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

02 14 2018

In the Matter of	)	
Impax Laboratories, Inc., a corporation,	)	**DOCKET NO. 9373**
Respondent	)	

COMPLAINT COUNSEL'S POST-TRIAL REPLY FINDINGS OF FACT AND CONCLUSIONS OF LAW

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I. IMPAX BACKGROUND

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

Response to Proposed Finding No. 1

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 2

This Proposed Finding is incomplete. Impax's business does not solely focus on generics, but also develops, manufactures, and markets branded drugs. (*See* CCF ¶¶ 2, 1460, 1467, 1469, 1471; *see also* CX4033 (Nestor, Dep. at 15) (at least since 2008, Impax has attempted to develop at least seven branded products)).

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

Response to Proposed Finding No. 3

This Proposed Finding is inaccurate and not supported by the testimony cited. While Impax had not marketed a branded product that it had internally developed prior to marketing Rytary in 2015, Impax had marketed branded products, including Carbitol, on behalf of other companies. (Nestor, Tr. 2931; CX4033 (Nestor, Dep. at 53) ("When the brand business was originally started, we were promoting other companies' products more on a contract sales organization basis, but we always wanted to get our own product.")).

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).

Response to Proposed Finding No. 4

This Proposed Finding is misleading to the extent that it suggests that Impax did not market branded products on behalf of other companies prior to launching Rytary in 2015. (*See* Complaint Counsel's Response to Proposed Finding No. 3).

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

Response to Proposed Finding No. 5

Complaint Counsel objects to the term "small" as vague. Although Complaint Counsel does not dispute that Impax's annual revenues are less than other pharmaceutical manufacturers,

Complaint Counsel has no specific response.

9. In comparison, .

Response to Proposed Finding No. 9

Complaint Counsel has no specific response, except to note that the Proposed Finding is not relevant to analyzing whether Endo's payment to Impaxa -2370 TdjSTc m

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)).

Response to Proposed Finding No. 13

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 14

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 15

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 16

Complaint Counsel has no specific response, except to note that opioids may be used to treat types of pain other than moderate to severe. (CX5002 at 014 (¶ 31) (Savage Report); CCF ¶ 34).

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

Response to Proposed Finding No. 17

Complaint Counsel has no specific response.

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

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 25

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. Within the category of opioids, there are significant differences and individual responses to different medications—including differences between immediate-release and extended release opioids. These differences can be important to the treatment of individual patients. (CCF ¶ 746). Because of individual variability in responses to opioids, it is impossible to reliably predict an individual patient's response to a new opioid. (CCF ¶ 753). Indeed, according to Impax's own medical expert, approximately 50% of patients do not tolerate the first opioid they try. (CCF ¶ 751; *see generally* CCF ¶¶ 741-88).

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).

Response to Proposed Finding No. 31

Complaint Counsel has no specific response.

B. Active Pharmaceutical Ingredients in Opioids

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).

Response to Proposed Finding No. 32

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 33

Complaint Counsel has no specific response.

34. There are a number of opioid-based APIs used to treat moderate to severe pain. They are

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 35

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 36

Complaint Counsel has no specific response, except to note that at all times relevant to this case, Opana ER has been the only branded extended-release oxymorphone product. (CCF ¶¶ 37, 831-36).

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).

Response to Proposed Finding No. 37

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 38

Complaint Counsel has no specific response, except to note that Xtampza was not approved until April 26, 2016, which is after the period of anticompetitive harm resulting from the conduct at issue in this case. (CX5000 at 195 (Ex. 4: Other Long Acting Opioids) (Noll Report)). Xtampza, therefore, is not relevant to analyzing whether Endo's payment to Impax to eliminate the risk of competition until January 1, 2013, violated the antitrust laws.

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

Response to Proposed Finding No. 39

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 40

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 41

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 42

Complaint Counsel has no specific response.

Ultram is the brand-name version of extended-release ... 753 -2.3 Td( )Tn Tw a3 12 0 0 12 72 464.16 Tm(42.)Tj/TT1 1 Tf0.000

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

Response to Proposed Finding No. 46

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 47

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 48

The Proposed Finding is misleading and not supported by the cited evidence to the extent that it suggests that both branded and generic drug manufacturers must compete on price to get their products into a wholesaler's network. In the cited testimony, Mr. Engle explains that a wholesaler will generally select one or more generic products from which to buy the particular generic product and that, as a result, generic companies must compete on price to get on this preferred list. This is one reason generic competition results in lower prices for consumers. However, Mr. Engle's testimony does not indicate, and there is no evidence in the record, that brand manufacturers must also compete with other brand manufacturers to get their branded product into a wholesaler's network. (CCF ¶ 669; *see also* CCF ¶¶ 654-716 (discussing the lack of price competition between different LAOs as indicated by the little interaction between events in the sale of one opioid on the sales of another opioid)). A wholesaler generally distributes most or all branded products, even from the same therapeutic class.

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).

Response to Proposed Finding No. 49

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 50

The Proposed Finding is misleading and not supported by the cited evidence to the extent that it suggests that both branded and generic drug manufacturers must compete on price to get their products into national pharmacy chains. In the cited testimony, Mr. Engle explains that a pharmacy chain will generally select one or two suppliers for a particular generic product and that, as a result, generic companies must compete on price to get their product into that pharmacy chain. This is one reason generic competition results in lower prices for consumers. Mr. Engle's testimony does not indicate, and there is no evidence in the record, that brand manufacturers must also compete with other brand manufacturers to get their branded product into a national pharmacy chain. (CCF ¶ 669 (citing Noll, Dep. at 188-89); *see also* CCF ¶¶ 654-716 (discussing the lack of price competition between different LAOs as indicated by the little interaction between events in the sale of one opioid on the sales of another opioid)). A national pharmacy chain generally stocks most or all branded products, even from the same therapeutic class.

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

Response to Proposed Finding No. 51

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 52

Complaint Counsel has no specific response.

D. The Role of Insurers

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).

Response to Proposed Finding No. 53

The Proposed Finding is incomplete. Because third-party payors are often responsible for most of a drug's cost, a common practice is to create a formulary that classifies drugs into tiers on the basis of the perceived cost-effectiveness of the drug. The highest tier includes drugs that are most preferred within a therapeutic class. (CCF ¶ 569). Normally, the most preferred tier contains only the generic version of the drug if a generic is available. (CCF ¶ 570).

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

Response to Proposed Finding No. 54

Complaint Counsel objects to the term "exert significant pressure" as it misstates the testimony and is inaccurate to the extent that it suggests doctors base prescribing decisions on pressure from insurance companies. In the cited

the use of the lower-cost medications, which are frequently the generics." (Michna, Tr. 2129).

Response to Proposed Finding No. 55

The Proposed Finding is misleading to the extent that it suggests doctors base prescribing decisions on pressure from insurance companies. (*See* Complaint Counsel's Response to Proposed Finding No. 54).

1. Co-Pay

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

Response to Proposed Finding No. 56

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 57

Complaint Counsel has no specific response.

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")).

Response to Proposed Finding No. 58

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 59

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 60

The Proposed Finding is misleading insofar as it suggests that doctors base prescribing decisions on formulary status of drugs or on pressure from insurance companies. Instead both medical experts, Dr. Michna and Dr. Savage, agree that a physician's primary concern is to select a drug that will deliver the greatest therapeutic benefit to the patients. Dr. Michna and Dr. Savage agree that a physician is generally unaware of the prices of different long-acting opioid medications and, therefore, is unlikely to change prescribing habits or switch a patient who is being successfully treated with Opana ER to another long-acting opioid based on minor fluctuations in price. (CCF ¶¶ 18, 19, 563-65).

The Proposed Finding is also not supported by the cited testimony. Mr. Bingol testified that his understanding of how formulary tiers work is based on his experience at Endo. He did not establish a basis for testifying as to whether "formularies are all about access," whether insurance companies "restrict[] access to certain categories of product," or whether insurance companies "steer[] their patients to the higher tiers." (Bingol, Tr. 1320-22). In addition, the testimony of the identified experts does not provide support for the factual propositions in the Proposed Finding.

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

¶ 563). Physicians do not have strong incentives to take into account the relative prices of drugs when selecting among them, especially if a substantial fraction of a patient's drug expenditures are covered by insurance or a government health plan. Indeed, physicians are often unaware of drug prices when selecting the appropriate medication. (CCF ¶¶ 18, 563-65).

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).

Response to Proposed Finding No. 62

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 63

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 64

Complaint Counsel objects to phrase "easiest and fastest" as vague and unsupported. Tier-one formulary drugs generally are cheaper than drugs listed on other tiers. It does not follow, however, that it is easier or faster to gain access to a tier-one drug as compared to drugs listed on other tiers.

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

Response to Proposed Finding No. 65

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 66

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 67

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 68

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 69

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 70

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 71

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 72

Complaint Counsel has no specific response.

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.")).

Response to Proposed Finding No. 79

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 80

Complaint Counsel has no specific response.

3. Pharmacies

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

Response to Proposed Finding No. 81

Complaint Counsel has no specific response.

After a prescription is filled, the pharmacy receives a reimbursebr95 frat the 8279.

Response to Proposed Finding No. 84

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 85

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 86

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 87

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 88

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 89

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 90

Complaint Counsel has no specific response.

Response to Proposed Finding No. 95

Complaint Counsel has no specific response.

D. The Endo-Impax Lawsuit

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)).

Response to Proposed Finding No. 102

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 103

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 104

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 105

Complaint Counsel has no specific response.

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.

Response to Proposed Finding No. 106

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 107

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 108

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 109

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 110

Complaint Counsel has no specific response.

F. Endo's Suits Against Other ANDA Filers

113. Endo also sued Actavis and all other Opana ER ANDA filers, alleging patent

contain payments, contained licensed entry dates in 2011 and 2012, respectively—earlier than Impax's January 2013 date. (CCF ¶ 1009).

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

Response to Proposed Finding No. 115

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 116

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 117

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 118

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 119

The Proposed Finding is misleading to the extent that it suggests that Endo and Impax were interested in working together on a business deal independently of settling patent litigation.

As part the fall 2009 settlement talks, Impax and Endo executed a confidential disclosure agreement and discussed partnering together on a deal concerning Endo's migraine drug, Frova. (CCF ¶ 216). During those settlement talks, Impax and Endo also discussed potential generic license entry dates. (CCF ¶ 217). When the patent settlement discussions faltered, Endo and Impax also ceased discussion of any business transaction. (CCF ¶ 218).

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)).

Response to Proposed Finding No. 120

Complaint Counsel has no specific response, except to note that settlement negotiations also resumed because Endo learned that the FDA tentatively approved Impax's ANDA for generic oxymorphone ER. (CCF ¶ 219). The FDA granted tentative approval to Impax's ANDA on May 13, 2010, which meant that the FDA had determined that Impax's ANDA would be ready for final approval upon the expiration of the 30-month stay on June 14, 2010. (CCF ¶ 220). That tentative approval also affirmed Impax's first-filer eligibility for the 5, 10, 20, 30, and 40 mg dosage strengths of generic Opana ER—the most profitable dosages for Endo (comprising over 95% of Endo's Opana ER sales). (CCF ¶¶ 101, 220).

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)).

Response to Proposed Finding No. 121

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 122

Complaint Counsel has no specific response, except to note that prior to the Impax-Endo Settlement Agreement, Impax also considered and was preparing for a launch of generic oxymorphone ER as early as June 14, 2010. (CCF ¶¶ 127-213). In February 2010, Impax's CEO Larry Hsu widely distributed Impax's finalized 2010 Company Key Goals to management personnel. (CCF ¶ 129). Successfully managing the new product launch of oxymorphone ER was one of those key goals; Impax's "financial success" in 2010 would "hinge heavily on [its] success in several key products," including oxymorphone ER. (CCF ¶ 130 (quoting CX2562 at 002)).

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).

Response to Proposed Finding No. 123

The Proposed Finding is incomplete in that it fails to acknowledge other possible scenarios, including that Impax may have "obtained a favorable judgment" at the district court level. (CCF ¶ 368 (quoting CX5007 at 044 (¶ 82) (Hoxie Rebuttal Report))).

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).

Response to Proposed Finding No. 124

The Proposed Finding is incomplete in that it fails to acknowledge that a generic company may also prevail in the patent litigation, in which case the generic may launch its product prior to patent expiration. The outcome of the Endo-Impax patent litigation at the trial and appellate levels was uncertain in June 2010. (CCF ¶¶ 363-64). Even if Endo won the patent litigation at the district court, it faced significant risk of loss on appeal, as there was the strong possibility that the district court's claim construction ruling could have been reversed by the Federal Circuit. (CCF ¶ 369 (citing CX5007 at 041-43 (¶¶ 76, 79) (Hoxie Rebuttal Report));

payment agreement. By agreeing not to launch its generic product for some period of time, Impax would lose profits it would earn on sales of its generic product. However, if Endo were to compensate Impax with a sufficiently large payment, Impax would be better off postponing its launch until a later date. (CCF ¶ 979). That is exactly what happened here. Going into the negotiations, Impax wanted to launch its generic oxymorphone ER "as early as possible." (CCF ¶ 122 (citing CX4030 (Hsu, Dep. at 28))). Indeed, Impax's Generic's Division President was initially hesitant to delay launch even until January 2011. (CCF ¶ 224 (quoting CX0505 at 001 (May 14, 2010 Mengler email) ("the cost of Jan '11 is lost/delayed sales — you know what they

Complaint Counsel objects to the term "pushed" as inconsistent with the cited evidence. The cited testimony indicates that Impax asked for a July 2011 entry date, but that Impax quickly acceded to Endo's position that Impax accept the 2013 entry date in exchange for the various forms of compensation, including the no-AG provision, Endo Credit, and DCA. (CX4032 (Snowden, Dep. at 94-95); CX4003 (Snowden, IHT at 56-57); CX4010 (Mengler, IHT at 110-11).

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).

Response to Proposed Finding No. 134

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 135

The Proposed Finding is misleading and incomplete because Endo's negotiating position says nothing about what Endo would actually accept in a settlement. (Addanki, Tr. 2390-91 ("I don't think you can infer what someone's true reservation date was from a negotiation posture in a settlement negotiation.")). It is simple negotiation logic that, rather than agreeing to a January 2013 entry date with a reverse payment such as the combined No-AG provision/Endo Credit—which actually resulted in a $102 million payment from Endo to Impax—Endo would have agreed to a date earlier than January 2013 without that amount of money being paid. (CCF ¶ 1441). In fact, Endo settled patent litigation concerning generic oxymorphone ER with five other generic companies. Each of those settlements included generic entry dates earlier than January 2013 and no reverse payment. (CCF ¶¶ 1447-52).

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 135.

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).

Response to Proposed Finding No. 140

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 135. In addition, the Proposed Finding is not supported by the testimony of Professor Noll. Professor Noll does not testify that Impax was able to move the entry date up two months through hard negotiations. In the cited testimony, Professor Noll explains that the negotiations did not focus on the entry date at all. Instead, "what they were really negotiating over was the price as opposed to when the date would be." (Noll, Tr. 1598-99). In other words, the negotiation focused on how

stay out of the market until 2013. (CCF ¶¶ 227-28). The subsequent settlement negotiations then focused on refining the compensation package. (CCF ¶¶ 1036-39). Indeed, each time Impax sought an earlier entry date, Endo responded with additional compensation. First, Impax sought an acceleration trigger that would move up Impax's entry date prior to 2013 if branded Opana ER sales dropped below a threshold level. (CCF ¶¶ 251-52). Endo rejected the accelerated entry, but agreed to sweeten the pot with the Endo Credit. (CCF ¶¶ 253-55, 1051). Under the Endo Credit, Endo paid Impax rather than facing earlier entry through an acceleration provision. (CCF ¶¶ 1051-52). Impax also suggested a "simple settlement" that would drop the compensation terms (No-AG provision, Endo Credit, and side deal), but with a generic entry date of July 2011—the same date Endo had grated to Actavis. (CCF ¶ 276). Endo refused the earlier entry date, but then discussed "better terms on the co-promote deal." (CCF ¶ 278).

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

1, 2013, **Response to Proposed Finding No. 143**

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 135 and 140.

144. There is no evidence that Endo ever offered an entry date earlier than January 1, 2013, despite Impax's efforts to secu

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 146

Complaint Counsel has no specific response.

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")).

Response to Proposed Finding No. 147

Complaint Counsel has no specific response, except to note that, like Impax, Actavis also believed it had received an express or implied license to future patents in its oxymorphone ER settlement with Endo. In a subsequent patent litigation, Actavis successfully asserted to the district court that the license it obtained from Endo extended to pending patent applications.

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not interested in seeking a freedom-to-operate license that covers all potentially relevant patents, including patents that might issue from pending applications owned or controlled by the licensor. (CCF ¶ 1411). This type of freedom-to-operate license is common in the pharmaceutical industry. (CCF ¶¶ 1408, 1411-12).

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)).

Response to Proposed Finding No. 150

Complaint Counsel has no specific response, except to note that it is common for a licensee seeking freedom to operate for a product to seek a license to all potentially relevant patents and patents issuing from pending applications owned or controlled by the licensor. (CCF ¶¶ 1408, 1411). Licensing some patents while still blocking the licensee's product with other patents frustrates the underlying purpose of the license, which is ordinarily to give the licensee freedom to operate. (CCF ¶ 1411).

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)).

Response to Proposed Finding No. 151

Complaint Counsel has no specific response, except to note that it is common for a licensee seeking freedom to operate for a product to seek a license to all potentially relevant patents and patents issuing from pending applications owned or controlled by the licensor. (CCF ¶¶ 1408, 11). Licensing some patents while still blocking the licensee's product with other patents frustrates the underlying purpose of the license, which is ordinarily to give the licensee freedom to operate. (CCF ¶ 1411).

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).

Response to Proposed Finding No. 152

Complaint Counsel objects to the term "fought hard" as inaccurate and contrary to the weight of the evidence. It is true that Impax—like other licensees—generally seeks a license broad enough to ensure it will have freedom to operate for the product at issue. (CCF ¶ 1413). The issue of including in the SLA a license to patents that may issue in the future from pending patent applications covering Endo's Opana ER did not arise until the last few days of negotiations. (CCF ¶¶ 1405-07). Impax and Endo did not discuss the scope of the patent license to be granted to Impax prior to reaching agreement in principle on June 3, 2010. (CCF ¶ 279). Mr. Mengler, Impax's primary negotiator until June 4, 2010, never "had a discussion with Endo about patents personally." (CCF ¶ 279 (citing Mengler, Tr. 524-25, 573); *see also* CX4022 (Mengler, Dep. at 226)). When Mr. Koch and Ms. Snowden took over negotiating responsibilities on June 4, 2010, the licensed entry date of January 1, 2013 was already set. (CCF ¶ 279). Mr. Koch and Ms. Snowden also did not raise the issue of the scope of the patent license with Endo. (CCF ¶ 279). Huong Nguyen, Impax's Senior Director of Intellectual Property, first became involved in the settlement talks on June 5, 2010. (CCF ¶ 280). That same day, Impax for the first time proposed broadening the patent license to "any patents and patent applications owned or licensed by Endo . . . that cover or could potentially cover" Impax's generic oxymorphone ER product. (CCF ¶ 280 (quoting CX0324 at 030 (June 5, 2010 draft SLA))). Endo and Impax settled the infringement case on June 8, 2010. (CCF ¶ 92).

The Proposed Finding is also misleading in that it suggests that the license Impax

generic version of Original Opana ER in January 2013, the parties disagreed over the interpretation of the license in the SLA. (CCF ¶ 1420). Endo eventually sued Impax for infringement of three patents Endo obtained after entering into the SLA. (CCF ¶ 1421). Indeed, if the parties had not settled that lawsuit, Impax could have been liable for damages and possibly even required to withdraw its generic oxymorphone ER product from the market. (CCF ¶ 1430; s*ee* Complaint Counsel's Response to Proposed Finding No. 157).

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).

Response to Proposed Finding No. 153

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)).

Response to Proposed Finding No. 155

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 156

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 157

The Proposed Finding is not supported by the testimony and contrary to the weight of the evidence. In the cited testimony, Mr. Koch testified that "Impax agreed to a specific launch date in return for eliminating uncertainty of the patent litigation." (Koch, Tr. 236). He did not, however, discuss any assurances regarding Impax's ability to launch generic oxymorphone ER free from patent risk. Instead, the evidence shows that the license did not eliminate all uncertainty. The license Impax received in the SLA was open to contradictory interpretations. (CCF ¶ 1416). After Impax began selling a generic version of Original Opana ER in January 2013, the parties disagreed over the interpretation of the license in the SLA. (CCF ¶ 1420). On May 4, 2016, Endo sued Impax for infringement of three patents Endo obtained after entering into the SLA. (CCF ¶ 1421). Impax moved to dismiss the case, which the court denied except as to one of the patents. Endo then provided Impax notice of termination of the SLA and requested

that Impax immediately stop selling what Endo characterized as Impax's infringing generic Opana ER product. (CCF ¶¶ 1415-25). In the notice, Endo stated "there is no legitimate dispute that Impax's current Opana ER generic tablets infringe Endo's patents" and demanded that "Impax should therefore honor Endo's patent rights and immediately ce Cn]TJ0.0012 Tc -0.00159 Tw T9d t

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 160

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 161

Complaint Counsel has no specific response.

But introducing a reformulated product can also protect the branded franchise from losing

Response to Proposed Finding No. 165

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 166

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 167

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 168

Complaint Counsel has no specific response, except to note that the weight of the evidence shows that Endo's plans to reformulate Opana ER date back to at least 2007. (CCF ¶ 73).

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

Response to Proposed Finding No. 169

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 170

The Proposed Finding is incomplete. Though Endo had not publicly disclosed its plans to reformulate Opana ER, Impax suspected Endo might switch to a new formulation before Impax could enter with its generic oxymorphone ER product. (CCF ¶ 246).

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).

Response to Proposed Finding No. 171

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 172

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 173

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 174

Complaint Counsel has no specific response, except to note that Mr. Mengler testified that during negotiations Impax "knew Endo was working on [a reformulated] product." (Mengler, Tr. 569 ("[A]t some point -- I don't remember where that -- we learned of this in the negotiation, but one of my -- one of my guys actually came up with -- I don't know if it was a

news release or an analyst report describing the fact that Endo had licensed in or was partnering with somebody on crush-resistant technology, so we felt it was a pretty safe bet that this was an effort on their part.")).

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

Response to Proposed Finding No. 175

Complaint Counsel has no specific response.

Complaint Counsel has no specific response.

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).

The Proposed Finding is misleading and incomplete because Endo's negotiating position says nothing about what Endo would actually accept in a settlement. (Addanki, Tr. 2390-91) ("I don't think you can infer what someone's true reservation date was from a negotiation posture in a settlement negotiation.")). Endo rejected the accelerated entry because it preferred to pay Impax to accept the January 2013 entry date rather

sales declined before the agreed-upon entry date for Impax's generic version of oxymorphone. If Endo did destroy the market for Original Opana ER, Impax wanted to be "made whole for the profits that [it] would have otherwise achieved." (Mengler, Tr. at 533; CCF ¶¶ 253-55, 1055-65).

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).

Response to Proposed Finding No. 186

Complaint Counsel objects to the term "penalty" as inaccurate for the reasons set forth in response to Proposed Finding No. 185.

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).

Response to Proposed Finding No. 187

Complaint Counsel objects to the terms "penalty" and "incentivize" as inaccurate for the reasons set forth in response to Proposed Finding No. 185.

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)).

Response to Proposed Finding No. 188

The Proposed Finding is misleading and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 185. The Proposed Finding is also not supported by the testimony cited. Dr. Ben-Maimon was not employed by Impax in 2010 and therefore had no involvement in this negotiation. (CX4021 (Ben-Maimon, Dep. at 11)). Thus, she lacks personal knowledge to testify that the purpose of the Endo Credit was to "prevent [Endo] from switching the market." (CX4021 (Ben-Maimon, Dep. at 118, 122)).

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).

Response to Proposed Finding No. 189

The Proposed Finding is misleading and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 185. The Endo Credit functioned to reimburse Impax, not to deter Endo from reformulating Opana ER and degrading the market for Impax's generic. (CCF ¶¶ 1059-63). Complaint Counsel objects to the term "incentivize" as misleading and inaccurate for the same reasons.

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)).

Response to Proposed Finding No. 190

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 191

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 192

The Proposed Finding is inaccurate and contrary to the weight of the evidence. Both Endo and Impax anticipated that the marketplace for Opana ER would change before Impax's generic entry in January 2013. Endo's long-standing strategy—as reflected by internal planning

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")).

Response to Proposed Finding No. 195

The Proposed Finding is inaccurate and contrary to the weight of the evidence. Although Impax now seeks to redefine the royalty provision as the mirror image of the Endo Credit, there is no contemporaneous supporting evidence. The purported "mirror images" were not proposed together or related to one another at any point during the negotiations. (CCF ¶ 1058). A royalty term was in the first written proposal exchanged on May 26, 2010. (CCF ¶ 1058). In contrast, a variant of the Endo Credit did not appear in a written proposal exchanged between Impax and Endo until June 4, 2010. (CCF ¶ 1058). Instead, at the time of settlement, Impax viewed the Endo Credit as market protection, because it functioned to reimburse Impax, not to deter Endo from reformulating Opana ER and degrading the market for Impax's generic. (CCF ¶¶ 1057-63).

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).

Response to Proposed Finding No. 196

generic sales, it would lose 100% of profits it could have earned from sales of an Endo AG.

(CCF ¶¶ 1064-65).

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

Response to Proposed Finding No. 197

The Proposed Finding is misleading and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding Nos. 184 and 196.

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)).

Response to Proposed Finding No. 198

The Proposed Finding is misleading and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 184.

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).

Response to Proposed Finding No. 199

Complaint Counsel has no specific response.

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))).

Response to Proposed Finding No. 200

The Proposed Finding is misleading insofar as it suggests that the No-AG provision would have no financial benefit to Impax because Impax would still face competition from Endo's branded Opana ER. Authorized generics ha

testimony, Mr. Mengler did not address whether there were meaningful, significant, or any other sort of discussions surrounding the No-AG provision. (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

27, 422-23). Getting downside protection in the event Endo reformulated Opana ER was "super, super important" to Mr. Mengler. (CCF ¶ 427 (quoting Mengler, Tr. 535-36)).

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).

Complaint Counsel has no specific response, except to note that the FDA ultimately

Response to Proposed Finding No. 209

This Proposed Finding is factually inaccurate and contrary to the weight of the evidence. To support this finding, Impax relies solely on a single accounting document from April 2012, almost two years after the conduct at issue. But Endo's long-standing strategy—as reflected by internal planning documents and confirmed by testimony of its executives—was to launch Reformulated Opana ER as soon as possible, and long before Impax's January 2013 entry date. (CCF ¶¶ 75, 482-87). Endo knew that a smooth transition to Reformulated Opana ER could take up to a year and that it would be harder to accomplish if generic oxymorphone ER was already on the market. (CCF ¶¶ 80, 482, 486-87). As early as December 2007, Endo's "Priority #1" for its Reformulated Opana ER introduction was to "Beat Generics by 1 Year." (CCF ¶ 75 (quoting CX2578 at 009)). As of April 2010, Endo's plan was to launch Reformulated Opana ER in "March 2011, but could range from Dec-10 to Jun-11." (CCF ¶ 484 (quoting CX3038 at 001)). Even after entering into the agreement with Impax, Endo maintained its intention to launch Reformulated Opana ER as soon as possible. (CCF ¶ 484 (citing CX1108 at 008 (Nov. 2010 internal presentation) (identifying "[c]urrent planning assumption is to stop shipping all OPANA ER by October 1, 2011"))). Indeed, none of Endo's

Impax's January 2013 entry date. (CCF ¶¶ 75, 482-87). As of April 2010, Endo's plan was to launch Reformulated Opana ER in "March 2011, but could range from Dec-10 to Jun-11." (CCF ¶ 484 (quoting CX3038 at 001)). Even after entering into the agreement with Impax, Endo maintained its intention to launch Reformulated Opana ER as soon as possible. (CCF ¶ 484 (citing CX1108 at 004 (Nov. 2010 internal presentation) (identifying "current planning assumption is to stop shipping all Opana ER by October 1, 2011"))). Endo planned to implement the transition by removing Original Opana ER from the market after introducing Reformulated Opana ER. (CCF ¶ 77 (citing CX1108 at 008, 013 (Revopan Board Update) (noting plan to launch Revopan in February 2011 and stop shipping Opana ER by October 2011))). This transition would take time—generally six to nine months. (CCF ¶ 80). Endo filed a supplemental NDA for Reformulated Opana ER in July 2010, but the FDA did not approve the application

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 209 and 210.

Response to Proposed Finding No. 215

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 216

Complaint Counsel has no specific response.

217. Endo consequently could "verbally talk about" crush-resistance, but could not "say it officially" with respect to its reformulat

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).

Response to Proposed Finding No. 221

Complaint Counsel objects to the phrase "fought hard to ensure that consumers had access" as misleading. Both consumers and Impax benefit from a generic being on the market (Mengler, Tr. 527 (the way Impax "make[s] money is by selling generic drugs")). The Proposed Finding is also misleading insofar as it suggests that Impax's conduct in seeking to maximize its sales of generic oxymorphone ER is surprising or altruistic. A rational company in Impax's position would seek to do the same and try to maximize its profits. (*See* Addanki, Tr. 2462-63).

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)).

Response to Proposed Finding No. 222

Complaint Counsel has no specific response.

223. Impax formally responded to the petition and offered scientific evidence that the discontinuation of Endo's original Opana ER wa

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 225

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 226

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 227

Complaint Counsel has no specific response.

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,

the market. (CCF ¶ 248). The discontinuation of Original Opana ER thus created a potentially "ideal scenario for Impax": Impax would "receive the contractual downside protection [the Endo Credit] *and* [would] still [be] able to launch the original Opana ER and drive sales by taking sales away from the new Opana ER." (RX-379 at 0001 (emphasis in original)).

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).

Response to Proposed Finding No. 229

Complaint Counsel objects to the phrase "to help consumers gain access" as misleading for the reasons set forth in response to Proposed Finding Nos. 221 and 228.

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)).

Response to Proposed Finding No. 230

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 221 and 228.

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)).

Response to Proposed Finding No. 231

Complaint Counsel has no specific response.

Impax then studied the effect of its efforts nationwide and region-by-region in order to

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

reverse payment was necessary to induce Impax to accept the license that it wanted and would benefit from. (CCF ¶¶ 1457-59).

The Proposed Finding is also incomplete. The license Impax received did not ensure freedom to operate. Instead, it left Impax exposed to considerable risk, uncertainty, and expense. (CCF ¶¶ 1415-17). In fact, on May 4, 2016, Endo filed a suit against Impax in New Jersey, alleging that Impax was in breach of the SLA with respect to three new patents—the ’122, the

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 Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 233.

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).

Response to Proposed Finding No. 249

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 233.

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).

Response to Proposed Finding No. 250

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 233 and 242.

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).

Response to Proposed Finding No. 251

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 233.

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)).

Response to Proposed Finding No. 252

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 233.

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

Response to Proposed Finding No. 253

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 233.

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).

Response to Proposed Finding No. 254

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 255

The Proposed Finding is incomplete. In a patent infringement lawsuit that Endo filed against Actavis on the ’122 and ’216 patents, Actavis successfully asserted at the district court level that the license it obtained from Endo extended to pending patent applications as well. (CCF ¶ 1414; CX3455 at 049 (Sep. 19, 2013 *Endo v. Actavis* transcript)). Another ANDA filer, Sandoz, obtained an option to license Orange Book patents that Endo might obtain in the future relating to Opana ER. (CCF ¶ 1414; CX3378 at 100 (Sandoz settlement, § 4.4)).

*** * ***

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).

Response to Proposed Finding No. 256

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 233.

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

Response to Proposed Finding No. 257

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 233 and 242.

E. Endo No Longer Sells Reformulated Opana ER

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).

Response to Proposed Finding No. 258

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 259

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 260

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 261

Complaint Counsel has no specific response.

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).

reformulated version of Opana ER from the market (*see* CX3189 at 002 (Endo's application for Reformulated Opana ER was not even filed with the FDA at the time of the Impax-Endo Settlement Agreement)). Indeed, it is still uncertain whether the Federal Circuit will reverse the lower court decisions that have enjoined other generic companies from marketing a generic version of Opana ER. (CCF ¶¶ 1431-32). As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. Instead, the relevant question is whether Endo shared its monopoly profits with Impax to avoid the risk of competition. *Actavis*, 133 S. Ct at 2236.

The Proposed Finding is also misleading and incomplete insofar as it suggests that the only reason there is an oxymorphone ER product on the market today is because of the Impax-Endo Settlement Agreement. At the time Impax entered into its agreement with Endo, there were myriad future outcomes. Impax may have launched at risk. (CCF ¶¶ 127-213). Impax may have proceeded with the litigation, won, and entered the market. (CCF ¶¶ 361-77). Endo may have faced different incentives in pursuing patent approvals, acquiring patents, or licensing patents to other companies. It is not possible to know what the market would look like today if Impax and Endo had not settled. (Noll, Tr. 1578-79 ("If there had been no settlement agreement, we do not know—it is incorrect to assert they would never have been on the market."); CCF ¶¶ 1431-35).

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)).

Response to Proposed Finding No. 265

Complaint Counsel has no specific response, except to note that Impax and Endo executed the DCA simultaneously with the SLA late on June 7, 2010. (CCF ¶ 314). The agreements' signature pages were placed in escrow until Endo signed a separate settlement with Sandoz, another generic manufacturer seeking to market generic Opana ER. (CCF ¶¶ 315-16). When Endo settled with Sandoz on June 8, 2010, the escrowed SLA and DCA were released. (CCF ¶ 317).

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)).

Response to Proposed Finding No. 266

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 267

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 268

Complaint Counsel has no specific response, except to clarify that Endo would make the payment to Impax if Impax successfully completed certain milestones on the way to commercializing the product agreed upon in the DCA. (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)).

Response to Proposed Finding No. 269

The Proposed Finding is an incomplete assessment of the rights granted under the DCA.

B. The DCA Payment

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)).

Response to Proposed Finding No. 271

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 272

The Proposed Finding is misleading and incomplete insofar as it suggests the $10 million payment was compensation for services provided under the DCA and not used to secure Impax's guarantee to stay off the market until January 2013. The terms of the DCA, including the $10 million payment, were negotiated as part of the patent litigation settlement, not as a standalone agreement. (CCF ¶¶ 1066-73). The DCA was also explicitly incorporated into the SLA by Section 9.3. (CCF ¶¶ 1066-67). Furthermore, Impax's 2010 budget update following the Endo settlement lists the $10 million payment as **{** [redacted] **}** (CX2701 at 004 (2010 Budget Update and 2011 Budget Preview) (*in camera*)). Endo continued to offer the $10 million upfront payment even after it learned that IPX-203 was an untested, pre-clinical compound that had not even been formulated and, thus, entailed far more risk than IPX-066, the original product under discussion. (CCF ¶¶ 295-97, 1082, 1203-06). The only logical reason for this is that the DCA "add[ed] significant topline revenue for Opana" by increasing to Impax's willingness to accept the January 2013 entry date for oxymorphone ER. (CX1701 at 005 (July 2010 Endo Corporate Development Update); *see also* CCF ¶¶ 232-39, 1082-83).

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).

Response to Proposed Finding No. 273

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 272.

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).

Response to Proposed Finding No. 274

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 272.

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).

Response to Proposed Finding No. 275

The Proposed Finding is misleading in that it suggests the DCA was a natural extension of Endo's reliance on collaboration agreements in general. The terms of the DCA were negotiated as part of "a package of deals" for the patent litigation settlement, not as a standalone agreement. (CCF ¶¶ 1066-73; Cobuzzi, Tr. 2632-33 (stating that the DCA and SLA were being negotiated together)). Unlike typical collaboration agreements, the DCA was used to secure Impax's guarantee to stay off the market until January 2013. (CCF ¶¶ 1066-73; *see also* CX2701 at 004 (2010 Budget Update and 2011 Budget Preview) (Impax, in fact, listed payments from the DCA as **{ }**) (*in camera*)).

