenbrand, Dep. at 209)).

c. No Representations About Launch to Customers

1334. On May 17, 2010, Mr. Engle told members of the Impax sales team that Impax's oxymorphone ER product was not ready to launch. (Engle, Tr. 1778-79; RX-323.0001).

1335. He explained that Impax's senior management had not yet made a decision about completing a launch build. (Engle, Tr. 1779; RX-323.0001 ("launch decision has not been made yet")).

1336. Mr. Engle consequently instructed his sales team that when customers inquired about the status of Impax's product, "There is nothing we can tell the customers yet." (RX-323.0001; *see* Engle, Tr. 1779).

d. No Pricing Contracts with Customers

1337. What is more, Impax did not have any pricing contracts with customers for oxymorphone ER. (Engle, Tr. 1780-81).

1338. Impax had engaged in no preselling activities in an effort to generate market demand for generic Opana ER. (Engle, Tr. 1782).

1339. AmerisourceBergen, one of the largest drug wholesale companies and an Impax customer, noted in June 2010 that "We haven't heard anything about a launch of oxymorphone any time soon. . . . We would know from the sales reps about the launch a few months in advance, and we have not heard anything." (RX-086 at 9).

1340. As a consequence, even if Impax had produced launch-ready quantities of its oxymorphone ER product and received Board approval to conduct an at-risk launch, Impax "wouldn't have anywhere to go with the product." (Engle, Tr. 1780-81).

1341. Instead, Impax had solicited certain letters of intent, whereby potential customers offer a good faith estimate of how much product they likely would buy if it came on the market so that Impax can secure a sufficient API quota from the Drug Enforcement Agency. (Engle, Tr. 1797-98).

1342. Those letters of intent, however, do not obligate potential customers to purchase any of the relevant product or otherwise represent sales in any other way. (CX4027 (Anthony, Dep. at 59)).

e. No Risk Mitigation System

1343. Impax never established a Risk Evaluation and Mitigation Strategy ("REMS") program for its generic Opana ER, a necessary step before any pharmaceutical company can sell opioid products. (RX-401.0001 (noting Impax has not completed a REMS program for "any of the strengths . . . as it involves effort and money")).

8. Impax's Routine Financial Planning Efforts Do Not Reflect a Decision Regarding Oxymorphone ER Launch Timing

1344. Impax creates five year plans to forecast a range of possibilities regarding its products. (Engle, Tr. 1720; CX4002 (Smolenski, IHT at 85) (financial forecasts prepared "for planning purposes to understand what the scenario would look like")).

1345. The five year plans do not always contain all relevant information. (Engle, Tr. 1720). Rather, they include assumptions depending on the purpose of the forecast. (Engle, Tr. 1766-67).

1346. Those assumptions can drive the outcomes depicted in the forecasts. (Engle, Tr. 1766-67).

1347. Sometimes the Impax sales and marketing department produces one-off forecasts when requested by senior management. (Engle, Tr. 1766-67).

1348. In one of those one-off forecasts, Todd Engle, Vice President of Sales and Marketing for Impax's Generics Division, assumed a potential launch of oxymorphone ER in June 2010 because it was the earliest possible date Impax could launch upon expiration of the thirty-month stay. (Engle, Tr. 1767, 1769; CX0004).

1349. But Mr. Engle and his team were not involved in the decision to launch any product and had no role in the discussion about launching oxymorphone ER. (Engle, Tr. 1771). They did not even know what the information was being used for or where many of the assumptions in the forecast came from. (Engle, Tr. 1768).

1350. That forecast, moreover, did not account for regulatory, legal, or any other risk associated with launch. (Engle, Tr. 1770-71; CX0004).

1351. In any event, Impax's senior management team noted that inclusion of June 2010 launch assumption in the five-year plan was an "obvious[] controversial element." (CX0514-001).

1352. It is normal, however, for companies to forecast many different scenarios, including upside, downside, and risks. (Hoxie, Tr. 2813; CX4002 (Smolenski, IHT at 85)).

1353. Impax also holds a quarterly Launch Planning Committee meeting intended to keep products in the development pipeline on schedule for planning purposes. (Engle, Tr. 1771).

1354. The Launch Planning Committee, however, does not make a decision regarding whether to launch at risk, or even whether senior management should recommend an at-risk launch. (Engle, Tr. 1754-55).

1355. Its sole purpose is to ensure Impax is able to launch identified products. (Engle, Tr. 1754-55).

1356. Stated differently, the Launch Planning Committee reviews "what it would take to be in a position to launch" and does not hold "meeting[s] to decide to launch." (CX4037 (Smolenski, Dep. at 116); *see* CX4002 (Smolenski, IHT at 120); CX4038 (Engle, Dep. at 197-98)).

1357. Mr. Engle would circulate documents before Launch Planning Committee meetings describing where products were in their development process in order to create a dialogue about next steps. (Engle, Tr. 1771-72).

1358. As of February 2010, Mr. Engle had not recommended an at-risk launch in those quarterly Planning Committee documents, but rather flagged that "the next logical step would be [to] consider obtaining board approval" if the product was going to launch in June 2010. (Engle, Tr. 1753-54, 1773-74; CX3347).

1359. As in other financial planning documents, Mr. Engle picked a projected launch date for oxymorphone ER based on the expiration of the thirty-month stay since it was the earliest possible date Impax could launch the product. (Engle, Tr. 1772-73 (discussing CX3347-002-03)).

1360. His Launch Planning Committee documents contained no risk assessment and did not reflect the status of any litigation or settlement discussions. (Engle, Tr. 1774-75, 1776-77; *see* CX3347; CX3348).

1361. In fact, the Launch Planning Committee documents simply reflected Mr. Engle's "thinking walking into th[e] meeting" and did not reflect the thinking of senior management at that time. (Engle, Tr. 1777).

1362. In any event, Mr. Engle's thoughts on logical next steps never proceeded beyond the Quarterly Launch Planning Committee. (Engle, Tr. 1777).

9. The Economic Incentives Weighed Against an At-Risk Launch of Oxymorphone ER

1363. From an economic perspective, the incentives weighed against an at-risk launch of oxymorphone ER. Indeed, had Impax launched at-risk the potential damages would have exceeded any profits Impax realized from the launch. (Addanki, Tr. 2379-80).

1364. [redacted] (CX2662-015).

1365. But Impax was risking as much as $18 million in monthly damages, which would have translated into $108 million in damages over six months, and $324 million in trebled damages over six months. (Hoxie, Tr. 2785-91).

1366. Additionally, had Impax launched at risk, it could have triggered a launch by Actavis, which would further deteriorate Impax's profitability while still exposing it to potential damages liability. (Addanki, Tr. 2380-81).

1367. Finally, had Impax launched at risk, it would have jeopardized Impax's 180-day exclusivity. (Addanki, Tr. 2381).

1368. Taken together, these economic disincentives meant that it "was perfectly reasonable for Impax to view a launch at risk as a losing proposition." (Addanki, Tr. 2380; *see* Addanki, Tr. 2381 ("it would make complete economic sense for Impax to view a launch at risk as a money-losing proposition")).

1369. Professor Noll, Complaint Counsel's economic expert, did not analyze Impax's economic incentives to determine whether Impax should have or should not have launched at risk. (Noll, Tr. 1601-02).

10. Endo Did Not Believe Impax Would Launch At Risk

1370. In the spring of 2010, Endo knew "there had been ANDAs filed for generic versions of Opana ER," but believed "there was not imminently at that point going to be a generic." (Cuca, Tr. 643).

1371. Indeed, when Impax suggested during settlement negotiations that it might launch at risk at the end of the Hatch-Waxman Act's thirty-month stay, Endo's lawyer laughed at the suggestion. (Snowden, Tr. 424; CX4032 (Snowden, Dep. at 26)).

1372. Endo's lawyer responded that "Impax never launches at risk. . . . That's not a realistic date." (Snowden, Tr. 424).

1373. Endo's internal documents make the same point, stating that at the time of settlement Impax was "not likely to launch at risk" because it had never done so before. (RX-086 at 9-10 (third-market intelligence firm noted that "Impax tends not to launch at risk")).

1374. Indeed, Endo surveyed doctors, drug wholesalers, pharmacists, academics, and financial analysts and reported that each "doubt[s] Impax would launch at risk." (RX-086 at 9).

1375. Endo nevertheless forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64).

1376. Those forecasts considered every "potential date when [Impax] could enter," including an at-risk entry at the end of the thirty-month stay. (Bingol, Tr. 1329).

1377. Demir Bingol, Endo's Senior Director of Marketing, testified that Endo always forecast "a number of different potential outcomes over the course of years. As a brand leader . . . you have to plan for all the contingencies," including possible generic launches at-risk. (Bingol, Tr. 1292).

1378. The scenarios in those forecasts, however, were created by Endo's marketing team, and their accuracy was "debatable." (Bingol, Tr. 1303).

1379. In fact, Endo's marketing team did not have any idea what Impax would actually do with respect to oxymorphone ER, and did not know if any of the many different assumptions in their forecasts would come true. (Cuca, Tr. 662-63).

1380. Endo's forecasts were instead intended to help it "be prepared" for "all scenarios" that could occur years in the future, and to anticipate how any future events would impact the company. (Bingol, Tr. 1310, 1328).

11. Complaint Counsel's Patent Expert Does Not Opine That Impax Would Have Launched At Risk

1381. Mr. Hoxie, Complaint Counsel's patent expert, posits that Impax may have been motivated to launch at risk because of the theoretical risks of not launching, including (1) Endo switching to a reformulated version of Opana ER; and (2) new patents issuing. (Hoxie, Tr. 2705-07).

1382. But Mr. Hoxie does not opine that Impax actually would have launched at risk at any time. (Hoxie, Tr. 2910).

1383. And Mr. Hoxie does not opine that Impax actually should have launched at risk. (Hoxie, Tr. 2910-11).

1384. This means that Mr. Hoxie does not opine that Impax would have launched at risk before receiving the District Court's decision. (Hoxie, Tr. 2767-68). In fact, Mr. Hoxie believed that Impax intended to wait until the District Court decided the Endo-Impax patent suit before deciding whether or not to launch. (Hoxie, Tr. 2770).

1385. It also means that Mr. Hoxie did not calculate the odds of an at-risk launch by Impax. (Hoxie, Tr. 2769).

1386. Mr. Hoxie conceded, moreover, that had Impax lost the patent litigation and been enjoined, Impax would not have violated the injunction and launched at risk. (Hoxie, Tr. 2768).

1387. Mr. Hoxie did not quantify the risk to Impax from an at-risk launch. (Hoxie, Tr. 2910). Nor did Mr. Hoxie conduct a risk-benefit analysis for an at risk launch by Impax. (Hoxie, Tr. 2769-70).

1388. As Mr. Hoxie explained, he "simply identified risks" but he did not "evaluate all those risks and say this is what I would do if I were Impax. That was not my—within the scope of my report." (Hoxie, Tr. 2760).

1389. But Mr. Hoxie did not even assess all of the risks to Impax associated with an at-risk launch because he claimed "[t]here are many risks. . . It's a very risky business. There are a lot of risks. Looking at patent litigation as the only risk . . . is unrealistic, and it's not the way that people making business decisions, in my experience, look at things." (Hoxie, Tr. 2759).

1390. As just one example, Mr. Hoxie did not evaluate the magnitude of potential lost-profit damages that Impax would have faced if it launched at risk. (Hoxie, Tr. 2782-83).

1391. Accordingly, Mr. Hoxie does not opine that an at-risk launch would have been a reasonable risk from Impax's perspective. (Hoxie, Tr. 2808).

1392. This may be because Mr. Hoxie's experience with at-risk launches has never involved a product with first-to-file exclusivity, but rather was spurred by a "race" to market, which Mr. Hoxie characterized as a "common fact pattern for launches at risk." (Hoxie, Tr. 2781-82).

12. Complaint Counsel's Economic Expert Does Not Opine That Impax Would Have Launched At Risk

1393. Professor Noll does not offer an opinion about whether Impax would have launched at risk. (Noll, Tr. 1600-01).

1394. Nor does Professor Noll offer an opinion about when Impax would have launched at risk if it did so. (Noll, Tr. 1601).

1395. Professor Noll has not conducted any economic analysis to determine if launching at risk would have been good, bad, or economically rational for Impax. (Noll, Tr. 1601-02).

1396. Indeed, Professor Noll explained that one need not evaluate the value of an at-risk launch to Impax. (Noll, Tr. 1484).

1397. Professor Noll testified only that an at-risk launch was a hypothetical possibility. (Noll, Tr. 1604, 1605-06).

C. Professor Noll's Claims of Anticompetitive Impact are Unsubstantiated

1. Professor Noll Advances an Untested and Unaccepted Model to Assess Competitive Effects

1398. Professor Noll claims that the competitive impact of the Endo-Impax settlement should be assessed according to a three-part test. Step one asks whether the settlement agreement eliminated the possibility of entry between when the FDA gives final approval to the ANDA and the entry date listed in the settlement agreement. (Noll, Tr. 1614-15).

1399. Step one can be satisfied by an entry-date-only settlement, even when there is no reverse payment. (Noll, Tr. 1615-16).

1400. And step one can be satisfied if there is a delay of just one day beyond the date of ANDA approval. (*See* CX5000-013).

1401. Step two asks whether the generic entrant received a payment that is larger than the litigation costs saved by the parties. (Noll, Tr. 1617).

1402. Step three asks whether the payment was unjustified. (Noll, Tr. 1619).

1403. Professor Noll considers payments justified if they are less than saved litigation expenses or reflect compensation for other goods, services, and assets. (Noll, Tr. 1619). No other justifications would satisfy Professor Noll's third step. (Noll, Tr. 1620).

1404. Under this test, any payment that is greater than the sum of the parties' litigating costs is automatically anticompetitive if it is unjustified. (Noll, Tr. 1660, 1662; *see* CX4039 (Noll, Dep. at 26-27) (if a settlement includes a payment in excess of saved litigation costs "it's a hundred percent certain it's anticompetitive")).

1405. The payment need not exceed saved litigation costs by a substantial amount. (Noll, Tr. 1618).

1406. Professor Noll's three-part test has never been published or peer-reviewed. (Noll, Tr. 1642).

1407. Nor has Professor Noll's three-part test ever been accepted or utilized by any court. (Noll, Tr. 1642).

2. Professor Noll Opposes Reverse-Payment Settlements Generally and Designed His Model Accordingly

1408. Professor Noll believes so-called reverse payment settlements are a problem. (Noll, Tr. 1493-94).

1409. Professor Noll believes that such payments deprive consumers "of the possibility that generic entry will occur before the settlement date," and claims that eliminating the risk of competition is an anticompetitive effect worthy of punishment. (Noll, Tr. 1660, 1692).

1410. Professor Noll consequently has worked with the FTC in opposing so-called reverse-payment settlements on multiple occasions, including in the *Cephalon* case, in which he offered the same three-part test and very similar opinions to those proffered here. (Noll, Tr. 1495).

1411. The only so-called reverse-payment cases on which Professor Noll has worked have been for the FTC. (Noll, Tr. 1490-91).

1412. In fact, Professor Noll views his three-part test as consistent with the FTC's litigation strategy. (Noll, Tr. 1503). He explained, "I've talked to them about this for years, and there is a commonality of how they think about what the appropriate test is and what I think the appropriate test is." (Noll, Tr. 1503).

1413. Professor Noll has been thinking about his three-part test since the *Schering-Plough* case was decided over fifteen years ago, a case he considers to be incorrectly decided as a matter of economics. (Noll, Tr. 1497-98).

1414. When *Actavis* was decided in 2013, Professor Noll did not change the formulation of his three-part test, he only modified some of the nomenclature. (Noll, Tr. 1501).

1415. Professor Noll also employs a chart in his expert report in these proceedings that is nearly identical to a chart the FTC used in its unsuccessful litigation of the *Schering-Plough* case. (Noll, Tr. 1536-37). A conceptually identical chart was also used by the FTC in Congressional testimony in 2009. (Noll, Tr. 1537-38).

3. Professor Noll's Focus on Payment Size is Unsupported

1416. Professor Noll claims that he need not assess "what's going to actually happen in the market" because it is sufficient to look at the value of the settlement instead. (Noll, Tr. 1661).

1417. Professor Noll's sole focus when considering anticompetitive effects consequently is the settlement payment. (Noll, Tr. 1669). He believes one can determine whether a settlement is anticompetitive from payment terms alone. (Noll, Tr. 1663; CX5004-065 ("the reverse payment itself is a reliable index of the welfare loss of consumers due to a reverse-payment settlement")).

1418. In fact, Professor Noll believes that a large reverse-payment settlement rules out the possibility that a settlement can be beneficial to consumers. (Noll, Tr. 1666-67). He

contends that "large, unexplained reverse payments are inherently anticompetitive." (CX5004-065).

1419. But from an economic perspective, large payments do not make an agreement anticompetitive. (Addanki, Tr. 2353).

1420. "[T]here are all kinds of reasons that firms may enter into agreements that include payments that are nevertheless procompetitive in the effect they have on consumers." (Addanki, Tr. 2353).

1421. What is more, at the time of settlement in June 2010, the fact and size of the payment under the Endo Credit could not be calculated with any degree of certainty. (Addanki, Tr. 2353).

1422. For this reason, Dr. Addanki explained that because neither party knew what would be payable when they signed the agreement, economists have "no way to calculate any meaningful value for that number." (Addanki, Tr. 2356).

1423. Professor Noll certainly did not calculate the expected value of the Endo Credit or No-Authorized Generic provisions, either together or separately. (Noll, Tr. 1590; Addanki, Tr. 2384).

1424. There is, consequently, no economic evidence to indicate that Impax received a large and unjustified payment at the time of settlement under the Endo Credit or the No-Authorized Generic term, whether taken together or separately. (Addanki, Tr. 2357-58).

1425. The actual payment under the Endo Credit was due to "a perfect storm of unpredicted events and in particular the shutdown of the Novartis plant that essentially maximized the amount that would be payable by Endo under the provision relating to the Endo Credit." (Addanki, Tr. 2354-56).

1426. Absent those events, Dr. Addanki as an economist would have expected Endo to manage its transition from original Opana ER to reformulated Opana ER to minimize any payments, and could have done so without complication. (Addanki, Tr. 2355).

4. Professor Noll's Analysis Ignores Real World Outcomes

1427. Professor Noll considers any event that occurs after execution of the settlement agreement irrelevant. (Noll, Tr. 1624-25).

1428. Accordingly, Professor Noll has not measured the actual competitive effects arising from the Endo-Impax settlement. (Noll, Tr. 1665 ("Q. You did not measure what the actual anticompetitive effects are[?] A. That's correct. I do not measure the actual anticompetitive harm in the market.")).

1429. Professor Noll has not assessed whether actual, post-settlement outcomes comported with any *ex ante* expectations. (Noll, Tr. 1668).

1430. His three-part test does not take into consideration whether Endo's patents were strong enough to be upheld as valid at the time of settlement. (Noll, Tr. 1623, 1634, 1644-45).

1431. The three-part test does not assess whether any purported competitive restraints were within the scope of any Endo patent. (Noll, Tr. 1623).

1432. Professor Noll does not consider whether the SLA allowed entry prior to patent expiration. (Noll, Tr. 1624-25).

1433. And Professor Noll offers no opinion on who would have won the Endo-Impax patent litigation. (Noll, Tr. 1644).

1434. Nor does the three-part test account for actual court decisions upholding Endo's later-acquired patents as valid and infringed. (Noll, Tr. 1625-26).

1435. This means that the three-part test does not consider whether Impax would have lost subsequent patent litigation that has resulted in permanent injunctions against all other ANDA holders. (Noll, Tr. 1643-44).

1436. The three-part test consequently does not calculate the average period of competition that would have resulted absent the settlement. (Noll, Tr. 1624).

1437. Put simply, Professor Noll's three-part test ignores whether Impax would have actually been able to launch a generic oxymorphone ER product before September 2013. (Noll, Tr. 1643).

1438. Finally, the three-part test does not attempt to calculate whether consumers would have saved money in some alternative but-for world. (Noll, Tr. 1666).

XIII. THE SLA HAD SIGNIFICANT PROCOMPETITIVE BENEFITS

A. Early and Continued Supply of Oxymorphone ER

1439. The broad patent license in the SLA gave Impax freedom to operate "[u]nder both the litigated patents as well as future patents that Endo might obtain in this area." (Figg, Tr. 1936-37).

1440. The SLA guaranteed Impax entry on January 2013 as well as protection against any future patents preventing continued sales of Impax's product. (Addanki, Tr. 2376).

1441. Those terms were unambiguous in their effect. (Hoxie, Tr. 2884). As Professor Noll testified, as "part of the settlement agreement" Impax is "not going to be challenged on the patents." (Noll, Tr. 1670).

1442. Although every other Opana ER ANDA filer settled patent claims asserted by Endo, no other manufacturer negotiated similar rights to future Opana ER patents. (RX-441; RX-442; RX-443; CX3192; *see* Snowden, Tr. 440; Figg, Tr. 1939-40, 1947; Hoxie, Tr. 2714, 2886).

1443. The immediate result of Impax's foresight in negotiating a broad patent license was that Endo did not assert its later-acquired patents against Impax's generic version of original Opana ER. (Snowden, Tr. 445, 450; Figg, Tr. 1951, 1963-64).

1444. There is "little doubt" that "Endo would have included claims of infringement against Impax" in the subsequent patent litigation absent settlement. (Figg, Tr. 1951).

1445. Endo has admitted as much. In a subsequent breach of contract action between Endo and Impax, Endo asserted that Endo would have sued Impax for infringing the '122 and '216 patents with respect to original Opana ER but for the fact that the Endo-Impax settlement included a license to future patents. (Hoxie, Tr. 2892-93).

1446. That breach of contract suit related to the SLA. Endo claimed that the SLA required a royalty payment for oxymorphone ER sales and that Impax had breached the agreement by not making any such payments. (Snowden, Tr. 394-95, 475-76).

1447. But even in the breach of contract dispute, Endo did not seek an injunction to prevent Impax from selling oxymorphone ER. (Hoxie, Tr. 2891).

1448. This meant that Impax was able to launch its product in January 2013, eight months before the original patents expired and sixteen years before the later-acquired patents expired, and then "continue with the sale of that product right up to the present day because . . . Endo did not sue Impax for infringement of the second wave patents or the third wave patents for the original Opana ER product." (Figg, Tr. 1971-72; *see* Noll, Tr. 1674).

1449. Impax's product is now the only oxymorphone ER product available to consumers. (JX-003-008 (¶ 59) (Second Set of Joint Stipulations); Figg, Tr. 1972).

1450. As Mr. Figg explained, the "real-world effect [of the SLA] is that there is a product on the market and available to consumers today that would not be there had Impax not

had the foresight to negotiate licenses to future patents." (Figg, Tr. 1975-76; *see* Figg, Tr. 1972 (oxymorphone ER "wouldn't be on the market had Impax not entered the settlement and license agreement in June of 2010"); CX4037 (Smolenski, Dep. at 43)).

1451. Dr. Addanki noted the same point, testifying that "[b]ut for the settlement, had there been continued litigation, as I fully expect there would have been . . . and had Impax not been willing to launch at risk, then Impax would not have launched at any date before January 1, 2013, if at all, to date, just based on the events that have actually occurred in the real world with the ongoing litigation." (Addanki, Tr. 2382).

1452. And one "can infer that the settlement was actually procompetitive," because Impax negotiated the right to enter earlier than it otherwise could have without facing significant patent risk. (Addanki, Tr. 2208-09, 2382).

1453. There is no evidence that these benefits could have been achieved without the SLA. In fact, Complaint Counsel's economic expert, Professor Noll, admits that consumers are better off today because Impax is selling oxymorphone ER. (Noll, Tr. 1669).

1454. Complaint Counsel's medical expert, Dr. Savage, also agrees that consumers are better off because they have access to oxymorphone ER. For some patients oxymorphone is "an especially good medication" and "having diversity in our choice of opioids improves patient care and outcomes." (Savage, Tr. 818).

1455. Dr. Savage further explained that "as a physician, certainly the more options we have available for clinical treatment, the better. (CX4041 (Savage, Dep. at 102); *see* Savage, Tr. 821 (patient care is improved "from having a diversity of options")).