1096 (citing Endo business plans)). Licensing or promoting Parkinson's drugs, like IPX-066 and IPX-203, also was not part of Endo's primary corporate strategy in 2010. (CCF ¶¶ 1085-95, Cobuzzi Tr. 2574-75, 2581-83; *see also* Cobuzzi Tr. 2578-80 (a consulting company paid by Endo specifically excluded Impax's carbidopa plus levodopa product from a list of drugs it recommend Endo pursue)). In fact, no one from Endo's corporate development group, the group that was responsible for "identif[ying] and evaluat[ing] potential licensing or acquisition candidates," ever sought a deal on Impax's Parkinson's products. (CX4016 (Cobuzzi, IHT at 20-21); Cobuzzi, Tr. 2585). Instead, Endo's chief negotiator for the Impax-Endo settlement, Mr. Levin, instructed Endo's corporate development group to assess Impax's Parkinson's products. (Cobuzzi, Tr. 2584-85).

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

Response to Proposed Finding No. 276

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 275.

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).

Response to Proposed Finding No. 277

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 275.

278. In fact, Endo's collaboration agreements regularly include early-stage development

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

Response to Proposed Finding No. 282

The Proposed Finding is incomplete. Endo acquired Penwest because the Endo-Penwest contractual commitments to sell Original Opana ER inhibited Endo's strategy to transition the market to Reformulated Opana ER. (CX4019 (Lortie, Dep. at 18-19); CCF ¶¶ 76-77 (discussing Endo's switch strategy)).

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).

Response to Proposed Finding No. 283

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 275.

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).

Response to Proposed Finding No. 284

The Proposed Finding is misleading, incomplete, and not supported by the evidence cited. Impax and Endo only engaged in collaboration discussions in the context of discussing settlement of the Opana ER patent litigation. Impax attempted to collaborate with Endo on Endo's migraine drug, Frova. (CCF ¶ 216). However, every time Impax "would talk to Endo about licensing the product from them, [Endo] would turn [Impax] down." (Nestor, Tr. 2932). Impax and Endo only entered a confidentiality agreement in fall 2009 to engage in discussions about Frova when they were simultaneously discussing settlement of the Opana ER patent infringement litigation. (CCF ¶ 216; Snowden, Tr. 454-56 (explaining that Mr. Fatholahi desired a Frova deal for Impax); CX4036 (Fatholahi, Dep. at 51-52) (Mr. Fatholahi did not discuss Frova

with Endo until late 2009)). The Frova discussions ended when the fall 2009 settlement negotiations broke down in December 2009. (CCF ¶ 218).

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).

Response to Proposed Finding No. 285

The Proposed Finding is not relevant and does not support Impax's claim that it has long pursued other collaborative opportunities with Endo. Endo and Penwest were completely separate companies in 2006. (*See* RX-491 at 0005).

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

Response to Proposed Finding No. 286

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 284. The Proposed Finding also is not supported by the evidence cited. None of the cited evidence supports the assertion that Endo was interested in collaborating with Impax on Frova in early 2009. In contrast, every time Impax attempted to talk with Endo about licensing Frova, Endo turned Impax down. (Nestor, Tr. 2932).

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).

Response to Proposed Finding No. 287

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 288

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).

Response to Proposed Finding No. 293

The Proposed Finding is factually inaccurate. Endo marketed a generic immediate-release version of Sinemet, not Sinemet itself. (CCF ¶ 1094).

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).

Response to Proposed Finding No. 294

Complaint Counsel has no specific response, except to note that extended-release versions of carbidopa-levodopa were available at the time of the DCA negotiations. (*See* CX2966 at 017 (discussing Sinemet CR)).

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).

Response to Proposed Finding No. 295

The Proposed Finding is factually inaccurate. (*See* RX-238 at 0010 ({[redacted]} (*in camera*)). The Proposed Finding is also misleading in that it suggests that carbidopa and levodopa products were not on the market for Parkinson's treatments. In fact, Endo was aware before signing the DCA that the carbidopa/levodopa market was highly genericized. (CCF ¶ 1266).

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).

Response to Proposed Finding No. 296

The Proposed Finding is misleading in that it suggests that at the time of the DCA Endo had a strategic focus on Parkinson's treatments. For a time, Endo marketed a generic immediate-release version of the Parkinson's disease treatment, Sine

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 296.

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

Response to Proposed Finding No. 300

The Proposed Finding is misleading and incomplete. Dr. Cobuzzi could recall specifics of only two other collaborations that Endo explored regarding Parkinson's treatments. (Cobuzzi, Tr. 2522). Endo never completed a deal with either company on a Parkinson's disease treatment. (Cobuzzi, Tr. 2575-76).

301. For instance, Endo explored potential Parkinson's collaboration opportunities with an

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).

Response to Proposed Finding No. 304

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 305

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 306

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 307

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 308

Complaint Counsel has no specific response, except to note that IPX-066 was not the subject drug product of the DCA.

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).

Response to Proposed Finding No. 309

Complaint Counsel has no specific response, except to note that IPX-066 was not the subject drug product of the DCA.

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).

Response to Proposed Finding No. 310

Complaint Counsel has no specific response, except to note that IPX-066 was not the subject drug product of the DCA.

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)).

Response to Proposed Finding No. 311

Complaint Counsel has no specific response, except to note that IPX-066 was not the subject drug product of the DCA.

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] **}**)

Response to Proposed Finding No. 312

The Proposed Finding is incomplete and misleading. At the time of the settlement negotiations, there was not sufficient information to determine if a next generation product was likely to improve upon IPX-066. In 2010, Impax was only at the beginning of the formulation

stage for IPX-203. (CCF ¶ 1153). In fact, **{** **}** (CCF ¶ 1148) (*in camera*); *see also* CCF ¶¶ 1248, 1250-51 (*in camera*)). Moreover, **{** **}** (CCF ¶ 1157) (*in camera*). **{** **}** (Cobuzzi, Tr. 2635 (stating "[w]e had no empiric data"); CCF ¶ 1159 (*in camera*)). Impax did not send any IPX-203 clinical data to Endo for review because no clinical data for IPX-203 was available at the time of the settlement. (CCF ¶ 1159). Furthermore, the product that is IPX-203 today is not the same product that was defined in the development agreement between Endo and Impax in 2010. (Snowden, Tr. 497; Nestor, Tr. 3045-49 (*in camera*)).

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).

Response to Proposed Finding No. 313

The Proposed Finding is incomplete and misleading for the reasons set forth in response to Proposed Finding No. 312.

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).

Response to Proposed Finding No. 314

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 315

The Proposed Finding is misleading and not supported by the evidence cited to the extent it suggests that Endo initially proposed IPX-066 as the subject of any collaboration deal and that Impax was not interested in discussing IPX-066. Impax and Endo discussed IPX-066 as the subject product of the DCA for over a week. (CCF ¶¶ 232-39, 285-94). Regarding Endo's interest in IPX-066, Meg Snowden previously testified that "what I am not sure of is if [Endo] expressed an interest and we said no." (CX4003 (Snowden, IHT at 93)). Moreover, Endo's corporate development group did not seek out the opportunity on IPX-066. (CCF ¶ 1095).

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, us4ds8saineme,opa a(5-9opa becaud(Drt Cobu perkinitialdo h2s)]TJ0.0012 Tc -0.0023 TJTd(e

1 e o57 cariodop/ levodopa

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).

Response to Proposed Finding No. 317

The Proposed Finding is misleading to the extent that it suggests that Impax's former CFO has personal knowledge about Endo's interest and plans for Endo's sales force.

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.")).

Response to Proposed Finding No. 318

The Proposed Finding is misleading and incomplete in that it suggests that Impax did not discuss IPX-066 as the subject of a potential development deal with Endo. Between May 17 and May 26, 2010, Impax and Endo discussed a potential joint development agreement for IPX-066. (CCF ¶¶ 232-39, 285-94). On both May 19 and 22, 2010, Impax's Vice President of Business Development, David Paterson, provided Endo with specific information and data on IPX-066. (CCF ¶¶ 235-36). **{**

} (CCF ¶¶ 287-290 (*in camera*)). It was only after more than a week of discussions that Impax switched the subject

while under the DCA, Endo was only permitted to promote IPX-203 to primary care doctors in the United States, not to neurologists, the largest prescribers of Parkinson's disease patients. (Nestor, Tr. 2874-75, 2948; CCF ¶ 1238).

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

Response to Proposed Finding No. 324

The Proposed Finding is irrelevant to the issue of whether Endo's $10 million payment to Impax under the DCA is unjustified. {[redacted]} (CCF ¶¶ 1140-43 (*in camera*)).

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).

Response to Proposed Finding No. 325

The Proposed Finding is not supported by the evidence cited. The cited testimony says nothing about whether Impax did or did not want a partner for IPX-066 in the United States or why Impax decided to switch the subject of the collaboration from IPX-066 to IPX-203. Instead, the cited testimony merely states that Impax and Endo discussed collaboration on IPX-203. The Proposed Finding is also misleading and incomplete in that it suggests that Impax and Endo never discussed IPX-066 as the subject of a potential development deal. Between May 17 and May 26, 2010, Impax and Endo discussed a potential joint development agreement for IPX-066. Impax sent data on IPX-066 to Endo and Endo took steps to evaluate IPX-066 as a potential

business development opportunity. On May 26, 2010, Impax switched the subject of the development deal from IPX-066 to IPX-203. (CCF ¶¶ 232-39, 285-94).

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).

Response to Proposed Finding No. 326

{ [redacted] **}** (CCF ¶¶ 295, 1141-43 (*in camera*)).

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).

Response to Proposed Finding No. 327

The Proposed Finding is misleading and incomplete in that it suggests that Impax and Endo never discussed IPX-066 as the subject of a potential development deal. Between May 17 and May 26, 2010, Impax and Endo discussed a potential joint development agreement for IPX-066. Impax sent data on IPX-066 to Endo and Endo took steps to evaluate IPX-066 as a potential business development opportunity. On May 26, 2010, more than one week after discussions began, Impax informed Endo that the development deal would be for a "product tbd." On May 27, 2010, Impax informed Endo that the development deal would be for a product designated as "066a," known internally at Impax as IPX-203. (CCF ¶¶ 232-39, 285-95). Endo was displeased when Impax switched the subject product of the agreement from IPX-066 to IPX-203. (CCF ¶ 1129). The Proposed Finding is also misleading to the extent that it suggests that Impax's Vice

President of Intellectual Property has any personal knowledge about Endo's interest in the Parkinson's space.

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)).

Response to Proposed Finding No. 328

The Proposed Finding is misleading and incomplete to the extent it suggests that Impax and Endo first discussed an agreement covering all of Impax's Parkinson's products on May 26, 2010. The parties first discussed a potential joint development agreement for IPX-066 on May 17. Between May 17 and May 26, 2010, Impax sent information and data on IPX-066 to Endo. Endo subsequently took steps to evaluate IPX-066 as a potential business development opportunity. It was only on May 26, 2010, more than one week after discussions began, that Impax switched the subject of the development deal from IPX-066 to IPX-203. (CCF ¶¶ 232-39, 285-94 (*in camera*)).

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).

Response to Proposed Finding No. 329

{ [redacted] **}** (CCF ¶¶ 1140, 1170 (*in camera*)). **{** [redacted] **}** (CCF ¶ 1116 (*in camera*)). **{** [redacted]

[redacted]**}** (CCF ¶¶ 295, 1141-43 (*in camera*)). The Proposed Finding is also misleading to the extent that it suggests that IPX-203 would improve "'dramatic control of Parkinson's' even more than IPX-066" given that, at the time of the DCA, IPX-203 was conceptual and had not even been formulated. (CCF ¶ 1098).

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

Response to Proposed Finding No. 330

{[redacted]**}** (CCF ¶¶ 1140, 1170 (*in camera*)). **{**[redacted]**}** (CCF ¶ 1116 (*in camera*)).

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")).

Response to Proposed Finding No. 331

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 332

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 333

The Proposed Finding is misleading and contrary to the weight of the evidence. The President of Impax's Branded Division, Michael Nestor, stated that the IPX-203 project was "not a slam dunk" given its early stage of development. He noted that the parties "really had no idea as to the success" of IPX-203 because the probability of success with any drug in the early stages of development is low. Ann Hsu, Impax's Vice President of Pharmacology, also believed that there would be difficulty in developing the specific formulation of IPX-203. (CCF ¶ 295).

{[redacted]} (CCF ¶¶ 1257-61 (*in camera*)).

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)).

Response to Proposed Finding No. 334

The Proposed Finding is misleading to the extent it suggests that Dr. Gupta's prior experience with formulation would lead to success in specifically formulating IPX-203. {[redacted]} (CCF ¶¶ 1257-61 (*in camera*)). The Proposed Finding is also contrary to the weight of the evidence, which indicates that other Impax employees had differing views on the feasibility of formulating IPX-203. (*See* Complaint Counsel's Response to Proposed Finding No. 333).

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)).

Response to Proposed Finding No. 335

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding No. 334.

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)).

Response to Proposed Finding No. 336

The Proposed Finding is irrelevant to Impax's probability of success in formulating IPX-203. The Proposed Finding is misleading to the extent it suggests that Dr. Gupta's prior experience with formulation would lead to success in specifically formulating IPX-203. **{** **}** (CCF ¶¶ 1257-61 (*in camera*)).

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)).

Response to Proposed Finding No. 337

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding No. 334.

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

Response to Proposed Finding No. 338

The Proposed Finding is misleading to the extent it suggests that Impax's prior experience with extended-release technologies would lead to success in specifically formulating IPX-203. **{** **}** (CCF ¶¶ 1257-61 (*in camera*)).

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)).

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)).

Response to Proposed Finding No. 342

The Proposed Finding is misleading to the extent it suggests that IPX-203 was beyond the conceptual stage of pharmaceutical development at the time the DCA was signed in June 2010. (CCF ¶ 1098). **{** [redacted] **}** (CCF ¶¶ 1144, 1147 (*in camera*)). **{** [redacted] **}** (CCF ¶¶ 1145-46 (*in camera*)). **{** [redacted] **}** (CCF ¶ 1148 (*in camera*)). **{** [redacted] **}** (CCF ¶ 1153 (*in camera*)). A formulation for a drug product must be determined prior to conducting any preclinical testing and often involves trying a number of different formulations before selecting the correct one. (CCF ¶¶ 1151, 1152).

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).

Response to Proposed Finding No. 343

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 344

The Proposed Finding is misleading to the extent it suggests that the SLA and DCA were not related. The SLA and DCA were not independent transactions. The agreements were negotiated together and individuals involved in the evaluation and negotiation of both deals characterized the agreements as related. (CCF ¶¶ 1066-70). The timing of the negotiation of the two agreements further supports the linkage between the two because Impax and Endo only discussed entering into a business development opportunity at the same time as discussing

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).

Response to Proposed Finding No. 346

The Proposed Finding is misleading and contrary to the weight of the evidence to the extent it suggests that the SLA and DCA were not related. The SLA and DCA were not independent transactions. The agreements were negotiated together and individuals involved in the evaluation and negotiation of both deals characterized the agreements as related. (CCF ¶¶ 1066-70). The timing of the negotiation of the two agreements further supports the linkage between the two because Impax and Endo only discussed entering into a business development opportunity at the same time as discussing settlement of the patent litigation. (CCF ¶¶ 1071-73). Mr. Nestor recognized that Endo was "on a tight time table" to complete the DCA "if they wish[ed] to settle prior to June 17." (CCF ¶ 1125). The SLA and DCA both were finalized and went into effect at the same time. (CCF ¶ 1074). Finally, the DCA was explicitly incorporated into the SLA by Section 9.3 of the SLA. (CCF ¶¶ 1066-67).

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).

Response to Proposed Finding No. 347

Complaint Counsel has no specific response.

Impax consequently assessed the DCA and the SLA individually and considered each a

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)).

Response to Proposed Finding No. 349

The Proposed Finding is misleading and contrary to the weight of the evidence to the extent that it suggests that the SLA and DCA were not related. Dr. Cobuzzi, Endo's Senior Vice President of Corporate Development, testified that the DCA and SLA were negotiated together and Mr. Levin, Endo's CFO, stated that he viewed the DCA as an integral part of the total collaboration between Endo and Impax. (CCF ¶¶ 1070, 1127). One of Endo's lead researchers for the DCA wrote in an email that the team's diligence on IPX-066 was "part of the Impax/Opana deal." (CX1015 at 001 (December 2010 Pong-Cobuzzi-Bradley email); *see also* Complaint Counsel's Response to Proposed Finding No. 346).

350. Alan Levin, Endo's CFO at the time of settlement and one of Endo's lead negotiators,

{

} (CCF ¶¶ 1261-63 (*in camera*)).

[redacted] **}** (CCF ¶ 1262 (*in camera*)).

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).

Response to Proposed Finding No. 357

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 358

{[redacted] **}** (CCF ¶¶ 1261-63 (*in camera*)).

359. [redacted] (CX2928-013).

Response to Proposed Finding No. 359

{[redacted] **}** (CCF ¶¶ 1261-63 (*in camera*)). **{**[redacted] **}** (CCF ¶¶ 1261-63 (*in camera*)).

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

Response to Proposed Finding No. 360

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 361

Complaint Counsel has no specific response, other than to note that in the over five years following the execution of the DCA until its termination, Endo and Impax never had any meeting of the joint development committee called for by the DCA. (CCF ¶¶ 1254-55).

362. [redacted] (CX3345-006).

Response to Proposed Finding No. 362

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 363

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 364

The Proposed Finding is misleading to the extent it suggests that meetings of the joint development committee were optional. Under the terms of the DCA, the joint development committee was required to meet a minimum of four times a year. **{**

} (CCF ¶¶ 1254-55 (*in camera*)).

365.

} (Nestor, Tr. 2963).

Response to Proposed Finding No. 365

The Proposed Finding is misleading to the extent it suggests that the **{** **}** of IPX-203 considered by Impax in 2015 is the same product contemplated under or covered by the DCA. (CCF ¶ 1261). The new **{** **}** was not covered by the DCA.

{

} (CCF ¶¶ 1261-63 (*in camera*)).

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

Response to Proposed Finding No. 366

Complaint Counsel objects to the phrase "makes clear" as inaccurate, and the Proposed Finding is misleading to the extent it suggests that the **{** **}** of IPX-203 considered by Impax in 2015 was covered by the DCA with Endo. The new **{** **}** was not covered by the DCA. (CCF ¶ 1261).

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).

Response to Proposed Finding No. 367

The Proposed Finding is misleading to the extent it suggests that Endo had communicated anything more than an indication of potential interest in Impax's development of a **{** **}** of IPX-203 or that Endo previously agreed to amend the DCA. **{** **}** (CCF ¶¶ 1263-64 (*in camera*)). Instead, although Endo had already paid $10 million to Impax and would not need to make further payments unless certain developmental milestones were met, Endo chose to terminate the DCA. (CCF ¶ 1267).

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).

Response to Proposed Finding No. 370

Complaint Counsel objects to the phrase "reversed course" as inaccurate in that it suggests that Endo had communicated anything more than an indication of potential interest in Impax's development of a **{** **}** of IPX-203 or that Endo previously agreed to amend the DCA. **{** **}** (CCF ¶ 1263 (*in camera*)). Endo stated that it "decided not to amend the existing agreement [s]ince [Impax's] existing program does not meet the definition of Product in the agreement." (CX2747 at 001 (Oct. 29, 2015 Macpherson/Ailinger email)).

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")).

Response to Proposed Finding No. 371

The Proposed Finding is misleading for the

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)).

Response to Proposed Finding No. 372

Complaint Counsel objects to the phrase "ret

The Proposed Finding is also irrelevant to the antitrust analysis because if and when the FTC responded to the parties' filing does not bear on whether the agreement is anticompetitive.

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).

Response to Proposed Finding No. 376

The Proposed Finding is misleading and irrelevant for the reasons stated in response to Proposed Finding No. 375.

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).

Response to Proposed Finding No. 377

The Proposed Finding is misleading and irrelevant for the reasons stated in response to Proposed Finding No. 375.

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).

Response to Proposed Finding No. 378

The Proposed Finding is inaccurate and not supported by the evidence cited. Mr. Figg is not an expert in antitrust law and therefore is not qualified to provide an opinion on the prevailing test for reverse-payment settlements at the time the parties settled their patent litigation. pai(t)SoF ¶¶ 1360 -62).(Inadidition, at the)]TJ-0.0006 Tw 192436 0 Td[tim the settlem nt n Junen 20(

prosecution. (CCF ¶ 1283). Similar to Impax's expert Mr. Figg, Mr. Hoxie is not an expert in antitrust law. (CCF ¶¶ 1283, 1360, 1361). Mr. Hoxie

1218 (*in camera*)); (4)

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

Response to Proposed Finding No. 387

The Proposed Finding is misleading to the extent it suggests that Dr. Cobuzzi's dissertation work relating to causative agents with Parkinson's disease is a substitute for receiving and evaluating preclinical and clinical data on IPX-203, Impax's carbidopa/levodopa ester Parkinson's disease treatment. (CCF ¶ 1166).

The Proposed Finding is also misleading to the extent it suggests that, at the time of the DCA, early-stage Parkinson's disease treatments were a focus of Endo's corporate strategy. The

Response to Proposed Finding No. 389

The Proposed Finding is misleading and incomplete to the extent it suggests that Endo employed a team of outside consultants to help review and analyze the IPX-203 opportunity. In May 2010, Endo engaged the Equinox consulting group to provide an abbreviated market analysis for a potential deal on IPX-066, Impax's late-stage Parkinson's disease product. When Impax changed the focus of the deal from IPX-066 to IPX-203, Endo did not ask Equinox to provide a new market analysis. (CCF ¶¶ 1200-02).

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).

Response to Proposed Finding No. 390

[redacted] (CCF ¶¶ 1155-59, 1161, 1248, 1251 (*in camera*)).

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

Response to Proposed Finding No. 392

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence to the extent it suggests that IPX-066 and IPX-203 were intended to be the same in terms of effectiveness to a patient. [redacted] (CCF ¶ 1142 (*in camera*)).

The Proposed Finding is also misleading to the extent it suggests that "the single chemical modification" of adding an ester of levodopa does not alter the chemical properties of IPX-203. [redacted] (CCF ¶¶1143, 1164 (*in camera*)).

[redacted] (CCF ¶¶ 1167-68, 1205, 1211 (*in camera*)).

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

Response to Proposed Finding No. 393

[redacted]

} (CCF ¶¶ 1143, 1164 (*in camera*)).

394.

(Cobuzzi, Tr. 2530; *see* RX-377.0031).

Response to Proposed Finding No. 394

Complaint Counsel has no specific response.

395.

(RX-377.0040-41; Cobuzzi, Tr. 2534).

Response to Proposed Finding No. 395

Complaint Counsel has no specific response.

396.

(RX-377.0043-44; Cobuzzi, Tr. 2535).

Response to Proposed Finding No. 396

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 397

The Proposed Finding is misleading because the vast majority of the information sent to Endo related to IPX-066, rather than IPX-203. (CCF ¶¶ 233-36). **{**

} (CCF ¶¶ 306-07 (

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

Response to Proposed Finding No. 398

The Proposed Finding is misleading and incomplete in that it suggests that Impax did not discuss IPX-066 as the subject of a potential development deal. Between May 17 and May 26, 2010, Impax and Endo discussed a potential joint development agreement for IPX-066. (CCF ¶¶ 232-39, 285-94). On May 19 and 22, Impax's Vice President of Business Development, David Paterson, provided Endo with specific information and data on IPX-066. (CCF ¶¶ 235-36). **{**

} (CCF ¶¶ 287-90 (*in camera*)). **{**

} (CCF ¶¶ 232-39, 285-94 (*in camera*)).

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

Response to Proposed Finding No. 399

The Proposed Finding is misleading to the extent it suggests that scientific information and data on IPX-066 could serve as a surrogate for IPX-203. **{**

} (CCF ¶ 1164 (*in camera*)). **{**

} (CCF ¶ 1163 (*in camera*)).

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

The Proposed Finding is misleading and contrary to the weight of the evidence to the extent it suggests that creating a product with an esterified levodopa aspect would be an easy task. The President of Impax's Branded Division, Michael Nestor, warned that IPX-203 "was not a slam dunk." Impax's Vice President of Pharmacology, Ann Hsu, also believed that there would be difficulty in developing the specific formulation of IPX-203. (RX-387 at 0001 (June 1, 2010 Nestor/Mengler email); CCF ¶ 295). Mr. Nestor further noted that the "parties really has no idea as to the success" of IPX-203 because the "probability of success with any drug at this point in the development it fairly low." (CCF ¶ 295 (citing RX-387 at 0001 (June 1, 2010 Nestor email to Mengler); CX4033 (Nestor Dep. at 116))). Even Endo recognized that "insufficient information [had] been provided in due diligence to completely characterize the pharmaceutical development and manufacturing risks for IPX-203." (CCF ¶ 1168 (citing CX1209 at 009 (Endo's Final Opportunity Evaluation Worksheet for IPX-203))). **{**

} (CCF ¶¶ 1257-58 (*in camera*)). **{**

} (CCF ¶¶ 1250-51, 1259 (*in camera*)).

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 was an appropriate commercial proxy for assessing IPX-203. However, she did not say that changes should not be made to the forecast to reflect the known differences between IPX-066 and IPX-203, such as differences in daily dosage or cost of goods or to reflect the increased regulatory risk of an early-stage product. Moreover, changing only the launch date and failing to re-evaluate all of the assumptions used in the market analysis was inconsistent with industry standards for preparing a financial valuation. (CCF ¶ 1204). **{**

} (CCF ¶ 1205 (*in camera*)). **{**

} (CCF ¶¶ 1206-10 (*in camera*)).

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")).

Response to Proposed Finding No. 402

The Proposed Finding is misleading and incomplete to the extent it suggests that Endo received information on IPX-066 as part of its ev

June 4, 2010, just three days before the DCA was signed. (CCF ¶ 1119). Moreover, the Proposed Finding is misleading to the extent it suggests that using market assumptions tailored to IPX-066 as a substitute for market assumptions pertaining to IPX-203 is a reasonable and accurate way in which to build a financial analysis for IPX-203.

The Proposed Finding is not supported by the evidence cited. **{**

} (Geltosky, Tr. 1100 (*in camera*)).

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

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Response to Proposed Finding No. 405

The Proposed Finding is misleading for the reasons set out in the response to Proposed Finding No. 401. In addition, the Proposed Finding is inaccurate insofar as it suggests that Endo's forecasts were conservative estimates for IPX-203 sales. In addition to using inappropriate assumptions in its financial evaluation of IPX-203, Endo also did not account for

Endo making any adjustment for the higher risk and uncertainties associated with IPX-203. Whereas IPX-066 was in the last stage of clinical development before filing with the FDA, IPX-203 was in the earliest stage of development. (CCF ¶ 234). **{**

} (CCF ¶ 1164 (*in camera*)). **{**

} (CCF ¶ 1163 (*in camera*)). Indeed, Impax's branded division president warned that the IPX-203 project "is not a slam dunk," with at least one scientist thinking "there will be difficulty with developing the formulation." (CCF ¶ 295). Despite the significantly higher risk associated with IPX-203, Endo ended up agreeing to an overall deal for IPX-203 that was worth double what it had been discussing for IPX-066. (CCF ¶¶ 298, 303).

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

Response to Proposed Finding No. 407

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 406.

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).

Response to Proposed Finding No. 408

The Proposed Finding is misleading for the reasons set forth in the response to Proposed Finding No. 406.

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).

Response to Proposed Finding No. 409

The Proposed Finding is misleading for the reasons set out in the response to Proposed Finding No. 406. **{** [redacted] **}** (CCF ¶¶ 1179-86 (*in camera*)).

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).

Response to Proposed Finding No. 410

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. Internal Endo documents reflected a process for evaluating pharmaceutical development assets that is consistent with industry standards. (CCF ¶ 1106). Specifically, Endo's internal documents indicated that it takes approximately six months to one year from initial evaluation of a deal to closing. (CCF ¶ 1110). Internal communications also indicate that Dr. Cobuzzi and other Endo employees recognized there was "very little time" to complete the evaluation of the DCA. (CCF ¶¶ 1125-26 (citing CX1007 at 001 (May 25, 2010 Cobuzzi email); CX1009 at 005 (May 21, 2010 Rasty/Equinox Group email) (describing an urgent forecasting need))).

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).

Response to Proposed Finding No. 411

The Proposed Finding is misleading and not supported by the evidence cited. As Dr. Cobuzzi made clear in his testimony, Endo looks at a large number of deals in a particular year. (Cobuzzi, Tr. 2514, 2565). But, Endo only signs a confidential agreement for a fraction of those potential deals (Cobuzzi, Tr. 2566-67), only conducts due diligence on a fraction of those, and only executes deals on an even smaller fraction (Cobuzzi, Tr. 2567). Thus, while Endo may

¶¶ 1125-26 (citing CX1007 at 001 (May 25, 2010 Cobuzzi email); CX1009 at 005 (May 21, 2010 Rasty to Equinox Group email) (describing an urgent forecasting need))).

The Proposed Finding is also misleading to the extent it suggests that Dr. Cobuzzi's dissertation work relating to causative agents with Parkinson's disease is a substitute for receiving and evaluating preclinical and clinical data on IPX-203. (CCF ¶ 1166).

The Proposed Finding is also misleading to the extent it suggests that scientific information and data on a related drug, such as IPX-066, could serve as a surrogate for IPX-203 without Endo making any adjustment for the higher risk and uncertainties associated with IPX-203. Whereas IPX-066 was in the last stage of clinical development before filing with the FDA, IPX-203 was in the earliest stage. (CCF ¶ 234). **{** [redacted] **}** (CCF ¶ 1164 (*in camera*)). **{** [redacted] **.}** (CCF ¶ 1163 (*in camera*)). Indeed, Impax's branded division president warned that the IPX-203 project "is not a slam dunk," with at least one scientist thinking "there will be difficulty with developing the formulation." (CCF ¶ 295). Despite the significantly higher risk associated with IPX-203, Endo ended up agreeing to an overall deal for IPX-203 that was worth double what it had been discussing for IPX-066. (CCF ¶¶ 298, 303).

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).

Response to Proposed Finding No. 415

The Proposed Finding is factually inaccurate, contrary to the weight of the evidence, and misleading for the reasons set forth in the response to Proposed Finding No. 414.

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).

Response to Proposed Finding No. 416

{ [redacted] **}** (CCF ¶¶ 1094, 1132 (*in camera*)).

{ [redacted] **}** (CCF ¶¶ 1093, 1132 (*in camera*)).

The Proposed Finding is also misleading for the reasons set forth in response to Proposed Finding No. 414.

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

Response to Proposed Finding No. 417

The Proposed Finding is misleading for the reasons set forth in the response to Proposed Finding No. 416.

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).

Response to Proposed Finding No. 418

The Proposed Finding is misleading to the extent it suggests that familiarity with carbidopa and levodopa is a substitute for information and data on the chemically-modified esterified version of levodopa to be used in IPX-203. **{**

}. (CCF ¶¶ 1141, 1143, 1163 (*in camera*)). **{**

.} (CCF ¶¶ 1093, 1132 (*in camera*)). In fact, Endo never completed a deal with either company on a Parkinson's disease product. (CCF ¶ 1093). At the time of the DCA, Parkinson's disease products were not a focus of Endo's corporate strategy. (CCF ¶¶ 1086-98). In 2008, Endo received a recommendation for late-stage product opportunities from a market and analytics research group. The analysis excluded Impax's carbidopa/levodopa Parkinson's disease products from the list of potential opportunities for Endo due to the fact that generic versions of carbidopa/levodopa products were already on the market. (CCF ¶¶ 1090-91).

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

Response to Proposed Finding No. 419

The Proposed Finding is factually inaccurate, contrary to the weight of the evidence, and misleading for the reasons set forth in the response to Proposed Finding Nos. 414 and 416.

The Proposed Finding is also incomplete. In the cited testimony, Dr. Cobuzzi qualified his answer, stating that he had "the information we needed *or were going in*

at that point." (Cobuzzi, Tr. 2563 (emphasis added)). Indeed, Dr. Cobuzzi confirmed that Endo had never before completed due diligence for a deal in a matter of days and made an upfront payment. (Cobuzzi, Tr. 2566).

2.

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).

Response to Proposed Finding No. 425

Complaint Counsel has no specific response.

426. [redacted] (CX1209-011).

Response to Proposed Finding No. 426

[redacted] (CCF ¶¶ 1093, 1132 (*in camera*)).

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)).

Response to Proposed Finding No. 427

The Proposed Finding is misleading to the extent it suggests that Endo's financial valuation was prepared accurately and followed industry standards. In fact, Endo's rushed financial analysis did not provide an accurate valuation of the deal. [redacted] (CCF ¶¶ 1191-1218 (*in camera*); *see also* CX4016 (Cobuzzi, IHT at 306 (acknowledging "the net present value of a product that has more risk would be lower")). It is critical to have high-quality and carefully-vetted numbers to

use in the financial analysis. Mark Bradley, who prepared the financial valuation of the IPX-203 opportunity for Endo, recognized that if the assumptions that went into the valuation were not accurate, "garbage in, garbage out right." (CCF ¶ 1194 (citing CX4031 (Bradley, Dep. at 53-54))).

The Proposed Finding is also misleading to the extent it suggests that Endo did not make an unjustified, large payment to Impax under the DCA. **{**

} (CCF ¶ 1260 (*in camera*)). **{**

}

The Proposed Finding is not relevant to whether Endo's negotiation and evaluation of the DCA was consistent with industry standards or Endo's own processes for negotiating and evaluating pharmaceutical development business opportunities.

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).

Response to Proposed Finding No. 430

The Proposed Finding is misleading and contrary to the weight of the evidence in that it suggests the DCA was consistent with Endo's sales footprint with the pain sales force that existed at the time. At the time of the DCA, early-stage Parkinson's disease treatments were not a focus of Endo's corporate strategy. (CCF ¶¶ 1086-95). {[redacted]} (CCF ¶¶ 1099-1102 (*in camera*)). {[redacted]} (CCF ¶1102 (*in camera*)).

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

Response to Proposed Finding No. 431

The Proposed Findings is not supported by the evidence cited. The evidence cited does not state that Endo's sales force was focused on primary care physicians who prescribed neurological medications. Rather, the evidence cited merely indicates that Endo had a sales force that would call on primary care physicians. (Nestor, Tr. 2948-49). {[redacted]} (CCF ¶¶ 1099-1102 (*in*

camera)). **{**

} (CCF ¶1102 (*in camera*)).

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

Response to Proposed Finding No. 434

The Proposed Finding is misleading and not supported by the evidence cited to the extent it suggests that Endo had sufficient information at the time of the agreement to assess whether IPX-203 would be a superior product or that IPX-066 necessarily would be superior to IPX-066 or other Parkinson's treatments. [redacted] (CCF ¶ 1220 (*in camera*)). The President of Impax's Branded Division, Michael Nestor, stated that the IPX-203 project was "not a slam dunk" given its early stage of development. He also noted that the parties "really had no idea as to the success" of IPX-203 because the probability of success with any drug [in the early stages of] development is fairly low." (CCF ¶ 295 (quoting RX-387 at 0001 (June 1, 2010 Nestor email to Mengler); CX4033 (Nestor, Dep. at 116))).

The Proposed Finding is also misleading and contrary to weight of the evidence to the extent it suggests that Endo thought a carbidopa-levodopa Parkinson's disease treatment was a good investment. In 2008, Endo received a recommendation for late-stage product opportunities from a market and analytics research group. The analysis excluded Impax's carbidopa/levodopa Parkinson's disease products from the list of potential opportunities for Endo because generic versions of carbidopa/levodopa products were already on the market. (CCF ¶¶ 1090-91).

The Proposed Finding is also misleading for the reasons set forth in response to Proposed Finding No. 433.

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

Response to Proposed Finding No. 435

The Proposed Finding is misleading and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 434. The Proposed Finding is also not supported by the testimony of Dr. Cobuzzi. **{**[redacted]**}** (Cobuzzi, Tr. 2537 (*in camera*)).

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

Response to Proposed Finding No. 436

{[redacted]

}

(Cobuzzi, Tr. 2623 (*in camera*)).

The Proposed Finding is also misleading and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 434.

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)).

Response to Proposed Finding No. 437

The Proposed Finding is misleading and contrary to the weight of the evidence in that it suggests that the DCA and SLA are not linked.

short time frame was that this deal was being done in connection with settlement negotiations; correct? A. As I understood it, yeah. There was a package of deals that were being done.")).

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 **{**

} (CX1209-011).

Response to Proposed Finding No. 439

Complaint Counsel has no specific response.

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")).

Response to Proposed Finding No. 440

The Proposed Finding is misleading to the extent that it suggests that IPX-203 would in fact extend the period of time over which a drug is absorbed and lower the doses needed for effective treatment. **{**

} (CCF ¶ 1220 (*in camera*)). The President of Impax's Branded Division, Michael Nestor, stated that the IPX-203 project was "not a slam dunk" given its early stage of development. He also noted that the parties "really had no idea as to the success" of IPX-203 because the "probability of success with any drug [in the early stages of] development is fairly

low." (CCF ¶ 295 (quoting RX-387 at 0001 (June 1, 2010 Nestor email to Mengler); CX4033 (Nestor, Dep. at 116))).

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

Response to Proposed Finding No. 441

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 440.

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

Response to Proposed Finding No. 442

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 440.

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).

Response to Proposed Finding No. 443

The Proposed Finding is misleading for the reasons set out in response to Proposed Finding No. 440.

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).

Response to Proposed Finding No. 444

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 440.

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).

Response to Proposed Finding No. 445

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 440.

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)).

Response to Proposed Finding No. 446

The Proposed Finding is not supported by reliable evidence. The Proposed Finding is supported only by testimony from Mr. Levin, Endo's Chief Financial Officer. At Endo, however, Dr. Cobuzzi (Senior Vice President of Corporate Development) and a team of employees were responsible for evaluating potential pharmaceutical business deals for further development. (CCF ¶ 1095). Mr. Levin was not part of this team. (CCF ¶ 1095 (citing Cobuzzi, Tr. 2584)). Indeed, IPX-203 did not move quickly through development. As of April 2013, nearly three years after signing the DCA, Impax had yet to complete a pharmacokinetic study for IPX-203. (Nestor, Tr. 3034). **{**

} (Nestor, Tr. 3050 (*in camera*)).

447. In particular Endo's OEW explained that **{**

} (/24 PaTf.0Tj37

The Proposed Finding is misleading to the extent it suggests that Impax could rely on clinical studies conducted on IPX-066 as a substitute for IPX-203, without Endo making any adjustment for the higher risk and uncertainties associated with IPX-203. Whereas IPX-066 was

The Proposed Finding is misleading and contrary to the weight of the evidence to the extent it suggests that Endo took into account the specific risk profile of IPX-203 during its evaluation of the DCA. Endo used market assumptions tailored to IPX-066 as a substitute for market assumptions pertaining to IPX-203 in its financial analysis for IPX-203. Endo's failure to re-evaluate the assumptions used in the market analysis once the product changed from IPX-066 to IPX-203 was inconsistent with industry standards for preparing a financial valuation. (CCF ¶ 1204). **{**

} (CCF ¶ 1205 (*in*

The Proposed Finding is misleading to the extent it suggests that Endo thought IPX-203 would not face hurdles in obtaining FDA approval. In its OEW for IPX-203, Endo recognized that "it is possible that the FDA could ask for additional studies to be conducted" in order to approve the levodopa ester in IPX-203 for human use. Endo specifically stated that "it is not possible to rule-out the occurrence of development-related challenges, including the potential need for non-clinical and pharmaceutical development work not anticipated in Impax's development plan" because IPX-203 contained an novel ester of levodopa. (CCF ¶¶ 1183-84 (citing CX1209 at 008 (Endo's Final Opportunity Evaluation Worksheet for IPX-203))). **{** **}** (CCF ¶ 1185 (citing CX1209 at 009 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*))). As Impax's branded division president testified, the parties "really had no idea as to the success" of IPX-203 because the "probability of success with any drug [in the early stages of] development is fairly low." (CCF ¶ 295 (quoting CX4033 (Nestor, Dep. at 116))).

451. Dr. Cobuzzi testified **{** **}** (Cobuzzi, Tr. 2537).

Response to Proposed Finding No. 451

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 450.

The Proposed Finding is also misleading to the extent it suggests that scientific information and data on IPX-066 could serve as a surrogate for IPX-203. **{** **}** (CCF ¶ 1164 (*in camera*)).

{[redacted]} (CCF ¶ 1163 (*in camera*)).

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

Response to Proposed Finding No. 452

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 450.

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).

Response to Proposed Finding No. 453

The Proposed Finding is misleading and contrary to the weight of the evidence. Endo chose to enter the DCA with minimal scientific information about IPX-203 and without applying any risk mitigation strategies. (CCF ¶ 1175). The structure of the payments in the DCA was "the exact opposite of the way agreements like this are structured." (CCF ¶ 1223 (citing Geltosky, Tr. 1072)). The customary approach to mitigate substantial uncertainty and risk in the pharmaceutical industry is to provide payments commensurate with progress on the program. (CCF ¶ 1173). Upfront payments typically reflect the value of work done on the project to date. (CCF ¶ 1220). {[redacted]} (CCF ¶ 1220 (*in camera*)). Yet, Endo made an upfront payment of $10 million to Impax, representing 25% of the deal's $40 million total value. (CCF ¶ 1221). Indeed, Endo's significant upfront payment for IPX-203 was unprecedented. Dr. Cobuzzi could not recall any other deals for a preclinical product in which Endo had made a similar $10 million upfront payment. (Cobuzzi, Tr. 2566). Dr. Cobuzzi identified two other Endo development deals

for early stage products, but in both of those deals, "there was no cash up front. It was contingent upon successful completion of certain milestones." (CX4016 Cobuzzi, IHT at 82).

{[redacted].}

(CCF ¶¶ 1174, 1224 (*in camera*)). Endo could also have structured the deal as an option agreement, where the potential partner pays a nominal sum upfront to hold the asset for a given period of time while the licensee decides whether to proceed with a full licensing or co-development transaction. (CCF ¶ 1227). **{**[redacted]**}** (CCF ¶ 1228 (*in camera*)). As Dr. Cobuzzi warned, "if you pay too much up front, you may never actually get to the point of realizing that value." (CCF ¶ 1174 (citing CX4016 (Cobuzzi, IHT at 69-70))).

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

Response to Proposed Finding No. 454

The Proposed Finding is misleading and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 453.

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).

Response to Proposed Finding No. 455

The Proposed Finding is misleading and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 453.

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).

Response to Proposed Finding No. 456

The Proposed Finding is misleading and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 453.

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

Response to Proposed Finding No. 457

The Proposed Finding is misleading insofar as it suggests that whether Impax would be expected to spend more money on IPX-203 than Endo is somehow meaningful in assessing whether Endo mitigated its risk in the IPX-203 project through the DCA. It is not. (*See* Complaint Counsel's Response to Proposed Finding No. 453).

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).

Response to Proposed Finding No. 458

The Proposed Finding is misleading insofar as it suggests that whether Endo performed any development work on IPX-203 is somehow meaningful in assessing whether Endo mitigated its risk in the IPX-203 project through the DCA. It is not. (*See* Complaint Counsel's Response to Proposed Finding No. 453).

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).

Response to Proposed Finding No. 459

The Proposed Finding is misleading insofar as it suggests that the profit-sharing provision under the DCA mitigated Endo's risks in entering the transaction. **{** [redacted]

the product. The President of Impax's Branded Division, Michael Nestor, stated that the IPX-203 project was "not a slam dunk" given its early stage of development. He also noted that the parties "really had no idea as to the success" of IPX-203 because the "probability of success with any drug [in the early stages of] development is fairly low." Ann Hsu, Impax's Vice President of Pharmacology, also believed that there would be difficulty in developing the specific formulation of IPX-203. (CCF ¶ 295). Endo recognized that IPX-203 might face development-related challenges because it contained "a novel LD ester as an API." (CCF ¶¶ 1183-85 (quoting CX1209 at 008 (Endo's Final Opportunity Evaluation Worksheet for IPX-203))). **{**

} (CCF ¶¶ 1257-60 (*in camera*)).

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

Response to Proposed Finding No. 463

Complaint Counsel objects to the phrase "easily understood" to the extent it suggests that IPX-203 was a low risk opportunity. **{**

} (CCF ¶ 1117 (citing Nestor, Tr. 2959 (*in camera*))).

The Proposed Finding is also inaccurate to the extent it suggests that development of IPX-203 would not be without hurdles. The President of Impax's Branded Division, Michael project wal

} (CCF ¶ 1167 (*in camera*)). In its OEW for IPX-203, Endo recognized that "it is possible that the FDA could ask for additional studies to be conducted" in order to approve the levodopa ester in IPX-203 for human use. Endo specifi

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

Response to Proposed Finding No. 465

payment terms not consistent with Endo's or industry's standards)). **{**

} (CCF ¶ 1084 (citing CX2701 at 004 (2010 Budget Update and 2011 Budget Preview) (*in camera*))).

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

and so from my perspective -- which was also shared by our president and CEO -- was that we've already taken all the risk, then we should get all the rewards for the product." (Nestor, Tr. 2941-42).

The Proposed Finding is also misleading insofar as it implies that Impax's desire to secure outside funding for IPX-203 is somehow meaningful in assessing whether Endo was buying a development project with its $10 million payment. It is not. The extensive record evidence shows that Endo was willing to pay $10 million not for the services Impax's provides in the DCA, but for Impax's commitment not to compete with a generic version of Opana ER until January 2013. (CCF ¶¶ 1066-73, 1125-27 (DCA negotiated as part of Opana ER settlement); CCF ¶¶ 1090-92 (lack of strategic fit); CCF ¶¶ 232-39, 1082-83 (offered same payment despite significant product change); CCF ¶¶ 1085-1265 (negotiation, due diligence, payment terms not consistent with Endo's or industry's standards)). **{**

}

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 470.

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

Response to Proposed Finding No. 473

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 470.

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).

Response to Proposed Finding No. 474

Complaint Counsel objects to the word "explored" as contrary to the weight of the evidence to the extent that it suggests Impax took steps to secure funding from a venture capital firm. The cited evidence merely indicates that Impax internally talked about reaching out to venture capital firms, but that the CEO at the time (Larry Hsu) did not think it was a very good idea. (Nestor, Tr. 2941). Mr. Nestor further testified, "We don't raise funding [for the development of a branded drug product]. Money is allocated from the corporate budget for projects." (CX4033 (Nestor, Dep. at 13)).

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

Response to Proposed Finding No. 475

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 476

The Proposed Finding is misleading for the reasons set out in response to Proposed Finding No. 470.

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).

Response to Proposed Finding No. 477

Complaint Counsel has no specific response.

478. [redacted] **} (Nestor, Tr. 2953; RX-247 {** [redacted] **}**.

Response to Proposed Finding No. 478

The Proposed Finding is misleading to the extent that it suggests that Impax had done significant amounts of work on the IPX-203 product by 2009. **{** [redacted] **}** (CCF ¶ 1248 (citing CX2928 at 001 (Impax Response to Interrogatory No. 17) (*in camera*))). **{** [redacted] **}** (CCF ¶ 1248 (citing CX2928 at 001 (Impax Response to Interrogatory No. 17) (*in camera*))).

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

Response to Proposed Finding No. 479

{ [redacted]

} (RX-241 (*in camera*)). **{**

} (CCF ¶ 1248 (*in camera*)). **{**

} (RX-241 (*in camera*)). As of April 2013, Impax had still not conducted the pharmacokinetic studies. (CCF ¶ 1251). **{**

} (CCF ¶ 1259 (*in camera*)). **{**

} (CCF ¶¶ 1260-62 (*in camera*)). **{**

} (CCF ¶ 1263 (*in camera*)).

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

Response to Proposed Finding No. 480

{

} (CCF ¶ 1248 (*in camera*)). **{**

} (CCF ¶ 1251 (*in camera*)). **{** **}** (RX-241 (*in camera*)). As of April 2013, Impax had still not conducted the studies. (CCF ¶ 1251). **{**

} (CCF ¶ 1259 (*in camera*)). **{**

} (CCF ¶¶ 1260-62

(

The Proposed Finding is misleading and inaccurate because it suggests Impax developed protocols for Phase II clinical trials, submitted those protocols to the FDA, and secured FDA approval for efficacy and safety studies of the esterized version of IPX-203 that was the subject of the DCA. (*See* Complaint Counsel's Response to Proposed Finding No. 481).

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)).

Response to Proposed Finding No. 483

The Proposed Finding is misleading to the extent it suggests that development of IPX-203, as originally conceived in the DCA, was delayed due to delays in the development of IPX-066. By 2014, Impax determined that the originally conceived levodopa-ester version of IPX-203 did not meet the target product profile to be categorized as a competitive product. (CCF ¶ 1258). {[redacted]} (CCF ¶ 1259 (*in camera*)). {[redacted]} (CCF ¶¶ 1260-62 (*in camera*)). {[redacted]} (CCF ¶ 1263 (*in camera*)).

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).

Response to Proposed Finding No. 484

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 483.

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).

Response to Proposed Finding No. 485

The Proposed Finding is misleading to the extent it suggests that the regulatory approval pathway of IPX-203 would be the similar to that of IPX-066. **{** **}** (CCF ¶ 1164 (*in camera*)). As Endo noted, IPX-203 could have been classified as an NCE, due to the presence of the novel levodopa-ester moiety in the API. For this reason, it was not possible to rule out the occurrence of development-related challenges, or the FDA requiring additional studies to be conducted. (CCF ¶¶ 1183-85).

486. Additionally, **{** **}** (Nestor, Tr. 2968).

Response to Proposed Finding No. 486

The Proposed Finding is misleading to the extent it suggests that development of IPX-203, as originally conceived in the DCA, was delayed due to receipt of an FDA warning letter. To start, Impax did not receive the FDA warning letter until 2011. (Nestor, Tr. 2986-87). **{** **}** (CCF ¶ 1248 (*in camera*)). **{** **}** (CCF ¶¶ 1257-58 (*in camera*)). **{** **}** (CCF ¶ 1259 (*in camera*)). **{**

} (CCF ¶¶ 1260-62 (*in camera*)). **{**

} (CCF ¶ 1263 (*in camera*)).

1260-62) (*in camera*). **{** [redacted] **}** (CCF ¶ 1263 (*in camera*)).

The Proposed Finding is also not relevant to the antitrust analysis because information regarding a potential Impax product that was not the subject of the DCA does not bear on whether Endo's payments under the June 2010 DCA are large and unjustified. (CCF ¶¶ 1261-62).

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).

Response to Proposed Finding No. 490

The Proposed Finding is misleading and not relevant for the reasons set forth in response to Proposed Finding No. 489.

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).

Response to Proposed Finding No. 491

The Proposed Finding is misleading and not relevant for the reasons set forth in response to Proposed Finding No. 489.

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).

Response to Proposed Finding No. 492

The Proposed Finding is misleading and not relevant for the reasons set forth in response to Proposed Finding No. 489.

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).

Response to Proposed Finding No. 493

The Proposed Finding is misleading and not relevant for the reasons set forth in response

The Proposed Finding is not relevant to the antitrust analysis because information regarding the FDA approval process for a potential Impax product that was not the subject of the DCA does not bear on whether payments under the June 2010 DCA are large and unjustified. (CCF ¶¶ 1261-62).

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

Response to Proposed Finding No. 499

The Proposed Finding is not relevant for the reason set forth in response to Proposed Finding No. 498.

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

Response to Proposed Finding No. 500

The Proposed Finding is not relevant for the reason set forth in response to Proposed Finding No. 498.

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).

Response to Proposed Finding No. 501

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 502

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 503

The Proposed Finding is misleading to the extent it suggests that Dr. Geltosky did not analyze the DCA in light of his 35-plus years in the pharmaceutical industry against industry standards for such evaluations and in view of Endo's own internal documents. (CCF ¶¶ 1112, 1191-1218; Geltosky, Tr. 1079-84).

The Proposed Finding is also inaccurate insofar as it implies that the only information relevant to assessing the justification for Endo's $10 million payment is an after-the-fact valuation analysis of the DCA. The extensive record evidence shows that Endo was willing to pay $10 million not for the services Impax's provides in the DCA but for Impax's commitment not to compete with a generic version of Opana ER until January 2013. (CCF ¶¶ 1066-73, 1125-27 (DCA negotiated as part of Opana ER settlement); CCF ¶¶ 1090-92 (lack of strategic fit); CCF ¶¶ 232-39, 1082-83 (offered same payment despite significant product change); CCF ¶¶ 1085-1265 (negotiation, due diligence, payment terms not consistent with Endo's or industry's standards)). **{** [redacted] **}** (CCF ¶ 1084 (citing CX2701 at 004 (2010 Budget Update and 2011 Budget Preview) (*in camera*))).

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

Response to Proposed Finding No. 504

The Proposed Finding is misleading and inaccurate for the reasons set forth in response to Proposed Finding No. 503.

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

Response to Proposed Finding No. 505

The Proposed Finding is misleading and inaccurate for the reasons set forth in response to Proposed Finding No. 503.

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

Response to Proposed Finding No. 506

The Proposed Finding is misleading and inaccurate for the reasons set forth in response to Proposed Finding No. 503.

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

Response to Proposed Finding No. 507

The Proposed Finding is misleading to the extent that it suggests that Dr. Geltosky does not have experience with financial valuations of pharmaceutical collaborations. Dr. Geltosky not only has participated in performing financial analysis, but he "understand[s] all the moving parts." (Geltosky, Tr. 1081). Dr. Geltosky has provided inputs into financial valuations of potential pharmaceutical collaborations over the course of his 35 year career, as part of a team effort. (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).

Response to Proposed Finding No. 508

The Proposed Finding is misleading to the extent that it suggests that Dr. Geltosky does not have experience with financial valuations of pharmaceutical collaborations and performing net present value calculations. Dr. Geltosky not only has participated in performing financial analysis, but he "understand[s] all the moving parts." (Geltosky, Tr. 1081). Dr. Geltosky has

the pharmaceutical industry’s usual and expected practice for early-stage development projects. (CX5003 at 5 (Ir39.92s

what deals go for, along with his recollections of the agreements he was involved in. (Geltosky Tr. 1139-40; CX4042 (Geltosky, Dep. at 97-100)). He stated "I'm relying on my memory and knowledge of the agreements I was involved in, and I compare and contrast." (Geltosky Tr. 1140). Based on his 35-plus years of experience, Dr. Geltosky concluded that the overall strategic fit, negotiation process, due diligence efforts, and terms of the DCA were not consistent either with Endo's or the pharmaceutical industry's usual and expected practice for early-stage development projects. (CX5003 at 5 (¶ 13) (Geltosky Report)).

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).

Response to Proposed Finding No. 513

The Proposed Finding is misleading to the ex

the pharmaceutical industry, he would expect to see upfront payments reflecting 5-10% of the total deal value for an early stage compound like IPX-203. (CCF ¶ 1221).

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

Response to Proposed Finding No. 514

The Proposed Finding is misleading for the reasons set out in the response to Proposed Finding No. 513.

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).

Response to Proposed Finding No. 515

The Proposed Finding is misleading to the extent that it suggests th

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

Response to Proposed Finding No. 517

The Proposed Finding is misleading for the reasons set forth in response to Proposed

payment despite significant product change); CCF ¶¶ 1085-1265 (negotiation, due diligence, payment terms not consistent with Endo's or industry's standards)). **{**

} (CCF ¶ 1084 (citing CX2701 at 004 (2010 Budget Update and 2011 Budget Preview) (*in camera*))).

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

Response to Proposed Finding No. 520

The Proposed Finding is misleading for the reasons set forth in the response to Proposed Finding No. 519.

The Proposed Finding is misleading for the reasons set forth in the response to Proposed Finding No. 519.

The Proposed Finding is also misleading to the extent that it s

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).

Response to Proposed Finding No. 526

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 527

The Proposed Finding is inaccurate and not supported by the evidence cited. Professor Noll did not agree that if Dr. Geltosky did not offer an opinion regarding the actual value of the DCA to Endo at the time it was executed, then "[he] would not include the $10 million as part of the large payment that was unjustified." (Noll, Tr. 1585-86). In fact, Professor Noll testified that "you don't have to estimate the price in order to reach a conclusion" about whether the DCA was justified. (1582-83). Although Dr. Geltosky does not use the word "

The Proposed Finding is also contrary to the weight of the evidence, which shows that Endo was willing to pay $10 million not for the services Impax's provides in the DCA, but for Impax's commitment not to compete with a generic version of Opana ER until January 2013. (CCF ¶¶ 1066-73, 1125-27 (DCA negotiated as part of Opana ER settlement); 1090-92 (lack of strategic fit); 232-39, 1082-83 (offered same payment despite significant product change); 1085-1265 (negotiation, due diligence, payment terms not consistent with Endo's or industry's standards)). **{** [redacted] **}** (CCF ¶ 1084 (citing CX2701 at 004 (2010 Budget Update and 2011 Budget Preview) (*in camera*))).

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)).

Response to Proposed Finding No. 528

The Proposed Finding is misleading to the extent it suggest that Dr. Geltosky needed to empirically analyze the value of the DCA. As Professor Noll testified, "you don't have to estimate the price in order to reach a conclusion" about whether the DCA was justified. (Noll, Tr. 1582-83).

The Proposed Finding is also misleading to the extent that it suggests that the profit-sharing rights that Endo received under the DCA justify payment of $10 million to Impax. The extensive record evidence shows that Endo was willing to pay $10 million not for the services Impax's provides in the DCA, but for Impax's commitment not to compete with a generic version of Opana ER until January 2013. (CCF ¶¶ 1066-73, 1125-27 (DCA negotiated as part of Opana ER settlement); 1090-92 (lack of strategic fit); 232-39, 1082-83 (offered same payment despite

significant product change); 1085-1265 (negotiation, due diligence, payment terms not consistent with Endo's or industry's standards)). {[redacted]} (CCF ¶ 1084 (citing CX2701 at 004 (2010 Budget Update and 2011 Budget Preview) (*in camera*))).

(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).

Response to Proposed Finding No. 529

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 530

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 531

The Proposed Finding is misleading and contrary to the weight of the evidence to the extent it suggests that Dr. Geltosky does not offer an opinion on whether under the DCA, Endo bore more risk than it should have given the circumstances. Dr. Geltosky pointed out that Endo chose to enter the DCA with minimal scientific information about IPX-203 and without applying any risk mitigation strategies. (CCF ¶ 1175 (citing CX5003 at 029 (¶ 45) (Geltosky Report)). The structure of the payments in the DCA was "the exact opposite of the way agreements like this are structured." (CCF ¶ 1223 (citing Geltosky, Tr. 1072)). The customary approach to mitigate substantial uncertainty and risk in the pharmaceutical industry is to provide payments

commensurate with progress on the program. (CCF ¶ 1173 (citing CX5003 at 029 (¶ 45) (Geltosky Report))). Upfront payments typically reflect the value of work done on the project to date. (CCF ¶ 1220 (citing CX5003 at 43 (¶ 72) (Geltosky Report))). **{**

} (CCF ¶ 1220 (citing CX5003 at 027-28 (¶¶ 41-42) (Geltosky Report) (*in camera*))). Yet, Endo made an upfront payment of $10 million to Impax, representing 25% of the deal's $40 million total value. (CCF ¶ 1221 (citing Geltosky, Tr. 1073)). **{**

} (CX5003 at 029 (¶ 45) (Geltosky Report); CCF ¶¶ 1174, 1224 (*in camera*)). Endo could also have structured the deal as an option agreement, where the potential partner pays a nominal sum to hold the asset for a given period of time while the licensee decides on whether to proceed with a full licensing or co-development transaction. (CCF ¶ 1227 (citing Geltosky, Tr. 1076)). **{**

} (CCF ¶ 1228 (*in camer*a)). Dr. Cobuzzi agreed, warning "if you pay too much up front, you may never actually get to the point of realizing that value." (CCF ¶1174 (citing CX4016 (Cobuzzi, IHT at 69-70))).

And Dr. Geltosky did not quantify any risk relatedquaually g

payments reflecting 5% to 10% of the total deal value for an early stage compound like IPX-203 (CCF ¶ 1221 (citing Geltosky, Tr. 1073)).

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).

Response to Proposed Finding No. 533

Complaint Counsel objects to the word "conceded" as misleading because it suggests that Dr. Geltosky agreed with Impax's estimated costs for the development of IPX-203. The evidence cited indicates that Dr. Geltosky was merely asked what Impax estimated its costs would be in developing IPX-203. The cited evidence does not demonstrate that Dr. Geltosky agreed with that amount. (Geltosky, Tr. 1138).

The Proposed Finding is also misleading insofar as it suggests that even if the development costs for IPX-203 were estimated

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).

Response to Proposed Finding No. 535

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 533.

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).

Response to Proposed Finding No. 536

The Proposed Finding is misleading and contrary to the weight of the evidence to the extent it suggests that the DCA favorably mitigated risks by capping Endo's costs and putting the development burden on Impax. Endo chose to enter the DCA with minimal scientific information about IPX-203 and without applying any risk mitigation strategies. (CCF ¶ 1175). The structure of the payments in the DCA was "the exact opposite of the way agreements like this are structured." (CCF ¶ 1223 (citing Geltosky, Tr. 1072)). The customary approach to mitigate substantial uncertainty and risk in the pharmaceutical industry is to provide payments commensurate with progress on the program. (CCF ¶ 1173). Upfront payments typically reflect the value of work done on the project to date. (CCF ¶ 1220). **{** [redacted] **}** (CCF ¶ 1220 (*in camera*)). Yet, Endo made an upfront payment of $10 million to Impax, representing 25% of the deal's $40 million total value. (CCF ¶ 1221). **{** [redacted] **}** (CCF ¶¶ 1174, 1224 (*in camera*)). Endo could also have structured the deal as an option agreement, where the potential partner pays a nominal sum to hold the asset for a given period of time while the

licensee decides on whether to proceed with a full licensing or co-development transaction. (CCF ¶ 1227). {[redacted]} (CCF ¶ 1228 (*in camera*)). As Dr. Cobuzzi warned "if you pay too much up front, you may never actually get to the point of realizing that value." (CCF ¶1174 (citing CX4016 (Cobuzzi, IHT at 69-70))).

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).

Response to Proposed Finding No. 537

The Proposed Finding is misleading and incomplete to the extent that it suggests that Dr. Geltosky opined that the DCA was not a strategic fit for Endo only because certain documents did not mention the words "Parkinson's disease." Dr. Geltosky opined that based upon his review of internal Endo presentations, Endo did not have a focus or interest in pursuing Parkinson's disease treatments. (Geltosky, Tr. 1071). Specifically, Dr. Geltosky reviewed corporate Endo documents which identified Endo's product area strategies and goals for filling its pipeline. (CX5003 at 17 (¶ 28) (Geltosky Report); CCF ¶¶ 1087-89). These documents did not mention neurology or Parkinson's disease as an area of interest, and instead stated that Endo's business focused on pain, urology, endocrinology, and oncology therapeutic areas. (CX5003 at 17 (¶ 28) (Geltosky Report); CCF ¶¶ 1087-89).

The Proposed Finding is further misleading and incomplete in that it suggests that Dr. Geltosky did not have access to the entire factual record and only reviewed documents "provided to him by Complaint Counsel," and that the documents he reviewed did not accurately reflect Endo's views about its strategic focus in 2010. Impax has not provided any evidence to undercut Endo's explicit statements in these documents or Dr. Geltosky's opinion on this topic.

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 545

The Proposed Finding is misleading to the extent it suggests that Endo routinely entered into early-stage development agreements. The cited evidence states that Endo's deals "cut across [the development] spectrum." (Cobuzzi, Tr. 2516). However, the cited evidence does not state that Endo regularly entered into early-stage development agreements. Moreover, Impax has not presented any evidence that Endo's other early-stage pharmaceutical partnership deals were negotiated and structured in the same manner as the DCA. In fact, Dr. Cobuzzi stated that he could not recall any development and co-promotion agreement that Endo entered into for a preclinical product where it made an upfront payment of $10 million. (Cobuzzi, Tr. 2565).

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

Response to Proposed Finding No. 546

[redacted]. (CCF ¶¶ 1172-75).

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

Response to Proposed Finding No. 547

{ } (CCF ¶¶ 1143, 1163-64 (*in camera*)). { } (CCF ¶¶ 1163 *(in camera*)).

The Proposed Finding is further misleading and contrary to the weight of the evidence to the extent that it suggests that the development of IPX-203 did not pose significant risks. { } (CCF ¶ 1167 (*in camera*)). { } (CCF ¶ 1170 (*in camera*)). Endo also noted that "because of the limited amount of information, potential issues around manufacturing and stability could not be fully determined . . . insufficient information has been provided in due diligence to completely characterize the pharmaceutical development and manufacturing risks for IPX-203." (CCF ¶ 1168 (quoting CX1209 at 009 (Endo's Final Opportunity Evaluation Worksheet for IPX-203))). { }

[redacted] (CCF ¶ 1160 (*in camera*)).

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

Response to Proposed Finding No. 548

The Proposed Finding is misleading and contrary to the weight of the evidence to the extent that it suggests that manufacturing a Parkinson's disease product having an ester of levodopa would be simple. [redacted] (CCF ¶ 1167 (*in camera*)). [redacted] (CCF ¶ 1170 (*in camera*)). Endo also noted that "because of the limited amount of information, potential issues around manufacturing and stability could not be fully determined . . . insufficient information has been provided in due diligence to completely characterize the pharmaceutical development and manufacturing risks for IPX-203." (CCF ¶ 1168 (quoting CX1209 at 009 (Endo's Final Opportunity Evaluation Worksheet for IPX-203))). [redacted] (CCF ¶ 1160 (*in camera*)).

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

Response to Proposed Finding No. 549

The Proposed Finding is misleading and contrary to the weight of the reasons set out in the response to Proposed Finding 547.

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

Response to Proposed Finding No. 550

The Proposed Finding is misleading and inaccurate. Dr. Geltosky testified only that he has been involved in a handful of deals where the potential subject product may not have had a lead drug identified, not that he has only worked on a handful of development deals in their early stages. (Geltosky, Tr. 1144-45). Over the course of his career, Dr. Geltosky has been involved in working on thousands of pharmaceutical business agreements. (Geltosky, Tr. 1054-55). He specifically worked on nine completed preclinical deals while at Bristol Myers Squibb and four completed preclinical deals while at SmithKlineBeecham. (CX5003 at 3-4 (¶¶ 3-4) (Geltosky Report)). All of the work he conducted at Arizona State University focused on early-stage technologies. (Geltosky, Tr. 1049). His work at CPRIT also focuses on early stage products. (Geltosky, Tr. 1052). Dr. Geltosky's currently works at JEG consulting and some of his clients have hired him specifically for his expertise with early stage products. (CX4042 (Geltosky, Dep. at 71)).

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).

Response to Proposed Finding No. 551

The Proposed Finding is misleading and inaccurate to the extent it suggests that Dr. Geltosky has never negotiated a development and co-promotion agreement. Dr. Geltosky only testified that he has not negotiated an agreement "exactly like this one." (Geltosky, Tr. 1142). In his 35-plus years in the industry, Dr. Geltosky has been involved in thousands of pharmaceutical

business agreements. (Geltosky, Tr. 1046-47, 1054-55). His experience includes co-development and co-promotion agreements. (Geltosky, Tr. 1045). He specifically worked on nine completed preclinical deals while at Bristol Myers Squibb and four completed preclinical deals while at SmithKlineBeecham. (CX5003 at 3-4 (¶¶ 3-4) (Geltosky Report)). All of the work he conducted at Arizona State University focused on early-stage technologies. (Geltosky, Tr. 1049). His work at CPRIT also focuses on early stage products. (Geltosky, Tr. 1052). Dr. Geltosky currently works at JEG consulting and some of his clients have hired him specifically for his expertise in early stage products. (CX4042 (Geltosky, Dep. at 71)). In Dr. Geltosky's ten years as a consultant, out of a dozen potential deals, two were executed, which is a reasonable rate of completion. (Geltosky, Tr. 1183-84).

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).

Response to Proposed Finding No. 552

Complaint Counsel has no specific response, except to note that Dr. Geltosky has also worked with smaller and midsized pharmaceutical companies as a consultant, and their processes for evaluating discovery-stage assets and the questions they ask are the same as that of larger companies. (Geltosky, Tr. 1141-42).

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).

Response to Proposed Finding No. 553

The Proposed Finding is misleading to the extent that it suggests that Dr. Geltosky's experiences on behalf of "net sellers" of pharmaceutical technology are not relevant to his analysis of the DCA. Dr. Geltosky testified that while working on behalf of net sellers, he gained

experience seeing how buyer companies approached development agreements and how they conducted due diligence. (Geltosky, Tr. 1184).

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).

Response to Proposed Finding No. 554

The Proposed Finding is misleading and inaccurate to the extent it suggests that Dr. Geltosky cannot speak to how the universe of small or midsized pharmaceutical companies approach partnerships for early-stage products. Dr. Geltosky testified that, through his experiences as both buyer and seller of pharmaceutical technologies, companies of all sizes have approached development agreements using the same general process. (Geltosky, Tr. 1184; CX4042 (Geltosky, Dep. at 85-86)). Dr. Geltosky's experience with the process for evaluating business development opportunities is consistent with Endo's own process for evaluating business development opportunities. (CCF ¶¶ 1103-10; 1135-38).

(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).

Response to Proposed Finding No. 555

The Proposed Finding is misleading and contrary to the weight of the evidence to the extent it suggests that Parkinson's disease treatments were a primary area of interest for Endo. At the time of the DCA, Endo's business was not focused on pursuing Parkinson's disease treatments. (CCF ¶¶ 1087-95). Endo's primary areas of interest were urology, endocrinology, oncology as well as pain. (CCF ¶¶ 1087-89). In 2008, Endo received a recommendation for late stage product opportunities from a market and analytics research group. The L.E.K. analysis

excluded Impax's carbidopa/levodopa Parkinson's disease products from the list of potential opportunities for Endo, because generic versions of carbidopa/levodopa products were already on the market. (CCF ¶¶ 1090-91). **{**

} (CCF ¶¶ 1099-1102 (*in camera*)). **{**

} (CCF ¶ 1102 (*in camera*)).

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).

Response to Proposed Finding No. 556

the issue with the product he was presenting to Endo was not with the particular therapeutic area of the product. Rather, the developmental stage of the product that Dr. Geltosky was presenting to Endo was too early for them. (Geltosky, Tr. 1173).

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).

The Proposed Finding is further misleading to the extent that it suggests that the documents Dr. Geltosky reviewed in opining that the DCA was not a strategic fit for Endo did not accurately reflect Endo's views. Impax has not provided any evidence to undercut Endo's explicit statements in these documents.

Yet Dr. Geltosky conceded that Endo's oppor

The Proposed Finding is further misleading to the extent that it suggests that the documents Dr. Geltosky reviewed in opining that the DCA was not a strategic fit for Endo did not accurately reflect Endo's views. Impax has not provided any evidence to undercut Endo's explicit statements in these documents.

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).

Response to Proposed Finding No. 560

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 561

The Proposed Finding is misleading to the extent it suggests that the document regarding Endo's due diligence practice reviewed by Dr. Geltosky and cited in his report, (CX2784 (Aug 2009 Endo Business Development Process Orientation document)), does not reflect the process that was in place at Endo in 2010. Impax has provided no evidence to suggest that the business development process identified in CX2784 is an inaccurate reflection of the process in place at Endo. In fact, during testimony, Dr. Cobuzzi verified that the process outlined in CX1701 (9 July 2010 Endo Corporate Development Update) was the process used at Endo. (Cobuzzi, Tr. 2568-74). In the forwarding email of the document, Dr. Cobuzzi notes that both the COO (Julie McHugh) and CFO (Alan Levin) agree with the process. (CX1701 at 001). This process consisted of the steps of asset identification, initial screening, evaluation, due diligence, and negotiation and deal closure. (CX1701 at 011-12). These steps are consistent with the steps outlined in CX2784, the document relied upon by Dr. Geltosky. (CX2784 at 024-27 (Prospective Identification), 031-50 (due diligence) 051-55 (negotiation/transaction phase))).