1456. The loss of Impax's oxymorphone ER product would have been bad for consumers because it would have caused "transient negative changes for some patients" and anxiety among others. (Savage, Tr. 817-18, 819).

1457. Complaint Counsel's patent expert does not dispute that consumers have benefited. Mr. Hoxie offers no opinion that any consumer was harmed as a result of the SLA. (Hoxie, Tr. 2745). In fact, Mr. Hoxie does not offer any opinions about the effect of the SLA period. (Hoxie, Tr. 2745, 2903 (conceding that he did not "offer any opinions about the effect of the settlement and license agreement in the long-acting opioid market")).

B. Professor Bazerman's Claims that an Alternative Settlement Theoretically was Possible Are Not Substantiated

1458. Complaint Counsel's economic expert, Professor Noll, did not attempt to determine whether an alternative settlement with an earlier entry date was feasible. (Noll, Tr. 1596-97, 1648).

1459. Instead, Professor Noll opined that the feasibility of an alternative settlement was irrelevant to his analysis. (Noll, Tr. 1484, 1597).

1460. Complaint Counsel consequently proffered Professor Max Bazerman as an expert in negotiation and managerial decision-making. (Bazerman, Tr. 844).

1461. Professor Bazerman opined that that Endo-Impax settlement "was linked to the no-AG/Endo credit agreement and also linked to the development and co-promotion agreement." (Bazerman, Tr. 877).

1462. The linkage between those terms and the settlement agreement purportedly "served as a means for Endo to compensate Impax to accept the January 2013 date." (Bazerman, Tr. 877).

1463. These terms also purportedly "served to move the entry date to a later point in time" than if the parties had pursued and accepted an "entry-only" agreement. (Bazerman, Tr. 877).

1464. It is Professor Bazerman's opinion that absent these terms, Endo and Impax could theoretically have negotiated an alternative settlement with an earlier entry date. (Bazerman, Tr. 907).

1465. But Professor Bazerman's opinion is not based on any actual analysis, and reflects his categorical opposition to reverse-payment settlements. There consequently is no economic analysis or record evidence suggesting that the substantial procompetitive benefits enjoyed by consumers could have been achieved without the SLA.

1. Professor Bazerman Opposes Any Transfer of Value From a Brand Drug Company to a Generic Drug Company

1466. Professor Bazerman believes that every reverse-payment settlement is both "nefarious" and "parasitic," which together are "similarly negative" qualities. (Bazerman, Tr. 900-01).

1467. Professor Bazerman is suspicious of the very existence of any reverse payment between a brand drug company and a generic drug company. (Bazerman, Tr. 900).

1468. Professor Bazerman wants Congress to make a "legislative change to address what [he] refer[s] to as pay-for-delay cases" because the legal system "has resulted in a set of decisions that are harmful to consumers." (Bazerman, Tr. 895).

1469. Indeed, Professor Bazerman cannot imagine a scenario in which consumers are better off under an agreement that contains a reverse payment. (Bazerman, Tr. 901-02).

1470. Professor Bazerman consequently testifies against pharmaceutical settlements in what he describes as "the pursuit of justice," serving as an expert witness for the FTC in four separate cases challenging reverse-payment settlements. (Bazerman, Tr. 882, 904-05).

1471. In each of those cases, Professor Bazerman testified that the terms in the settlement agreements were linked. (Bazerman, Tr. 886-87).

1472. And in each case, Professor Bazerman opinioned that the linkage served to delay generic entry. (Bazerman, Tr. 887).

1473. Indeed, Professor Bazerman's views on reverse-payment settlements have not changed since his expert work for the FTC in the *Schering-Plough* case over fifteen-years ago. (Bazerman, Tr. 895).

1474. Each time Professor Bazerman is hired by the FTC to oppose purported reverse-payment settlements he accepts the work "because [he] care[s] about justice." (Bazerman, Tr. 905).

1475. As Professor Bazerman testified, "as I think about taking this work, I don't think I want to work for the FTC, I think I want to create justice for consumers." (Bazerman, Tr. 905).

1476. For this reason, Professor Bazerman has never been employed as an expert for a drug company in so-called reverse-payment litigation or any other form of litigation. (Bazerman, Tr. 906).

1477. Indeed, Professor Bazerman is disinclined to consult for any company that even raises the idea of a reverse payment settlement. (Bazerman, Tr. 899-900).

1478. Professor Bazerman is similarly disinclined to work for any company that is willing to consider a No-Authorized Generic term in settlement negotiations. (Bazerman, Tr. 901).

1479. Any such work would violate Professor Bazerman's personal set of ethics. (Bazerman, Tr. 899-900).

1480. As just one example of how Professor Bazerman's ethics are applied in practice, Professor Bazerman testified about contingency contracts. (Bazerman, Tr. 926-28).

1481. Ordinarily, Professor Bazerman loves contingency contracts. (Bazerman, Tr. 926).

1482. He believes they create value by allowing negotiators to stop arguing about their divergent beliefs and instead leverage their differences through bets that both sides expect to win. (Bazerman, Tr. 926-27).

1483. This includes licensing agreements whereby the licensor either receives money if the licensed product sells well or owes money if the licensed product does not sell well. (Bazerman, Tr. 927-28).

1484. The Endo Credit and Royalty provisions are an example of a contingency contract that addressed Impax's and Endo's different beliefs about what was going to happen to Opana ER sales. (Bazerman, Tr. 928).

1485. Professor Bazerman nevertheless condemns the terms because he has an ethical objection to the use of a contingency contract in this particular case. (Bazerman, Tr. 928).

1486. Still, Professor Bazerman concedes that an entry-date only settlement, his preferred outcome to the Endo-Impax litigation, would have included a transfer of value to the generic company. (Bazerman, Tr. 882).

1487. Entry-date only settlements similarly eliminate the risk of competition from the generic company. (Bazerman, Tr. 882).

2. Professor Bazerman's Lack of Analysis Reflects the Pure Speculation Underlying His Opinion of an Alternative Settlement

1488. Professor Bazerman opined that Endo and Impax could have secured an earlier entry date with an "entry-only" agreement. (Bazerman, Tr. 845-46, 877).

1489. In forming his opinions, Dr. Bazerman did not speak to any individual employed by Endo or Impax. (Bazerman, Tr. 880).

1490. Professor Bazerman only spoke to FTC staff. (Bazerman, Tr. 879). Indeed, it was the FTC staff that identified which documents Professor Bazerman should read and which portions of deposition transcripts he should review. (Bazerman, Tr. 881).

1491. Accordingly, any suggestion that the "parties would have agreed to a settlement that was materially different from the settlement they actually agreed to, the one before us, is pure speculation." (Addanki, Tr. 2359).

1492. The reason for this is because there are no facts suggesting an alternative settlement would actually have been acceptable to the parties. "To hypothesize a settlement and say they would have agreed to it would be the purest speculation." (Addanki, Tr. 2374).

a. No Analysis Regarding the Settlement's Impact on Consumers

1493. Professor Bazerman testified that Endo-Impax settlement was "parasitic." (Bazerman, Tr. 896).

1494. Professor Bazerman opines that the negotiations between Impax and Endo created a structure that was likely to be bad for consumers. (Bazerman, Tr. 896-97).

1495. But Professor Bazerman has not analyzed whether the settlement agreement between Impax and Endo was actually anticompetitive. (Bazerman, Tr. 928-29 ("I haven't used the word 'anticompetitive' anywhere in my report.")).

1496. Professor Bazerman does not address what actually happened in the real world as a result of the settlement agreement between Endo and Impax, explaining that his "opinions were not dependent on . . . outcomes." (Bazerman, Tr. 897).

1497. Professor Bazerman has not analyzed what has transpired since the settlement to determine the settlement's overall impact on consumers, including whether it was actually bad for them. (Bazerman, Tr. 897, 929).

1498. And Professor Bazerman has not assessed the benefits consumers received as a result of the settlement agreement when compared the benefits they might have gotten if there had been another settlement. (Bazerman, Tr. 897).

1499. Indeed, Professor Bazerman does not offer an opinion about whether the settlement between Endo and Impax was bad for consumers when compared to any outcome that would have occurred absent the settlement. (Bazerman, Tr. 929).

1500. Professor Bazerman has not assessed whether consumers would have been better off if Impax had continued to litigate against Endo, with or without an at-risk launch. (Bazerman, Tr. 897, 930).

1501. Professor Bazerman admits, moreover, that if Impax continued to litigate against Endo and lost, consumers would not have benefited. (Bazerman, Tr. 906).

1502. Professor Bazerman did not conduct any analysis regarding consumer impact even though he has the technical skills to do so. (Bazerman, Tr. 897-99).

b. No Analysis Regarding an Earlier Entry Date

1503. Professor Bazerman opined that Endo and Impax theoretically could have negotiated an earlier entry date. (Bazerman, Tr. 907).

1504. But Professor Bazerman cannot identify what the earlier entry date would have been. (Bazerman, Tr. 907).

1505. Professor Bazerman cannot even identify the zone of possible entry-date agreements for Endo and Impax. (Bazerman, Tr. 913-14).

1506. In fact, Professor Bazerman cannot say with certainty that an alternative settlement was possible in this case. (Bazerman, Tr. 914).

1507. Professor Bazerman admits that Impax asked for earlier entry dates and Endo rejected them. (Bazerman, Tr. 907).

1508. Impax also asked for a date-only settlement with entry in 2011, which Endo rejected. (Bazerman, Tr. 915-16).

1509. Professor Bazerman, moreover, has not seen any evidence in the record that Endo offered an earlier entry date. (Bazerman, Tr. 907).

1510. In any event, Professor Bazerman testified about the importance of reservation values—the alternative dates that negotiating parties would have agreed to before walking away from the negotiations—when assessing settlements. (Bazerman, Tr. 853).

1511. Professor Bazerman, however, did not identify Impax's reservation date with respect to the Endo patent license. (Bazerman, Tr. 912; *see* Addanki, Tr. 2496-97).

1512. Nor did Professor Bazerman identify Endo's reservation date. (Bazerman, Tr. 913; *see* Addanki, Tr. 2497).

1513. Endo's reservation date could be impacted by the psychological precedent created by Endo's settlement with Actavis, requiring a later date for Impax. (Bazerman, Tr. 918).

1514. Endo's reservation date would also be impacted by its expectations about the patent litigation with Impax. (Bazerman, Tr. 913).

1515. Impax's reservation date would be impacted by Impax's expectations regarding the outcome of its patent litigation against Endo. (Bazerman, Tr. 913).

1516. Yet Professor Bazerman offers no opinions regarding the parties' expectations with respect to the patent suits. (Bazerman, Tr. 913).

1517. Professor Bazerman also pointed to the settlement agreement between Endo and Actavis as an example of an earlier entry date. (Bazerman, Tr. 877).

1518. But Professor Bazerman has not done any analysis of the Actavis settlement. (Bazerman, Tr. 916-17).

1519. He admits, moreover, that one of the reasons Endo settled with Actavis was because the two dosages on which Actavis was the first to file did not represent a meaningful portion of Endo's Opana ER sales. (Bazerman, Tr. 917).

1520. And Professor Bazerman admits that the negotiations and settlement agreement with Impax were likely more important to Endo than the negotiations and settlement with Actavis. (Bazerman, Tr. 917-18).

c. No Analysis Regarding the Endo Credit Term

1521. Professor Bazerman never calculated the expected value of the Endo Credit. (Bazerman, Tr. 923).

1522. Nor has Professor Bazerman seen any analysis in which Impax valued the Endo Credit prior to settlement. (Bazerman, Tr. 912).

1523. Professor Bazerman has not, for example, seen any calculations prepared by Impax assessing the value of the Endo Credit during settlement negotiations. (Bazerman, Tr. 923).

1524. Professor Bazerman similarly has not seen any calculations prepared by Endo assessing the value of the Endo Credit during settlement negotiations. (Bazerman, Tr. 923).

1525. Professor Bazerman admits, moreover, that once Impax signed the settlement agreement with Endo, it had no control over the existence or size of any Endo Credit payment. (Bazerman, Tr. 912, 923).