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).

Response to Proposed Finding No. 562

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 561.

The Proposed Finding is also misleading insofar as it suggests that Dr. Geltosky does not opine about whether Endo's due diligence for IPX-203 was consistent with Endo's own standards and industry standards. As Dr. Geltosky explained, based on his 35-plus years of experience, he concluded that the overall strategic fit, negotiation process, due diligence efforts, and terms of the DCA were not consistent either with Endo's or the pharmaceutical industry's usual and expected practice for early-stage development projects. (Geltosky Tr. 1059, 1067; CX5003 at 5 (¶ 13) (Geltosky Report); CCF ¶¶ 1111, 1113, 1120-23, 1128, 1130-34, 1135-39).

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).

Response to Proposed Finding No. 563

The Proposed Finding is misleading and inaccurate to the extent that it suggests 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. Dr. Geltosky testified that commercial market information about IPX-066 could provide a baseline for the analysis of IPX-203, but he did not "think there were enough data available to . . . hang your hat on at that point." (Geltosky, Tr. 1155). IPX-203 needed to be superior to IPX-066 in order to be successful. (Geltosky, Tr. 1093-94). The parties would have had to do a Phase III study to see if IPX-203 was superior to IPX-066 in order to see if information on IPX-066 could be used as a benchmark. (Geltosky, Tr. 1154-55). {[redacted]} (CCF ¶¶

1250-51, 1259 (*in camera*)). Moreover, one would need to make adjustments to any variables to account for the different risks associated with each IPX-066 and IPX-203, which Endo did not do. (CCF ¶¶ 1203-18).

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).

Response to Proposed Finding No. 567

Complaint Counsel has no specific response, except to point out that the burden of performing due diligence on IPX-203 was on Endo

generic Opana ER from staying out of the market until 2013, and the No-AG/Endo Credit payment provided compensation for the costs of waiting until 2013 to sell. (CCF ¶¶ 1046-47). The overwhelming weight of the evidence links the No-AG/Endo Credit payment and the January 2013 entry date. (CCF ¶¶ 1034-54).

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).

Response to Proposed Finding No. 572

The Proposed Finding is misleading and not supported by the evidence cited in that it suggests that neither Endo nor Impax had any control over whether an Endo Credit payment would be made. The magnitude of the Endo Credit depended primarily on whether and when Endo introduced a reformulated version of Opana ER prior to January 2013. (CCF ¶¶ 326-27). Endo had significant control over this decision. (CCF ¶¶ 482-87; *see also* Complaint Counsel's

Impax number by a specified amount to calculate the final sum due. (Snowden, Tr. 437; *see* CX2626-006; Engle, Tr. 1749-50).

Response to Proposed Finding No. 573

The Proposed Finding is factually inaccurate in that it states all of the listed information is required to determine "the prospect of a payment." The possibility of a payment under the Endo Credit existed as soon as the SLA was entered. Impax and Endo each understood that the Endo Credit might be triggered and require a sign

calculate the Endo Credit before the payment was actually made in 2013. (CCF ¶ 463). Indeed, based on the size of Opana ER sales at the time of settlement, the Endo Credit (if triggered) would be at least $62 million (CCF ¶ 470).

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).

Response to Proposed Finding No. 575

The Proposed Finding is factually inaccurate about what Endo was required to pay Impax and misleading about the conditions under which a royalty would be paid. First, Endo was required to forgo sales of an authorized generic during Impax's first-filer exclusivity period. (CCF ¶¶ 411, 1041). That requirement continued even if Impax's opportunity for generic Original Opana ER was preserved or enhanced. (CCF ¶¶ 1064-65). Forgoing these lucrative AG sales was a payment from Endo to Impax. (CCF ¶¶ 410-11). Second, the SLA did not require Impax to pay a royalty if original Opana ER sales were only preserved; rather specified growth rates were required to trigger the royalty in section 4.3 of the SLA. (CCF ¶ 1064). Even if that royalty was triggered and the market opportunity for generics was better, Endo would receive only 28.5% of profits from Impax's generic sales, instead of 100% of profits Endo would earn from sales of its own AG. (CCF ¶ 1065).

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)).

Response to Proposed Finding No. 576

The Proposed Finding is misleading and incomplete. At the time it executed the SLA, Impax viewed the chances of the No-AG/Endo Credit payment resulting in zero value as "so unlikely it wasn't worth worrying about." (CCF ¶ 480; *see also* Complaint Counsel's Response to Proposed Finding No. 569).

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).

Response to Proposed Finding No. 577

The Proposed Finding is misleading in that it suggests that Impax preferred an outcome that did not result in any payment from Endo. To the extent that Impax preferred to launch a generic product "into a robust, large market a pay a royalty," Impax simply preferred to receive the payment from Endo in the form of the No-AG provision rather than the Endo Credit (which was ultimately more than $102 million). If the sales of Opana ER continued to increase such that Impax was required to pay a royalty, then the value of the No-AG provision would also grow. (CCF ¶¶ 467-68). In all cases, the benefit to Impax from being the only seller of a generic oxymorphone ER product would be greater than what it would be required to pay Endo in royalties. (CCF ¶¶ 467-68).

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).

Response to Proposed Finding No. 578

This Proposed Finding is misleading for the reasons stated in response to Proposed Finding No. 577.

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)).

Response to Proposed Finding No. 579

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 580

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)).

Response to Proposed Finding No. 585

The Proposed Finding is misleading to the extent that it suggests that Endo had no expectation that the Endo Credit might be triggered and require a significant payment. Endo extensively negotiated changes to the formula that would reduce its payment obligation. (CCF ¶¶ 261-63, 268-69, 431). Moreover, implementing reformulation in accordance with Endo's plans both before and after entering the settlement would necessarily trigger a substantial payment to Impax under the Endo Credit. (*See* Complaint Counsel's Response to Proposed Finding Nos. 593 and 1425).

The Proposed Finding is misleading and incomplete because it assesses the Endo Credit separately from the No-AG provision. The Endo Credit was intended to make Impax whole if Endo degraded the market opportunity for generic Opana ER, including the no-AG provision, in advance of Impax's launch in 2013. (CCF ¶¶ 1058-61). If Endo did not harm the market for

66). In addition, the Proposed Finding is misleading for the reasons stated in response to Proposed Finding No. 587.

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")).

Response to Proposed Finding No. 590

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding No. 587. In addition, the Proposed Finding is incomplete. In the cited testimony, Mr. Levin could not recall how he reached that conclusion and could not explain why he discounted other possibilities. (CX4017 (Levin, Dep. at 103) ("Q. In reaching that conclusion, did you assess the various possibilities of what could occur under the Endo credit? A. […] I don't remember the details of my process for arriving at this conclusion" and "it would not be appropriate for me to hypothesize about possibilities")).

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)).

Response to Proposed Finding No. 591

The Proposed Finding is misleading and incomplete. Generally accepted accounting principles (GAAP) are "strict." (Cuca, Tr. 667). To be booked and put in Endo's financials, a liability cannot be a range, but must be "a precise number," which could not have been "estimable" by Endo before knowing the quarterly peak sales of Opana ER between July 2010 and September 2012. (Cuca, Tr. 668-69). Thus, any liability could not be estimable in June 2010, when the SLA was signed. But even though Endo did not account for the Endo Credit liability in its financial statement until the precise size of the payment was estimable, that does not mean

that Endo did not face the prospect of making a significant payment under the Endo Credit as of June 2010. (Koch, Tr. 329-30) (a company can face a business loss from a contingency before it must reflect the loss in a financial statement).

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)).

Response to Proposed Finding No. 592

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 591.

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)).

Response to Proposed Finding No. 593

The Proposed Finding is misleading and incomplete by suggesting that whether Impax received a payment depended on post-settlement events. As part of the SLit pnts. Apac29Event[(No-AG/redre t1(

at the time of settlement was $62 million (CCF ¶ 470); if the Endo Credit was not triggered, Impax would have received value of at least $16.5 million under the No-AG provision. (CCF ¶ 471). The profits Impax received from the No-AG/Endo Credit payment increased as sales of Original Opana ER grew prior to 2013, and the SLA envisioned the increased potential for Impax from higher Original Opana ER sales. (CCF ¶¶ 1064-65). Whether Impax got that increased profit potential from selling the only generic version of Opana ER for 180 days or from the Endo Credit depended on whether sales of Original Opana ER declined (e.g., by Endo reformulating).

The Proposed Finding is further misleading and incomplete with respect to the Novartis supply issue and whether it accelerated the withdrawal of Original Opana ER. At the time of settlement, Endo expected to get FDA approval for Reformulated Opana ER by late 2010 or early 2011. (CCF ¶¶ 77-78). Endo planned to quickly launch the reformulated version in the place of Original Opana ER. (CCF ¶ 78). The settlement did not change Endo's strategy, and Endo continued post-settlement to target launch of Reformulated Opana ER in early 2011. (RX-78 at 0012 (Dec. 16, 2010 Revopan Launch Readiness Review showing planned launch date for Reformulated Opana ER as Feb. 28, 2011)). But contrary to expectations, Endo did not get FDA approval for Reformulated Opana ER until December 2011. (CCF ¶ 83). To say that any supply issues caused Endo to accelerate launch of Reformulated Opana ER to a time period earlier than Endo expected at the time of settlement is factually inaccurate.

594. But Dr. Bazerman, one of Complaint Counsel's own experts, admits that the FDA's

plant did not shut down. To the contrary, Professor Bazerman testified that it would have been very difficult for Endo to time the reformulation in a way that allowed Endo to avoid making an Endo Credit payment and simultaneously fully convert the marketplace to reformulated product. (CX4040 (Bazerman, Dep. at 135-36); *see also* CCF ¶ 80 ("Generally, it takes six to nine months to transition a market from an original branded product to a reformulated branded product") (citing testimony from Impax and Endo employees); RX-095 at 0002 (Endo draft memo discussing Endo being "particularly concerned" about trying to transition to reformulated Opana ER in a few months "as we knew that Purdue's OxyContin transition took 6 months")). And because of the magnitude of potential sales of reformulated Opana ER, a rational decisionmaker would choose to make the Endo Credit payment rather than risk a partial transition. (Addanki, Tr. 2463 ("[I]f [Endo] could make profit elsewhere by incurring the Endo [C]redit, they would"); CX4040 (Bazerman Dep. at 135-36) ("the amount of funds that [Endo] would forgo of lost sales [of] a branded Opana product would be larger than the money that they would save by not paying out the Endo Credit")). Indeed, Endo projected generating more than $1 billion in revenues from sales of Reformulated Opana ER between 2012 and 2016 if reformulation occurred before generic entry. (CX2724 at 004 (Jan. 2010 presentation on forecast scenarios for Reformulated Opana ER)). As such, the Endo Credit payment would be "simply a cost of doing business." (CX4040 (Bazerman Dep. at 136)). Indeed, even after the Impax-Endo Settlement Agreement, Endo planned to get approval for Reformulated Opana ER later in 2010 or early in 2011 and launch as soon as possible. (CCF ¶¶ 78-81, 484 (citing CX1108 at 004) (Nov. 2010 presentation to the Endo board of directors stating that Endo's "current planning assumption is to stop shipping all [Original] Opana ER by October 1, 2011"), 486-87).

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

Response to Proposed Finding No. 595

Complaint Counsel has no specific response except to note that the second source does not support the Proposed Finding, as Mr. Levin testified he could not remember Endo's Opana sales in 2010. (CX4017 (Levin, Dep. at 151) ("Frankly, I don't remember at this point.")).

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)).

Response to Proposed Finding No. 596

Complaint Counsel has no specific response except to note that the second source does not support the Proposed Finding, as Mr. Levin testified he did not know if that amount accurately reflected Endo's expected Opana sales in 2011. (CX4017 (Levin, Dep. at 151-52)).

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)).

Response to Proposed Finding No. 597

The Proposed Finding is not relevant to the Impax-Endo Settlement Agreement or Impax's or Endo's expectations about Opana ER sales at the time of settlement. The cited sources—which were admitted for nonhearsay purposes and were not admitted for the truth of the matters asserted—were published after the Impax settlement, so could not have informed Endo or Impax when they were negotiating the settlement. Indeed, each cited source was published in response to the Impax settlement. (*See* RX-419 (June 8, 2010 Buckingham Research Group report, "Settlement with Impax Largely Removes Generic Opana ER Overhang Through Jan. 2013"); RX-422 (June 14, 2010 Piper Jaffray report, "Endo Pharmaceuticals: Revising Model to Reflect Opana ER Settlements")). In addition, the sources are not reliable about pre-settlement expectations because analysts' opinions for Opana ER sales in the cited sources changed as a result of the Impax settlement as generic entry would not occur until 2013, contrary

to previous analyst predictions of earlier generic entry. (RX-422 at 0001 ("our model now reflects a generic erosion starting in 2013 compared to our previous estimate in the 2011/2012 timeframe"); *see generally* RX-419 at 0001 (stating that the settlement, which prevents generic entry until 2013, "should allow growth for this franchise")). For all of these reasons, the cited sources are not relevant to pre-settlement expectations about growth of Opana ER sales or the Impax-Endo Settlement Agreement.

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)).

Response to Proposed Finding No. 598

The Proposed Finding is misleading and incomplete. Respondent appears to be using the reports to suggest that Opana sales would not have grown substantially after the Impax settlement and in advance of the Endo Credit payment. But the cited sources were published before the Impax settlement, and the decline in Opana sales were projected as a result of generic entry that analysts expected earlier than January 2013. (RX-417 (May 14, 2010 Cowen & Co. report on Endo Pharmaceuticals discussing Impax's tentative FDA approval and projecting Opana ER sales decline in 2011); *see also* RX-422 (June 14, 2010 Piper Jaffray report noting that pre-settlement model reflected generic entrant in 2011/2012 timeframe)). Respondent does not address this fact and, therefore, the inferences Respondent attempts to draw from this Proposed Finding about a potential Opana sales decline are misleading, speculative, and incomplete. And there is no indication that Impax or Endo relied upon the figures in these analyst reports when negotiating the SLA. Moreover, the cited sources were admitted for nonhearsay purposes and were not admitted for the truth of the matters asserted. They thus offer no independent support for the proposition that Opana ER sales would have declined after the settlement.

599. [redacted] (RX-414).

Response to Proposed Finding No. 599

Complaint Counsel objects to the Proposed Finding as vague and potentially not supported by the evidence cited, which is a large spreadsheet broken down by NDC and customer category and includes sales measured on multiple bases, including dollar sales and volume sales. The Proposed Finding does not indicate how Respondent measured purported sales growth. Moreover, it is unclear which dosage strengths Respondent measures, specifically whether it includes the 7.5 mg and 15 mg dosage strengths, which were discontinued by Endo in 2011 and for which a generic version was introduced by Actavis in 2011. (CCF ¶¶ 631, 841).

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).

Response to Proposed Finding No. 600

The Proposed Finding is misleading and incomplete in that Respondent appears to suggest that the payment made under the Endo Credit could not have been expected because of increased sales of Opana ER by late 2011. But the SLA envisioned that sales of Original Opana ER could increase before January 2013 and that Impax would receive increased profits from the No-AG provision. (CCF ¶ 1065). If Endo had not reformulated, Impax would have received those higher profits through the No-AG provision by selling the only generic product for six months in the larger market. (CCF ¶ 415; *see also* Complaint Counsel's Response to Proposed Finding No. 593). The Endo Credit was structured to provide Impax the corresponding value of the exclusivity period as a cash payment if the market for Original Opana ER deteriorated before 2013. (CCF ¶¶ 254-55, 325-27, 1061).

The Proposed Finding is also misleading in that it suggests that, had Opana ER sales not grown faster than expected after the June 2010 settlement, the Endo Credit payment would not

have been large. But Professor Noll calculated that, even if sales of Opana ER peaked in June 2010 (and thus did not grow at all after the settlement), the ***smallest possible payment*** under the Endo Credit (if triggered) was $62 million. (CCF ¶ 470). Impax does not challenge this calculation. (CCF ¶ 479).

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).

Response to Proposed Finding No. 601

The Proposed Finding is misleading and incomplete. Endo had to stop selling the original formulation of Opana ER because it chose to sell the reformulated version under the exact same brand name as the original formulation. To eliminate confusion for patients, the FDA permitted Endo only to sell one formulation under that brand name at a time on a strength-by-strength basis. (CX4017 (Levin, Dep. at 138-39); RX-095 at 0003). The FDA did not force Endo to sell the original and reformulated versions under the same "Opana ER" brand name; that decision was Endo's. (*See* CX2730 at 003 (Oct. 26, 2010 Endo presentation showing that Endo's choice of name for the reformulated product would be driven by whether the FDA allowed Endo to make additional labeling claims)).

The Proposed Finding is also misleading in that it suggests that, had Opana ER sales not grown faster than expected after the June 2010 settlement and then declined sharply in early-2012, the Endo Credit payment would not have been large. But Professor Noll calculated, that, even if sales of Opana ER peaked in June 2010 (and thus did not grow at all after the settlement), the ***smallest possible payment*** under the Endo Credit (if triggered) was $62 million. (CCF ¶ 470). Impax does not challenge this calculation. (CCF ¶ 479).

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

RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)).

Response to Proposed Finding No. 603

The Proposed Finding is misleading and incomplete insofar as it suggests that Endo could not have expected to make a payment under the Endo Credit until after the Novartis plant shutdown. In June 2010, at the time of the settlement, Endo's reformulation plans anticipated that sales of Original Opana ER would be zero in the last quarter of 2012. (CCF ¶¶ 78, 243-45). At that time, Endo expected to get FDA approval for Reformulated Opana ER by late 2010 or early 2011 and planned to quickly launch the reformulated version in the place of Original Opana ER. (CCF ¶¶ 77-78, 243-45). Under that plan, sales in the last quarter of 2012 would have been zero. (*See also* Complaint Counsel's Response to Proposed Finding Nos. 602 and 1425).

The Proposed Finding is also misleading insofar as it suggests that Impax would not have

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 602 and 603. Moreover, the Proposed Finding is not supported by the evidence cited, which only references discussions in which a single employee was involved during a specific time period. (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)).

Response to Proposed Finding No. 606

The Proposed Finding is misleading and incomplete. Generally accepted accounting principles (GAAP) are "strict." (Cuca, Tr. 667). To be booked and put in Endo's financials, a liability cannot be a range, but must be "a precise number," which could not have been "estimable" by Endo before knowing the quarterly peak sales of Opana ER between July 2010 and September 2012. (Cuca, Tr. 668-69). Thus, any liability could not be estimable in June 2010, when the SLA was signed. But even though Endo did not account for the Endo Credit liability in its financial statement until the precise size of the payment was estimable, that does not mean that Endo did not face the prospect of making a significant payment under the Endo Credit as of June 2010. (Koch, Tr. 329-30) (a company can face a business loss from a contingency before it must reflect the loss in a financial statement).

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).

Response to Proposed Finding No. 607

The Proposed Finding is not supported by the evidence cited, which is testimony from a single Impax employee—who did not join Impax until January 2012—about when he "heard a payment *would be* due under the Endo Credit." (Reasons, Tr. 1199-1200, 1228 (emphasis added)). In other testimony, Mr. Reasons agreed that the No-AG and Endo Credit provisions

worked in tandem to provide compensation to Impax: "[I]f the market for Opana ER did not decline, the value of the No-AG provision would be higher, but if the market did decline, Impax would get a payment under the Endo Credit." (CCF ¶ 438).

The Proposed Finding is also misleading insofar it suggests that Impax did not expect a payment under either the Endo Credit or No-AG provision until May 2012. The No-AG/Endo Credit payment was structured so that Impax would profit either from the No-AG provision or the Endo Credit. (CCF ¶¶ 435-38). Indeed, Impax believed that the chances of getting nothing from either the No-AG provision or the Endo Credit were "so unlikely it wasn't worth worrying about." (CCF ¶ 480). Impax was even telling investors in 2011—well before the time cited in the Proposed Finding—that Impax had "a reasonable outcome almost no matter what happens." (CCF ¶ 438).

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

Response to Proposed Finding No. 608

The Proposed Finding is misleading and not relevant to the issue of whether Impax would be paid under the No-AG/Endo Credit payment. The settlement was structured to ensure Impax received value from the No-AG/Endo Credit payment, and Impax knew of that value as soon as the settlement was signed. (CCF ¶¶ 435-38). Impax was even telling investors in 2011—a year before the time cited in the Proposed Finding—that Impax had "a reasonable outcome almost no matter what happens." (CCF ¶ 438).

Further, even the limited point made by the Proposed Finding is not supported by the evidence cited. The cited testimony is one witness stating that he could not recall personally doing any calculations of the Endo Credit amount until he was asked to do so in the third quarter of 2012.

43). Similarly, Impax would not have been willing to stay out of the market—which it was preparing to enter as early as mid-2010—until 2013 unless it received compensation to offset its lost sales. (CCF ¶¶ 1044-47). The primary compensation for Impax staying out of the market was the No-AG/Endo Credit payment. The No-AG/Endo Credit is, therefore, directly connected to Impax's agreement to stay out of the market until the licensed entry date.

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

Response to Proposed Finding No. 610

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 609.

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)).

Response to Proposed Finding No. 611

The Proposed Finding is not supported by the evidence cited. Only one source is cited for the Proposed Finding, and that testimony related specifically to a question about the license Impax obtained to patents that did not exist at the time of settlement. In response to that question, the witness said there was nothing he could remember [illegible] (CX 4012 (Donatiello, IHT at 173) ("Q. a 223Qater the

Response to Proposed Finding No. 612

settlement negotiations and allow the parties to agree to a settlement with an entry date for Impax beyond what would have been expected without the payment. (CCF ¶ 994). If Endo agreed to January 2013 entry coupled with a significant payment to Impa

and CX3007 at 003 ("If Impax launches, Endo will launch its authorized generic. . . .")). Endo projected that sales of that AG could offset more than one-third of its lost branded Opana ER sales in 2010 after a generic first launched. (CCF ¶ 84). Endo designed a generic tablet, obtained labels, created new SKUs, informed drug wholesalers that Endo would launch an AG as soon as Impax began selling, and manufactured enough generic Opana ER to support a June 2010 AG launch. (CCF ¶¶ 86-90, 400-03). Endo would have the same strong incentives to sell an AG when Impax launched in 2013 if Endo's reformulation strategy failed—e.g., if the FDA had not approved Reformulated Opana ER (which the FDA later asked Endo to withdraw from the marketplace for reasons of safety)—because an AG would offset some of the losses from decreased branded sales. (CCF ¶ 84). Indeed, Endo launched an AG of immediate-release Opana just a few months after the Impax settlement, when generic versions of immediate-release Opana launched. (CCF ¶ 1350). If Endo had not reformulated, the No-AG provision would have caused Endo to forgo valuable Opana ER authorized generic sales that it otherwise would have had the incentive to make. (CCF ¶ 1041). Instead, Endo reformulated and paid the Endo Credit.

617. Brian Lortie, Endo's Senior Vice President for Pain Solutions at the time of settlement, similarly explained that "we never seriously

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 616.

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).

Response to Proposed Finding No. 619

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 616.

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).

Response to Proposed Finding No. 620

The Proposed Finding is misleading and not relevant to whether Impax would receive a payment under the No-AG/Endo Credit payment provisions. Under the SLA, Impax would receive a large payment either through increased generic sales generated by Endo forgoing an AG (i.e., the No-AG provision) or through a cash payment under the Endo Credit if the market opportunity for generic Original Opana ER declined before Impax's launch. (CCF ¶ 271-72, 1031). Because the Proposed Finding assumes that Endo switched to a reformulated Opana ER product, sales of an AG would be irrelevant to the specific value Impax received from the No-AG/Endo Credit payment. Impax would receive the payment under the Endo Credit. (CCF ¶¶ 271-72).

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)).

Response to Proposed Finding No. 621

The Proposed Finding is misleading and not relevant to whether Impax would receive a payment under the No-AG/Endo Credit payment provisions for the reasons set forth in response to Proposed Finding No. 620.

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)).

Response to Proposed Finding No. 622

The Proposed Finding is misleading and not relevant to whether Impax would receive a payment under the No-AG/Endo Credit payment provisions for the reasons set forth in response to Proposed Finding No. 620.

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).

Response to Proposed Finding No. 623

The Proposed Finding is misleading and incomplete. Endo frequently sells authorized generics when a generic is launched for one of its branded products. Since 2010, Endo has launched AGs for immediate-release Opana, Lidoderm, Fortesta gel, and Voltaren gel. (CCF ¶ 1350). Impax has not identified an Endo branded product for which Endo did not launch an authorized generic around the time of an initial generic launch since 2010.

The Proposed Finding is further misleading and incomplete because it omits the remainder of Mr. Koch's testimony from the same answer, in which Mr. Koch states that AG launches happen "frequently" and "often" and that Impax routinely forecasted that Endo would sell an authorized generic for Opana ER (Koch, Tr. 233; CCF ¶ 413-14).

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).

Response to Proposed Finding No. 624

The Proposed Finding is misleading and incomplete. While Impax could not be certain that Endo would launch an AG of Opana ER, Impax forecasted that Endo would launch an AG and that an AG would significantly lower Impax's market share and sales price during the 180-day first-filer exclusivity period, cutting Impax's revenues by more than half. (CCF ¶¶ 412-14). By preventing sales of an AG during its first-filer exclusivity period, Impax ensured that it would more than double its revenues from generic Opana ER in the first six months of 2013 compared to what Impax would earn if it faced an AG (unless Endo reformulated and paid Impax through the Endo Credit, which was designed to replicate Impax's profits from the exclusivity period in the event that Opana ER sales declined significantly before 2013). (CCF ¶¶ 271-72, 410-15). While Impax would derive value from selling its generic product, it would derive substantially more value from selling generic Opana ER without facing competition from an AG. Thus, obtaining a No-AG provision is "among the more important things" in a settlement negotiation for Impax. (CCF ¶ 231 (quoting Mengler, Tr. 526); *see also* CCF ¶¶ 1482-84). The only purpose of the No-AG provision in the SLA was to prevent Endo from selling an AG in competition with Impax during the first-filer exclusivity period.

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).

Response to Proposed Finding No. 625

The Proposed Finding is not supported by the evidence cited because it mischaracterizes testimony responding to a question about the effect of reformulation and Mr. Mengler's response how Impax would lose value from selling generic Opana ER, with or without an AG, in the event the market moved to a new product. (Mengler, Tr. 528-29). Indeed, Mr. Mengler also testified

that obtaining a No-AG provisi

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)).

Response to Proposed Finding No. 628

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. Before Impax and Endo started having substantive negotiations in 2010, Impax executives were concerned about postponing Impax's projected oxymorphone ER entry date beyond 2010, but were willing to do so for a settlement with a No-AG provision. (CCF ¶ 224 (citing CX0505 at 001 (May 14, 2010 Mengler/Hsu email chain showing generics division president objecting to "postponing the launch of Oxymorphone" until Impax CEO suggested a settlement "with No AG")). Every proposal exchanged between Endo and Impax with an entry date in 2013 contained a No-AG provision, and the Endo Credit was developed as insurance to Impax for the value of the No-AG provision in the event the market opportunity for generic Opana ER declined before 2013 and Impax could not benefit from the No-AG provision. (CCF ¶¶ 255-57, 1034, 1036-39). The No-AG/Endo Credit payment makes no sense unless linked to the 2013 entry date. Endo would not be willing to forgo valuable AG sales or make a cash payment to Impax unless it was getting something in return, specifically the ability to sell its branded product until 2013 without generic competition. (CCF ¶¶ 1005, 1040-43). Similarly, Impax would not have been willing to stay out of the market—which it was preparing to enter as early as mid-2010—until 2013 unless it received compensation to offset its lost sales. (CCF ¶¶ 1044-47). The primary compensation for Impax staying out of the market was the No-AG/Endo Credit payment. The No-AG/Endo

Credit is, therefore, directly connected to Impax's agreement to stay out of the market until the licensed entry 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).

Response to Proposed Finding No. 629

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 628.

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)).

Response to Proposed Finding No. 630

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 628. Further, the Proposed Finding is not supported by the cited source, CX4012, which related specifically to a question about the license Impax obtained to patents that did not exist at the time of settlement. In response to that question, the witness said there was nothing he could remember. (CX 4012 (Donatiello, IHT at 173) ("Q. Did the addition of the license to future patents change the commencement date? A. I don't remember any of the sections being related to one another, or discussions with Impax about any of that.")). This does not support the conclusion Respondent draws that there was no link between the No-AG provision and a "later entry date."

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

Response to Proposed Finding No. 631

The Proposed Finding is factually inaccurate and contrary to the we4 sg No. 6h inC4fnce

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).

Response to Proposed Finding No. 632

The Proposed Finding is misleading and incomplete. The No-AG/Endo Credit payment was structured so that Impax would profit eith

product)); RX-095 at 0002 (discussing Endo being "particularly concerned" about trying to transition to reformulated Opana ER in a few months "as we knew that Purdue's OxyContin transition took 6 months")). And the cost of failure could be significant for Endo if patients started using a generic version of Original Opana ER rather than ever starting on the more expensive Reformulated Opana ER. (CX4040 (Bazerman, Dep. 135-36)). The success of Endo's entire strategy was contingent on Endo converting patients to the reformulated version before generic oxymorphone hit the market. (CCF ¶¶ 482-83; Complaint Counsel's Response to Proposed Finding No. 594). These facts support Impax's belief that the possibility of getting nothing from the No-AG/Endo Credit payment was "so unlikely." (CCF ¶ 480).

Indeed, viewing the settlement when it was signed, Endo's reformulation plans would have guaranteed a payment under the Endo Credit. When the settlement was being negotiated and signed, Endo expected to get FDA approval for Reformulated Opana ER by late 2010 or early 2011 and planned to quickly launch the reformulated version in the place of Original Opana ER. (CCF ¶¶ 77-78). Under that plan, Endo could have expected that it would owe a payment under the Endo Credit. The settlement did not change Endo's strategy, and Endo continued to target launch of Reformulated Opana ER in early 2011. (RX-078 at 0012 (Dec. 2010 Revopan Launch Readiness Review showing planned launch date for Reformulated Opana ER as Feb. 28, 2011)). Endo's original reformulation plan was not achieved, as Endo did not get FDA approval for Reformulated Opana ER until December 2011. (CCF ¶ 83). Endo launched Reformulated Opana ER after that and the market was largely converted to Reformulated Opana ER by the fourth quarter of 2012. (CCF ¶¶ 440-41). Endo then paid Impax more than $102 million due to the Endo Credit. (CCF ¶ 444).

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)).

Response to Proposed Finding No. 633

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 632.

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).

Response to Proposed Finding No. 634

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 632.

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).

Response to Proposed Finding No. 635

The Proposed Finding is misleading, incomplete and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 632 (including Mr. Mengler's conflicting testimony that it takes 6-9 months to switch market to a reformulated product). Moreover, the Proposed Finding omits Mr. Mengler's further testimony that he considered the probability of this scenario to not evenns sel4w4Tdnsc5.ot eTd[(red tPes7b2295 ity of tits)]TJ-040

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).

Response to Proposed Finding No. 636

The Proposed Finding is misleading and incomplete. Both before and after entering the SLA, Endo planned its transition from Original Opana ER to Reformulated Opana ER in late 2010 or early 2011. (*See* Complaint Counsel's Response to Proposed Finding Nos. 209 and 632). When Endo completed its 2012 budget in October 2011—when Reformulated Opana ER still had not been approved by the FDA—Endo "contemplated a targeted launch of Aug 2012 and full conversion [from Original Opana ER] within 2 – 3 months." (RX-095 at 0002). But that was not a final plan, as there were "significant uncertainties" and Endo was "particularly concerned" about being able to convert Opana ER quickly enough before generic entry. (RX-095 at 0002 (discussing the fact that OxyContin took six months to convert to a reformulated product)). And Endo risked losing Reformulated Opana ER sales if the market was not fully converted by the time Impax launched its Original Opana ER generic in January 2013. (*See* Complaint Counsel's Response to Proposed Finding No. 594). Thus, a conversion in late 2012 was clearly *not* Endo's intention around the time of settlement or in th

plan from 2011 and was just reading the document in front of him. (CX4017 (Levin, Dep. at 131)). Moreover, he went on to state that "it was such a fluid situation that we may have looked at a range of possible launches as part of the budgeting effort." (CX4017 (Levin, Dep. at 132)).

637. Endo's original budget for 2012 consequently projected original Opana ER sales

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).

Response to Proposed Finding No. 639

The Proposed Finding is misleading and incomplete insofar as it suggests that calculation of the expected value of all or part of the SLA was possible or necessary to determine that the payments at issue in this case were large. Although Dr. Addanki criticized Professor Noll for not calculating expected values for the payments to Impax, he conceded that calculating such expected values would not be "in any practical sense doable." (CCF ¶ 479). Moreover, it was not necessary to calculate the expected value of the SLA payments to determine that they were large. Professor Noll used historical Opana ER sales data and Impax's own contemporaneous documents to calculate the value of the No-AG agreement and Endo Credit to Impax in every reasonable scenario. (CCF ¶¶ 461-72). His analysis shows that, in any such scenario, the combination of these provisions would result in a payment of at least $16.5 million to Impax, and likely far more. (CCF ¶¶ 467-72). Of course, the actual value of the Endo Credit turned out to be $102 million. (CCF ¶¶ 444, 479). Impax does not challenge or rebut any of Professor Noll's calculations.

Because the actual outcome resulted in an enormous payment, and because the vast

zero-payment would have to be overwhelmingly large to pull the expected value of the payment below saved litigation costs. Professor Noll assumed two outcomes—the payment of $102 million which we know was a reasonable outcome because it happened, and a payment of zero. (CX5004 at 073 (¶ 153) (Noll Rebuttal Report)). He

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).

Response to Proposed Finding No. 641

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 639.

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).

Response to Proposed Finding No. 642

The Proposed Finding is factually inaccurate and unsupported by the evidence cited. Professor Noll testified that "there [were] attempts to calculate [the Endo Credit's] value under certain circumstances." (Noll, Tr. 1610). Even though the precise value of the Endo Credit was not known at the time to the settlement, it was based on a mathematical formula, and the range of possible payments could be estimated on the basis of product plans and sales forecasts. (CCF ¶¶ 463, 465). An Endo executive charged with evaluating the Endo Credit provision, Mr. Cuca, testified that he would have analyzed "the potential financial impact" of the Endo Credit being triggered "at certain times or in certain ways." (CX4035 (Cuca, Dep. at 79-80)).

The Proposed Finding is also misleading and incomplete to the extent it implies the Endo Credit had no value, because substantial contemporaneous evidence proves that the Endo Credit had substantial value to Impax. (CCF ¶¶ 428-29, 431, 434-38, 482-87, 489-91).

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

Response to Proposed Finding No. 643

The Proposed Finding is misleading and incomplete. Generally accepted accounting principles (GAAP) are "strict." (Cuca, Tr. 667). To be booked and put in Endo's financials, a

liability cannot be a range, but must be "a precise number," which could not have been "estimable" by Endo before knowing the quarterly peak sales of Opana ER between July 2010 and September 2012. (Cuca, Tr. 668-69). Thus, any liability could not be estimable in June 2010, when the SLA was signed. But even though Endo did not account for the Endo Credit liability in its financial statement until the precise size of the payment was known, that does not mean that Endo did not face the prospect of making a significant payment under the Endo Credit as of June 2010. (Koch, Tr. 329-30) (a company can face a business loss from a contingency before it must reflect the loss in a financial statement).

Although the precise value of the Endo Credit was not known at the time of the settlement, it was based on a mathematical formula, and the range of possible payments could be estimated on the basis of product plans and sales forecasts. (CCF ¶¶ 463, 465). An Endo executive charged with evaluating the Endo Credit provision, Mr. Cuca, testified that he would have analyzed "the potential financial impact" of the Endo Credit being triggered "at certain times or in certain ways." (CX4035 (Cuca, Dep. at 79-80)). Moreover, the Endo Credit – together with the No-AG provision – was worth tens of millions of dollars to Impax under any reasonable scenario facing Impax at the time of the settlement. (CCF ¶¶ 466-71). For example, the smallest possible payment due to Impax under the Endo Credit if it were triggered was $62 million. (CCF ¶ 470). This scenario assumes that sales of Opana ER would have peaked at the time of the settlement, and then fallen just enough to trigger the Endo Credit. (CCF ¶ 470). If, instead, sales of Opana ER declined from the time of settlement, but the Endo Credit was not triggered, the No-AG provision would have still been worth $16.5 million to Impax. (CCF ¶ 471). Under any reasonable scenario, the value of the combined No-AG and Endo Credit

provisions was large compared to saved litigation costs of approximately $3 million for each company. (CCF ¶ 472).

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).

Response to Proposed Finding No. 644

The Proposed Finding is misleading and incomplete. Although it was theoretically possible that both the Endo Credit and the No-AG provision could have resulted in zero value to Impax, there is no evidence that this outcome was plausible, let alone sufficiently likely to occur such that the expected value of the payment terms was less than saved litigation costs. (*See* Complaint Counsel's Response to Proposed Finding No. 639; CCF ¶ 472). The No-AG provision was worth substantial value to Impax when the SLA was executed because it ensured that Impax would face no generic competition during its exclusivity period. (CCF ¶¶ 410-17). The Endo Credit was designed to insulate Impax against a substantial decrease in sales of Opana ER which would reduce the value of the No-AG provision. The Endo Credit was "super, super important" to Impax's chief negotiator (CCF ¶ 427), as it was intended to make Impax whole for the sales Impax would have otherwise achieved. (CCF ¶¶ 429-30). Together, as Impax's CFO told investors, these terms ensured that Impax would have a "reasonable outcome almost no matter what happens." (CCF ¶ 438). Indeed, at the time it executed the SLA, Impax viewed the chances that the No-AG/Endo Credit payment would result in zero value as "so unlikely it wasn't worth worrying about." (CCF ¶ 480).

The Proposed Finding is misleading and incomplete by suggesting that whether Impax received a payment depended on post-settlement events. As part of the SLA, Impax received the No-AG/Endo Credit payment. (CCF ¶¶ 321-28). Under the No-AG provision, Endo agreed not to sell an authorized generic during Impax's first-filer exclusivity period, allowing Impax to

generate significantly more profits. (CCF ¶¶ 410-14). As insurance for Impax, the Endo Credit was structured to replicate the profitability of the exclusivity period for Impax if the market for Original Opana ER deteriorated. (CCF ¶¶ 325-27, 1061). Whether Impax got value from the No-AG provision or from the Endo Credit would be governed by post-settlement events, but that Impax would get value from the No-AG/Endo Credit payment was all but ensured by the SLA and did not depend on post-settlement events. (CCF ¶¶ 270-75).

b. The No-Authorized Generic Provision

645. Professor Noll similarly did not calculate an expected value to Impax of the No-

The Proposed Finding is misleading and incomplete. It ignores that, at the time of the settlement, Endo did know when or if it would get FDA approval for its reformulated product. (CCF ¶¶ 78, 82-83). Thus, Endo planned to launch an authorized generic in the event that a generic version of Opana ER was launched before Endo could market a reformulated product. (CCF ¶ 85). The Proposed Finding is also misleading and incomplete because substantial evidence proves that Endo planned to launch an authorized generic in the event of a generic launch. (CCF ¶¶ 84-92). Endo had substantial financial incentives to launch an authorized generic of oxymorphone ER, and forecasted that it could recoup as much as $25 million in otherwise lost sales following generic entry. (CCF ¶ 84). And contemporaneous business documents show that Endo intended to launch an authorized generic if Impax entered the market with oxymorphone ER. (CX2576 at 003 ("We will launch on word/action of first generic competitor"); CX3007 at 003 ("If Impax launches, Endo will launch its authorized generic. . . ."); CCF ¶ 85). Endo went so far as to take active steps to manufacture and sell an authorized generic – designing tablets and receiving labels for a generic version of Opana ER. (CCF ¶ 86). In the first half of 2010, Endo informed drug wholesalers that it would launch an authorized generic immediately upon Impax's launch, created new SKUs for its authorized generic oxymorphone ER, manufactured enough generic oxymorphone ER to support a launch in June 2010, and was assessing which customers to target with its launch of an authorized generic. (CCF ¶¶ 87-90). It was only after the settlement with Impax that Endo concluded that it could destroy its oxymorphone ER inventory. (CCF ¶ 92).

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

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 645 and 647.

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.")).

Response to Proposed Finding No. 649

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 639.

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

Response to Proposed Finding No. 650

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 639.

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).

Response to Proposed Finding No. 651

The Proposed Finding is misleading and incomplete because it ignores the fact that Impax negotiated for and received the Endo Credit act that se it ig009No. 650

The Proposed Finding is also misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 646 and 647.

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

Response to Proposed Finding No. 652

The Proposed Finding is misleading and incomplete because, as Professor Noll testified, Impax knew the value of an authorized generic and the effect an authorized generic would have on its sales of oxymorphone ER. (Noll, Tr. 1593-94 ("They knew what the impact on them would have been had an authorized generic been launched.")). Impax executives estimated that if Endo launched an authorized generic when Impax entered, the authorized generic would capture roughly half of sales and cause substantially lower generic prices during Impax's exclusivity period. (CCF ¶ 412). Impax's contemporaneous modeling showed that the presence of an authorized generic would cause a reduction in Impax's revenues of at least $23 million in the four and a half months following entry of the authorized generic. Thus the no-AG provision was worth at least $23 million. (CCF ¶ 413 ("Upside" scenario forecast assuming AG launched about two months after generic entry)). And Impax's more conservative "Base" scenario showed that Endo's authorized generic would launch simultaneously and reduce Impax's revenues by about $33 million during the exclusivity period. (CCF ¶ 414). The value of the No-AG provision would have been even higher had the revenues from Original Opana ER continued to increase. (CCF ¶ 415).

c. The Royalty Provision

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

Response to Proposed Finding No. 653

(Hoxie, Tr. 2711; CCF ¶¶ 1415-18). Even Impax's expert acknowledged that the purportedly "broad" patent license did not ensure that Impax would not be sued on Endo's later obtained patents. (CCF ¶¶ 1388-89). Impax was, in fact, sued on patents that Endo later acquired. (CCF ¶¶ 1419-30). Impax's expert, Mr. Figg, was not even aware of that lawsuit when he submitted his expert report in this case. (CCF ¶ 1391). As a result, his opinions about the value of Impax's patent license are unreliable and unfounded. (CCF ¶ 1391). **{** **}**

(CCF ¶¶ 1426-28 (*in camera*)).

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).

Response to Proposed Finding No. 655

The Proposed Finding is also misleading and incomplete for the reasons set forth in response to Proposed Finding No. 654.

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).

Response to Proposed Finding No. 656

The Proposed Finding is misleading and incomplete to the extent it suggests that it is necessary to examine the effect of each provision of the SLA on consumer welfare. It is not. (Noll, Tr. 1647 ("I did not unpack the effect of each provision on consumer welfare because that's not the appropriate way to do it.")). In this case, the amount of the reverse payment constitutes a lower bound on the loss of consumer welfare arising from the settlement agreement. (Noll, Tr. 1460-61). The Proposed Finding is also misleading and incomplete for the reasons set forth in response to Proposed Finding No. 654.

IX. THERE IS NO DIRECT EVID

Report)). This framework is not appropriate. The fact that brand-name firm makes a large and unjustified payment to guarantee against possible entry by a certain date in and of itself demonstrates that there was a real risk that the generic firm could enter by that date. (CCF ¶ 986).

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).

Response to Proposed Finding No. 658

Complaint Counsel has no specific response, except to note that as Professor Noll explained, the presence of monopoly power can be demonstrated by the fact that the branded firm made a large, unjustified reverse payment to the generic firm. (CCF ¶¶ 389, 970; CX5000 at 104, 139 (¶¶ 239, 318) (Noll Report)). A branded firm would not make a large, unjustified reverse payment to a generic firm unless it was purchasing an extension of its monopoly profits (i.e., extending its monopoly power). (CCF ¶¶ 389, 970; CX5000 at 104, 139 (¶¶ 239, 318) (Noll Report)).

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

Response to Proposed Finding No. 659

Complaint Counsel has no specific response.

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

Response to Proposed Finding No. 660

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. (*See* CCF ¶¶ 853-896). In particular, the evidence demonstrates that despite the presence of other LAOs, both branded and generic, Endo successfully grew sales of Opana ER while

{ }. (CCF ¶ 990; CX5000 at 219 (Exhibit 7A) (Noll Report (*in camera*))). Generic versions of oxymorphone ER entered and **{ }**, thus lowering the average drug price substantially, while simultaneously taking approximately half of Opana ER's share of the oxymorphone ER market. (CCF ¶¶ 499, 881; CX5000 at 082, 219 (¶ 182, Exhibit 7A) (Noll Report) (*in camera*)). The fact that generic oxymorphone took substantial share from Endo, and lowered the average price, indicates that the entry of generics diminished market power Endo held when it did not face generic competition. (CCF ¶¶ 642, 672-73; Noll, Tr. 1374-75, 1380-82; CX5000 at 008, 089, 091 (¶¶ 14, 200, 205) (Noll Report)).

A. There is No Evidence of Reduced Output

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

Response to Proposed Finding No. 661

The Proposed Finding is factually inaccurate. Monopolists do face competitive constraints. The very testimony cited for Proposed Finding No. 661 says as much: "[Monopolists] monopolize a market, which means that there's not *enough* competition constraining them." (Addanki, Tr. 2349 (emphasis added)). A profit-seeking monopolist will raise its price to the point where further price increases are unprofitable because enough customers abandon the monopolized product in favor of some other product. (CX5004 at 034 (¶

the branded firm had market power prior to generic entry. (CX5004 at 040 (¶ 84) (Noll Rebuttal Report)).

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).

Response to Proposed Finding No. 664

The Proposed Finding is misleading and inaccurate to the extent it implies an output reduction is the only method of determining market power or inflicting consumer harm. Market power can be observed, and consumer harm inflicted, by supracompetitive prices, irrespective of whether output is reduced or increased. (CX6054 at 005 (§ 1) (*Horizontal Merger Guidelines*); *see also* Complaint Counsel's Response to Proposed Finding Nos. 662 and 663).

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).

Response to Proposed Finding No. 665

The Proposed Finding is misleading because a dissipation of monopoly power does not necessarily result in an expansion of output. In a situation in which the overall demand for a product is declining prior to the dissipation of monopoly power, as was the case with Opana ER, a dissipation of market power would not necessarily result in an expansion of output, but rather an arrestment of that decline. (CX5004 at 010, 042 (¶ 18, 87) (Noll Rebuttal Report)). If output remained constant, and the entry of generics lowered the average price of a drug, then that would be evidence that prior to the entry the branded firm was charging a supracompetitive price for the drug and it therefore enjoyed monopoly power that the entry dissipated. (CX5004 at 040-43 (¶¶ 84-87) (Noll Rebuttal Report)). Moreover, the Proposed Finding is misleading to the extent it implies prices are not "real." Data on net average price exists, was produced by Endo and Impax,

and was analyzed by both economic experts. (CX5004 at 012, 014, 048-49 (¶¶ 22, 25, 103) (Noll Rebuttal Report)).

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).

Response to Proposed Finding No. 666

The Proposed Finding is inaccurate and contrary to well-established economic principles. (*See* Complaint Counsel's Response to Proposed Finding Nos. 662-65). Demand for Opana ER was declining prior to generics' entry—therefore the entry of generics would not necessarily result in an output expansion. (CX5004 at 010, 042 (¶ 18, 87) (Noll Rebuttal Report)). Moreover, the Proposed Finding ignores that monopoly power and consumer harm can be evidenced by elevated pricing, not simply reduced demand. (CX6054 at 005 (§ 1) (*Horizontal Merger Guidelines)*; (CX5004 at 040-41 (¶¶ 84-85) (Noll Rebuttal Report)).

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

Response to Proposed Finding No. 667

The Proposed Finding is factually inaccurate. The entry of Impax's generic product, as measured by sales, did expand output in absolute terms. (CCF ¶ 964; (CX5004 at 042, 091 (¶ 87, Exhibit 3) (Noll Rebuttal Report)). The data show that **{** [redacted] **}** (CCF ¶ 964; (CX5004 at 042, 091 (¶ 87, Exhibit 3) (Noll Rebuttal Report) (*in camera*)). Moreover, this increase in output occurred when sales of Opana ER overall were declining. (CCF ¶ 965; CX5004 at 042 (¶ 87) (Noll Rebuttal Report); CX4039 (Noll, Dep. at 206-08)). The fact that generic entry arrested the decline that was occurring prior to its entry means Impax's entry did

effectively increase output (compared to what would be observed if it did not enter). (CCF ¶ 965; CX4039 (Noll, Dep. at 206-08)).

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).

Response to Proposed Finding No. 668

The Proposed Finding is factually inaccurate for the reasons set forth in Response to Proposed Finding No. 667. The Proposed Finding is also misleading, inaccurate and contrary to well-established economic principles to the extent it implies that evidence of an expansion in output after generic entry is necessary to demonstrate that the brand manufacturer possessed market power prior to generic entry. (*See* Complaint Counsel's Response to Proposed Finding Nos. 662-66).

entry is necessary to demonstrate that the brand manufacturer possessed market power prior to generic entry. (*See* Complaint Counsel's Response to Proposed Finding Nos. 662-66).

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

Response to Proposed Finding No. 670

The Proposed Finding is misleading, inaccurate and contrary to well-established economic principles to the extent it implies that evidence of an expansion in output after generic entry is necessary to demonstrate that the brand manufacturer possessed market power prior to generic entry. (*See* Complaint Counsel's Response to Proposed Finding Nos. 662-66). The Proposed Finding is also factually inaccurate to the extent it implies that generic oxymorphone ER entry did not result in an increase in output of oxymorphone ER. For the reasons set forth in response to Proposed Finding No. 667, the entry of generic oxymorphone ER did result in an increase in output.

{ } (RX-085 at slides 57 and 59 (*in camera*)). { } (RX-085 at slides 57 and 59 (*in camera*)). { } (RX-085 at slides 57 and 59 (*in camera*)).

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

Response to Proposed Finding No. 671

The Proposed Finding is misleading, inaccurate, and contrary to well-established economic principles for the reasons stated in response to Proposed Finding 670.

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).

Response to Proposed Finding No. 672

The Proposed Finding is inaccurate **{**

}. (*See* CCF ¶¶ 859-96, 961-62 (*in camera*)).

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).

Response to Proposed Finding No. 673

The Proposed Finding is inaccurate. First, the Lerner Index is not a means to track gross margins. Rather, the Lerner Index is the ratio of the mark-up of price over marginal cost to price. (CCF ¶ 882; CX5000 at 095-96 (¶ 215) (Noll Report)). The "Lerner Index is a standard measure in economics of a firm'[s] market power in selling a particular product." (CX5004 at 050 (¶ 106) (Noll Rebuttal Report)).

674. Professor Noll used the Lerner Index to estimate that Endo's gross profit margins were

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)).

Response to Proposed Finding No. 675

The Proposed Finding mischaracterizes Professor Noll's testimony. Professor Noll testified he used the Lerner Index as one tool to determine whether Endo set prices above the competitive level. (Noll, Tr. 1412-13). Professor Noll went on to testify that he saw other evidence indicating Endo enjoyed market power, namely its ability to exclude competition. (Noll, Tr. 1417-18).

The Proposed Finding also mischaracterizes Professor Noll's testimony to the extent it suggests Endo was allowed to profitably set prices above a competitive level because of its high profit margins. Professor Noll testified he observed a high Lerner Index which is consistent with

from marginal cost associated with monopoly.'") (citing W. Kip Viscusi, Joseph E. Harrington, Jr., and John M. Vernon, *Economics of Regulation and Antitrust* (4th Edition), MIT Press, 2005, pp. 294-95 and Frederic M. Scherer and David Ross, *Industrial Market Structure and Economic Performance* (3rd Edition), Houghton Mifflin, 1990, p. 70, respectively)). The use of the Lerner Index as a measure of market power is widely accepted among economists. (CX5004 at 053 (¶ 113) (Noll Rebuttal Report)). Dismissing all high values of the Lerner Index as "tell[ing] you nothing at all about market power" is not consistent with accepted economic practice. (CX5004 at 054 (¶ 114) (Noll Rebuttal Report)).

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")).

to do research and development and to get an NDA unless you expected that you would have several years of essentially monopoly, of a circumstance where you could exercise substantial market power."); CX5004 at 051-52 (¶ 110) (Noll Re

producing one more unit of output (CX5000 at 089

highly competitive prior to generic entry, then entry by generics will not have a significant effect); CX5000 at 072-73 (¶ 158) (Noll Report) (there was little price competition between Opana ER and other LAOs, but the introduction of generic oxymorphone resulted in a high diversion of sales from Opana ER to generic oxymorphone ER)).

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).

Response to Proposed Finding No. 683

The Proposed Finding is misleading and contrary to well-established economic principles to the extent it implies that a branded firm's higher long-run costs allow it to charge a higher price. While a branded firm may need to charge higher prices in order to be profitable so that it can recoup higher fixed costs and address higher long-run costs, it cannot do so unless it enjoys substantial market power. (CX5004 at 051-52 (¶ 110) (Noll Rebuttal Report)). So if the entry of generic versions of a drug pulls down that drug's average price, that is evidence the branded firm was charging a supracompetitive price and, thus, exercising monopoly power. (CX5000 at 100 (¶ 227) (Noll Report); CX5004 at 040 (¶ 84) (Noll Rebuttal Report)).

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).

Response to Proposed Finding No. 684

The Proposed Finding is inaccurate and contrary to well-established economic principles for the reasons set forth in response to Proposed Finding No. 683. The Proposed Finding is also misleading to the extent it suggests that the mere presence of market power is anticompetitive. A firm may also achieve monopoly power through superior efficiency, such as strong patent rights or strong economies of scale. As Professor Noll explained: "That's monopoly power, but it's not anticompetitive, because it wasn't achieved by anticompetitive means." (Noll, Tr. 1419).

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).

Response to Proposed Finding No. 685

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 686

The Proposed Finding is inaccurate. Although patents do not always confer monopoly power, they can depending on the circumstances. Indeed, the 2017 *IP Guidelines* contain an entire section titled "Intellectual Property and Market Power." (CX5004 at 043 (¶ 89) (Noll Rebuttal Report) (citing the 2017 *IP Guidelines* at 4-5)). In this section, the *IP Guidelines* state: "Although 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." (CX5004 at 043 (¶ 89) (Noll Rebuttal Report) (quoting the 2017 *IP Guidelines* at 4)). Thus, the *IP Guidelines* clearly state that IP such as patents can confer market power, so long as there are not close substitutes for the product.

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).

Response to Proposed Finding No. 687

The Proposed Finding is misleading to the extent it suggests that Endo's patents could not have conferred monopoly power regarding Opana ER. (*See* Complaint Counsel's Response to Proposed Finding No. 686).

(¶ 227) (Noll Report); *see also* CCF ¶ 642; Noll Tr. 1380-81 (noting that the fall in price following the entry of generics tells us the market was not competitive before generics entered)). Generics enter at a lower price because that is how they compete and take share away from the branded product. That is the essence of the why consumers benefit from generic entry.

The Proposed Finding is also misleading to the extent it implies generics will necessarily be sold at a lower price than the branded drug. It is true that the entry of generics generally result in a lower average price of the drug. (*See* Complaint Counsel's Response to Proposed Finding No. 682; CCF ¶ 24; CX5000 at 048 (¶ 104) (Noll Report); CX6055 at 010). But Dr. Addanki has produced no evidence or analysis that it is universally the case that generics are offered at a lower price than branded drugs.

Finally, the Proposed Finding is misleading because it is untrue that a drug has to be

one product would cause buyers to switch their purchases to the other"); *see also* CCF ¶¶ 511-39; Noll, Tr. 1373-74 ("either product differentiation or switching costs can take a market that contains products that are used for the same function but that are not close economic substitutes because of consumer preferences, because of brand reputations, brand loyalties, behavior, sort of being stuck in the mud and, you know, inflexible in behavior, or simply switching costs, for all those reasons, functional substitutes are not necessarily close economic substitutes")). Regardless of whether there are a large number of good therapeutic substitutes available, the market definition hinges on which ones are close economic substitutes. (CCF ¶ 918).

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).

Response to Proposed Finding No. 692

The Proposed Finding is misleading and inaccurate for the reasons set forth in response to Proposed Finding Nos. 683, 690, and 691. A branded firm can charge a supracompetitive price for a drug only if it faces weak competition and thus exercises market power. If generic versions of a drug enter, and result in a decrease in the average price of the drug, that is evidence that generic entry constrained the branded firm's ability to charge a supracompetitive price. (CCF ¶ 642; Noll, Tr. 1380-81). If a market is highly competitive prior to generic entry, then entry by generics will not have a significant effect on average price or sales of the branded product. (Noll, Tr. 1380-81). Thus, the fact that generics lowered the price of a drug is evidence that the branded firm has monopoly power. (CX5000 at 100 (¶ 227) (Noll Report); CX5004 at 040 (¶ 84) (Noll Rebuttal Report)).

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)).

Response to Proposed Finding No. 693

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 694

The Proposed Finding is inaccurate. As described in the *Horizontal Merger Guidelines*, the foundational consideration when determining the relevant product market is whether a single firm in the market (a "hypothetical monopolist") could profitably impose a small but significant increase in price ("SSNIP") on the products in the hypothesized market. (CX6054 at 012 (§ 4.1.1) (*Horizontal Merger Guidelines*)). But even if a hypothetical monopolist's SSNIP is profitable, the test explicitly assumes there will be some loss of sales to other products which are nonetheless outside the product market. (CX6054 at 012 (§ 4.1.1) (*Horizontal Merger Guidelines*) ("Therefore, Products A and B satisfy the hypothetical monopolist test using a five percent SSNIP, and indeed for any SSNIP size up to ten percent. *This is true even though two-thirds of the sales lost by one product when it raises its prices are diverted to products outside the relevant market*.") (emphasis added)). So the fact that customers do switch to alternative products in the event of a price increase does not, in and of itself, identify whether the products they switch to are in fact close economic substitutes and in the same market. Thus, the Proposed Finding offers an improper framework for assessing the product market, and applying it would lead to overly broad definitions of the market.

Moreover, where products already are priced at supracompetitive levels, simply looking at what other products customers switch to can lead to overly broad definitions of the market. This analytical mistake occurs when one falsely concludes products outside the relevant market are substitutes by examining competitive interactions that occur when the reference product is already priced supracompetitively. (CCF ¶ 931; CX5004 at 034 (¶ 68) (Noll Rebuttal Report)).

Even monopolists face constraints from competing products when selling their product at supracompetitive prices—but the fact that customers would turn to these other products in the event that the monopolist raised its price is not evidence that those competing products are in the same relevant product market. (CCF ¶¶ 931-32; CX5004 at 034-35 (¶¶ 68-71) (Noll Rebuttal Report)).

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).

Response to Proposed Finding No. 695

The Proposed Finding is inaccurate and contrary to the weight of the evidence. *See generally* CCF ¶¶ 579-792 for a lengthy and detailed discussion of the evidence that demonstrates that the relevant market for assessing the conduct at issue in this case is oxymorphone ER. In particular, the evidence shows:

Impax and Endo both forecasted that generic versions of oxymorphone ER (whether AB-rated or not) would significantly erode Opana ER's market share and degrade its price. (CCF ¶¶ 583-607, 611-13, 618-21). Endo submitted sworn testimony in various legal actions that Impax was likely to significantly erode Opana ER's market share and degrade its price, and that other LAOs would not and did not have a comparable effect. (CCF ¶¶ 608-10, 614-17, 622-27).

Actual data from Impax's generic entry shows that generic oxymorphone ER did indeed substantially erode Endo's market share and degrade the average price of oxymorphone ER. (CCF ¶¶ 628-44).

When pricing generic oxymorphone ER, Impax looked exclusively at the price of Opana ER and other generic oxymorphone ER, and did not look at the price of other

the presence of both branded and generic versions of other LAOs did nothing to hinder Opana ER's rapid growth from 2008 to 2011. (CX5004 at 048-49 (¶ 103) (Noll Rebuttal Report)). Opana ER's **{** **}**. (CX5004 at 047-48 (¶ 101-02) (Noll Rebuttal Report) (*in camera*)). During the 2009 to 2011 period in which Opana ER was growing share while maintaining price: (1) generic morphine was available; (2) branded hydromorphone, Exalgo, was launched; (3) generic fentanyl was available; and (4) branded tapentadol, Nucynta ER, was launched. (CCF ¶¶ 687-88 (morphine), ¶¶ 692-94 (hydromorphone), ¶¶ 703-04 (fentanyl), ¶¶ 712-13 (tapentadol)). If these other drugs were close substitutes for oxymorphone ER and in the same market, then the availability of generic versions of these drug and the launch of branded versions of these drugs should have resulted in a diversion of sales from Opana ER to these drugs and a decrease in Opana ER's price. (CCF ¶¶ 670-73). Yet this did not occur. In fact, in a declaration submitted to a federal court, Endo's Senior Marketing Director for the Opana brand of products stated: "despite the presence of new entrants in the market who are actively promoting their new products (EMBEDA and EXALGO), and despite the fact that Endo's promotional spend has declined, Endo's share of the market with OPANA ER continues to grow at a steady rate." (CX3273 at 004 (¶ 8) (Bingol Decl.)). If these other, more heavily-promoted, LAOs were close substitutes and in the same market as Opana ER, it would not have been possible for Opana ER to grow at a steady rate.

In fact, the data show that once generic versions of oxymorphone ER launched, **{** **}**. (CCF ¶¶ 583-85; 609-10; 628-42; CX5000 at 219 (Exhibit 7A) (Noll Report) (*in camera*)). This demonstrates that the market was

not competitive prior to the launch of generic oxymorphone ER and other LAOs did not compete vigorously with Opana ER. (CCF ¶ 642; Noll Tr. 1380-82). Thus, generic oxymorphone is a close economic substitute to Opana ER, while other LAOs are not. So the product market includes Opana ER and generic oxymorphone ER, but not other LAOs.

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).

Response to Proposed Finding No. 697

The Proposed Finding is misleading and inaccurate to the extent it suggests that the determination of relevant market turns on whether extended-release opioids are "interchangeable" rather than economic substitutes. (CCF ¶ 525 ("In the end, whether products are in the same market is not simply a matter of functional definition and technical description, but whether customers regard the products as suffi

approximately *half* of all patients do not tolerate the first opioid they try. (Michna, Tr. 2169; *see also* CCF ¶¶ 746-61).

The Proposed Finding is also inaccurate in characterizing different LAOs as competing vigorously on price. Generic oxymorphone ER entry substantially lowered the average price of oxymorphone ER. (CCF ¶¶ 636-37). From 2009 to 2011, Endo was actually able to maintain the net realized price of Opana ER despite the launch of other LAOs and the presence of generic versions of other LAOs. (*See* Complaint Counsel's Response to Proposed Finding No. 696). We would not observe this pattern if different LAOs competed vigorously on price. (Noll, Tr. 1380-82 ("if the market already is highly competitive before the generics enter, then you wouldn't expect that there would be any significant effect of

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).

Response to Proposed Finding No. 698

The Proposed Finding is misleading to the extent it suggests that all extended-release opioids are substitutable for one another. Both Complaint Counsel's and Respondent's medical experts agree that there are significant differences in opioids and in individual responses to different medications, and that these differences

The Proposed Finding is misleading to the extent it suggests that all extended-release opioids are substitutable for one another. Both Complaint Counsel's and Respondent's medical experts agree that there are significant differences in opioids and in individual responses to different medications, and that these differences can be very important to the treatment of individual patients. (CCF ¶¶ 658, 746-49). Indeed, Dr. Michna testified that approximately half of all patients do not tolerate the first opioid they try. (Michna, Tr. 2169; *see also* Complaint Counsel's Response to Proposed Finding Nos. 697 and 698).

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).

Response to Proposed Finding No. 701

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 700.

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")).

Response to Proposed Finding No. 702

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 700.

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).

Response to Proposed Finding No. 703

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 700. In addition, the Proposed Finding is inaccurate to the extent it implies that particular comorbid conditions cannot in fact limit the opioids options available. For instance,

Report)). Products can also be horizontally differentiated, in which case none are necessarily objectively superior to the other, but each has different qualitative attributes that cause individuals to prefer some over the other. (CX5000 at 020-21 (¶ 47) (Noll Report)). Regardless of whether products are differentiated horizontally or vertically, whether they are in the same market is defined by whether enough buyers switch products in response to small changes in price. (CX5000 at 020-21 (¶ 47) (Noll Report)). So to the extent no LAO is "superior" to another, that has no bearing on whether they are in the same market as each other.

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).

Response to Proposed Finding No. 705

The Proposed Finding is inaccurate and mischaracterizes Professor Noll's testimony. Professor Noll testified that"*[i]n the abstract, without more information*, I don't think even a doctor knows what the superior prescription is." (Noll, Tr. 1504-05 (emphasis added)). But Professor Noll then went on to testify: "My understanding of how doctors behave is they try to match the drug to the conditions of the patient, but again, I'm not a doctor and I'm not going to perform that match." (Noll, Tr. 1505). Professor Noll's testimony is consistent with the testimony by Dr. Savage. She explained that in deciding which opioid to prescribe, she takes a patient's history, and inquires into the patient's experience with other medications and side effects. (Savage, Tr. 710-11).

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).

Response to Proposed Finding No. 706

different medications, and that these differences can be very important to the treatment of individual patients. (CCF ¶¶ 658, 746-49).

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).

Response to Proposed Finding No. 708

The Proposed Finding is not supported by the evidence cited. Dr. Michna testified that he had never seen a patient for whom multiple LAO options were not available. (Michna, Tr. 2148). However, Dr. Michna did not testify that the remaining options would be "equally safe and effective." Indeed, Dr. Michna agrees that there are significant differences in opioids and in individual responses to different medications, and that these differences can be very important to the treatment of individual patients. (CCF ¶¶ 658, 746-49). Professor Noll testified that a doctor can prescribe a new patient any opioid, subject to professional ethics and the rules of the insurer. (Noll, Tr. 1548). Professor Noll did not testify that there are multiple opioid options available that would be equally safe and effective for patients with unique medical conditions. Respondent has presented no evidence that in every situation in which a patient has a medical condition that prevents the use of some LAOs, "there are always" "equally safe and effective" multiple options available.

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).

Response to Proposed Finding No. 709

Complaint Counsel has no specific response.

710. This means that there is no identifiable group of patients for which oxymorphone ER or

The Proposed Finding mischaracterizes the record to the extent it suggests that prescribers freely and routinely switch between different LAOs once an adequate treatment is found. Dr. Savage explained that "[i]f they're tolerating [Opana ER] well and it's meeting their needs, I'd prefer to keep them on the drug that they're using." (Savage, Tr. 770). Respondent's expert Dr. Michna agreed: "[A]s humans we're afraid of the unknown, so you could understand, if a patient has been on a medication for months or years and getting good pain relief, that there

The Proposed Finding is inaccurate because the labels for LAOs do not contain identical language. For example:

> The label for OxyContin (oxycodone) includes a black box warning that the concomitant use of OxyContin with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal oxycodone overdose. (CX3268 at 001 (OxyContin Label)). This reflects the fact that OxyContin engages the CYP 450 system, and that creates the risk for drug-drug interactions that is not present with Opana ER. (CX5002 at 026, 106 (¶ 72, Appendix C) (Savage Report)). Opana ER's

The label for MS Contin (morphine sulfate ER) contains a contraindication for hypersensitivity to morphine. (CX3264 at 001 (MS Contin Label)). Opana ER's label contains no such contraindication. (CX3266 at 001 (Opana ER Label)).

Contrary to the Proposed Finding, the labels of different LAOs actually reflect some of the differentiating characteristics between them. (CX5002 at 106 (Appendix C) (Savage Report) (summary the distinctions between different LAOs)).

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

Response to Proposed Finding No. 713

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 712.

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).

Response to Proposed Finding No. 714

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 716.

715. REMS programs are required by the FDA to ensure that the benefits of a particular medication outweigh the medication's risks. (Michna, for Tr. 2110). Such programs allow the FDA to identify potential problems with prescription drugs and institute actions to address those problems. (Michna, Tr. 2110).

Response to Proposed Finding No. 715

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 716

Complaint Counsel has no specific response to the first sentence in the Proposed Finding. The second sentence of Proposed Finding, however, is inaccurate for the reasons set forth in response to Proposed Finding No. 716.

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).

Response to Proposed Finding No. 718

The Proposed Finding is inaccurate because the FDA does not treat all LAOs identically. (*See* Complaint Counsel's Response to Proposed Finding Nos. 712 and 716). The Proposed Finding is also misleading to the extent it suggests that the DEA "treats all extended-release opioids identically." The DEA's regulations only relate to the potential abuse of extended-release opioids. (RX-547 at 0033-34 (¶ 65) (Addanki Report) ("Schedule II controlled substances are those that have the highest potential for abuse among all controlled substances with accepted medical uses.")). Thus, like REMS, the DEA schedule does not relate to or reflect the product-specific risks of LAOs, such as the different side effects and different drug-drug interactions posed by different LAOs.

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).

Response to Proposed Finding No. 719

The Proposed Finding is inaccurate, misstates Dr. Addanki's testimony, and is contrary to the weight of the evidence. Dr. Addanki did not testify that the fact that the WHO groups LAOs together for a particular purpose means they are "undifferentiated." (Addanki, Tr. 2243-44). Indeed, the same document that Dr. Addanki cites for WHO's analgesic ladder identifies the significant and meaningful differences between LAOs. (*See* RX-547 at 0032 (¶ 62 n.74)

(Addanki Report) (citing RX-122)). For example, the document notes that there is "[w]ide patient variability in response to opioids," and that opioid rotation can be necessary due to both "[l]ack of efficacy" and "[d]evelopment of intolerable side effects." (RX-122 at 0018, 0020). The fact that patients must be rotated through LAOs because some of them are ineffective or result in intolerable side effects demonstrates that LAOs are in fact differentiated in their effectiveness and tolerability profile. If LAOs were not differentiated and were equally effective, opioid rotation would not be necessary.

Moreover, there is no evidence that the criteria WHO employs to determine where it

from rotator cuff problems. Therefore it is unlikely they are close substitutes for patients with rotator cuff problems. Thus, Exhibit 4 *undercuts* Dr. Addanki's analysis. (CX5004 at 021-22 (¶ 41) (Noll Rebuttal Report).

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).

Response to Proposed Finding No. 721

The Proposed Finding is inaccurate. There are many indications for which a particular LAO is not used. (*See* Complaint Counsel's Response to Proposed Finding No. 720). Indeed, for 81 of the 100 indications at least one particular LAO is not used. (CX5004 at 021-22 (¶ 41) (Noll Rebuttal Report)).

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).

Response to Proposed Finding No. 722

The Proposed Finding is misleading to the extent it implies that LAOs are reliably interchangeable. As Dr. Savage testified, because of the significant differences in opioids and individual responses to them, Opana ER is not reliably interchangeable with other opioids. (CCF ¶¶ 745-49; Savage, Tr. 697-98 ("Opana ER as a specific opioid is not reliably interchangeable with other long-acting opioids.")). An individual may experience different levels of pain relief and different side effects from different long-acting opioids. (Savage, Tr. 697-98). Therefore one LAO may be effective for treating a patient's medical condition while another LAO is not, so simply because two different LAOs have been used to treat the same condition does not mean they are close substitutes for each other.

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

Response to Proposed Finding No. 723

The Proposed Finding is inaccurate and misstates Dr. Savage's testimony. Dr. Savage testified that there are many reasons why a doctor should prescribe one particular LAO over another. For example, Dr. Savage testified that the black box warning relating to CYP 450 on OxyContin steers her towards prescribing a different drug without such a warning, such as oxymorphone ER. (Savage, Tr. 734-35). She testified that some patients who have musculoskeletal pain need to take hot baths as part of their treatment, and for such patients fentanyl patches would not be an appropriate LAO. (Savage, Tr. 741-42). In sum, Dr. Savage testified that "in the clinical setting, for individual patients with specific types of pain in specific contexts, almost always there is a medication or medications that are better than other medications." (Savage, Tr. 743-44).