1526. Endo similarly lacked complete control over the events that led to the Endo Credit Payment. (Bazerman, Tr. 923).

1527. Once the FDA shut down the Novartis plant, the existence and size of an Endo Credit payment were no longer in Endo's hands. (Bazerman, Tr. 924).

1528. Before that point, Professor Bazerman admits that he had not seen any analysis in which Endo expected to make a payment to Impax pursuant to the Endo Credit. (Bazerman, Tr. 912).

1529. And Professor Bazerman never modeled or calculated how likely it was that Endo would have shifted demand to a reformulated product without having to pay anything under the Endo Credit. (Bazerman, Tr. 924).

1530. At bottom, Professor Bazerman cannot say what impact the Endo Credit provision had on the entry date in the Settlement and License Agreement. (Bazerman, Tr. 910).

d. No Analysis Regarding the No-Authorized Generic Term

1531. Professor Bazerman similarly did not calculate the expected value of the No-Authorized Generic term. (Bazerman, Tr. 924).

1532. And although Professor Bazerman believes that No-Authorized Generic and Endo Credit provisions are linked, he did not calculate an expected value for the combination of the No-Authorized Generic and Endo Credit terms. (Bazerman, Tr. 890, 924).

1533. Professor Bazerman has not seen any analysis prior to settlement where Impax valued the no-Authorized Generic provision. (Bazerman, Tr. 912).

1534. For these reasons, Professor Bazerman cannot say what impact the No-Authorized Generic term had on the entry date in the Endo-Impax settlement agreement. (Bazerman, Tr. 910).

e. No Analysis Regarding the Development and Co-Promotion Agreement

1535. Professor Bazerman did not calculate an expected value for the Development and Co-Promotion Agreement. (Bazerman, Tr. 924).

1536. This means that Professor Bazerman did not calculate the value of the profit-sharing rights Endo received under the DCA. (Bazerman, Tr. 925).

1537. Despite failing to value the rights Endo received, Professor Bazerman nevertheless declares that Endo overpaid Impax. (Bazerman, Tr. 925-26).

1538. Professor Bazerman believes Endo should have paid Impax less than $10 million. (Bazerman, Tr. 926). Yet Professor Bazerman does not opine how much less than $10 million Endo should have paid Impax. (Bazerman, Tr. 926).

1539. In fact, Professor Bazerman admits that had Endo and Impax entered the same Development and Co-Promotion Agreement years after their settlement, the DCA would not create any problems from Professor Bazerman's perspective. (Bazerman, Tr. 925).

1540. Indeed, had the same Development and Co-Promotion agreement been entered years after the Endo-Impax settlement, Professor Bazerman would "have no reason to suspect that it would be an example of parasitic value creation." (Bazerman, Tr. 926).

1541. And once again, Professor Bazerman cannot say what impact the DCA had on the entry date found in the Settlement and License Agreement. (Bazerman, Tr. 911).

f. No Analysis Regarding the Broad Patent License

1542. Professor Bazerman did not assess the quantitative value of the broad patent license Impax received under the Settlement and License Agreement. (Bazerman, Tr. 925).

1543. In fact, Professor Bazerman does not offer any opinions related to the licenses. (Bazerman, Tr. 925).

1544. He is aware, however, that Actavis—which also settled with Endo regarding Opana ER patent litigation—did not receive the same broad patent license that Impax secured. (Bazerman, Tr. 918).

1545. Professor Bazerman is also aware that because Actavis did not secure the same broad patent license, it is not selling Opana ER today. (Bazerman, Tr. 918).

1546. Yet Professor Bazerman has not done any analysis regarding which settlement agreement has been better for consumers. (Bazerman, Tr. 918-20).

1547. Professor Bazerman has not done an analysis of the expected value of the Actavis settlement to consumers. (Bazerman, Tr. 919).

1548. And Professor Bazerman has not calculated an expected value for consumers of the Impax settlement. (Bazerman, Tr. 919).

g. No Analysis Regarding Best Alternatives to the Negotiated Settlement

1549. "In any important negotiation one of the first steps would be to . . . identify your own" best alternative to negotiated agreement. (Bazerman, Tr. 902).

1550. To identify a best alternative to negotiated agreement, it is good practice to "play out almost in decision tree format what are the possible events that would occur and try to estimate the probability of those various events and calculate the value of those events for Impax." (Bazerman, Tr. 902-03).

1551. This process requires a probabilistic assessment of the different possible scenarios Impax was facing. (Bazerman, Tr. 903).

1552. Professor Bazerman did not perform the decision tree analysis to determine Impax's best alternative to negotiated agreement. (Bazerman, Tr. 903).

1553. Professor Bazerman did not calculate the expected values of the possible outcomes facing Impax. (Bazerman, Tr. 903).

1554. Even for alternatives like continuing to litigate against Endo or launching at-risk, Professor Bazerman has not quantitatively evaluated possible outcomes. (Bazerman, Tr. 904).

h. No Analysis Regarding an At-Risk Launch

1555. Professor Bazerman also testified that there was a possibility that Impax would have launched at risk. (Bazerman, Tr. 920).

1556. But Professor Bazerman could not put odds on the possibility that Impax would have launched at risk. He could not, for instance, say that an at-risk launch was more likely than not. (Bazerman, Tr. 921-22; *see* Bazerman, Tr. 876 (not opining that Impax "definitely would have launched generic Opana at risk")).

1557. Professor Bazerman similarly did not quantitatively analyze the risks to Impax of an at-risk launch. (Bazerman, Tr. 921).

1558. This may be because Professor Bazerman has never advised a generic drug company considering an at-risk launch. (Bazerman, Tr. 920).

1559. Professor Bazerman admitted, however, that there are very serious penalties if Impax would have launched at risk and then lost its patent case against Endo. (Bazerman, Tr. 922).

1560. Those penalties would be measured with reference to Endo's lost profits, which could be up to ten time as much as Impax's profits. (Bazerman, Tr. 922).

1561. Such penalties mean that any generic company deciding whether to launch at risk must make its decision with care. (Bazerman, Tr. 922).

1562. Professor Bazerman did not calculate the likelihood that the court presiding over the Endo-Impax challenge would have ruled in favor of Impax. (Bazerman, Tr. 922).

1563. Professor Bazerman admitted, moreover, that Impax needed to pose a credible threat of launching at risk for settlement negotiation purposes. (Bazerman, Tr. 920-21).

1564. Appearing as a credible threat to launch at risk improves Impax's potential negotiation outcomes, even if it is a form of bluffing. (Bazerman, Tr. 920-21).

3. There is No Economic Basis to Assume an Alternative Settlement was Possible

1565. Despite Professor Bazerman's claims that an alternative settlement was theoretically possible, there is no economic evidence to suggest that some purportedly less-restrictive alternative was feasible.

1566. For patent litigation to settle solely on some division of the remaining patent term (also referred to as a term-split or entry-date only settlement), both sides must prefer settlement to continued litigation. (RX-547.0061).

1567. Since the outcome of any litigation is uncertain, each party must rely on its own assessment of their chances to prevail and, by extension, the likelihood that generic entry will occur soon (patentee loses) or much later (patentee loses). (RX-547.0061; Hoxie, Tr. 2665, 2753).

1568. Those assessments affect the parties' willingness to accept a settlement, and there is no economic basis to assume that parties will hold identical assessments. (RX-547.0062).

1569. Asymmetric information regarding future demand further undermines the likelihood of a term-split agreement by driving a wedge between the entry dates the parties deem preferable. (RX-547.0063).

1570. This type of asymmetry in information existed between Endo and Impax given Endo's plans to launch a reformulated version of Opana ER and Endo's refusal to confirm those plans at the time of settlement. (CX4017 (Levin, Dep. at 100-01); CX4010 (Mengler, IHT at 41-42); CX0117-002).

1571. Finally, the existence of a new product—even if known to both parties during negotiations—may render a term-split settlement infeasible. (RX-547.0065-66).

1572. Expected profits for the generic manufacturer—which are often driven by demand for an equivalent branded product—turn on whether it can enter the market before the launch of the new product. (RX-547.0065-66). Entry dates after the projected launch consequently are worth much less to the would-be entrant than entry dates before the projected launch. (RX-547.0066).

1573. The opposite is true for patentees, driving a wedge between the earliest entry date the patentee is willing to offer and the last entry date a would-be entrant is willing to accept. (RX-547.0066).

1574. This renders the prospect of any term-split agreement unlikely. (RX-547.0066).

RESPONDENT'S PROPOSED CONCLUSIONS OF LAW

I. BURDEN OF PROOF

1. The parties' burdens of proof are governed by Federal Trade Commission Rule 3.43(a), 16 C.F.R. § 3.43(a), and the Administrative Procedure Act ("APA"), 5 U.S.C. § 556(d).

2. Pursuant to Commission Rule 3.43(a), "[c]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a).

3. Under the APA, "which is applicable to administrative adjudicatory proceedings unless otherwise provided by statute," *In re Rambus Inc.*, No. 9302, 2006 FTC LEXIS 101, at *45 (F.T.C. Aug. 20, 2006) (quoting *Steadman v. SEC*, 450 U.S. 91, 95–102 (1981)), Complaint Counsel must establish "[e]ach element of the case must be established by a preponderance of the evidence." *In re Adventist Health Sys./West*, No. 9234, 1994 FTC LEXIS 54, at *28 (F.T.C. Apr. 1, 1994); *see also In re Chicago Bridge & Iron Co.*, 138 F.T.C. 1024, 1027 n.4 (2005) ("[W]e take it as settled law that regardless of the standard under which a reviewing court must accept the Commission's findings of fact, the Commission (and the [Administrative Law Judge]) normally must base findings upon a 'preponderance of the evidence.'") (citing *Carter Prods., Inc. v. FTC*, 268 F.2d 461, 487 (9th Cir. 1959))).

4. The Sherman Act and burdens applied by federal courts under it apply to Complaint Counsel in this case. *See, e.g.*, *Fashion Originators' Guild, Inc. v. FTC*, 312 U.S. 457, 463–64 (1941); *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 451–52 (1986).

5. The Court may rely upon Sherman Act cases to determine a violation of law under § 5 of the FTC Act. *See Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 32 (D.C. Cir. 2005) ("[T]he analysis under § 5 of the FTC Act is the same . . . as it would be under § 1 of the Sherman Act.").

II. THE RULE OF REASON IS THE APPROPRIATE TEST IN THIS CASE

6. The Supreme Court held that cases involving alleged reverse-payment settlements "should proceed by applying the rule of reason." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013); *see also* Opinion and Order of the Commission at 8–11, *In re Impax Labs., Inc.*, No. 9373 (F.T.C. Oct. 27, 2017) [*hereinafter* "Comm'n Decision"].

7. Thus, this case should be decided pursuant to the "traditional, full-fledged rule of reason standard." *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 398 n.15 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016).

8. Thus, the fact that Complaint Counsel has fashioned its claims to allege a reverse-payment settlement does not justify a departure from the "well-mapped" rule of reason analysis. *King Drug*, 791 F.3d at 411; *see id.* at 399 (*Actavis* did "not redefine . . . the already well-established rule of reason analysis"); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 551 n.12 (1st Cir. 2016) [*hereinafter "Loestrin I"*] ("considerations" listed in *Actavis* "should not overhaul the rule of reason"); *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014) (*Actavis* mandates "traditional 'rule of reason'").

III. COMPLAINT COUNSEL DID NOT PROVE THAT IMPAX RECEIVED A "LARGE & UNJUSTIFIED" PAYMENT

9. An alleged reverse-payment settlement is not subject to antitrust scrutiny under the rule of reason unless Complaint Counsel proves that the generic company received a payment that was both large and unjustified. *See Actavis*, 133 S. Ct. at 2237 ("a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects.").

A. Burden of Proof

10. Complaint Counsel has the burden of proving that each challenged payment term was large and unjustified. *See Actavis*, 133 S. Ct. at 2237 ("a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects.").

11. In order to meet its burden of establishing that a reverse payment is both large and unjustified, Complaint Counsel must present evidence that would allow the Court to "assess the value" of the alleged reverse payment terms and to determine which portion, if any, of that value is unjustified. *See In re Loestrin 24 Fe Antitrust Litig.*, No. 1:13-md-2472-S-PAS, — F. Supp. 3d —, 2017 WL 3600938, at *21 (D.R.I. Aug. 8, 2017) [*hereinafter "Loestrin II"*] ("The deal must be valued at the time the parties entered the deal.").

12. In *Actavis*, the Supreme Court held that a large reverse payment may be unjustified—and therefore subject to antitrust scrutiny—only where it constitutes "payment in return for staying out of the market." *See* 133 S. Ct. at 2234–37; *King Drug*, 791 F.3d at 412 ("the plaintiff must prove payment for delay").

B. "Large" and "Unjustified" Are Separate And Discrete Requirements

13. Under *Actavis*, "large" and "unjustified" are discrete requirements. *See Lipitor*, 868 F.3d at 251 ("Reverse payment settlement agreements give rise to those antitrust concerns . . . when the payments are both 'large and unjustified.'") (quoting *Actavis*, 133 S. Ct. at 2237).

14. A settlement agreement does not "bring with it the risk of significant anticompetitive effects"—and therefore is not subject to antitrust scrutiny—unless it conveyed to the generic company a payment that is ***both*** "large and unjustified." 133 S. Ct. at 2237; *see In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251 (3d Cir. 2017); *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 (RA), 2015 WL 5610752, at *13 (S.D.N.Y. Sept. 22, 2015), *rev'd on other grounds*, 848 F.3d 89 (2d Cir. 2017).

15. *Actavis* provides a "safe harbor" for small reverse payments. *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015). It likely provides a safe harbor for payments that are justified. *See Actavis*, 133 S. Ct. at 2237.

16. In its proposed framework, Complaint Counsel improperly merges the discrete "large" and "unjustified" payment elements by defining "large" as anything that exceeds expected future litigation costs. Saved litigation costs were cited by the Supreme Court as an example of a payment that is "justified," ***not*** whether the payment is large. *See Actavis*, 133 S. Ct. at 2236 (saved litigation costs are a "justification[]"). By defining "large" as anything that exceeds expected litigation costs, Complaint Counsel also renders the Supreme Court's "large" requirement a nullity.

17. Moreover, not all payments that exceed litigation costs ***are*** necessarily "large" under *Actavis*. Were this the case, *Actavis* would "subject virtually any settlement to antitrust scrutiny—a result the Court [in *Actavis*] could not have intended." *Actos End Payor*, 2015 WL 5610752, at *14; *see Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15-cv-6549 (CM), 2016 WL 4992690, at *13 (S.D.N.Y. Sept. 13, 2016) ("To trigger antitrust concern under Actavis, a settlement term must be (1) a 'payment' that is (2) made in 'reverse' . . . and is [3] 'large,' and (4) 'unexplained.'") (quotation omitted).

18. Nor are all reverse payments in excess of saved litigation costs necessarily "unjustified." For example, the Supreme Court found that a reverse payment may be "justified" by the value of goods or services the patent holder received in exchange for the payment. *See Actavis*, at 133 S. Ct. at 2236 ("That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to

develop a market for that item."). The Supreme Court explicitly held that there "may be other justifications" in addition to saved litigation costs. *See id.*

C. Complaint Counsel Failed to Prove that the DCA Conveyed a Large and Unjustified Payment

19. There is nothing inherently illegal about negotiating and entering a development and co-promotion deal while also negotiating and entering a settlement agreement of a Hatch-Waxman patent infringement case. *See* DOJ & FTC, *Antitrust Guidelines For Collaborations Among Competitors* §§ 2.1, 3.31(a) (2000) (stating that "most" research and development collaborations are "pro-competitive" because they "may enable participants more quickly or more efficiently to research and develop new or improved goods"). Therefore, like any agreement including a payment in an alleged reverse-payment case, Complaint Counsel must prove any payments under the DCA are both large and unjustified.

20. In order to meet its burden of establishing a reverse payment that is both large and unjustified, Complaint Counsel must present evidence that would allow this Court to "assess the value" of the alleged payment terms, *Loestrin 24 Fe*, 814 F.3d at 551, at the time of the deal, *see In re Loestrin 24 Fe Antitrust Litig.*, No. 1:13-md-2472-S-PAS, — F. Supp. 3d —, 2017 WL 3600938, at *21 ("The deal must be valued at the time the parties entered the deal."), and to determine which portion, if any, of that value is "unjustified."

21. Complaint counsel has not met its burden with regard to the DCA.

22. If Endo received "fair value" in exchange for the payment it made and agreed to make pursuant to the DCA, those payment obligations were not "unjustified" pursuant to *Actavis*. 133 S. Ct. at 2236, 2239.

23. Complaint Counsel failed to prove that the DCA payment obligations did not represent "fair value" for the profit-sharing rights obtained by Endo obtained under the DCA. *See Actavis*, 133 S. Ct. at 2234.

24. The purported expert testimony offered by Complaint Counsel relating to the DCA does not even speak to the issue of fair value, and thus does not meet Complaint Counsel's burden.

25. Specifically, Dr. John Geltosky's testimony suggesting that the parties' diligence was "strikingly superficial," *In re Schering-Plough Corp.* ("*Schering I*"), No. 9297, 2002 WL 1488085, at *50, *93 (F.T.C. June 27, 2002), and "fell astonishingly short of industry standards," *Schering-Plough v. FTC* ("*Schering II*"), 402 F.3d 1056, 1069 (11th Cir. 2005), does not speak to—let alone establish—that the agreement was anything other than "a bona fide side deal for fair value." *Schering I*, 2002 WL 1488085, at *94–95; *see Schering II*, 402 F.3d at 1071.

26. Likewise, Dr. Geltosky's testimony that the $10 million upfront payment was "unusually large" for an early stage development collaboration, absent an opinion that the payment exceeds the value of Endo's DCA profit-sharing rights by a large amount, does not speak to whether the payment was large or unjustified.

27. The DCA does not "represent[] an unexplained large transfer of value from the patent holder to the alleged infringer," and is therefore not "subject to antitrust scrutiny." *King Drug*, 791 F.3d at 399, 402–03.

D. Complaint Counsel Failed to Prove The SLA Included a Large and Unjustified Payment

28. At the time of the deal, both of the alleged payment terms under the SLA—the Endo Credit term and co-exclusive license or No-AG term—were contingent in nature; whether

Impax would receive something of value under either or both—and if so, how much value—was uncertain and depended on future events outside Impax's control.

29. To value a contingent liability, "it is necessary to discount it by the probability that the contingency will occur and the liability become real." *In re Xonics Photchem., Inc.*, 841 F.2d 198, 200 (7th Cir. 1988) (Posner, J.); *see also id.* ("By definition, a contingent liability is not certain—and often is highly unlikely—ever to become an actual liability."); *Box v. Northrop Corp.*, 459 F. Supp. 540, 553 (S.D.N.Y. 1978) ("The present value of these payments is a function of both the expected amount of these payments and the probability that that amount will be paid."); *see also In re Loestrin II*, 2017 WL 3600938, at *21 ("The deal must be valued at the time the parties entered the deal.").

30. "Tempting as it is to correct uncertain probabilities by the now certain fact," value must be assessed "as of the time when the act is done." *Ithaca Trust Co. v. United States*, 279 U.S. 151, 155 (1929) (Holmes, J.).

31. In order to estimate the value to Impax of the Endo Credit and No-AG terms, one would have to account for their uncertain and contingent nature of the terms. *See Xonics Photchem., Inc.*, 841 F.2d at 200 ("By definition, a contingent liability is not certain—and often is highly unlikely—ever to become an actual liability. To value the contingent liability it is necessary to discount it by the probability that the contingency will occur and the liability become real."); *Box v. Northrop Corp.*, 459 F. Supp. 540, 553 (S.D.N.Y. 1978) ("The present value of these payments is a function of both the expected amount of these payments and the probability that that amount will be paid.").

32. Payment obligations contingent on highly uncertain outcomes often carry little to no expected value. *See Burnet v. Logan*, 283 U.S. 404, 413 (1931) (where "the promise of future

money payments [is] wholly contingent upon facts and circumstances not possible to foretell with anything like fair certainty," the contingent promise "ha[s] no ascertainable fair market value").

33. Because Complaint Counsel failed to offer evidence or expert testimony calculating the probability-weighted expected value of the alleged SLA payment terms at the time of the deal, Complaint Counsel cannot establish that either or both of them constitute a large and unjustified payment to Impax. *See Loestrin I*, 814 F.3d at 551 (the "court or factfinder" must be able to "assess the value of the payment"); *Actos End Payor*, 2015 WL 5610752, at *13 ("in order for the Court to find an unlawful reverse payment, it must be able to estimate the value of the term, at least to the extent of determining whether it is 'large' and 'unjustified'").

34. Relying on the ultimate amount of a contingent payment (even if discounted to the present value at the time of the agreement) is inappropriate because it introduces "hindsight bias." *See Paloian v. LaSalle Bank, N.A.*, 619 F.3d 688, 693 (7th Cir. 2010) (Easterbrook, J.) ("Hindsight is wonderfully clear, but in determining the Hospital's solvency in mid-1997 it was necessary to determine the expected value of this liability as of mid-1997, not the actual value as of 1999 or 2000. Hindsight bias is to be fought rather than embraced."); *Cty. of Harding v. Frithiof*, 483 F.3d 541, 548 (8th Cir. 2007) ("Equating the value of the ***chance*** with the value of the ***realized*** contingency is somewhat analogous to equating the value of a lottery ticket with the value of the jackpot.") (emphasis added).

35. Complaint Counsel's economic expert's analysis of the alleged "payment" terms is unreliable because it relies on the ultimate payment made under the Endo Credit terms, rather than calculating the probability-weighted expected value of the alleged "payment" terms as of the time of the settlement.

36. Therefore, Complaint counsel's methodology for valuing the alleged "payment" terms in the SLA fails to meet Complaint Counsel's burden of proving that those terms conveyed a "large" and "unjustified" payment to Impax at the time the SLA was executed.

IV. COMPLAINT COUNSEL HAS NOT MET ITS BURDEN OF ESTABLISHING AN ANTITRUST VIOLATION UNDER THE APPLICABLE RULE OF REASONS ANALYSIS

A. Complaint Counsel Did Not Prove That Endo Possessed Monopoly Power in a Properly Defined Relevant Market

37. The antitrust laws do "not purport to afford remedies for all torts committed by or against persons engaged in interstate commerce." *Hunt v. Crumboch*, 325 U.S. 821, 826 (1945).

38. "Substantial market power is an indispensable ingredient of every claim under the full Rule of Reason." *Chicago Prof'l Sports Ltd. P'ship v. Nat'l Basketball Ass'n*, 95 F.3d 593, 600 (7th Cir. 1996).

39. "Proving the existence of monopoly power through indirect evidence requires a definition of the relevant market." *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 435 (3d Cir. 2016) (quoting *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 307 (3d Cir. 2007).

40. A cognizable relevant market is comprised of all products that are "reasonably interchangeable by consumers for the same purposes." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956); *see In re N.C. Bd. of Dental Exam'rs*, 152 F.T.C. 75, 161 (2011) ("courts have found the 'reasonable interchangeability' standard to be the essential test for ascertaining the relevant product market"), *aff'd*, 152 F.T.C. 640 (2011).

41. Reasonable interchangeability does not require identicality or literal equivalence. *See United States v. E.I. du Pont de Nemours & Co.*, 351 at 394 ("[I]llegal monopoly does not

exist merely because the product said to be monopolized differs from others. If it were not so, only physically identical products would be a part of the market.").

42. "Without a well-defined relevant market, a court cannot determine the effect that an allegedly illegal act has on competition." Initial Decision at 123, *In re 1-800 Contacts, Inc.*, No. 9372 (F.T.C. Oct. 27, 2017) [*hereinafter "1-800 Contacts*"] (quoting *Se. Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 613 (8th Cir. 2011)); *see N.C. Bd. of Dental*, 152 F.T.C. at 160 (assertion that "market definition is not a prerequisite to establishing liability under the rule of reason" is "contrary to established law"); *Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 828–33 (3d Cir. 2010) (affirming jury verdict for defendants on rule of reason claim where plaintiffs failed to prove relevant market).

1. Complaint Counsel Bears the Burden of Establishing a Cognizable Antitrust Market

43. "The scope of the market is a question of fact as to which the plaintiff bears the burden of proof." *Broadcom*, 501 F.3d at 307.