Moreover, Dr. Addanki's Exhibit 4 shows that many LAOs are not used to treat certain conditions. (CX5004 at 021-22 (¶ 41) (Noll Rebuttal Report); *see* Complaint Counsel's Response

medications, and antibiotics) may be appropriately treated with oxymorphone ER than other LAOs. (CCF ¶¶ 765-68).

Evidence shows that Opana ER has a longer half-life than some other LAOs, including OxyContin. (CCF ¶¶ 778-80). Thus, for doctors who want to ensure more reliable dosing and pain relief, Opana ER can be a better option. (CCF ¶ 783).

Unlike some other LAOs, oxymorphone is available in both a tablet and injectable form. (CCF ¶ 784). This dosing flexibility allows patients using Opana ER to use oxymorphone delivered through an IV without going through the process required to switch between opioids (and vice versa). (CCF ¶¶ 784-85).

Oxymorphone can create less euphoria than other LAOs, including OxyContin. (CCF ¶¶ 787-88). Therefore Opana ER can be a better option for patients for whom euphoria is a concern.

Opana ER is not known to cause particular side effects caused by other LAOs (such as irritability and hyperflexia). (CCF ¶¶ 789-92). Opana ER may be a better option for patients for whom such side effects could be an issue.

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).

Response to Proposed Finding No. 725

The Proposed Finding is misleading to the extent it selectively refers to Dr. Michna's testimony. When asked what factors he considers in deciding which LAO to prescribe first, Dr. Michna testified: "So we look at the patient's prior experience, what opioids they've tolerated in the past, what opioids they haven't. There's personal preference. Most physicians are comfortable prescribing a certain opioid as their choice and they tend to prescribe that." (Michna,

Tr. 2119). Thus, Dr. Michna testified that physicians must consider a number of clinical factors, including the tolerance and effectiveness of particular LAOs, which underscores the fact that LAOs are not reliably interchangeable.

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).

Response to Proposed Finding No. 726

The Proposed Finding is misleading and misstates Professor Noll's testimony. Professor Noll testified that "physicians' habits and experiences influence their choice." (Noll, Tr. 1529). He did not testify that the LAO prescribed in the first instance "is a matter of physician preference." There are a number of clinical factors which determine which LAOs are suitable as treatment. (*See* Complaint Counsel's Response to Proposed Finding No. 724).

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).

Response to Proposed Finding No. 727

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 728

The Proposed Finding is inaccurate. The record shows there are many reasons that particular LAOs are not interchangeable with one another. (*See* CCF ¶¶ 745-49; Savage, Tr. 697-98 ("Opana ER as a specific opioid is not reliably interchangeable with other long-acting opioids.")). Respondent's medical expert Dr. Michna testified th

to different LAOs and that approximately *half* of all patients do not tolerate the first opioid they try. (Michna, Tr. 2169, 2191-93).

Dr. Addanki's conclusion that LAOs are interchangeable is contrary to the opinion of the medical experts. Dr. Addanki is not himself a medical doctor, and indeed he did not even consider Dr. Savage's report in forming his opinions. (CX4044 (Addanki, Dep. at 153-54) (Dr. Addanki "maybe" read "parts" of Dr. Savage's report, but didn't consider the report enough to list it in his materials considered)).

Finally, the Proposed Finding is misleading insofar as it implies that determination of a relevant market turns on whether particular products are clinical substitutes, rather than economic substitutes. It does not. (CCF ¶ 525 ("In the end, whether products are in the same market is not simply a matter of functional definition and technical description, but whether customers regard the products as sufficiently close substitutes that a small change in the price of one product would cause buyers to switch their purchases to the other"); *see also* CCF ¶¶ 511-39).

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")).

Response to Proposed Finding No. 729

The Proposed Finding is inaccurate. Opioid rotation is not "routine." Nor does switching between different LAOs occur for economic reasons. Dr. Savage testified that opioid rotation (i.e., switching different opioids) is warranted when a patient develops a tolerance for a particular opioid or experiences side effects from use of a particular opioid. (CCF ¶ 752). However, she also explained that opioid rotation is not advised unless ther

supervision that rotation requires.

that "[t]here are times" when he has switched medications in response to insurance changes. (Michna, Tr. 2125).

The Proposed Finding also is misleading to the extent it disregards the medical reasons that require switching between LAOs. The first reason offered by Dr. Michna on why patients switch LAOs is that patients can develop a tolerance for a particular LAO and therefore not experience pain relief. (Michna, Tr. 2124-25). As Dr. Savage explained, patients may also need to start opioid rotation because they find an LAO creates side effects. (CX5002 at 060-61 (¶ 170) (Savage Report); *see also* RX-122 at 0020 (opioid rotation can be necessary due to "[l]ack of efficacy" and "[d]evelopment of intolerable side effects")). The fact that a given opioid may not provide effective pain relief for a patient or can create side effects demonstrates that LAOs are not reliably interchangeable. Regardless of the reason for switching, the evidence shows that the overall rate of switching is very low, approximately 3%. (*See* Complaint Counsel's Response to Proposed Finding No. 747; (citing RX-060.0002 at slide 26)). So, within the already-low universe of switches that occur, the frequency of switching for wholly non-medical reasons must be even lower than that.

The Proposed Finding is also misleading and incomplete because switching patterns between opioids are only informative about the relevant market if the switching is in response to a small but significant increase in price. (CCF ¶¶ 533, 544, 659). Moreover, the question is not whether any consumers switch in response to a [illegible] Tw 21.305 0 Td [(ide 2.6(nstra)6ep)75 0 Td (reover, t4, 6 rc

Merger Guidelines) (*see* Example 10 cautioning against using too large a price increase as a SSNIP)).

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).

Response to Proposed Finding No. 732

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 733

Complaint Counsel has no specific response.

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")).

Response to Proposed Finding No. 734

The Proposed Finding is misleading to the extent it implies switching is done readily by doctors and switching costs are insignificant. Dr. Savage testified: "If they're tolerating [Opana ER] well and it's meeting their needs, I'd prefer to keep them on the drug that they're using." (Savage, Tr. 770). Dr. Savage also noted with respect to opioid rotation (i.e., switching opioids):

> Because of individual variability in pharmacodynamics (receptor and other physiologic activation) and pharmacokinetic (drug uptake, distribution, and metabolic processing) responses to opioids, it is impossible to predict reliably what an individual patient's response will be to a new opioid. Therefore, patients going through opioid rotation must be closely monitored because the transition period is fraught with potential risks: too much opioid can lead to sedation or overdose; too little can lead to unrelieved pain. . . . [B]ecause of the complexity and inherent risks in the process of rotation, it is not advised unless there is a clear indication for a change in opioid and the clinician is prepared to provide adequate supervision as the rotation is undertaken.

(CX5002 at 061-62, 63 (¶¶ 172, 176) (Savage Report)).

The Proposed Finding is also misleading to the extent it implies that switching does not incur substantial costs (both financial and to the patient's time). (CCF ¶¶ 734-35; *see also* CX1101 at 005 (Medical Assessment of a Recall) ("[T]he process of switching from one opioid to another is difficult, fraught with dangers, and requires careful follow-up with the medical

The Proposed Finding is misleading and incomplete, as it incorrectly suggests that a patient could freely switch from one opioid to any another opioid. In fact, Dr. Savage's testimony was much more limited; she testified that, given a broad array of opioids, she would expect that "most patients" could find another opioid. (CX4041 (Savage, Dep. at 64) ("I did not intend to imply, just in case you're perceiving it that way, that all patients can be switched from one opioid to any other opioid.")). Dr. Savage never testified that a patient could easily switch to any other opioid. Moreover, Dr. Savage has encountered patients that attempted to switch off oxymorphone ER and ended up switching back because the new opioid did not work as well. (CCF ¶ 756).

The Proposed Finding is also misleading and incomplete to the extent that it suggests therapeutic equivalence is determinative in finding the relevant antitrust market. It is not. Rather the relevant question is whether drugs are close economic substitutes. (CCF ¶ 915; Noll, Tr. 1373-74).

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).

Response to Proposed Finding No. 740

The Proposed Finding is misleading and incomplete, as it incorrectly suggests that a patient could freely switch from one opioid to any another opioid. (*See* Complaint Counsel's Response to Proposed Finding Nos. 734 and 739).

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).

Response to Proposed Finding No. 741

The Proposed Finding is misleading because it implies that switching between LAOs is common or significant. The real-world data shows that regardless of how many people switch on

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).

Response to Proposed Finding No. 744

The Proposed Finding is misleading to the extent it implies that such switching of molecules is medically ideal. Dr. Savage testified that it is preferable not to switch discharged patients to a different opioid because "you reduce one more uncertainty when you have somebody on the same molecule in the hospital that you discharge them on." (Savage, Tr. 801).

The Proposed Finding is also misleading because it implies that the overall rate of switching between opioids is significant. The real-world data show that regardless of how many people switch when discharged from the hospital, the overall rate of switching is very low, approximately 3%. (RX-060.0002 at slide 26; *see* Complaint Counsel's Response to Proposed Finding No. 747).

Similarly, patients who take both extended-re

we add a new medication in, we have risks of add

therapy. (RX-060.0002 at slide 26 (Opana ER Business Plan)). Thus, 97% of any given LAO's business comes from existing patients and patients just starting opioid therapy. Accordingly, in the overall LAO sector, only 3% of new prescriptions come from patients who are switching from a different LAO. (*See also* RX-083.0003 at slide 36 ("New to Brand Business & Share," "Switch To" only approximately 2%) and 37 (the vast majority of Opana ER's "Source of Business" are either "Restarts" and "Continuations;" a small fraction are "Switch Tos")).This real-world data demonstrates that once patients are on a particular opioid, they are unlikely to switch, which is consistent with Dr. Savage's testimony that she will only switch LAOs if there is a clinical need, and will not do so in response to minor changes in price. (Savage, Tr. 773; *see also* Complaint Counsel's Response to Proposed Finding No. 816). Since physicians generally only switch LAOs in response to

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence insofar as it is inconsistent with the real world data that shows there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45). The document cited, RX-073.0002, actually demonstrates that as of early 2013 the actual level of switching is small overall, and that generic oxymorphone ER was a far more significant competitor to Opana ER than other LAOs. According to RX-073.0002, there were 65,333 prescriptions for Opana ER in February 2013. (RX-073.0002 at

(*See* CX5000 at 177-83 (Exhibits 2A1-2A7) (Noll Report) (as of February 2013, Impax's prescription volume was relatively small) (*in camera*)). As time went on, Impax's market share gradually grew, eventually approaching nearly **{ }**. (*See* CX5000 at 177-83 (Exhibits 2A1-2A7) (Noll Report) (Impax's market share steadily grew from February 2013 onwards) (*in camera*)). So, the phenomenon evidenced in RX-073, that generics were already a more significant competitive constraint on Opana ER than other LAOs, only grew over time.

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).

Response to Proposed Finding No. 750

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence insofar as it is inconsistent with the real world data that shows there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45).

The Proposed Finding also is misleading in that it misunderstands the relevant product market analysis. What matters in determining whether products are close economic substitutes is cross-elasticity of demand, or whether a "small but significant non-transitory increase in price" (SSNIP) of one product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899; CX6054 at 013-14 (§ 4.1.2) (*Horizontal Merger Guidelines*) (*see* Example 10 cautioning against using too large of a price increase as a SSNIP)). But by Impax's medical expert's own admission, insurance coverage changes are "dramatic" events, and he would not be aware of small changes in the price of long-acting opioids. (CCF ¶¶ 18, 565, 667).

The Proposed Finding is also inaccurate insofar as it states that switching is "often driven by economic factors." Both medical experts testified that the primary concern of doctors is the clinical well-being of the patient being treated. (Savage, Tr. 771 ("[M]y concerns here are for the clinical well-being of the patient, and those would take priority over more abstract financial concerns."); Michna, Tr. 2177 (agreeing that he prescribes the product that he feels is best for the patient's clinical situation, and that ultimately his priority is the safety and health of the patient); *see also* CCF ¶¶ 18, 563). Thus, because of the variation in LAOs' effectiveness and risks inherent in 011 Tc -0uD011itychs tfrm toneLAOs to

The Proposed Finding is inaccurate and misstates Dr. Michna's testimony. Dr. Michna did not testify that he "frequently" switches patients between LAOs in response to a formulary change. He testified that he did so "several times." (Michna, Tr. 2147-48). Indeed, the Proposed Finding is contrary to the uncontroverted evidence provided by both medical experts, which shows that the primary concern of doctors is the clinical well-being of the patient being treated. (Savage, Tr. 771 ("[M]y concerns here are for the clinical well-being of the patient, and those would take priority over more abstract financial concerns."); Michna, Tr. 2177 (agreeing that he prescribes the product that he feels is best for the patient's clinical situation, and that ultimately his priority is the safety and health of the patient); *see also* CCF ¶¶ 18, 563). Dr. Savage explained that in the event of a change in insurance coverage, she will try to get special authorization from the insurer to keep the patient on the initial LAO: "If they're tolerating [their current opioid] well and it's meeting their needs, I'd prefer to keep them on the drug that they're using." (Savage, Tr. 761-62, 770). But, if Dr. Savage is unable to get such authorization, she will try to "do [her] best with whatever opioids are available." (Savage, Tr. 761-62).

The Proposed Finding is also factually inaccurate and contrary to the weight of the evidence insofar as it is inconsistent with the real world data that shows there was no pattern of

provider, which may be difficult in the current healthcare system. . . . The process of switching a patient to a different opioid requires skill, trial-

testimony on Respondent's behalf – as representative of medical practice generally. (Michna, Tr. 2164; *see* Complaint Counsel's Response to Proposed Finding No. 754).

The Proposed Finding is also factually inaccurate and contrary to the weight of the evidence insofar as it is inconsistent with the real world data that shows there was no pattern of substitution between Opana ER and other long-acting opioids, including oxycodone. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45; *see also* Complaint Counsel's Response to Proposed Finding No. 747).

Response to Proposed Finding No. 758

The Proposed Finding is factually inaccurate, contrary to the weight of the evidence, and misleading for the reasons set forth in response to Proposed Finding Nos. 750 and 757.

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).

Response to Proposed Finding No. 759

The Proposed Finding is misleading insofar as it implies that prescribing doctors are generally aware of drug prices or make their prescription decisions based on price, rather than clinical factors. (*See* Complaint Counsel's Response to Proposed Finding No. 757).

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. (MichnrrCi Tws eedb(ckdi)]TJ0.0016 Tc -0.0016 Tw 1805 0 Td[rctllyfrorm

Response to Proposed Finding No. 762

The Proposed Finding is misleading insofar as it implies that prescribing doctors are generally aware of drug prices or make their prescription decisions based on price, rather than clinical factors. (*See* Complaint Counsel's Response to Proposed Finding No. 757).

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).

Response to Proposed Finding No. 763

The Proposed Finding is factually inaccurate, contrary to the weight of the evidence, and misleading for the reasons set forth in response to Proposed Finding Nos. 750 and 757.

The Proposed Finding is also not supported by the evidence cited. As Professor Noll testified, the UPMC study did not measure patient switches. Instead, it attempted to measure the number of people who got an OxyContin prescription before and after the formulary change at issue. (Noll, Tr. 1557 ("It's not following a patient through time and seeing if the patient switched.")). Moreover, the UPMC study does not establish why the underlying formulary change occurred; Respondent has provided no evidence that the study was undertaken because of a change in relative price. (Noll, Tr. 1560-61). Indeed, Dr. Addanki testified that he was not aware of the price change that resulted from the formulary change studied in RX-087 (Addanki, Tr. 2505-06) and that he was not even aware of whether a relative price change had actually occurred. (Addanki, Tr. 2505-06).

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).

Response to Proposed Finding No. 764

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 763.

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).

Response to Proposed Finding No. 765

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 763.

766. Only 329 patients, roughly 20 percent, remained on OxyContin post-formulary change. (RX-087; *see* Noll, Tr. 1561).

Response to Proposed Finding No. 766

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 763.

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).

Response to Proposed Finding No. 767

The Proposed Finding is misleading and misstates the evidence. Dr. Addanki testified he did not know what, if any, change in relative price UPMC received that resulted in the formulary change. (Addanki, Tr. 2505-06 ("The price change we're talking about there, I don't know what the price change was. I don't know

w invidence. Dr.

possible to support the conclusion that the formulary change resulted in a change in relative price to the insurer or whether any price change was in the range of a SSNIP.

changes that affect a patient's out-of-pocket costs, she will seek special authorization from the insurer to keep the patient on the preferred opioid, and only if authorization is denied would she try to "do our best with whatever opioids are available." (Savage Tr. 761-62).

Switching opioids presents risks and requires monitoring (which incurs costs). Dr. Savage stated that switching opioids "is not advised unless there is a clear indication for a change in opioid and the clinician is prepared to provide adequate supervision as the rotation is undertaken." (CX5002 at 063 (¶ 176) (Savage Report)). Dr. Savage's observations are consistent with Endo's experience. In a letter to the FDA, Endo noted that "the process of switching from one opioid to another is difficult, fraught with dangers, and requires careful follow-up with the medical provider, which may be difficult in the current healthcare system. . . . The process of switching a patient to a different opioid requires skill, trial-and-error, and intense medical supervision, and will be costly and time-cons

But even if 50% of oxymorphone patients could be successfully treated with oxycodone, that would not show that different LAOs are equally safe and effective. Instead, it would be consistent with Dr. Savage's testimony that, because of individual variability in responses to opioids, it would be impossible to reliably predict an individual patient's response to a new opioid. (CCF ¶ 753). Indeed, in this hypothetical, the new LAO would be just as likely to work or not work for a patient. If one sold a car that starts 100% of the time and bought a new car that only starts 50% of the time, one would be hard-pressed to call the new car "equally effective."

772. Before Endo introduced Opana ER in 2006, Dr. Savage was able successfully to treat patients with chronic pain. (Savage, Tr. 818).

Response to Proposed Finding No. 772

The Proposed Finding is misleading and incomplete because it selectively quotes Dr. Savage's testimony. Immediately after the cited testimony, Dr. Savage followed up with the observation that "I believe having diversity in our choice of opioids improves patient care and outcomes." (Savage, Tr. 818).

The Proposed Finding is also misleading in that it misunderstands the relevant product market analysis. Close substitutes are identified by determining what alternative products customers would switch to in response to a small but significant increase in price, not what alternative products customers would switch to if the reference product were no longer available. (CCF ¶¶ 516-20). Whether patients could be treated prior to Endo introducing Opana ER in 2006 has no bearing on what products are economic substitutes for Opana ER.

3. Switching Through Opioid Rotation Therapy

773. Some doctors employ "opioid rotation" therapy. (Savage, Tr. 760-61).

Response to Proposed Finding No. 773

Complaint Counsel has no specific response to the Proposed Finding.

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).

Response to Proposed Finding No. 774

The Proposed Finding is misleading and incomplete because it selectively quotes Dr. Savage's testimony. Immediately after the cited testimony, Dr. Savage noted medical professionals use opioid rotation "when there's a clear reason that somebody needs to change from one opioid to another." (Savage, Tr. 760-61). Dr. Savage testified that a "clear reason" can be because the patient has developed a tolerance to the first opioid or has developed side effects. (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).

Response to Proposed Finding No. 775

The Proposed Finding is misleading and mischaracterizes Dr. Savage's testimony. Dr. Savage did not testify that opioid rotation does not involve any risks. To the contrary, Dr. Savage agreed that she would not typically rotate a patient from one opioid to another absent a clinical need to do so. Indeed, the complexity and risks inherent in opioid rotation mean that it is not advised unless there is a clear clinical indication for a change and the clinician is prepared to provide adequate supervision of the rotation. (Savage, Tr. 769-70; *see also* CCF ¶¶ 735-36 (*citing* CX1101 at 005 (Endo letter to the FDA noted "the process of switching from one opioid to another is difficult, fraught with dangers, and requires careful follow-up with the medical provider, which may be difficult in the current healthcare system. . . . The process of switching a patient to a different opioid requires skill, trial-and-error, and intense medical supervision, and will be costly and time-consuming for the patient.")).

The Proposed Finding also misstates Dr. Michna's testimony. Although Dr. Michna testified that he was personally unaware of any situations in which switching between LAOs could not be accomplished safely, he did not testify that doing so did not involve any risks. (Michna, Tr. 2126).

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).

Response to Proposed Finding No. 776

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence insofar as it is inconsistent with the real world data showing that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45). The cited document, RX-073.0002, shows that the overall frequency of switching between LAOs is very small, less than 3%. (*See also* Complaint Counsel's Response to Proposed Finding Nos. 747 and 749).

777. And Dr. Michna has always been able to find effective extended-release opioids through rotation therapy. (Michna, Tr. 2147).

Response to Proposed Finding No. 777

The Proposed Finding is misleading to the extent it suggests that different LAOs are reliably interchangeable and close substitutes in an economic sense. Because of individual variability in response to opioids, it is impossible to reliably predict an individual patient's response to a new opioid. Thus, as Dr. Michna explains, "patients can be switched to a new ER Opioid without negative clinical implications, assuming the switch is performed slowly and with the proper understanding of these medications." (RX-549 at 0025 (¶ 57) (Michna Report); *see also* Complaint Counsel's Response to Proposed Finding Nos. 695, 724, and 728).

4. Switching Costs are Insignificant

778. Switching from one extended-release opioid to another requires physician monitoring. (Michna, Tr. 2127).

Response to Proposed Finding No. 778

Complaint Counsel has no specific response.

779. This includes follow-up visits with the doctor in order to assess whether the patient is getting adequate pain relief. (Michna, Tr. 2127).

Response to Proposed Finding No. 779

Complaint Counsel has no specific response.

780. Physician monitoring can also include telephone conversations between doctor and patient. (Michna, Tr. 2127).

Response to Proposed Finding No. 780

The Proposed Finding is misleading because it understates the costs involved in switching between LAOs. Patients switching from one opioid to another must be closely monitored because the transition period is fraught with potential risks: too much opioid can lead to sedation or overdose; too little can lead to unrelieved pain. (CCF ¶ 753). Indeed, when it faced a potential recall of Opana ER, Endo sent the FDA a letter that noted "the process of switching from one opioid to another is difficult, fraught with dangers, and requires careful follow-up with the medical provider, which may be difficult in the current healthcare system. . . . The process of switching a patient to a different opioid requires skill, trial-and-error, and intense medical supervision, and will be costly and time-consuming for the patient." (CCF ¶¶ 734-35, quoting CX1101 at 005; *see also* CX5002 at 061-62 (¶ 172) (Savage Report) (noting that patients going through opioid rotation must be closely monitored because the transition period presents risks to the patient)).

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).

Response to Proposed Finding No. 781

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 780. Moreover, Impax has provided no da

Response to Proposed Finding No. 782

The Proposed Finding is misleading, is based on speculation, and relies on expert testimony to prove a factual point. Dr. Michna has no foundation for his testimony. Dr. Michna does not work for insurance companies, and Respondent has not produced any evidence that Dr. Michna has performed any financial analysis that

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).

Response to Proposed Finding No. 785

The Proposed Finding is misleading and factually inaccurate insofar as it suggests that

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-

same market is not simply a matter of functional definition and technical description, but whether customers regard the products as sufficiently close substitutes that a small change in the price of one product would cause buyers to switch their purchases to the other. (CCF ¶ 525).

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence insofar as it is inconsistent with the real world data proving that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45). In contrast, real world dan contshow(pioids698t]TJ0.0ung7 Tc -0.0001c)Tjc

other LAOs compete with Opana ER, his sworn declaration makes clear that other LAOs did not present the same competitive constraint as generic oxymorphone ER. That sums up why generic oxymorphone ER and Opana ER are in the same relevant market, but other LAOs are not. (*See also* Complaint Counsel's Response to Proposed Finding No. 695).

Finally, the document cited in the Proposed Finding reinforces that different LAOs have different characteristics and are therefore not close economic substitutes. CX2610, Endo's Revopan Playbook, notes the distinguishing characteristics of Opana ER, including "[t]rue 12-hour dosing," "[n]o CYP450 PK [drug-drug interactions]," "[l]ong half-life," and "[l]ow euphoria." (CX2610 at 014 (Revopan Playbook) (Revopan was the potential brand name of Reformulated Opana ER)). This document also lists the "Key Revopan Advantage[s]" of oxymorphone ER over alternative LAOs. (CX2610 at 024). Mr. Bingol testified that, to the extent Opana ER was competing against other LAOs, it was doing so by product differentiation, i.e., by emphasizing the differences between Opana ER and other LAOs. (Bingol, Tr. 1265, 1270 (the heritage of oxymorphone refers to "the intrinsic qualities of oxymorphone as a molecule that might have had – that might have meaningful importance to clinicians or patients"); CCF ¶ 940). Product differentiation reinforces brand loyalty to particular products, which in turn undermines price competition between them and makes them more distant, not closer, substitutes. (CCF ¶ 941).

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)).

Response to Proposed Finding No. 789

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 788.

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)).

Response to Proposed Finding No. 790

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 788.

established and competitive market that consisted of many products that had been on the market for years." (CX3273-003).

Response to Proposed Finding No. 793

The Proposed Finding is misleading to the extent it implies any similarity between the competitive constraint imposed on Opana ER by (1) other long-acting opioids and (2) generic oxymorphone ER. The real world data demonstrates that there was no pattern of substitution between Opana ER and other long-acting opio

The Proposed Finding is misleading, factually inaccurate, and contrary to the weight of the evidence for the reasons set forth in Complaint Counsel's Response to Proposed Finding No. 788.

796. Indeed, those documents [redacted] (Addanki, Tr. 2259).

Response to Proposed Finding No. 796

The Proposed Finding is misleading. The documents, two of which were summarized in Exhibit 2 of Professor Noll's Rebuttal Report, emphasize that Endo engages in efforts to differentiate Opana ER from other long-acting opioids. (CCF ¶¶ 919, 940 (citing CX5004 at 089-90 (Exhibit 2) (Noll Rebuttal Report) (RX-085 is EPI001538036 and RX-060 is EPI001165532))). The third document (RX-112) also emphasizes the product differentiation of Opana ER. (*See* RX-112 at slide 83 (OPANA ER – Situation Analysis) (the "Most Compelling Opana ER Message[s]" are "[t]rue 12-hour dosing that lasts" and "[n]o known CYP450 drug-drug interactions at clinically relevant doses.")). A promotional strategy that focuses on product differentiation reduces the intensity of price competition and does not increase it. (CCF ¶ 941).

797. In June 2007, for example, [redacted] (RX-085 at 57).

Response to Proposed Finding No. 797

The Proposed Finding is misleading insofar as it implies that Endo's tracking of other long-acting opioids for business purposes is determinative of whether these other products are in the same relevant product market for antitrust purposes. It is not. What matters in determining whether products are close economic substitutes is cross-elasticity of demand, or whether a "small but significant non-transitory increase in price" (SSNIP) of one product would cause a

sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899). The real world data demonstrates that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45).

Moreover, the very document Respondent cites, an Opana ER Brand Strategy, includes various reasons why Opana ER and other long-acting opioids are not close economic substitutes:

> On slide 5, the document notes "Unmet Need – Based on variability of patients' response to competitive therapies, many patients do not receive adequate pain relief due to either lack of efficacy or intolerable [adverse events]." (RX-085 at slide 5).
>
> Slides 15, 18 and 27 identify features that differentiate Opana ER from other LAOs, including Opana ER's longer half-life, lack of CYP 450 interaction, 12-hour dosing, dosing flexibility, and lower CNS effects than OxyContin. (RX-085 at slides 15, 18, 27).
>
> Slide 25 states that "OPANA ER is a unique treatment option which provides durable efficacy and a unique set of dosing advantages for patients suffering moderate to severe pain." (RX-085 at slide 25).
>
> Slide 57 illustrates {[redacted]} (RX-085 at slide 57). If different long-acting opioids were close economic

substitutes of one another, then the genericization of one drug should result in diversions from other branded drugs. (CCF ¶¶ 671-72; Noll, Tr. 1374-75). This is because generic drugs are generally cheaper than branded drugs, and the entry of a generic drug is thus akin to a price decrease. (CCF ¶¶ 671-72; Noll, Tr. 1374-75). **{** **}** (RX-085 at slide 57; *see also* slides 58 and 59). This data further supports the conclusion that different long-acting opioids are not close economic substitutes of one another.

798. **}** (RX-085 at 57). (RX-085 at 59).

Response to Proposed Finding No. 798

The Proposed Finding is misleading insofar as it implies that the fact that Endo's business documents identify an LAO market is determinative of whether all long-acting opioids are in the same relevant product market for antitrust purposes. It is not. What matters in determining whether products are close economic substitutes is cross-elasticity of demand, or whether a "small but significant non-transitory increase in price" (SSNIP) of one product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899). In fact, the evidence shows that there was no pattern of substitution between Opana ER and oxycodone. From 2006 until 2011, sales of Opana ER grew substantially each year even though generic oxycodone ER was widely available. (CCF ¶ 938 (Opana ER sales were $5 million in 2006 and $384 million in 2011); *see also* CCF ¶ 676; CX5000 at 196 (Exhibit 5A1) (Noll Report) (*in camera*)). Opana ER sales would not have grown if oxycodone ER was in fact a close economic substitute, because patients would opt to buy the cheaper oxycodone ER. (CCF ¶¶ 672, 684; Noll, Tr. 1374-75).

799.

}

Opana ER Message[s]" are "[t]rue 12-hour dosing that lasts" and "[n]o known CYP450 drug-drug interactions at clinically relevant doses")). Product differentiation reduces the intensity of price competition between products, making them less likely to be close economic substitutes. (CCF ¶¶ 822, 941).

801.

} (RX-026.0005).

} (RX-026.0006-08).

Response to Proposed Finding No. 801

The Proposed Finding is misleading to the extent it implies substantial switching between LAOs. The real world data shows that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45). Respondents have presented no evidence as to why Endo believed the divestiture of Kadian to Actavis might drive Opana ER sales.

The Proposed Finding is also misleading insofar as it draws any conclusion about the relevant antitrust product market from the fact that Opana ER sales might have increased due to an oxycodone shortage. What matters in determining whether products are close economic substitutes is cross-price elasticity of demand, or whether a small but significant nontransitory increase in price (a "SSNIP") of one product would cause a sufficient amount

Response to Proposed Finding No. 802

The Proposed Finding is misleading insofar as it implies that the fact that Endo's business documents identify other long-acting opioids as competitors is determinative of whether these products are in the same relevant product market for antitrust purposes. It is not. What matters in determining whether products are close economic substitutes is cross-elasticity of demand, or whether a "small but significant non-transitory increase in price" (SSNIP) of one product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899). The real world data shows that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45).

Indeed, the very document Respondent cites supports the conclusion that other long-acting opioids are not in the same relevant product market as Opana ER. RX-078 is a Revopan Launch Readiness Review, dated December 16, 2010. According to this launch plan, Endo's pricing strategy for Revopan (Reformulated Opana ER) was "[p]arity pricing and contracting to Opana ER." (RX-078 at slide 19). In other words, Endo planned to base its price for Reformulated Opana ER solely on the price of Original Opana ER, without regard to the price of other long-acting opioids. The fact that Endo considered the price of Original Opana ER, and only Original Opana ER, in pricing Reformulated

products are in the same relevant product market for antitrust purposes. It is not. What matters in determining whether products are close economic substitutes is cross-elasticity of demand, or whether a "small but significant non-transitory increase in price" (SSNIP) of one product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899). The real world data shows that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45).

Indeed, the very documents Respondent cites indicate that long-acting opioids are not in the same relevant antitrust market as Opana ER. RX-115 identifies key points of differentiation between Opana ER and other LAOs. (RX-115 at slide 5, 7 (Opana ER Playbook)). RX-111 also shows that Endo sought to differentiate Opana ER from other LAOs on the basis of "[t]rue 12-hour dosing," "[n]o known CYP450 PK DDIs at clinically relevant doses," and "[f]lexible dosing and individualized therapy." (RX-111 at slide 3, 29 (Opana ER Customer Plan)). In addition, RX-111 demonstrates that the vast majority of Opana ER business is based on continuations (the blue portion of the bar), with a much smaller portion based on switches from other opioids (the red portion of the bar). (RX-111 at slide 37 (Opana ER Customer Plan)). In the last month for which data is available, June 2011, switches to Opana ER from other opioids accounted for only 3,684 of a total of 94,203 total prescriptions in the month, or 3.9%. (RX-111 at slide 37 (Opana ER Customer Plan); *see also* Complaint Counsel's Response to Proposed Finding No. 747 (RX-060 at slide 26 also confirms that the overall level of switching in the LAO sector is just 3%)).

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).

Response to Proposed Finding No. 804

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 788 and 802. In addition, the document Respondent relies upon, RX-060, supports the conclusion that other long-acting opioids are not in the same relevant product market as Opana ER. (*See* Complaint Counsel's Response to Proposed Finding Nos. 747 and 803).

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).

Response to Proposed Finding No. 805

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 788, 802, and 803. The Proposed Finding also mischaracterizes the cited evidence. RX-060 does *not* indicate Endo viewed capturing volume from OxyContin and morphine sulfate as the "biggest opportunity" in the market. Instead, the document actually states "that New Therapy Starts are the biggest opportunity in the market." (RX-060.0002 at slide 29 (Opana ER Business Plan)). That observation is consistent with the data showing that over three times as many prescriptions come from new therapy starts than switches. (RX-060.0002 at slide 26 (Opana ER Business Plan) (new therapy starts account for 10% of LAO business, switches only 3%)). But the vast majority of business comes from the continuation of existing patients. (RX-060.0002 at slide 26 (Opana ER Business Plan) (continuation on current drug accounts for 87% of LAO business)). This data is consistent with Dr. Savage's testimony that switching LAOs is not medically advisable unless there is a clinical need to do so. (Savage, Tr. 770 ("If they're tolerating [an LAO] well and it's meeting their needs, I'd prefer to keep them on the drug that they're using."); *see also* CCF ¶¶ 752, 754 (switching LAOs is not advised unless there is a clear clinical indication a change is required)).

806. In April 2013, {[redacted]}

(RX-073.0002 at 7; Addanki, Tr. 2262-63).

Response to Proposed Finding No. 806

The Proposed Finding is misleading in that it misunderstands the relevant product market analysis. What matters in determining whether products are close economic substitutes is cross-

The Proposed Finding is also misleading insofar as it suggests that a monopolist does not compete for sales. If the price of a particular product is already elevated due to the presence of market power, then products that are outside a properly-defined relevant product market will become economic substitutes. (CCF ¶ 931). Thus, even a monopolist faces competition from products outside the monopoly. (CCF ¶¶ 928, 933).

807. [redacted] (RX-073.0002 at 39; Addanki, Tr. 2264).

Response to Proposed Finding No. 807

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 749, 788, 803, and 806.

808. At the same time, [redacted]

(RX-073.0002 at 38; Addanki, Tr. 2263-64).

Response to Proposed Finding No. 808

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence insofar as it is inconsistent with the real world data proving that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45). The document cited actually demonstrates that, as of early 2013, the level of switching was small overall and generic oxymorphone ER was a far more significant competitor to Opana ER than other LAOs. According to RX-073.0002, there were 65,333 prescriptions for Opana ER in February 2013. (RX-073.0002 at slide 15). In that same month, Opana ER gained a total of 1,010 prescriptions from OxyContin—1.55% of total prescription volume. (RX-073.0002 at slide 16). This is consistent with the low rate of overall switching (3%) evidenced by RX-060.0002 at slide 26. (*See* Complaint Counsel's Response to

Proposed Finding No. 747). The Proposed Finding is also misleading for the reasons set forth in response to Proposed Finding Nos. 749, 788, 803, and 806.

809.

(Addanki, Tr. 2264-65).

Response to Proposed Finding No. 809

The Proposed Finding is misleading insofar as it implies that the fact that Endo's business documents identify other long-acting opioids as competitors is determinative of whether these products are in the same relevant product market for antitrust purposes. It is not. What matters in determining whether products are close economic s

product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899). The real world data shows that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45). The Proposed Finding is also misleading for the reasons set forth in response to Proposed Finding No. 806.