44. Complaint Counsel must meet this burden with reference to the rules of reasonable interchangeability and cross-elasticity of demand. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997); *United States ex rel. Blaum v. Triad Isotopes, Inc.*, 104 F. Supp. 3d 901, 924 (N.D. Ill. 2015).

45. This is because the relevant market inquiry centers on "the choices available to consumers." *Little Rock Cardiology Clinic PA v. Baptist Health*, 591 F.3d 591, 596 (8th Cir. 2009).

46. "Analysis of the market is a matter of business reality—a matter of how the market is perceived by those who strive for profit in it." *See 1-800 Contacts* at 132 (quoting *FTC*

v. Coca-Cola Co., 641 F. Supp. 1128, 1132 (D.D.C. 1986), *vacated as moot*, 829 F.2d 191 (D.C. Cir. 1987)).

47. The market definition inquiry "'must take into account the realities of competition.'" *1-800 Contacts* at 124 (quoting *FTC v. Whole Foods Mkt.*, 548 F.3d 1028, 1039 (D.C. Cir. 2008)).

48. This requires an evaluation of "the nature of the commercial entities involved and by the nature of the competition that they face." *See United States v. Phillipsburg Nat'l Bank & Trust Co.*, 399 U.S. 350, 360 (1970).

49. This is especially important in cases involving the pharmaceutical industry because it exhibits numerous unique institutional features. *See FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 46 (D.D.C. 1998) ("It is imperative that the Court, in determining the relevant market, take into account the economic and commercial realities of the pharmaceutical industry.").

2. Complaint Counsel's Proposed Oxymorphone ER-only Product Market is Improper; the Relevant Product Market is Long Acting Opioids

50. A prescription drug, like any other product, is not automatically its own market. *See Mylan*, 838 F.3d at 437 (finding the drug Doryx competed in a market with other prescription drugs).

51. Courts in pharmaceutical cases must undergo the same analysis in pharmaceutical cases to define a relevant market as in any other antitrust case. *See Mylan*, 848 F.3d at 435–36.

52. One "test used by economists to determine a product market is the hypothetical monopolist test. . . . This test queries whether a hypothetical monopolist who has control over the products in an alleged market could profitably raise prices on those products." *Fed. Trade Comm'n v. Staples, Inc.*, 190 F. Supp. 3d 100, 121 (D.D.C. 2016) (internal citations omitted).

This is often referred to as a "small but significant and non-transitory increase in price" or "SSNIP" test. *Id.*

53. Complaint Counsel did not attempt a SSNIP test to define the relevant product market.

54. Complaint Counsel does not offer any way to identify a set of patients that could not substitute another long acting opioid for an oxymorphone ER product in response to a SSNIP, or any other legally cognizable way.

a. Ordinary Course Business Documents

55. Firms' perceptions of competition are highly probative of the relevant market. As this Court has stated, "[o]rdinary course business documents reveal the contours of competition from the perspective of the parties, who may be presumed to 'have accurate perceptions of economic realities.'" *1-800 Contacts* at 124–25 (quoting *Whole Foods*, 548 F.3d at 1045 (Tatel, J., concurring)); *see Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) ("industry or public recognition" may serve as "practical" indicator of relevant market); *Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 497 (3d Cir. 1992) (evidence that "Chrysler dealers perceive[d] themselves as competing with dealers handling other cars" indicated that the relevant market was not limited to Chrysler cars).

56. "[C]ourts often pay close attention to the defendants' ordinary course of business documents" when "determining the relevant product market." *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 52 (D.D.C. 2011).

57. That manufacturers of long acting opioids, in ordinary course business documents, consistently defined the market in which Endo competed as including other long acting opioids, is probative of a long acting opioid product market. *See Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, Civ. No. 12-3824, 2015 WL 1736957, at *9 (E.D. Pa. Apr. 16,

2015), *aff'd*, 838 F.3d 421 (3d Cir. 2016) ("Years of internal marketing documents further confirm that tetracyclines are reasonable substitutes for one another.").

b. Price-Induced Switching

58. Evidence of "how customers have shifted purchases in the past in response to relative changes in price" is directly probative of product market definition. U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 4.1.3 (2010).

59. Price-induced switching is the essence of product market definition. *See Apple, Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1196 (N.D. Cal. 2008) ("Whether products are part of the same or different markets under antitrust law depends on whether consumers view those products as reasonable substitutes for each other and would switch among them in response to changes in relative prices."); *see also Mylan*, 838 F.3d at 437 (evidence of price-related switching was the "[m]ost convincing[]" proof that Doryx competed in the same market as other oral tetracyclines).

60. While Impax does not carry the burden of establishing the relevant market, Impax has shown evidence of price-induced switching among long-acting opioids, especially with regard to formulary changes.

61. What little price-switching evidence Complaint Counsel has offered in response does not support Complaint Counsel's proposed market definition.

62. The only price-switching observations offered by Complaint Counsel is Dr. Noll's evaluation of sales trends after the entry of generic opioid products, which is inconclusive with regard to market definition.

c. Product Differentiation Insufficient

63. "[P]roduct differentiation does not indicate substantial market power for anyone. Indeed, highly competitive firms advertise [and] vary products." Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 520c (rev. ed. 2017).

64. That competitors in the long acting opioid market attempt to differentiate their products through advertising or similar means of differentiation does not mean that each opioid occupies a separate market. *See Town Sound*, 959 F.2d at 478–81 (evidence that Chrysler's advertising compared the "features of its autos with other companies' [cars]" supported conclusion that "Chrysler cars compete vigorously with many other companies' automobiles").

65. To the contrary, detailing efforts emphasizing different long-acting opioids purported "advantages" over rival long acting opioid products supports, rather than undermines, the conclusion that they were "effective substitutes for each other." *See Mylan*, 2015 WL 1736957, at *10.

d. Consumer Preference Insufficient

66. Without any way of identifying a patient population that could not switch from oxymorphone ER to another long acting opioid, these alleged patients cannot delineate a relevant market. *See Horizontal Merger Guidelines* §§ 3, 4.1.4 (markets defined by "targeted customers" must be based on "observable characteristics").

67. Even if some patients simply ***prefer*** Opana ER over other long acting opioids, this does not make those patients a relevant market unto themselves. *See Queen City Pizza*, 124 F.3d at 437 ("Interchangeability implies that one product is roughly equivalent to another for the use to which it is put; while there may be some degree of preference for the one over the other, either would work effectively.") (quoting *Allen-Myland, Inc. v. IBM Corp.*, 33 F.3d 194, 206 (3d Cir. 1994)); *see also Mylan*, 2015 WL 1736957, at *10 ("even if there are patients for whom Doryx is

a preferred treatment, the 'test for a relevant market is not commodities reasonably interchangeable by a particular plaintiff, but commodities reasonably interchangeable by consumers for the same purposes'") (quoting *Queen City Pizza*, 124 F.3d at 438).

e. Relevant Market

68. Competitive realities, ordinary course business documents, price-induced switching, and the lack of any identifiable group of patients for whom oxymorphone ER has no substitute, lead to the inexorable conclusion that the relevant market includes numerous long acting opioids. *See United States v. Continental Can Co.*, 378 U.S. 441, 457 (1964) (relevant market's "contours must, as nearly as possible, conform to competitive reality"); *Whole Foods*, 548 F.3d at 1039 ("As always in defining a market, we must 'take into account the realities of competition.'") (quoting *Weiss v. York Hosp.*, 745 F.2d 786, 826 (3d Cir. 1984)).

69. The relevant market in which Opana ER competed was the market for long acting opioids.

3. Complaint Counsel Failed to Meet Its Burden Of Proving That Endo Exercised Monopoly Power In the Market

70. Complaint Counsel "must also show that the defendant has market power in the relevant market, which means that 'it can raise prices above a competitive level without losing its business.'" *Blaum*, 104 F. Supp. 3d at 924 (quotation omitted).

71. The SLA could not have harmed competition unless Endo possessed monopoly power in the relevant market at the time. *Chicago Prof'l Sports*, 95 F.3d at 600.

72. Monopoly power can be proven either directly or indirectly. *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995).

a. Indirect Method

73. "Proving the existence of monopoly power through indirect evidence requires a definition of the relevant market." *Broadcom*, at 307.

74. The indirect method requires Complaint Counsel to prove that (1) Endo had a significant share of the relevant market, (2) there are significant barriers to entry in the relevant market, and (3) incumbent competitors in the relevant market cannot increase their output in the short run. *Rebel Oil*, 51 F.3d at 1434; *see In re Gen. Foods Corp*., 103 F.T.C. 204, 333, 356–57 (1984) (if incumbent firms can "respond [to a restriction of output] by expanding their output to make up the shortfall," then "there is no monopoly power").

75. Endo did not have a significant share of the relevant market at the time of the challenged agreement.

76. Market share of 10% or less falls far short of monopoly power. *See Cohlmia v. St. John Med. Ctr.*, 693 F.3d 1269, 1283 (10th Cir. 2012) ("a market share of less than 20% is woefully short under any metric from which to infer market power").

77. It is "inconceivable" that Endo could have commanded monopoly power with less than 10% share of the relevant market. *See Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1461 (9th Cir. 1993) ("no danger of monopoly power" where defendant "controlled only 10% of the market"); *Ryko Mfg. Co. v. Eden Servs.*, 823 F.2d 1215, 1232 (8th Cir. 1987) ("clearly" defendant whose "share of the entire relevant market is at most between 8% and 10%" does not possess market power); *MHB Distribs., Inc. v. Parker Hannifin Corp.*, 800 F. Supp. 1265, 1270 (E.D. Pa. 1992) ("Even assuming Parker's market share were 10%, the percentage is insufficient to bestow market power upon Parker.").

78. Complaint Counsel failed to show by indirect evidence that Endo has monopoly power in the long acting opioid market because Endo only had a 3.4% market share.

b. Direct Method

79. The direct test for monopoly power requires "direct evidence of supracompetitive prices ***and*** restricted output." *Broadcom*, 501 F.3d at 307 (emphasis added); *see Rebel Oil*, 51 F.3d at 1434 (same).

80. Proof of supracompetitive prices requires, among other things, evidence that the "defendant had an ***abnormally*** high price-cost margin." *Mylan*, 838 F.3d at 434 (emphasis added) (quoting *Geneva Pharm. Tech. Corp. v. Barr Labs, Inc.*, 386 F.3d 485, 500 (2d Cir. 2004)).

81. Endo's Lerner Index says nothing about whether it was charging supracompetitive prices or otherwise exercising monopoly power. *See Mylan*, 2015 WL 1736957, at *7–8 (defendant's margin of 83% did not show monopoly power since there was no evidence that margin was "abnormally high"); *In re Wireless Tel. Servs. Antitrust Litig.*, 385 F. Supp. 2d 403, 422 & n.27 (S.D.N.Y. 2005) (testimony that defendants' Lerner Indices were 0.85 and 0.5 did not establish monopoly power).

82. The ownership of a patent does not "equal [a] market power' presumption." *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 44 (2006).

83. The antitrust agencies have found, "[a]lthough the intellectual property right confers the power to exclude with respect to the specific product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power." U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (2017).

84. Complaint Counsel failed to meet the direct test for monopoly power in the long acting opioid market because it offered no evidence of supracompetitive prices or restricted output.

B. Because Complaint Counsel Did Not Prove the SLA Had Actual Anticompetitive Effects, the SLA Is Not Illegal under the Rule of Reason

1. The Rule of Reason Requires a Showing of Actual Anticompetitive Harm

85. "In the context of reverse payment patent settlement lawsuits, . . . market power alone cannot be sufficient to demonstrate anticompetitive effects under the rule of reason." *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 755 (E.D. Pa. 2015), *aff'd*, 868 F.3d 132 (3d Cir. 2017).

86. The rule of reason requires proof that the challenged restraint had actual anticompetitive effects in the relevant market. *See, e.g.*, *Hennessy Indus. Inc. v. FMC Corp.*, 779 F.2d 402, 404 (7th Cir. 1985) ("application of the Rule of Reason has inevitably resulted in a finding of anticompetitive effects.").