811.

}

Response to Proposed Finding No. 811

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 810. The Proposed Finding is also misleading insofar as it suggests that a monopolist does not compete for sales. **{**

} (CX5000 at 196-98 (Exhibits 5A1 through 5A3) (Noll Report) (*in camera*)). Accordingly, Purdue had a monopoly over the oxycodone market. If the price of a particular product is already elevated due to the presence of market power, then products that are outside a properly-defined relevant product market will become economic substitutes. (CCF ¶ 931). Thus, even a monopolist faces competition from products outside the monopoly. (CCF ¶¶ 928, 933).

The Proposed Finding is also misleading to the extent it implies any similarity between the competitive constraint imposed on OxyContin by (1) other long-acting opioids and (2) {3} {(2) powera /TT0 005 f 0

(*in camera*)). No similar effect occurred due to the introduction of other long-acting opioids. (CCF ¶¶ 674-85).

The very document Respondent cites actually underscores the unique competition between a brand and its generic counterpart. RX-449 notes that **{**

} (RX-449 at 0009 (*in camera*)). **{** **}** (*See* CX5000 at 199, 208 (Exhibits 5B1 and 5E1) (Noll Report) (*in camera*)). **{**

}. (CX5000 at 196 (Exhibits 5A1 through 5A3) (Noll Report) (*in camera*)). This would not have occurred if long-acting opioids were close economic substitutes for one another. (CCF ¶ 684).

812.

Response to Proposed Finding No. 812

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 810 and 811. The Proposed Finding is also inaccurate, because the data actually show that new LAO patients were a much larger—over three times—source of prescriptions than switches from other LAOs. (*See* Complaint Counsel's Response to Proposed Finding 747 (citing RX-060.0002 at 26, which shows that in the LAO sector overall, 10% of prescriptions come from patients who are just starting therapy, while only 3% of prescriptions come from patients who are switching from a different LAO)).

813.

} (Addanki, Tr. 2266-67).

Response to Proposed Finding No. 813

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence insofar as it is inconsistent with the real world data proving that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45). The Proposed Finding is also inaccurate, because the data show that new LAO patients were a much larger—over three times—source of prescriptions than switches from other LAOs. (*See* Complaint Counsel's Response to Proposed Finding 747 (citing RX-060.0002 at 26, which shows that in the LAO sector overall, 10% of prescriptions come from patients who are just starting therapy, while only 3% of prescriptions come from patients who are switching from a different LAO)). This data is entirely consistent with a lack of overall growth in prescriptions of opioids, because patients discontinue therapy. Thus, new long-acting opioids can enter the market and attract new patients initiating therapy, rather than taking sales away from other existing products. And the real world data in RX-060.0002 demonstrates that that was exactly the case.

814.

Response to Proposed Finding No. 814

The Proposed Finding is misleading and factually inaccurate to the extent it implies that the "extended-release opioid market" is a properly-defined relevant market. What matters in determining whether products are close economic s

of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45). The Proposed Finding is also misleading for the reasons set forth in response to Proposed Finding Nos. 788, 806, and 811.

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).

Response to Proposed Finding No. 815

The Proposed Finding is misleading and incomplete to the extent it omits that LAO manufacturers compete primarily by emphasizing the distinguishing characteristics of their products. (*See* Complaint Counsel's Response to Proposed Finding No. 788 (explaining that LAO sellers differentiate their products based on the different characteristics of LAOs and that this differentiation reinforces brand loyalty); CX4025 (Bingol, Dep. at 104 ("Differentiation is always your mission in marketing.")). This product differentiation decreases the intensity of price competition between brand-name prescription drugs. (CCF ¶¶ 573, 724-25).

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).

Response to Proposed Finding No. 816

The Proposed Finding is misleading in that it misunderstands the relevant product market analysis. What matters in determining whether products are close economic substitutes is cross-elasticity of demand, or whether a "small but significant non-transitory increase in price" (SSNIP) of one product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899; CX6054 at 013-14 (§

4.1.2) (*Horizontal Merger Guidelines*) (see specifically Example 10, which cautions against using too large of a price increase as a SSNIP)). There is no basis to depart from the standard methods used in antitrust economics to determine whether different drugs are in the same product market. (CX5004 at 011-13 (¶¶ 20-23) (Noll Rebuttal Report)). Even in the pharmaceutical industry, it is appropriate to estimate cross-elasticities of demand between two products (which informs whether they are close substitutes) by observing whether a decline in the price of one results in a reduction of sales in the other. (CX5004 at 012-13 (¶¶ 21-23) (Noll Rebuttal Report)). That analysis can be performed without regard to whether the industry is disjointed. Here, the real world data demonstrates that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45).

The Proposed Finding is also misleading to the extent it implies physicians make prescribing decisions based on economic factors like small changes in relative price, rather than clinical needs. (Savage, Tr. 771 ("Q. Now, why wouldn't minor changes in price change your prescribing habits? A. First, because I'm generally not aware of the minor changes in price. Second, because the – my clinical – my concerns here are for the clinical well-being of the patient, and those would take priority over more abstract financial concerns."); *see also* Michna, Tr. 2187 (stating he would only be aware of "dramatic changes" in price)).

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.

Response to Proposed Finding No. 817

The Proposed Finding is factually inaccurate insofar as it asserts that LAO manufacturers compete vigorously on price. The data show that once generic versions of oxymorphone ER

launched, **{** **}** and the average price of the oxymorphone ER dropped substantially. (CCF ¶¶ 628-42; CX5000 at 219 (Exhibit 7A) (Noll Report) (*in camera*)). This real world data is also consistent with the expectations of both Impax and Endo, both of which forecasted that generic oxymorphone ER would have a dramatic effect on the market for Opana ER. (CCF ¶¶ 583-85, 589, 609-10). Generic oxymorphone ER entry would not have had this effect on Opana ER's market share and the price of the drug if it were true that Opana ER competed vigorously with other LAOs. (Noll, Tr. 1381 ("[I]f the market already is highly competitive before the generics enter, then you wouldn't expect that there would be any significant effect of generic entry.")). Respondent's economic expert, Dr. Addanki, does not attempt to explain how LAOs can be close economic substitutes to Opana ER when they did not have the same price effect that generic oxymorphone ER had on Opana ER. (CX5004 at 016 (¶ 31) (Noll Rebuttal Report)). Similarly, Dr. Addanki does not address the fact that entry events of other branded and generic LAOs had no effect on Opana ER sales, or explain how, in light of that, they could be close economic substitutes to Opana ER. (CX5004 at 016-17 (¶¶ 32, 34) (Noll Rebuttal Report)). These real-world facts, which Dr. Addanki simply ignores, p(Th5lTd(d]TJ0.06p 004 Tc -0.00.06p 0008 Tw -15.715 -2.3 3t entry evr)T Pntiom)d Findingis Re-2554.2(amera)clos4.2(amers.3(rket9)]TJ01(ke)T.00 decisIm)ecasted thffeh(Cp005cribeTc -0.0009 Tw T*((’.

Respondent's medical expert, Dr. Michna, testified that he was only aware of "dramatic changes" in price and that his ultimate priority was the safety and health of his patient. (Michna, Tr. 2177, 2187).

The Proposed Finding is also misleading in that it misunderstands the relevant product market analysis. What matters in determining whether products are close economic substitutes is

The Proposed Finding is incomplete. Because third-party payors are often responsible for most of a drug's cost, a common practice is to create a formulary that classifies drugs into tiers on the basis of the perceived cost-effectiveness of the drug. The highest tier includes drugs that are most preferred within a therapeutic class. (CCF ¶ 569). Normally, the most preferred tier

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 818 and 819.

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).

Response to Proposed Finding No. 821

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 818 and 819.

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).

Response to Proposed Finding No. 822

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 818 and 819.

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).

Response to Proposed Finding No. 823

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 818 and 819. The Proposed Finding also misstates Professor Noll's testimony. Professor Noll testified that it is true that drugs do not appear on formulary "by accident." But Professor Noll disputed that the only way to obtain favorable formulary placement is by offering lowering prices. (Noll, Tr. 1546 ("That's one way, but it's not the only way.")). Formulary placement can also reflect promotional activity, which emphasizes the differentiation between LAOs. (CX5004 at 032-33 (¶ 65) (Noll Rebuttal Report)). Product differentiation reinforces brand loyalty to particular products

between them and makes them more distant, not closer, substitutes. (CCF ¶ 941). Critically, outside of a few sporadic, anecdotal examples, Respondent's expert Dr. Addanki did not determine whether the formulary changes he analyzed were actually prompted by price competition or by product differentiation. (Addanki, Tr. 2478 ("Q. Now, you don't know what caused the changes in formulary status that you represent in Exhibit 9I; correct? A. I do not. In

The Proposed Finding is misleading and inaccurate for the reasons set forth in response to Proposed Finding Nos. 818, 819, and 823. In addition to price concessions, formulary placement can also reflect promotional activity, which emphasizes the differentiation between LAOs. (CX5004 at 032-33 (¶ 65) (Noll Rebuttal Report)). Dr. Addanki did not actually analyze to what extent the formulary decisions observed were driven by price competition as opposed to product differentiation or whether any price changes were within the magnitude of a SSNIP. (*See* Complaint Counsel's Response to Proposed Finding No. 823).

oxymorphone ER. The fact that generics come into the market at a cheaper price than the brand is evidence that generics—not other branded drugs—force prices to a competitive level. (CCF ¶ 947).

831. **{** **}** (RX-547.0053-54; Noll, Tr. 1681-83).

Response to Proposed Finding No. 831

}. (*See* CX5000 at 219 (Exhibit 7A) (Noll Report) (*in camera*)).

g No. 832

The Proposed Finding is misleading and mischaracterizes Professor Noll 1 2s testimony.

timony, Professor Noll is discu

cing for all brand name drugs. ITjthis context,

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favorable formulary tier)). If it were true that

competition for formulary placement is in fact successful in controlling branded drug prices, then the release of generic oxymorphone ER would not have caused the average price of oxymorphone ER to decline substantially. (*See* Complaint Counsel's Response to Proposed Finding No. 830 (the launch of generic oxymorphone ER pulled the average price of oxymorphone ER down to a lower level than obtained when Endo was the sole supplier of the drug)).

833. Indeed, Professor Noll's statement is premised on list prices. (CX5000-090-95 (discussing documents related to list prices)).

Response to Proposed Finding No. 833

The Proposed Finding is misleading and mischaracterizes the record for the reasons set forth in response to Proposed Finding No. 832. Professor Noll's analysis is not premised on list prices. The fifteen exhibits relating to price in Professor Noll's report contain both list and net (realized) prices. (CX5000 at 184-90, 219-26 (Exhibits 2B1 through 2B7, 7A, 7B1 through 7B7) (Noll Report) (*in camera*); Noll, Tr. 1681).

Second, as Professor Noll explained, the single best factor at controlling drug prices is the availability of generics. (Noll, Tr. 1524 ("[B]y far the most important competitive factor affecting drug prices" for insurers is the availability of generic drugs and the fact that insurers almost always give generic versions of a drug the most favorable formulary tier.)). Professor Noll's analysis demonstrating that generic entry lowered the average price of oxymorphone ER is based on net prices, not list. (CX5000 at 219 (Exhibit 7A) (Noll Report) (Endo's and Impax's average net prices are the red and purple lines, respectively) (*in camera*)).

834. [redacted] (Addanki, Tr. 2290).

Response to Proposed Finding No. 834

Complaint Counsel has no specific response.

835.

(Noll, Tr. 1684-85). **{** **}** (Noll, Tr. 1681).

Response to Proposed Finding No. 835

Complaint Counsel has no specific response.

a. Contemporaneous Evidence of Endo's Price Competition

837. In 2009, many doctors believed that Opana ER did not have sufficient coverage on insurance plans. (CX1106-009).

Response to Proposed Finding No. 837

The Proposed Finding is not supported by the cited evidence. While the document states that healthcare professionals perceive a lack of insurance coverage for Opana ER, it does not quantify whether this perception was shared by "many," "some," or "few" doctors or indicate whether this perception was accurate. (CX1106 at 009).

The cited document (Endo's 2010 Opana Brand Strategic Plan) also undermines Respondent's suggestion that competition from other LAOs was effective in constraining the

already is highly competitive before the generics enter, then you wouldn't expect that there would be any significant effect of generic entry.")).

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).

on.")). Which in turn means different LAOs are not close substitutes. (CCF ¶¶ 517-18). If LAOs were close substitutes and price competition between them was indeed vigorous and effective,

become economic substitutes. (CCF ¶ 931). Thus, anecdotal evidence that Endo competed with other LAOs to secure preferred formulary status does not demonstrate that LAOs are in the same relevant product market. If other LAOs provided a meaningful competitive constraint on Opana ER, then entry of generic versions of Opana ER would not have reduced the average price of oxymorphone ER and Opana ER's market share as

differentiating Opana ER from other LAOs, not on price. (CCF ¶¶ 940-41). RX-558 also shows that **{**

} (RX-558 at 0001 (*in camera*)). **{**

} (CCF ¶¶ 517-18, 871-76 (*in camera*)).

842. In 2011,

Response to Proposed Finding No. 844

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 818-19 and 839-40.

845. Also in 2011, [redacted] (RX-021.0005; Addanki, Tr. 2296). [redacted] **}** (RX-021.0005).

Response to Proposed Finding No. 845

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 818-19 and 839-40.

846. [redacted] **}** (RX-021.0005; Addanki, Tr. 2298). [redacted] **}** (RX-021.0005; Addanki, Tr. 2298-99).

Response to Proposed Finding No. 846

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 818-19 and 839-40.

847. [redacted] **}** (RX-021.0007).

Response to Proposed Finding No. 847

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 839 and 840.

848. In 2012, [redacted] (RX-022.0004; Addanki, Tr. 2300-01). {[redacted] **}** (Addanki, Tr. 2301).

Response to Proposed Finding No. 848

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 818-19 and 839-40.

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).

Response to Proposed Finding No. 849

The Proposed Finding is misleading for the reasons set forth in response to Proposed

changes that you discuss relating to formulary changes constituted a small price change; right? A. I didn't carry out a SSNIP analysis.")).

850. Also in 2012, [redacted] (CX3206-002).

Response to Proposed Finding No. 850

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 818-19 and 839-40. The Proposed Finding is also inconsistent with the weight of the evidence. The vast majority of Opana ER pricing proposals do not mention any other LAOs. (CX5000 at 067, 069 (¶¶ 146, 152) ("Endo's internal documents rarely mention relative prices as an important factor in determining sales of Opana ER."; "Most Endo documents that deal with Opana ER pricing do not refer to any other drugs.")).

The Proposed Finding is also misleading insofar as it implies that Endo's purported discount of Opana ER had any real world effect on substitution patterns. (CX5000 at 068-69 (¶ 150) (there are no documents that indicated what effect the proposed discounts had)). The real world data demonstrates that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45).

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).

Response to Proposed Finding No. 851

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 818-19 and 839-40. The Proposed Finding is also misleading to the extent it implies that Endo's exclusive placement agreements demonstrate price competition. As Dr.

}. (CX5000 at 177-83, 219 (Exhibits 2A1-2A7, 7A) (Noll Report) (*in camera*)). This data suggests that Endo's competition with other LAOs was focused on factors other than price.

852. Endo also negotiated deals with Humana, Optum, and UPMC to list Opana ER on their

costs (such as patients needing to begin a new medication to relieve side effects resulting from switching LAOs). (*See* Complaint Counsel's Response to Proposed Finding No. 767).

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

The Proposed Finding is misleading in that it concludes that the formulary plan gains of 3% and 7% actually include the UPMC formulary change. The UPMC formulary change apparently occurred prior to 2009. (RX-087 (noting the post-formulary change period evaluated in the study commenced on January 1, 2009)). The document cited as evidence of Endo's formulary plan gains is dated April 9, 2013—*over four years later*. (RX-110.0002 at slide 1 (Opana ER with INTAC Business Review)).

The Proposed Finding is also misleading to the extent it implies that the formulary changes that occurred were a function of price competition. Dr. Addanki made no effort to systematically analyze whether it was in fact price competition that resulted in formulary changes or whether such competition was in the magnitude of a SSNIP. (Addanki, Tr. 2475-76, 2478).

The Proposed Finding is also misleading to the extent it implies other LAOs are close economic substitutes to Opana ER. The very document Respondent cites actually undermines this conclusion:

> RX-110 notes that the level of switching in the overall LAO sector is low, at 3%. (RX-110.0002 at slide 7). This data point is consistent with other evidence. (*See*, RX-060.0002 at slide 26 (Opana ER Business Plan); RX-111 at slide 37 (Opana

While switches account for a higher level of Opana ER's business (8%) this is dwarfed by switching to generic oxymorphone ER—29%. (RX-110.0002 at slide 7 (Opana ER with INTAC Business Review)). This is strong evidence that generic oxymorphone ER can rely on switches for an appreciable portion of its business, but branded LAOs cannot.

Slide 13 notes that Opana ER enjoyed a net gain in switches against OxyContin in February 2013, but "this gain was offset

Review) (14.6 – 11.2 = 3.4; 3.4/11.2 = 30.4%)). In just two months, generic oxymorphone ER was rapidly growing and quickly taking share from Opana ER. Slide 16 indicates that in February 20

in effective price competition with Opana ER, then competition from generic oxymorphone ER would not have such a significant impact on Endo's revenues. (CCF ¶¶ 906-11).

Finally, RX-110 notes that Opana ER had a 20-25% pricing advantage over OxyContin. (RX-110.0002 at slide 35 (Opana ER with INTAC Business Review)). Yet as of February 2013, OxyContin accounted for 27.8% of LAO sales while Opana ER only accounted for 3.9% of LAO sales. (RX-110.0002 at slide 4 (Opana ER with INTAC Business Review)). If Opana ER was a close economic substitute to OxyContin, and it was priced 20-25% more cheaply, then customers would have switched to Opana ER from OxyContin. The fact that even in the face of a substantial price differential, OxyContin still held a far greater share of LAO sales than Opana ER is evidence that the two products are not close economic substitutes. Indeed, from February 2012 to February 2013, Opana ER share fell from 5.8% to 3.9% of the LAO market, a 49% drop. (RX-110.0002 at slide 4 (Opana ER with INTAC Business Review)). During the same period, OxyContin's share fell from 28.8% to 27.8% of the market, which is only a 3% drop. (RX-110.0002 at slide 4 (Opana ER with INTAC Business Review)). Thus, Opana ER lost share at a faster rate than OxyContin, despite the fact that Opana ER was 20-25% cheaper.

Taken together, the data and information conveyed in RX-110 demonstrate that generic oxymorphone ER was a much stronger competitive constraint on Opana ER than other LAOs.

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).

Response to Proposed Finding No. 856

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence as it is inconsistent with the real world data proving that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45). The Proposed Finding is also misleading and not supported by the evidence. First, Dr. Addanki acknowledged that he did not evaluate what price changes, if any, led to the various formulary changes he analyzeiooz(e. Addank, TDr.2475-76. ⁋23l)]TJ0.0013 Tc -0.004 Tw Q.

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).

Response to Proposed Finding No. 858

The Proposed Finding is misleading to the extent it suggests that branded products appearing in a more favorable formulary status than generic versions of the same drug is a frequent occurrence. The evidence in this case is that such situations are unusual. (CCF ¶ 946 (citing Addanki, Tr. 2314-15 (Dr. Addanki testified that when generics are released, they are "virtually uniformly" given preferred formulary status)); *see also* Bingol, Tr. 1291-92; CX5004 at 029-30 (¶ 58) (Noll Rebuttal Report)).

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).

Response to Proposed Finding No. 859

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 857.

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).

Response to Proposed Finding No. 860

The Proposed Finding is misleading and incomplete. While there may be isolated contrary examples, the generic versions of a drug are "virtually uniformly" given the most favorable formulary status. (CCF ¶ 946 (citing Addanki, Tr. 2314-15 (Dr. Addanki testified that when generics are released, they are "virtually uniformly" given preferred formulary status)). In addition, while there may be isolated contrary examples, the vast majority of Opana ER pricing proposals do not mention other drugs. (*See* Complaint Counsel's Response to Proposed Finding No. 850).

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).

Response to Proposed Finding No. 861

between LAOs did occur was a function of price, as opposed to differentiation. (CCF ¶ 941, 943-44). In fact, the evidence demonstrates that there was not effective price competition between LAOs. (*See* Complaint Counsel's Response to Proposed Finding Nos. 805 (the overall level of switching between LAOs is low, only 3%), 841 (**{**

}), 855 (only generic oxymorphone ER would diminish Opana ER revenues while competing with other LAOs would not; Opana ER was 20-25% cheaper than OxyContin yet it lost share at a faster rate), and 863 (OxyContin was the most preferred brand despite the availability of generic morphine and fentanyl)).

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).

Response to Proposed Finding No. 863

The Proposed Finding is misleading to the extent it implies that OxyContin being the most preferred brand on commercial formularies at the time of the settlement is evidence of price competition between LAOs. The fact that OxyContin was the most preferred brand on commercial formularies is actually evidence of the contrary. As of 2010 (the date of the chart at RX-547 at 0114), both morphine and fentanyl had genericized. (*See* CX5000 at 199, 208

864.

(RX-547.0039-40).

Response to Proposed Finding No. 864

Complaint Counsel has no specific response, except to note that this evidence supports the conclusion that other long-acting opioids are not close economic substitutes for Opana ER.

865.

(RX-547.0114; Addanki, Tr. 2316).

Response to Proposed Finding No. 865

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 866

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 862.

867. Similar variation existed on Medicare Plans at the time of settlement,

} (RX-547.0115; Addanki, Tr. 2317; see RX-[(r)-79n exmp Mesctin

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 855 and 862.

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).

Response to Proposed Finding No. 869

The Proposed Finding is misleading to the extent it suggests that any change in formulary placement was a result of price competition for the reasons set forth in response to Proposed Finding No. 862.

870. [redacted] (RX-547.0126; Addanki, Tr. 2318).

Response to Proposed Finding No. 870

The Proposed Finding is misleading to the extent it implies that more plans making Opana ER a preferred drug indicates there is strong price competition between Opana ER and other LAOs. (*See* Complaint Counsel's Response to Proposed Finding Nos. 855 and 862).

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).

Response to Proposed Finding No. 871

The Proposed Finding is misleading to the extent it implies that changes in formulary status indicate strong price competition between Opana ER and other LAOs. (*See* Complaint Counsel's Response to Proposed Finding Nos. 855 and 862).

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).

Response to Proposed Finding No. 872

The Proposed Finding is misleading to the extent it implies that changes in formulary status indicate strong price competition between Opana ER and other LAOs. (*See* Complaint Counsel's Response to Proposed Finding Nos. 855 and 862).

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).

Response to Proposed Finding No. 873

The Proposed Finding is misleading to the extent it implies that changes in formulary status indicate strong price competition between Opana ER and other LAOs. (*See* Complaint Counsel's Response to Proposed Finding Nos. 855 and 862).

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).

Response to Proposed Finding No. 874

The Proposed Finding is misleading to the extent it implies that changes in formulary status indicate strong price competition between Opana ER and other LAOs. (*See* Complaint Counsel's Response to Proposed Finding Nos. 855 and 862).

The Proposed Finding is also misleading because it ignores the significance of generic competition. To the extent that any movement in formulary placement is reflective of competition, generic versions of a drug are "virtually uniformly" given preferred formulary status. (CCF ¶ 946 (citing Addanki, Tr. 2314-15); *see also* Bingol, Tr. 1291-92; CX5004 at 029-30 (¶ 58) (Noll Rebuttal Report)). Yet in the formulary analysis referenced in the Proposed Finding, Dr. Addanki systematically excluded generics from his data set. (CCF ¶¶ 946, 947). Dr. Addanki's systematic exclusion of generics from the analysis rendered any conclusions drawn about the level of competition unreliable. (CCF ¶¶ 946, 947).

The Proposed Finding is also misleading because it suggests that these changes in formulary placement offer conclusions about "all the other LAO suppliers' competitive efforts." Dr. Addanki only included six LAOs in this analysis—he did not look at all LAOs. (CCF ¶ 948). Moreover, three of the six drugs Dr. Addanki examined in his formulary analysis contain morphine. (CCF ¶ 948). Because three of the six drugs share the same molecule and thus any characteristics of the molecule, they are more likely to be good substitutes for each other. (CCF ¶ 948). While patterns of formulary placement do not provide us with useful information about the state of competition, even if they did, the sample set chosen by Dr. Addanki would lead to skewed results and thus unreliable conclusions. (CCF ¶ 948).

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")).

Response to Proposed Finding No. 875

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 862.

The Proposed Finding is further misleading in that it misunderstands the relevant product market analysis. What matters in determining whether products are close economic substitutes is cross-elasticity of demand, or whether a "small but significant and non-transitory increase in price" (SSNIP) of one product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899; CX6054 at 012-14 (§§ 4.1.1, 4.1.2) (*Horizontal Merger Guidelines*) (see specifically Example 10, which cautions against using too large of a price increase as a SSNIP)). Even if the churn observed is a function of competition, Respondent has made no effort to determine whether the churn results

from price competition or competition based on product differentiation. (Addanki, Tr. 2477-78). Competition through product differentiation weakens price competition and makes it less likely two differentiated products are economic substitutes. (CCF ¶ 941). The real world data demonstrates that—regardless of some churn in formulary status—there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713).

*** * ***

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).

Response to Proposed Finding No. 876

The Proposed Finding is misleading in that it misunderstands the relevant product market analysis. What matters in determining whether products are close economic substitutes is cross-elasticity of demand, or whether a "small but significant non-transitory increase in price" (SSNIP) of one product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899; (CX6054 at 012-14 (§§ 4.1.1, 4.1.2) (*Horizontal Merger Guidelines*) (see specifically Example 10, which cautions against using too large of a price increase as a SSNIP)). Critically, Dr. Addanki did not analyze the reasons insurers adjusted their formularies. (Addanki, Tr. 2478 ("Q. Now, you don't know what caused the changes in formulary status that you represent in Exhibit 9I; correct? A. I do not. In other words, I don't know for each formulary that changed all the factors that prompted the change. I do not.")). Without having analyzed why insurers adjusted their formularies, it is not possible to draw a reliable conclusion that the formulary adjustments reflect economic substitutability (as opposed to competition through product differentiation). (CCF ¶¶ 941, 943-44). Moreover, the real world data demonstrates that—regardless of some adjustments in

formulary status—there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713).

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).

Response to Proposed Finding No. 877

The Proposed Finding is misleading in that it misunderstands the relevant product market analysis. What matters in determining whether products are close economic substitutes is cross-elasticity of demand, or whether a "small but significant non-transitory increase in price" (SSNIP) of one product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899; CX6054 at 012-14 (¶¶ 4.1.1, 4.1.2) (*Horizontal Merger Guidelines*) (see specifically Example 10, which cautions against using too large of a price increase as a SSNIP)). Dr. Addanki did not analyze the reasons the various formulary changes were made, so he is unable to conclude that they were the result of price competition, as opposed to competition through product differenti

you discuss relating to formulary changes constituted a small price change; right? A. I didn't carry out a SSNIP analysis.")). Without knowing whether any underlying price changes were within the level of a SSNIP or exceeded it, it is not possible to know whether they inform the relevant market definition.

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 878.

880. [redacted] (Addanki, Tr. 2270; *see* RX-085 at 21).

Response to Proposed Finding No. 880

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 878.

881. In 2007, for example, {[redacted] (RX-085 at 22; Addanki, Tr. 2274).

Response to Proposed Finding No. 881

The Proposed Finding is factually inaccurate and not supported by the evidence cited. Neither RX-085 nor Dr. Addanki's testimony contain any indication that sales of Opana ER {[redacted]} (RX-085 at slide 22; Addanki, Tr. 2274 (*in camera*)). To the contrary, real world sales data produced in this case show that prescriptions and sales of Opana ER {[redacted]} (CX5000 at 177, 179, 181, 183, 191-93 (Exhibits 2A1, 2A3, 2A5, 2A7, 3A, 3B, and 3C) (Noll Report) (*in camera*)). Moreover, the data prove that there is no pattern of substitution between sales of Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713).

882. [redacted] (RX-085 at 21).

Response to Proposed Finding No. 882

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 878. The Proposed Finding is also factually inaccurate and contrary to the weight of

the evidence. Mr. Demir Bingol, the Endo executive in charge of marketing Opana ER, made clear that the presence of generic oxycodone had no effect on Endo's strategy for promoting Opana ER, which was based on differentiation of Endo's product. (CCF ¶ 718; Bingol, Tr. 1278-79 ("[W]hether there's a brand or generic of OxyContin doesn't really matter.")).

883.

} (RX-085 at 22).

Response to Proposed Finding No. 883

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 878. The Proposed Finding is also misleading because it is incomplete, as RX-085 identifies a large number of "threats," "challenges," and "opportunities" for Opana ER, not just those excerpted in the Proposed Finding. For example, Endo stated that an "unmet need exist[ed] for a significant number of patients who are not appropriate for oxycodone or morphine therapy (lack of efficacy or tolerability)." (RX-085 at slide 19 (Opana Brand SWOT Analysis); *see also* RX-085 at slide 18 ("Oxymorphone is a unique molecule . . . Opana ER provides proven [illegible] Perceiv d lo

887. In 2008,

} (RX-547.0110; RX-040.0008 (detailing tens of thousands of doctor visits per month); Addanki, Tr. 2277).

Response to Proposed Finding No. 887

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 878.

888. In total, **{**

(RX-547.0038, 112; Addanki, Tr. 2279).

Response to Proposed Finding No. 888

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 878.

889.

(Addanki, Tr. 2279).

Response to Proposed Finding No. 889

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 878. The Proposed Finding is also factua

own admission, formulary changes are “dramatic” events and he would not be aware of small changes in the price of long-acting opioids. (CCF ¶¶ 18, 565, 667). The Proposed Finding is also misleading and incomplete as it omits the uncontroverted evidence provided by both medical experts, which shows that the primary concern of doctors is the clinical well-being of the patient being treated. (Savage, Tr. 771 (“[M]y concerns here are for the clinical well-being of the patient, and those would take priority over more abstract financial concerns.”); Michna, Tr. 2177 (agreeing that he prescribes the product that he feels is best for the patient’s clinical situation, and that ultimately his priority is the safety and health of the patient); *see also*

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)).

Response to Proposed Finding No. 894

The Proposed Finding is not supported by the evidence cited because Dr. Addanki is not qualified to opine on the "information that matters to physicians." Dr. Addanki is an economist, not a doctor, and cannot offer a reliable opinion about the types of information that doctors care about in making prescribing decisions. (Addanki, Tr. 2244 ("Well, I'm not a clinician, so I rely – I defer to [the medical experts] for the clinical opinions . . .")). Moreover,

own admission, formulary changes are "dramatic" events and he would not be aware of small changes in the price of long-acting opioids. (CCF ¶¶ 18, 565, 667, citing CX4046 (Michna, Dep. at 149) (noting "dramatic" events include moving a drug from a non-incentivized to a preferred tier)). The Proposed Finding is also factually inaccurate and contrary to the weight of the evidence insofar as it is inconsistent with the real world data proving that there was no pattern of substitution between Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713, 944-45).

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)).

Response to Proposed Finding No. 895

The Proposed Finding is misleading and not supported by the evidence for the reasons set

supported by the evidence cited as it purports to use the opinions of Impax's economic expert to establish a factual proposition that should be proven by witness testimony or documents.

Endo **{ }**, for example, each pursued marketing strategies to inform

3.

Response to Proposed Finding No. 900

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899.

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).

Response to Proposed Finding No. 901

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899. The Proposed Finding is also not supported by the evidence cited as it purports to use the opinions of Impax's economic expert to establish a factual proposition that should be proven by witness testimony or documents.

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] **}**).

Response to Proposed Finding No. 902

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899. The very fact that coupons greatly reduce or eliminate out-of-pocket costs for patients is exactly why the existence of couponing programs is misleading and irrelevant to the antitrust market definition analysis. (CCF ¶¶ 517-18 (explaining that the product market is defined by examining customers' reactions to *small* changes in price)).

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).

Response to Proposed Finding No. 903

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899. The Proposed Finding is also not supported by the evidence cited as it purports

to use the opinions of Impax's economic expert to establish a factual proposition that should be proven by witness testimony or documents.

904. [redacted] (RX-028.0011 [redacted]).

Response to Proposed Finding No. 904

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899.

905. [redacted] (RX-028.0011; Addanki, Tr. 2281).

Response to Proposed Finding No. 905

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899.

906. In response to such [redacted] (RX-028.0011).

Response to Proposed Finding No. 906

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899.

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).

Response to Proposed Finding No. 907

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899.

908. In 2011, [redacted]

[redacted] (RX-123.0006; Addanki, Tr. 2285).

Response to Proposed Finding No. 908

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899.

909. And in 2012, [redacted] (RX-119.0002; Addanki, Tr. 2286).

Response to Proposed Finding No. 909

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899. The Proposed Finding is also not supported by the evidence insofar as it claims that Endo's program ensured that patient out-of-pocket expenses would "never" be more than $15 for Opana ER. In fact, Endo's program only applied to "commercially covered lives." (RX-119 at 0002).

910. [redacted]

Response to Proposed Finding No. 910

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899.

911. In 2013, [redacted]

Response to Proposed Finding No. 911

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899.

912.

}

Response to Proposed Finding No. 912

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899.

913.

Response to Proposed Finding No. 913

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 899.

914. Such aggressive price discounting indicates that Opana ER competed against all other easons set forth in response to Proposed Finding No. 899.

can be very important to the treatment of individual patients. (CCF ¶¶ 746-49; CX5006 at 009 (¶ 18) (Savage Rebuttal Report)). It is undisputed that prescribers of long-acting opioids need to understand these differences, including the drug substance, formulation, strength, dosing interval, key instructions, specific information about conversion between products, specific drug interactions, use in opioid-tolerant patients, product-specific safety concerns, and relative potency to morphine. (CCF ¶¶ 759-60). To be sure, patient preferences may come into play in prescribing decisions (Savage, Tr. 742, 745, 822), but ultimately it is the patient's doctor who

Response to Proposed Finding No. 920

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 918. The Proposed Finding is also not supported by the evidence cited because Dr. Savage testified that fentanyl "may be preferred" over an oral medication by some patients or in patients who have difficulty swallowing or absorbing an oral medication. (Savage, Tr. 740-41). This issue is not limited to a patient preference, but also reflects the physical needs of such patients, who may not be able to use an oral medication effectively. (Savage, Tr. 740-41; CX5002 at 053 (¶ 147) (Savage Report); CX5006 at 005, 009 (¶¶ 10, 18) (Savage Rebuttal Report)).

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).

Response to Proposed Finding No. 921

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 918.

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)).

Response to Proposed Finding No. 922

The Proposed Finding is not supported by the evidence cited. The cited portion of Dr. Savage's testimony has nothing to do with identifying the numbers of patients for whom oxymorphone ER (or any other opioid) is the best available choice. More to the point, the treatment of pain is highly individual, and each patient is different; thus, it is not possible to quantify with any accuracy the patients for whom oxymorphone ER is the best available opioid. (CX5002 at 007 (¶ 12) (Savage Report); Michna, Tr. 2192-93; CX4046 (Michna, Dep. at 191) ("Every patient is an experiment and you never know exactly what's going to happen . . .")).

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)).