87. In other words, "[u]nder the rule of reason the plaintiff must allege and prove anticompetitive effects." *Great Escape, Inc. v. Union City Body Co.*, 791 F.2d 532, 539 (7th Cir. 1986)

88. Indeed, *Actavis* instructs that the "basic question" is the same as in any other rule of reason case—namely, "that of the presence of significant unjustified anticompetitive consequences." 133 S. Ct. at 2238.

89. Proof of competitive effects is imperative to any rule of reason claim under the antitrust laws. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 389–90 (D. Mass. 2013) (requiring plaintiffs to establish both market power and anticompetitive consequences).

90. This "requires courts to engage in a thorough analysis of the relevant market and the effects of the restraint in that market." *1-800 Contacts* at 119.

91. Consistent with this, the rule of reason the Supreme Court concluded should apply to reverse payment settlements hinges on "anticompetitive consequences," *Actavis*, 133 S. Ct. at 2237–38, and a "consequence" inherently "***follows as an effect*** of something that came before." *Black's Law Dictionary* (10th ed. 2014) (emphasis added). Nothing in Actavis contemplates courts myopically focusing on ex ante conditions while ignoring real-world competitive outcomes.

92. Thus, as the Commission unanimously held in this matter, post-settlement effects are relevant to a rule of reason inquiry regarding reverse payment settlements challenged under Actavis. Comm'n Decision 11–13.

93. This entails an analysis of "real market conditions," *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 903 (2007), and the restraint's "actual effect" therein, *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984).

94. The rule of reason analysis considers "the facts peculiar to the business to which the restraint is applied," including "its condition before and after the restraint was imposed." *Bd. of Trade of City of Chi. v. United States*, 246 U.S. 231, 238 (1918).

95. The ultimate question is whether the challenged restraint, "***as it actually operates in the market***, has unreasonably restrained competition." *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 29 (1984) (emphasis added).

96. In a reverse-payment case, proving anticompetitive effects requires a showing that the alleged payment actually "delayed" entry. *See King Drug*, 791 F.3d at 412 ("the plaintiff must prove payment for delay"). To prove anticompetitive harm, a plaintiff must prove as an element of liability that the settlement in fact delayed competition. *See, e.g.*, *King Drug*, 791 F.3d at 404 ("'paying the challenger to stay out' of the market . . . for longer than the patent's

strength would otherwise allow . . . 'constitutes the relevant anticompetitive harm,' which must then be analyzed under the rule of reason") (quoting *Actavis*, 133 S. Ct. at 2236–37); *Cipro*, 348 P.3d at 863 ("[T]he relevant benchmark in evaluating reverse payment patent settlements should be no different from the benchmark in evaluating any other challenged agreement: What would the state of competition have been without the agreement?" "[D]elayed entry . . . beyond what the patent's strength warranted" constitutes "cognizable anticompetitive harm.").

97. Courts may not infer anticompetitive effects—including delayed entry—"from the mere presence of a reverse payment." Comm'n Decision at 8.

2. Complaint Counsel's Proposed Reading of The Rule of Reason Is Little More Than a Per Se Rule

98. "[A]bandonment of the 'rule of reason' in favor of presumptive rules (or a 'quick look' approach) is appropriate only where an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Actavis, Inc.*, 133 S. Ct. at 2237 (quoting *Cal Dental*, 526 U.S. 770)).

99. The Supreme Court held it was inappropriate to abandon the rule of reason in favor of a lesser showing of proof in reverse-payment cases. *Id.*

100. Dr. Noll's three-part test is not sufficient to prove liability under the rule of reason because it merely infers anticompetitive harm without engaging in the "fact-intensive rule of reason" analysis. *See W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 99 (3d Cir. 2010) (defendants' agreements condemned "only if evaluation under the ***fact-intensive rule of reason*** indicates that they unreasonably restrain trade.") (emphasis added).

101. The Commission rejected Complaint Counsel's position that harm to competition may be inferred from the mere presence of a reverse payment. The Commission held that, under

the Rule of Reason as laid out in *Actavis*, "anticompetitive effects should not be presumed from the mere presence of a reverse payment." Comm'n Decision, at 8.

102. Dr. Noll's assertion that numerous facts relevant to the rule of reason inquiry—including the viability of Impax's claims in the patent litigation or the likelihood that Impax would launch at risk—are irrelevant to his analysis does not comport to the rule of reason analysis.

103. Dr. Noll's analysis conflates the initial question of whether Impax received a "large and unjustified" ***payment*** with the ultimate question of whether the challenged settlement caused "significant unjustified anticompetitive ***consequences***." *Actavis*, 133 S. Ct. at 2237–38 (emphasis added).

104. Dr. Noll's proposed analysis is effectively a *per se* rule because it assumes the agreement is "inherently anticompetitive" based on the existence of a payment. *See Copperweld*, 467 U.S. at 768 ("Certain agreements . . . are thought so inherently anticompetitive that each is illegal per se without inquiry into the harm it has actually caused.").

105. Complaint Counsel's refusal to conduct "further inquiry into the practice's actual effect" is consistent with a *per se* rule, not the rule of reason. *See In re Music Instruments & Equip. Antitrust Litig.*, 798 F.3d 1186, 1191 (9th Cir. 2015) (under *per se* rule, "[o]nce the agreement's existence is established, no further inquiry into the practice's actual effect on the market . . . is necessary").

106. Complaint Counsel's proposed per se framework conflicts with the Supreme Court's guidance in *Actavis*.

3. Complaint Counsel Has Not Met Its Burden of Proving Actual Anticompetitive Effects

107. Complaint Counsel bears the burden of "show[ing] that [the alleged] conduct unreasonably restrained competition." *United States v. Microsoft Corp.*, 253 F.3d 34, 95 (D.C. Cir. 2001); *see Schering I*, 2002 WL 1488085, at *88 ("In a rule of reason case, Complaint Counsel must prove that the challenged agreements had the effect of injuring competition.").

108. Only after Complaint Counsel has met this burden, does the burden shift to the respondent to show that the procompetitive effects outweigh any anticompetitive effects proven by Complaint Counsel. *N.C. Bd. of Dental*, 152 F.T.C. at 205.

109. Complaint Counsel failed to put on evidence of anticompetitive effects, and this dooms its antitrust claims. *See Jefferson Par.*, 466 U.S. at 31 ("Without a showing of actual adverse effect on competition, respondent cannot make out a case under the antitrust laws."); *Cal. Dental Ass'n v. FTC*, 224 F.3d 942, 958 (9th Cir. 2000) ("Under rule-of-reason analysis, then, because CDA's advertising restrictions do not harm consumer welfare, there is no antitrust violation. In other words, the FTC has failed to demonstrate substantial evidence of a net anticompetitive effect.").

110. The "true test of legality" examines "the facts peculiar to the business to which the restraint is applied," including "its condition ***before and after*** the restraint was imposed." *Bd. of Trade of City of Chi. v. United States*, 246 U.S. 231, 238 (1918) (emphasis added).

111. Complaint Counsel's failure to evaluate effects in the market after the agreement was entered is contrary to the traditional rule of reason analysis. *United States v. Microsoft Corp.*, 253 F.3d 34, 95 (D.C. Cir. 2001)

112. Complaint counsel does not offer any evidence that the SLA delayed generic competition, especially in light of the various patent lawsuits.

C. Impax Offered Convincing Evidence that the Agreement Had Significant Procompetitive Benefits

113. After Complaint Counsel proves that the agreement resulted in anticompetitive effects—which it has not—"[t]he burden then shifts to defendants to offer pro-competitive justifications for the arrangement." *Geneva Pharm.*, 386 F.3d at 509.

114. Thus, under the rule of reason, Impax is entitled to show that the SLA was in fact procompetitive. *N.C. Bd. of Dental*, 152 F.T.C. at 205.

115. In other words, "an antitrust defendant may show in the antitrust proceeding that legitimate justifications are present." *Actavis*, 133 S. Ct. at 2236.

116. In denying Complaint Counsel's Motion for Partial Summary Judgment, the Commission noted that "this case involves factual circumstances not presented in *Actavis*. In particular, this case involves patents beyond those in litigation at the time of the Settlement Agreement, and a provision of that agreement allowed generic entry notwithstanding the potential that such patents might issue." Comm'n Decision at 12.

117. The Commission further held that "the extent to which [the] settlement allow[ed] entry prior to patent expiration" is relevant to "balancing anticompetitive harms and procompetitive benefits." *Id.* (emphasis omitted).

118. The SLA was procompetitive because it allowed generic entry eight months prior to the expiration of the '456 and '933 patents.

119. The SLA was procompetitive because it allowed generic entry over ten years before the expiration of the '122 and '216 patents.

120. The SLA was procompetitive because it allowed generic entry over 16 years before the expiration of the '779 patent.

121. The SLA benefited consumers and competition by "eliminating an independent and substantial hurdle to generic entry" reflected in the additional patents Endo secured after executing the SLA, and thereby achieving "the 'full freedom to operate' without the risk of [a further] patent infringement claim," the SLA ensured that consumers would have early and reliable access to a low-cost generic version of Opana ER. *Wellbutrin*, 133 F. Supp. 3d at 759; *see FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 437 (E.D. Pa. 2015) (agreement that "facilitat[ed] Teva's ability to compete in the cholesterol drug market [was] good for the consumer" and procompetitive under *Actavis*); *Toscano v. PGA Tour, Inc.*, 201 F. Supp. 2d 1106, 1123 (E.D. Cal. 2002) (challenged restraints "further[ed] consumer welfare" where they "provide[d] a product that would not otherwise exist").

122. The Supreme Court has held that "enabl[ing] a product to be marketed which might otherwise be unavailable . . . widen[s] consumer choice . . . and hence can be viewed as procompetitive." *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 102 (1984).

123. Therefore, there can be no dispute that, on net, the SLA promoted competition and enhanced consumer welfare. *See Cal. Dental Ass'n*, 526 U.S. at 771 (restraints that have "net procompetitive effect" are not unlawful); *Microsoft*, 253 F.3d at 95 ("[P]laintiffs must show that [defendants'] conduct was, on balance, anticompetitive.").

124. Impax's five years of sustained sales, made possible by the SLA, have benefited consumers, and these competitive benefits far outweigh the hypothetical elimination of some unparticularized "risk" of competition posited by Complaint Counsel. *See Eisai, Inc.*, 821 F.3d at 403 ("assuring [consumers] the availability of supply" is a consumer benefit); *Wellbutrin*, 133 F. Supp. 3d at 760 ("ensuring consistent supply of product" is procompetitive).

125. The benefit inured to consumers from the SLA, including Impax's five years of sustained sales, far outweigh any hypothetical benefits from a hypothetical at risk launch. *See Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016) ("assuring [consumers] the availability of supply" is a consumer benefit); *Wellbutrin*, 133 F. Supp. 3d at 760 ("ensuring consistent supply of product" is procompetitive).

126. Complaint Counsel has not offered any evidence that even purports to outweigh the real-world, procompetitive benefits proven by Impax. Under the rule of reason, this is dispositive. *See Microsoft*, 253 F.3d at 95 ("[I]t is plaintiffs' burden to show that the anticompetitive effect of the conduct outweighs its benefit.").

D. Complaint Counsel Must Prove That The Agreement As A Whole Is Anticompetitive

127. Complaint Counsel's argument that the procompetitive benefits analysis under the rule of reason may only consider the alleged "payment" terms of the SLA, not the entire challenged restraint, ignores that courts must "look[] at the whole of the settlement to determine its alleged effect on competition." *Loestrin II*, 2017 WL 3600938, at *16; *see Geneva Pharm.*, 386 F.3d at 507 (defendant entitled to "offer evidence of the pro-competitive effects of the[] ***agreement***") (emphasis added); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) (competitive effects of challenged settlement and side deals must be assessed as a whole rather than "in isolation").

128. It is inappropriate to "evaluate the settlement . . . in a piecemeal, provision-by-provision approach," since settlements are "negotiated as a whole, agreed to as a whole, and [go] into effect as a whole." *Wellbutrin*, 133 F. Supp. 3d at 753–54; *see also* Comm'n Decision at 12–13 ("Some courts have held that the context of the broader settlement agreement in which a reverse payment occurs is relevant in assessing its anticompetitive effects.") (citing *Wellbutrin*,

133 F. Supp. 3d at 753–54, and *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015)).

129. Complaint Counsel's assertion that any procompetitive benefits must be attributable to the alleged payment terms is nonsensical, since a payment never has competitive effects in isolation from the rest of the agreement. *See* 15 U.S.C. § 1 (prohibiting ***agreements*** in restraint of trade); *Black's Law Dictionary* (10th ed. 2014) (defining "restraint of trade" as "[a]n agreement between two or more businesses" that eliminates competition); *Bd. of Trade*, 246 U.S. at 238 ("restrain" means to "bind").

130. Nor is this approach consistent with Complaint Counsel's allegations that the anticompetitive effects flow from the SLA as a whole, rather than the alleged reverse payment terms alone.

131. Complaint Counsel's approach would also permit it to cherry-pick value-conveying terms (alleged "payments") that it considers objectionable, while ignoring others.

E. Complaint Counsel Did Not Prove That a Less Restrictive Alternative Was Actually Feasible Under the Circumstances

132. Under the rule of reason, once the defendant has made a showing of procompetitive effects, the burden shifts back to the plaintiffs to prove that any legitimate competitive benefits offered by defendants could have been achieved through less restrictive means." *Geneva Pharm.*, 386 F.3d at 507.

133. In order to counter the unrebutted procompetitive effects flowing from the SLA, Complaint Counsel "must demonstrate that the restraint is not reasonably necessary to achieve the stated [procompetitive] objective," *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993), or in other words, that the "legitimate objectives can be achieved in a substantially less

restrictive manner," *O'Bannon v. NCAA*, 802 F.3d 1049, 1070 (9th Cir. 2015) (quoting *Tanaka v. Univ. of S. Cal.*, 252 F.3d 1059, 1063 (9th Cir. 2001), *cert. denied* 137 S. Ct. 277 (2016)).

134. The showing that a less restrictive alternative was feasible is unequivocally complaint counsel's burden. *O'Bannon*, 802 F.3d at 1074; *In re McWane, Inc.*, No. 9351, 2014 WL 556261, at *36 (F.T.C. Jan. 30, 2014).

135. Complaint Counsel must "make a ***strong evidentiary showing***" that its proposed less restrictive alternative would be "viable." *O'Bannon*, 802 F.3d at 1074 (emphasis added).

136. Complaint Counsel's proposed alternative "must be 'virtually as effective' in serving the procompetitive purposes of the [challenged restraint], and 'without significantly increased cost.'" *Id.* (quoting *Cty. of Tuolomne v. Sonora Cmty. Hosp.*, 236 F.3d 1148, 1159 (9th Cir. 2001)).

137. The speculative expert testimony Complaint Counsel offers is inadequate to "show" a less restrictive alternative. *Cf. Martin v. Omni Hotels Mgmt. Corp.*, 321 F.R.D. 35, 40–41 (D.D.C. 2017) ("a party cannot avoid summary judgment when it offers an expert opinion that is speculative and provides no basis in the record for its conclusions").

138. Complaint Counsel has not shown—or even ***attempted*** to show—that the procompetitive benefits from the SLA could have been achieved through some less restrictive alternative.

139. This, too, is fatal to Complaint Counsel's claims. *See N. Am. Soccer League, LLC v. U.S. Soccer Fed'n, Inc.*, No. 17-CV-05495 (MKB), — F. Supp. 3d —, 2017 WL 5125771, at 15, *19–21 (E.D.N.Y. Nov. 4, 2017) (plaintiffs failed to show likelihood of success where defendant adduced evidence of procompetitive benefits and plaintiffs failed to "provide some alternative to the [challenged restraint] that offer[ed] the same procompetitive benefits . . .

'without significantly increased cost'"; denying motion for preliminary injunction) (quoting *O'Bannon*, 802 F.3d at 1074).

V. COMPLAINT COUNSEL HAS NOT PROVEN WHY ANY OF ITS PROPOSED REMEDIES ARE APPROPRIATE

140. Each remedy must have a "reasonable relation to the unlawful practices found to exist." *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (9th Cir. 1978) (quoting *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394–95 (1965)).

141. Courts may not sanction overbroad remedies, especially those that would prevent or chill procompetitive conduct. *See Fanning v. FTC*, 821 F.3d 164, 177 (1st Cir. 2016) (remedy impermissibly overbroad when it lacked limits reasonably related to violation).

142. A remedy is impermissibly overbroad if it lacks limits reasonably related to violation. *See Fanning*, 821 F.3d at 177.

143. Virtually ***every*** patent settlement can be characterized as conveying "something of value" to the alleged infringer. *See Asahi Glass Co. v. Pentech Pharm, Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.) ("any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement"). Therefore a remedy forbidding an exchange of value is overly broad.

144. Expansive remedies are particularly inappropriate given the lack of evidence that Impax acted in "blatant and utter disregard of the law" or has "a history of engaging in unfair trade practices." *See Standard Oil*, 577 F.2d at 662 (both "circumstances which should be considered in evaluating the relation between the order and the unlawful practice").

145. Complaint Counsel's proposed remedies are inappropriate because there is no proof of any ongoing actual or threatened injury to competition or consumers.

146. The Supreme Court has denied injunctive relief to plaintiffs if the plaintiff fails to "show that he is under threat of suffering 'injury in fact' that is concrete and particularized" and "the threat must be actual and imminent, not conjectural or hypothetical. . . ." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009). Where "the activity of the kind complained of by the Government has ceased" and "no substantial basis has been established by credible evidence that there is any danger of recurrent violation . . . there is no warrant for injunctive relief." *U.S. v. Uniroyal, Inc.*, 300 F. Supp. 84, 88 (S.D.N.Y. 1969).

147. The majority of Federal Circuit Courts viewed Impax's conduct as per se ***legal*** at the time of the settlement because the SLA fell within the scope of Endo's patents. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335 (Fed. Cir. 2008) (adopting the "scope-of-the-patent" test); *In re Tamoxifen Citrate Antitrust Litig.*, 446 F.3d 187, 212–13 (2d Cir. 2006) (same); *Schering II*, 402 F.3d at 1076 (same); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003) (same). Because Impax's conduct was legal at the time, and Complaint Counsel has offered no evidence to suggest any danger that Impax would violate the legal standard established by the Supreme Court in 2013 in *FTC v. Actavis* nearly three years after Impax entered into the SLA, there is no basis to find there is a threat of repetition and no need for a broad injunctive remedy.

148. Impax has not given "express or implied consent" to Complaint Counsel's alterations to its remedies from those originally proposed in the administrative complaint. *See* 16 C.F.R. § 3.15(a)(2) (allowing Complaint Counsel to add or alter remedies only with consent of respondent).

149. Complaint Counsel's proposed ban on "agreements settling a patent infringement dispute in which: (1) the brand drug company provides to the generic drug company something

of the value other than the right to market its generic drug product prior to the expiration of the patent at issue in the litigation; and (2) the generic drug company agrees not to launch its product for some period of time" overbroad and would chill significant procompetitive conduct.

150. Complaint Counsels proposal banning Impax "from entering any agreement with another drug company that prevents, restricts, or disincentives the brand drug company from selling or authorizing a competing product for some period of time," is overly broad, ambiguous and lacks limits reasonably related to the alleged violation.

151. Complaint Counsel's proposals requiring Impax "to submit periodic reports describing compliance efforts" and "fund an independent monitor to determine Impax's compliance" is overbroad and redundant.

Dated: December 20, 2017

By: */s/ Edward D. Hassi*
Edward D. Hassi
ehassi@omm.com

Edward D. Hassi
ehassi@omm.com
Michael E. Antalics
mantalics@omm.com
Benjamin J. Hendricks
bhendricks@omm.com
Eileen M. Brogan
ebrogan@omm.com
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, D.C. 20006
Telephone: +1-202-383-5300
Facsimile: +1-202-383-5414

Anna M. Fabish
afabish@omm.com
Stephen J. McIntyre
smcintyre@omm.com
O'MELVENY & MYERS LLP
400 South Hope Street
Los Angeles, CA 90071
Telephone: +1-213-430-6000
Facsimile: +1-213-430-6407

Counsel for Impax Laboratories, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on December 27, 2017, I filed the foregoing document using the FTC's E-Filing System, which will send notification of such filing to:

Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, D.C. 20580
ElectronicFilings@ftc.gov

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, D.C. 20580

I also certify that I caused a copy of the foregoing to be served upon the following individuals by electronic mail:

Markus Meier
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: mmeier@ftc.gov

Bradley Albert
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: balbert@ftc.gov

Daniel Butrymowicz
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: dbutrymowicz@ftc.gov

Nicholas Leefer
Federal Trade Commission
600 Pennsylvania Ave, NW

Washington, DC 20580
Telephone: 202-326-3759
Email: nleefer@ftc.gov

Synda Mark
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: smark@ftc.gov

Maren Schmidt
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: mschmidt@ftc.gov

Eric Sprague
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: esprague@ftc.gov

Jamie Towey
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: jtowey@ftc.gov

Chuck Loughlin
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: cloughlin@ftc.gov

DATED: December 27, 2017

/s/ *Eileen M. Brogan*
Eileen M. Brogan

CERTIFICATE FOR ELECTRONIC FILING

I hereby certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

DATED: December 27, 2017

/s/ *Eileen M. Brogan*
Eileen M. Brogan

Notice of Electronic Service

I hereby certify that on December 27, 2017, I filed an electronic copy of the foregoing RESPONDENT IMPAX LABORATORIES, INC.'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, RESPONDENT IMPAX LABORATORIES, INC.'S POST-TRIAL BRIEF, with:

D. Michael Chappell
Chief Administrative Law Judge
600 Pennsylvania Ave., NW
Suite 110
Washington, DC, 20580

Donald Clark
600 Pennsylvania Ave., NW
Suite 172
Washington, DC, 20580

I hereby certify that on December 27, 2017, I served via E-Service an electronic copy of the foregoing RESPONDENT IMPAX LABORATORIES, INC.'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, RESPONDENT IMPAX LABORATORIES, INC.'S POST-TRIAL BRIEF, upon:

Bradley Albert
Attorney
Federal Trade Commission
balbert@ftc.gov
Complaint

Daniel Butrymowicz
Attorney
Federal Trade Commission
dbutrymowicz@ftc.gov
Complaint

Nicholas Leefer
Attorney
Federal Trade Commission
nleefer@ftc.gov
Complaint

Synda Mark
Attorney
Federal Trade Commission
smark@ftc.gov
Complaint

Maren Schmidt
Attorney
Federal Trade Commission
mschmidt@ftc.gov
Complaint

Eric Sprague
Attorney
Federal Trade Commission
esprague@ftc.gov
Complaint

Jamie Towey
Attorney

Federal Trade Commission
jtowey@ftc.gov
Complaint

Chuck Loughlin
Attorney
Federal Trade Commission
cloughlin@ftc.gov
Complaint

Alpa D. Davis
Attorney
Federal Trade Commission
adavis6@ftc.gov
Complaint

Lauren Peay
Attorney
Federal Trade Commission
lpeay@ftc.gov
Complaint

James H. Weingarten
Attorney
Federal Trade Commission
jweingarten@ftc.gov
Complaint

Edward D. Hassi
O'Melveny & Myers, LLP
ehassi@omm.com
Respondent

Michael E. Antalics
O'Melveny & Myers, LLP
mantalics@omm.com
Respondent

Benjamin J. Hendricks
O'Melveny & Myers, LLP
bhendricks@omm.com
Respondent

Eileen M. Brogan
O'Melveny & Myers, LLP
ebrogan@omm.com
Respondent

Anna Fabish
O'Melveny & Myers, LLP
afabish@omm.com
Respondent

Stephen McIntyre
O'Melveny & Myers, LLP
smcintyre@omm.com
Respondent

Rebecca Weinstein

Attorney
Federal Trade Commission
rweinstein@ftc.gov
Complaint

Garth Huston
Attorney
Federal Trade Commission
ghuston@ftc.gov
Complaint

I hereby certify that on December 27, 2017, I served via other means, as provided in 4.4(b) of the foregoing RESPONDENT IMPAX LABORATORIES, INC.'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, RESPONDENT IMPAX LABORATORIES, INC.'S POST-TRIAL BRIEF, upon:

Markus Meier
Attorney
Federal Trade Commission
mmeier@ftc.gov
Complaint

Eileen Brogan
Attorney