Response to Proposed Finding No. 923

The Proposed Finding is not supported by the evidence cited. Dr. Savage did not testify that most people can get equally effective and safe pain relief from numerous extended-release opioids. Pressed for speculation, Dr. Savage stated that "most" patients could "probably" switch from oxymorphone to oxycodone. (CX4041 (Savage, Dep. at 66-67) ("I mean, it is generalizing, and it's very hard for me to generalize. . . . I'm

70, 80, 90 percent could successfully switch" from oxymorphone ER to oxycodone ER. (Savage, Tr. 792-93). Only upon being pressed to speculate about a number did Dr. Savage suggest "probably 50 percent," but she didn't offer that opinion "with certainty that [she was] correct." (Savage, Tr. 793). Moreover, Dr. Savage also testified that, although it is usually possible to find an "alternative opioid that will give some relief," it may provide less relief or carry undesirable

therapeutically equivalent and interchangeable with a brand reference drug.")). Therapeutic equivalence requires that the drugs have essentially the same formulation and uses, and so are essentially perfect functional substitutes. (CCF ¶ 548). Even two drugs containing the same active pharmaceutical ingredient might not be therapeutic equivalents. (CCF ¶ 549). In fact, generic oxymorphone ER was not therapeutically equivalent to the reformulated version of Opana ER. (CCF ¶ 579). The Proposed Finding is also contrary to the substantial and largely unrebutted evidence of the meaningful clinical differences between oxymorphone ER and other long acting opioids. (CCF ¶¶ 746-92). The Proposed Finding is also misleading and incomplete to the extent that it suggests therapeutic equivalence is determinative in finding the relevant antitrust market. It is not. Rather the relevant question is whether drugs are close economic substitutes. (CCF ¶¶ 915; Noll, Tr. 1373-74).

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)).

Response to Proposed Finding No. 926

Complaint Counsel objects to the phrase "no doctor can predict" as overbroad, inaccurate, and not supported by the evidence cited. Although it is often the case that a doctor cannot predict prospectively how a given patient will respond to a given long-acting opioid, this is not always true. (CCF ¶¶ 507-09). For example, the patient's history, including prior experience with opioids, may allow a physician to determine which opioid or opioids will work best for that patient. (Savage, Tr. 710-11, 729-30; CX4041 (Savage, Dep. at 38) ("And we are often not able to prospectively identify how a patient is going to respond. More often we know by trial and error . . . or by history, collecting a good history from the patient.")). Dr. Michna's testimony does not suggest otherwise. He merely states that he could not identify in advance a

hypothetical patient able to take only oxymorphone ER. (Michna, Tr. 2148-49; *see also* Michna, Tr. 2167 ("[W]e treat the patient based on their prior experiences . . . and we prescribe according to prior history, medical conditions, et cetera.")).

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).

The Proposed Finding is misleading and incomplete insofar as it suggests that treatment usually continues with the first opioid tried for the patient. Rather, it is often the case that the first opioid is not well tolerated, requiring a process of trial and error to find the best opioid treatment option for the patient. (CCF ¶¶ 507-09, 751; *see also* Savage, Tr. 789-90 ("Sometimes the first opioid is well-tolerated without side effects; sometimes it's not."); Michna, Tr. 2168-69 (approximately 50 percent of people don't tolerate the first opioid tried)).

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).

Response to Proposed Finding No. 932

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 933

The Proposed Finding is misleading and incomplete. There is no dispute between the medical experts that no opioid is superior in the abstract. (CX5006 at 005 (¶ 7) (Savage Rebuttal Report)). But in many cases there is a best opioid for an individual patient in light of that patient's clinical situation. (CCF ¶¶ 504, 509, 746; Savage, Tr. 743-44 ("[A]lmost always there is a medication or medications that are better than other medications, so in that sense, there are superior choices for individuals in particular contexts."); CX5006 at 005, 009, 017 (¶¶ 7, 18, 35) (Savage Rebuttal Report); CX4041 (Savage, Dep. at 59-60)). The goal of the prescribing physician is to find the best opioid treatment option for each individual patient. (Michna, Tr. 2177 ("Q. Okay, but you prescribe the product that you feel is best for your patient in his or her clinical situation? A. Yes."); Savage, Tr. 774-75 ("My primary considerations are matching the

patient to a medication that's clinically effective for them with the least amount of side effects and one that meets convenience issues . . .")).

934. No extended-release opioid is better, for example, for men than for women. (Savage, Tr. 791).

Response to Proposed Finding No. 934

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 933.

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).

Response to Proposed Finding No. 935

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 933.

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).

Response to Proposed Finding No. 936

The Proposed Finding is not supported by the evidence cited. Dr. Savage never testified that the "only differences in extended release opioid treatments" exist in individual patients. To the contrary, Dr. Savage provided unrebutted testimony about the numerous, clinically significant differences between different long-acting opioids. (CCF ¶¶ 745-49, 757-60; Savage, Tr. 727-43 (discussing Appendix C and Figures 4-12 of her report); CX5002 at 037-60 (¶¶ 103-69) (Savage Report) (discussing how oxymorphone ER "differs in many important ways – both pharmacologically and medically – from other long acting opioids"); CX5002 at 106 (Appendix C) (Savage Report)). Many of these differences are incontrovertible scientific distinctions between the opioid molecules used in different long-acting opioids; for example, the metabolic

pathways used to break down the drugs (CCF ¶¶ 762-74), the half-lives of the drugs (CCF ¶¶ 775-83), and risks of particular side effects associated with the drugs (CCF ¶ 791 (some opioids, but not oxymorphone, may result in QTc elongation)). Respondent did not, and could not, argue that these differences do not exist, as they are recognized by the FDA as important for prescribers to be knowledgeable about—to whic

may be variable" and "the side effect profile that they experience may be different."); (CX5002 at 042 (¶ 116) (Savage Report)).

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).

Response to Proposed Finding No. 938

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 936.

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)).

Response to Proposed Finding No. 939

The Proposed Finding is misleading and irrelevant insofar as it misunderstands the relevant product market analysis. Defining a product market based on the targeting of particular customers is only one possible way to define the relevant antitrust market. (CX6054 at 015 (§ 4.1.4) (*Horizontal Merger Guidelines*)). Inability to target particular customers is not determinative. In general, the relevant product market is defined by examining the cross-elasticity of demand, or whether a "small but significant non-transitory increase in price" (SSNIP) of one product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899; CX6054 at 011-15 (§§ 4.1.1-4.1.4) (*Horizontal Merger Guidelines*) (describing the hypothetical monopolist test and SSNIP analysis)). In this case, Endo made the demand for its product less elastic through product differentiation, so that it was able to charge prices substantially above a competitive level without needing to target particular patients for price discrimination. (CX4039 (Noll, Dep. at

170-72); CCF ¶¶ 721-32, 919 (Endo focused on product differentiation); CCF ¶¶ 864-81 (Endo sustained prices above a competitive level)).

3. Unique Characteristics of Oxymorphone ER

a. CYP 450 Metabolism

940. Oxymorphone is metabolized in the liver. (Savage, Tr. 715-16).

Response to Proposed Finding No. 940

Complaint Counsel has no specific response.

941. Other extended-release opioids are metabolized via a pathway known as CYP 450. (Michna, Tr. 2151; Savage, 715-16).

Response to Proposed Finding No. 941

Complaint Counsel objects to the phrase "other extended release opioids" as vague and ambiguous. The record evidence shows that, unlike most other long-acting opioids, oxymorphone ER is not metabolized by the CYP 450 system. (CCF ¶ 762). The Proposed Finding is also misleading to the extent that it suggests the CYP 450 system does not involve the liver—in fact metabolism via the CYP 450 system occurs in the liver. (CCF ¶ 762). Oxymorphone, although also metabolized in the liver, is metabolized by a process known as glucuronidation and does not significantly engage the CYP 450 system. (CCF ¶ 767). Thus, drug interactions involving the CYP 450 system and the genetic variability among patients with respect to the functioning of the CYP 450 system do not affect oxymorphone. (CCF ¶ 768).

942. The CYP 450 pathway is utilized by a majority of medications prescribed generally. (Michna, Tr. 2151).

Response to Proposed Finding No. 942

Complaint Counsel objects to the phrase "majority of medications prescribed generally" as vague and ambiguous. The relevant fact, supported by the opinions of both medical experts and contemporaneous Endo documents, is that many drugs commonly used by pain patients,

such as antidepressants, anti-seizure medications, and antibiotics, use or otherwise interact with the CYP 450 pathway. (CCF ¶ 764; CX2558 at 31-33 (Opana ER Presentation)). Thus, the risks of CYP 450 drug-drug interactions are significant when treating patients with long-acting opioids. (CCF ¶ 770 (risk of 25-30%)).

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).

Response to Proposed Finding No. 943

The Proposed Finding is misleading and incomplete, as it describes only one possible complication associated with CYP 450 drug-drug interactions. As Dr. Savage testified, a patient taking a CYP 450-metabolized opioid along with another drug metabolized by the CYP 450 system may unexpectedly experience

Response to Proposed Finding No. 944

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. The record evidence overwhelmingly shows that the potential for CYP 450 is

establishes that Endo believed that Opana ER's lack of CYP 450 interactions was clinically significant. (CCF ¶¶ 727-29, 731, 733, 761, 769-70).

box warning regarding CYP 450 interactions for many opioids would steer doctors away from using those medications in a patient for whom there was another option for treatment. (Savage, Tr. 735; *see also* Savage, Tr. 796 (noting that some long-acting opioids have a black box warning not to use them with other CYP 450 interacting drugs)).

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).

Response to Proposed Finding No. 948

The Proposed Finding is misleading and incomplete insofar as it suggests that a doctor could reliably substitute morphine or hydromorphone for a patient instead of using Opana ER. The record evidence establishes that patients respond differently to different opioids and that Opana ER has characteristics that make it the best choice for many patients. (CCF ¶¶ 746-49, 757-58). For example, both morphine and hydromorphone can have neuroexcitatory effects, which can cause irritability, hyperreflexia, and even seizures. (CCF ¶ 792; Savage, Tr. 738-39; CX5002 at 047, 049 (Figures 5 and 6) (Savage Report)). This is a factor that a doctor would need to consider when deciding whether to use morphine or hydromorphone in place of oxymorphone ER. (Savage, Tr. 739). As another example, Exalgo (ER hydromorphone) is indicated for opioid-tolerant patients only—which is not the case for Opana ER. (Savage, Tr. 739-740; CX3355 at 014 (FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics); CX5002 at 049 (Figure 6) (Savage Report)). According to internal documents, Endo also had evidence that Opana ER had a lower incidence of adverse events than morphine products. (CX5002 at 047 (¶ 131) (Savage Report); CCF ¶ 790).

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).

Response to Proposed Finding No. 949

The Proposed Finding is misleading insofar as it suggests that Dr. Michna's experience—as one doctor practicing in one state, is representative of the practice of medicine generally.

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).

Response to Proposed Finding No. 950

Complaint Counsel has no specific response.

951. But the availability of oxymorphone ER in both injectable and tablet form is not a clinically relevant factor. (Michna, Tr. 2149-50).

Response to Proposed Finding No. 951

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. The evidence shows that the availability of multiple dosage forms for oxymorphone provides a potential advantage over some other long-acting opioids. (CX5002 at 039-40 (¶ 108) (Savage Report); CX5006 at 012-13 (¶ 23) (Savage Rebuttal Report); CCF ¶¶ 784-86). The advantage of keeping a patient on the same opioid molecule when switching from intravenous to oral medication is that the doctor already knows the patient tolerates the opioid and gets adequate pain relief. (Savage, Tr. 802; CX2529 at 059 (Opana ER Strategic Platform)).

952. Dr. Michna explained that he has never seen oxymorphone stocked in any form in a hospital. (Michna, Tr. 2149-50).

Response to Proposed Finding No. 952

The Proposed Finding is misleading insofar as it suggests that Dr. Michna's experience, as one doctor practicing in one state, is representative of the practice of medicine generally.

953. Indeed, the most commonly used opioids in emergency rooms and other inpatient settings are hydromorphone, fentanyl, and morphine. (Savage, Tr. 787).

Response to Proposed Finding No. 953

Complaint Counsel has no specific response.

954. The most commonly prescribed opioids in outpatient settings are oxycodone, hydrocodone, and morphine. (Savage, Tr. 786; Michna, Tr. 2150).

Response to Proposed Finding No. 954

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 955

The Proposed Finding is not supported by the evidence cited. Neither Dr. Savage nor Dr. Michna testified that patients are "almost always switched from one opioid to an entirely different opioid." The actual evidence does not establish that this practice is nearly universal. Dr. Savage merely testified that it was "common practice" to switch to a different opioid when switching dosage form (Savage, Tr. 798, 799-800), and Dr. Michna testified that "a majority of patients" are switched in such circumstances (Michna, Tr. 2150). This is consistent with Dr. Savage's testimony elsewhere that this is something doctors may consider when switching a patient from intravenous to oral opioids. (Savage, Tr. 802).

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).

Response to Proposed Finding No. 956

Complaint Counsel objects to use of the term "unique" in this context. Dr. Savage's opinion is that the relatively long half-life of oxymorphone ER is a significant difference between it and many other long acting opioids. (CX5002 at 038 (¶ 105) (Savage Report)). More broadly, Dr. Savage's opinions include that oxymorphone ER is not reliably interchangeable with other long-acting opioids and that doctors would not switch a patient to other long-acting

opioids based on minor changes in price. (Savage, Tr. 697-98, 770-71; CX5002 at 008, 64 (¶¶ 17, 180) (Savage Report); CCF ¶¶ 565, 745-49). In any case, whether oxymorphone is unique is irrelevant to defining the rele

The Proposed Finding is misleading to the extent it implies that the use of the distinguishing characteristics of oxymorphone ER in Endo's marketing materials suggests that the differences are not clinically significant. The evidence shows that the FDA considered many of the distinguishing factors discussed in Endo's marketing materials clinically significant. (CCF ¶ 760; CX3355 010-21 (FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics); Savage, Tr. 757 ("[T]he FDA recommends that it's incumbent on us to understand [the differences between opioids] and to accommodate them.")). Impax's medical expert agrees that it is important for prescribers to understand these differences. (CCF ¶¶ 759-60). Moreover, the reason that Endo discussed the distinguishing characteristics of Opana ER in its marketing materials was to educate doctors so that they would prescribe Opana ER to patients for whom it was the best

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 960. The Proposed Finding is also misleading to the extent it suggests that marketing and other promotional strategies are a form of price competition between different long-acting opioids for the reasons set forth in response to Proposed Finding No. 878.

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).

Response to Proposed Finding No. 963

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 960.

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).

Response to Proposed Finding No. 964

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 960. The Proposed Finding is also misleading to the extent it suggests that marketing and other promotional strategies are a form of price competition between different long-acting opioids for the reasons set forth in response to Proposed Finding No. 878.

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).

Response to Proposed Finding No. 965

The Proposed Finding is not supported by the evidence cited because Dr. Michna's opinion on this point was not timely disclosed in his expert report and, pursuant to the Court's rulings, should not be considered. (Tr. 2160 ("My ruling was, just so everyone is clear, that an expert's opinions are supposed to be proffered in the report. . . . when an opposing expert brings out an opinion during their testimony in trial, then an opposing expert can respond to that new

information . . . if that’s not what occurred before the break, then the answer won’t be considered.”). In her initial report, Dr. Sava described characteristics of Opana ER that are not

economic substitutes for one another. Identifying functional similarity is only a beginning to identifying potential economic substitutes. (CCF ¶ 560). Respondent has made no showing that over-the-counter pain medications are, in fact, economic substitutes for one another. The Proposed Finding is also misleading and irrelevant insofar as it tries to draw a parallel between over-the-counter medications for mild pain and long-acting opioids, which are given by prescription only, are for the treatment of more severe pain, and are subject to tight oversight and regulation as controlled substances. (CCF ¶¶ 174, 561 (oxymorphone is a Schedule II substance, the use of which is regulated by the DEA); CCF ¶¶ 562-63 (for prescription drugs, the central figure in decision making is the patient's physician)). For over-the-counter medication, the patient typically selects the medication and pays the full cost, and therefore has an incentive to take relative prices into account. In contrast, physicians do not pay for prescription drugs, and therefore do not have a strong incentive to take relative prices of drugs into account when prescribing them. (CCF ¶ 564). As a result, pharmaceutical companies devote substantial resources to providing physicians with information about the differentiated therapeutic benefits of their drugs. (CCF ¶¶ 566, 722-23). This product differentiation decreases the intensity of price competition between brand-name prescription drugs. (CCF ¶¶ 573, 724-25). By contrast, over-the-counter pain medications are not promoted to physicians and lack the extensive differentiation characteristic of prescription drugs. (CX4041 (Savage, Dep. at 136) ("I had never – do not recall having a nonsteroidal anti-inflammatory maker . . . or acetaminophen producer market in hospitals. Those are over-the-counter, available over the counter. It's usually consumer decision-making.")).

968. Yet Dr. Savage admits that each over-the-counter pain reliever can be used for the same problems. (Savage, Tr. 814-15).

Response to Proposed Finding No. 968

The Proposed Finding is misleading and irrelevant for the reasons set forth in response to Proposed Finding No. 967.

969. And Dr. Savage admits that each over-the-counter pain reliever competes for the same consumers. (Savage, Tr. 815-16).

Response to Proposed Finding No. 969

The Proposed Finding is misleading and irrelevant for the reasons set forth in response to Proposed Finding No. 967.

970. In the same fashion, extended-release opioids compete for the same consumers, even if they treat pain differently. (Savage, Tr. 816).

Response to Proposed Finding No. 970

The Proposed Finding is misleading and irrelevant for the reasons set forth in response to Proposed Finding No. 967.

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).

Response to Proposed Finding No. 971

The Proposed Finding is misleading and incomplete. Dr. Savage also made clear that there are potentially serious risks involved in switching a patient from one opioid to another. In particular, there is a risk of giving the patient too high or too low a dose of medication. Too high a dose can result in overdose or other side effects, while too low a dose will result in unrelieved pain. (Savage, Tr. 758-59, 767-68; CCF ¶ 753). These risks exist because doctors cannot predict an individual's response to a new opioid. (Savage, Tr. 759-60; CCF ¶ 753). Even a relatively straightforward switch, for example switching a patient on a relatively low dose of an opioid to a new treatment option, carries risks of side effects or unsatisfactory pain relief. (Savage, Tr. 769). Moreover, switching a patient to a new opioid is time consuming for both doctor and patient, as

it must be done under the careful supervision of the prescribing physician. (Savage, Tr. 762; CCF ¶¶ 663, 735). Opioid switches also result in additional healthcare costs. (Savage, Tr. 769-70; CCF ¶ 735). As a result of the complexities, risks, and costs of opioid switches, doctors generally do not switch patients from one opioid to another absent a clinical need to do so. (Savage, Tr. 770; CCF ¶ 754). Thus, avoiding opioid switching is not just a matter of Dr. Savage's preference, but is also in the best clinical in

interchangeable and often not, but we cannot know that prospectively. Therefore, I believe that they're not reliably predictably interchangeable.")). The Proposed Finding is also misleading and incomplete to the extent that it suggests therapeutic equivalence is determinative in finding the relevant antitrust market. It is not. Rather the relevant question is whether drugs are close economic substitutes. (CCF ¶ 915; Noll, Tr. 1373-74).

976. And to the extent patients develop side effects, those side effects can be treated with additional medications. (Savage, Tr. 785).

Response to Proposed Finding No. 976

The Proposed Finding is misleading and incomplete and not supported by the evidence cited. Although it is possible to treat side effects with additional medications, this is not desirable. (Savage, Tr. 783 ("That was not what I intended. I don't mention giving people additional medications.")). It is preferable to find an option that has lesser side effects that do not require treatment. (Savage, Tr. 820-21 ("Simple is better. When you can accomplish the same thing with one medication, it's preferable not to be[] adding"); *see also* Savage, Tr. 761-62).

G.

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).

Response to Proposed Finding No. 978

Complaint Counsel has no specific response, except to note that the phrase "extended-release oxymorphone ER" is unnecessarily duplicative. Professor Noll opined that "the relevant market in this case consists of the extended-release versions of oxymorphone, and it does not include the immediate-release versions of oxymorphone or the other long-acting opioids." (Noll, Tr. 1372-73; CCF ¶¶ 498, 501).

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

Noll failed in establishing that cross-elasticity between oxymorphone ER and other products is not supported by any citations to the record and contrary to the weight of the evidence. Substantial evidence shows that doctors are unlikely to switch patients from oxymorphone ER to other drugs based on minor changes in price. (CCF ¶¶ 565, 658-69). And substantial evidence shows that events such as product launch or generic entry for one long-acting opioid had little or no effect on sales of other long-acting opioids. (CCF ¶¶ 670-716). Moreover, Endo's contemporaneous documents confirm that other long-acting opioids did not meaningfully constrain Opana ER prices or sales. (CCF ¶¶ 717-40).

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).

Response to Proposed Finding No. 980

The Proposed Finding is misleading and incomplete insofar as it suggests that this is the only analysis that Professor Noll performed. As detailed in Complaint Counsel's Proposed Findings of Fact, Professor Noll considered substantial evidence in reaching his conclusions that oxymorphone ER is the relevant antitrust market in this case, including the parties' contemporaneous business documents, the testimony of both medical experts, and the real world sales data of the various available long-acting opioids. (CCF ¶¶ 498-809; *see also* Noll, Tr. 1377 ("The first kind of information I used was to understand the relationship between the characteristics of the products and what was likely to affect the ability to switch from one to the other . . . the second thing I looked at was the actual effects of generic entry . . .")).

981. Professor Noll admits, however, that he did not conduct a SSNIP test. (Noll, Tr. 1514).

Response to Proposed Finding No. 981

The Proposed Finding is misleading and incomplete as it suggests that conducting the literal SSNIP test is required to determine the relevant product market. This is not the case, as economists are able to infer the lack of cross-elasticity of demand based on other evidence. (Noll, Tr. 1514 ("I had to infer it from observed sales behavior from changes that – in market conditions that I knew were related to price."); *see also* CCF ¶¶ 526-29, 654-655, 898-99). Professor Noll was able to observe the high cross-elasticity of demand between Opana ER and generic oxymorphone ER. (CCF ¶¶ 628-44). The real world data shows that generic

10). Respondent's economist admitted that it would likely be impossible to calculate cross-elasticity of demand, which is why it was necessary and proper to infer the lack of cross-elasticity from other evidence. (CCF ¶ 655).

Professor Noll was able to observe the high cross-elasticity of demand between Opana ER and generic oxymorphone ER. (CCF ¶¶ 628-44). The real world data shows that generic oxymorphone ER imposes a competitive restraint on Opana ER, which means they are in the same relevant product market. (CCF ¶ 643). In contrast, the data shows that changes in the market environments for other long-acting opioids had no discernible effect on Opana ER, which means other long-acting opioids do not impose a competitive restraint on Opana ER and are not in the same relevant product market. (CCF ¶¶ 670-716). Professor Noll's conclusion is corroborated by Impax's own testimony. Impax's marketing director testified that, as far as he was aware, Impax's generic oxymorphone took sales *only* from other oxymorphone products. (CX4038 (Engle, Dep. at 122-23) ("I haven't seen any data indicating the growth of [generic oxymorphone sales] comes from other molecules.")).

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).

Response to Proposed Finding No. 983

The Proposed Finding is misleading and incomplete to the extent it suggests Professor Noll did not analyze cross-elasticity of demand for the reasons set forth in response to Proposed Finding No. 982. The Proposed Finding is also unsupported by the evidence because Professor Noll did not "fault" Endo for not estimating cross-elasticity of demand—he merely observed that Endo had not attempted to estimate the profitability of a price proposal using an estimate of cross-elasticity of demand. (CX5000 at 068-69 (¶ 150) (Noll Report)).

Response to Proposed Finding No. 985

The Proposed Finding is misleading and not supported by the evidence for the reasons set forth in response to Proposed Finding No. 984.

Finally, Professor Noll failed to advance any

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).

Response to Proposed Finding No. 988

The Proposed Finding is misleading and incomplete as it truncates Professor Noll's opinions on this topic. As Professor Noll went on to explain, "[a] necessary condition for things to be economic substitutes are that they're functional substitutes, but it's not sufficient." (Noll, Tr. 1374). In other words, if two products are not close economic substitutes, they are not in the same relevant product market, even if they might be functional substitutes. (Noll, Tr. 1373-74). The failure of Respondent's expert, Dr. Addanki, to distinguish between functional and economic substitution is a serious flaw in his analysis. (CCF ¶¶ 915-26).

There are many reasons that functionally similar products may not be close economic substitutes. For example, the nature and intensity of competition among pharmaceuticals is heavily influenced by the unique environment in which the industry operates. (CCF ¶¶ 560-78). This environment includes FDA regulations (CCF ¶ 561), the need for a doctor's prescription (CCF ¶¶ 562-65), pharmaceutical company marketing (CCF ¶ 566), and generic substitution laws (CCF ¶¶ 567-72, 574-78). Moreover, drugs within a therapeutic class usually exhibit product differentiation such that a brand-name drug faces—at best—weak price competition from other drugs in the same class. (CCF ¶ 573). Pharmaceutical companies devote ique (preen7git)T -0.000D

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).

Response to Proposed Finding No. 989

The Proposed Finding is misleading, incomplete, and factually inaccurate because it ignores the fact that Professor Noll conducted extensive analysis of the sales and price data of the available long-acting opioids and concluded that there was no pattern of substitution between oxymorphone ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713). The Proposed Finding is misleading and incomplete because switches between opioids are only relevant to the extent they are based on small changes in relative price, not if they are based on clinical considerations. (CCF ¶¶ 533, 544, 659). Moreover, the question is not whether any consumers switch in response to a relative price increase, but instead whether enough consumers switch such that a small but significant price increase would not be profitable. (CCF ¶¶ 517-18). Respondent's Proposed Finding ignores these important points.

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).

Response to Proposed Finding No. 990

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 989. The Proposed Finding is also factually inaccurate and not supported by the evidence cited. Professor Noll did not "dismiss" Respondent's purported evidence of switching between extended-release opioids based on formulary placement. (Noll, Tr. 1520-21 ("I do not dismiss it. . . . The point is, formularies are not the only thing going on in the market.")). The real issue, which Respondent and Dr. Addanki ignore, is whether jockeying for formulary placement is sufficient to cause the price of long-acting opioids to be driven down

to the competitive level. (Noll, Tr. 1519). The only way to address that question is to do exactly what Professor Noll did: see if events like introducing substantially lower prices by generic entry

Response to Proposed Finding No. 992

The Proposed Finding is misleading, incomplete, and not supported by the evidence for the reasons set forth in response to Proposed Finding Nos. 984 and 991. The Proposed Finding is also misleading and incomplete as it omits the part of Professor Noll's testimony where he

competitive level. (Noll, Tr. 1369, 1395-97). Based on the real world sales and price data, Professor Noll concluded that there is not. (Noll, Tr. 1520-21).

The Proposed Finding is also factually inaccurate and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding Nos. 984 and 989. The real world sales and price data prove that there is

The Proposed Finding is misleading and incomplete insofar as it suggests that clinical differences between products do not affect patie

effects—if any—changes in formulary position had on the sales of long-acting opioids. (CCF ¶¶ 944-45). Thus, Dr. Addanki's assertion that formulary-based switching amounted to economic substitution is entirely unfounded and not supported by the evidence. (CCF ¶ 945). In addition, Dr. Addanki entirely neglected to analyze how generic drugs interact with drug formularies. (CCF ¶ 946). The undisputed evidence shows that generic drugs almost always enter the market at a cheaper price than the corresponding brand and that they are placed on a more favorable formulary tier as a result. (CCF ¶¶ 946-47). Thus it is generics, and not branded drugs, that force drug prices to a competitive level. (CCF ¶ 947). The real world sales and price data analyzed by Professor Noll confirms these facts and disproves the Proposed Finding. There is no pattern of substitution between sales of Opana ER and other long-acting opioids. (CCF ¶¶ 673, 676, 682, 689, 693, 698-99, 704-05, 709, 713). And the entry of generic oxymorphone ER had a unique effect on the market for brand name Opana ER. (CCF ¶¶ 628-643).

The Proposed Finding is also misleading insofar as it suggests that a monopolist does not compete for sales. If the price of a particular product is already elevated due to the presence of market power, then products that are outside a properly-defined relevant product market will become economic substitutes. (CCF ¶ 931). Thus, even a monopolist faces competition from products outside the monopoly. (CCF ¶¶ 928, 933).

997. Professor Noll also opined that manufacturers promotional efforts "focused primarily on product differentiation," which argues against a broad product market. (Noll, Tr. 1394).

Response to Proposed Finding No. 997

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 998

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 999

The Proposed Finding is not supported by reliable evidence, as RX-023 appears to be an unidentified draft document sent by an individual—Kara Zubey—who never appeared at trial, offered sworn testimony, or was identified in any way. Moreover, the document was prepared for the stated purpose of "trying to help think through the 'story' we need to tell." Ms. Zubey also admitted on the face of her email that she felt "completely out of the loop with vacation and all of [her] kids' issues" and that she was working on "1.5 hours of sleep." (RX-023 at 0001). Thus there is no reason to believe that the document accurately reflects any relevant information.

prevent effective economic competition among extended-release opioids. (Addanki, Tr. 2329).

Response to Proposed Finding No. 1000

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. Respondent cites no facts, but rather only Dr. Addanki's conclusory statement that clinical differences between long-acting opioids "are not major." But the vast weight of the evidence proves that the differences between different long-acting opioids are clinically significant. (CCF ¶¶ 746-49; CX5006 at 009 (¶ 18) (Savage Rebuttal Report)). Both medical experts agreed that prescribers of long-acting opioids should be aware of these clinical differences between products—consistent with FDA guidelines. (CCF ¶¶ 758-59). The weight of the evidence shows that these differences mean that patients cannot easily switch between opioids. (CCF ¶¶ 658-64). This allowed Endo to set prices substantially above the competitive level. (CCF ¶¶ 864-81). And there is no evidence of significant price competition between different long-acting opioids. (CCF ¶¶ 669-716). Internal documents from Endo also prove that other long-acting opioids did not meaningfully constrain Opana ER. (CCF ¶¶ 717-40). Dr. Addanki's conclusory statement is also contrary to the undisputed fact that entry of generic oxymorphone ER had a dramatic effect on sales of Opana ER. This could not have occurred if other long-acting opioids were already providing effective economic constraints on Opana ER. (CCF ¶¶ 906-09).

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," si

customers is only one possible way to define the relevant antitrust market. (CX6054 at 015 (§ 4.1.4) (*Horizontal Merger Guidelines*)). Inability to target particular customers is not determinative. In general, the relevant product market is defined by examining the cross-elasticity of demand, or whether a "small but significant non-transitory increase in price" (SSNIP) of one product would cause a sufficient amount of sales to shift to another product such that the price increase would be unprofitable. (CCF ¶¶ 517-18, 526, 899; CX6054 at 011-15 (§§ 4.1.1-4.1.4) (*Horizontal Merger Guidelines*) (describing the hypothetical monopolist test and SSNIP analysis)). In this case, Endo made the demand for its product less elastic through product differentiation, so that it was able to charge prices substantially above a competitive level without needing to target particular patients for price discrimination. (CX4039 (Noll, Dep. at 170-72); CCF ¶¶ 721-32, 919 (Endo focused on product differentiation); CCF ¶¶ 864-81 (Endo sustained prices above a competitive level)).

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).

Response to Proposed Finding No. 1002

The Proposed Finding is misleading, incomplete, factually inaccurate, and contrary to the weight of the evidence because it relies on an improper definition of the relevant antitrust

markets. (RX-547 at 0022-23 (¶¶ 41-42) (Addanki Report) ("the methods used to analyze and assess a relevant market in prescription pharmaceuticals are different from the ones economists may use in other industries."); Addanki, Tr. 2210 (explaining that "institutional features" has "profound effect on how we analyze competition" and involves a "very different" approach than an "everyday case")). Using the properly defined product market, it is uncontested that Endo had substantial market power at all times. (CCF ¶¶ 828-42). For example, in 2010 Endo had 100% of the market for oxymorphone ER. (CCF ¶ 830). In 2011, Actavis entered the oxymorphone ER market, but only with dosage strengths that comprised 5% of Endo's oxymorphone ER revenues. (CCF ¶ 832). Endo remained the only seller of the five most profitable dosage strengths of oxymorphone ER until 2013, when Impax entered the market. (CCF ¶ 835). Even after Impax's entry, Endo retained substantial market share and at all times retained a high concentration of market power above the HHI threshold set by the *Horizontal Merger Guidelines*. (CCF ¶¶ 841-42). Both direct and indirect methods of analyzing market power were discussed at length in Professor Noll's opinions and establish that Endo possessed market power at all relevant times. (CCF ¶¶ 819-52; Noll, Tr. 1405-11 (describing the indirect method); CCF ¶¶ 853-96; Noll, Tr. 1411-18 (discussing the direct method)).

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

"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)).

Response to Proposed Finding No. 1004

The Proposed Finding is misleading, incomplete, factually inaccurate, and contrary to the weight of the evidence for the reasons set fo

1007. In 2012, Endo again estimated that it was "currently hovering around the 4% mark" of the "long acting opioid market." (RX-139.0001).

Response to Proposed Finding No. 1007

The Proposed Finding is misleading, incomplete, factually inaccurate, and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 1002.

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).

Response to Proposed Finding No. 1008

The Proposed Finding is misleading, incomplete, factually inaccurate, and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 1002.

1009. And because Endo possessed such a small share of the extended-release opioid market, Endo never possessed monopoly power. (Addanki, Tr. 2333).

Response to Proposed Finding No. 1009

The Proposed Finding is misleading, incomplete, factually inaccurate, and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 1002.

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).

Response to Proposed Finding No. 1010

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. Economic analysis shows that the inquiry Dr. Addanki suggests is inappropriate and unnecessary. A brand-name firm will not make a large and unjustified payment to a generic firm unless the agreement increases the brand-name firm's expected monopoly profits. (CX5000 at 105 (¶ 242) (Noll Report); CCF ¶¶ 1005-07). As a result, the existence of a large and unjustified payment shows that the brand-name firm expects the payment to allow it to recover monopoly

conclusion that the parties could not enter any other settlement, Dr. Addanki ignored that a large payment—in the form of the No-AG provision—was part of the settlement negotiations from the beginning. (CCF ¶¶ 227-28; CX0320 at 009-10 (E

The Proposed Finding is misleading and contrary to the weight of the evidence to the extent it suggests that Impax abandoning its patent challenge was a realistic alternative to

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing

infringement claims against Impax. (CX5004 at 066-67 (¶ 141) (Noll Rebuttal Report); CCF ¶ 1330).

Dr. Addanki and Mr. Figg have no answer to the question why Endo paid so much to settle an infringement case on worse terms than Dr. Addanki and Mr. Figg claim than Endo could have expected to achieve had they just

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).

Response to Proposed Finding No. 1018

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. The evidence shows that the outcome of Impax-Endo patent litigation was uncertain. (Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644; CCF ¶ 1270). The district court's claim construction in favor of Endo was not dispositive—even after the court's claim construction, the outcome of the '456 and '933 patent litigation remained uncertain. (Hoxie, Tr. 2693-94 (testifying that the outcome of the patent litigation could not be predicted after the claim construction); Figg, Tr. 2008). Despite having its claim construction adopted by the court, the claim construction order posed potential problems for Endo's case. (Hoxie, Tr. 2668; *see also* CCF ¶¶ 1284-1300). The evidence shows that Endo may have faced difficulty defending against Impax's invalidity case. (CCF ¶¶ 1289-1300). The evidence shows that Endo may have faced difficulty proving infringement. (*See* CCF ¶¶ 1284-1288).

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.

Response to Proposed Finding No. 1019

The Proposed Finding is misleading in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

The Proposed Finding is also factually inaccurate and contrary to the weight of the evidence in that it asserts that Complaint Counsel offered no evidence regarding who would have won the underlying patent litigation between Endo and Impax and provided no reason to find that Impax would have prevailed had it continued to litigate. The evidence shows: that the outcome of Impax-Endo patent litigation was uncertain (Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644; CCF ¶ 1270); that Endo may have had difficulties defending against Impax's invalidity claims; and that there were weaknesses in Endo's infringement claims (CCF ¶¶ 1284-1300).

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).

Response to Proposed Finding No. 1020

Complaint Counsel has no specific response.

effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1025

The Proposed Finding is misleading to the extent it implies that the claim construction hearing in the underlying patent litigation was dispositive. The evidence shows that the claim construction ruling was not dispositive in that the case continued after the ruling and the ultimate outcome remained uncertain. (Hoxie, Tr. 2693-94 (testifying that the outcome of the patent litigation could not be predicted after the claim construction); Figg, Tr. 2008).

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1026

The Proposed Finding is misleading to the extent it implies that the claim construction

construction ruling was not dispositive in that the case continued after the ruling and the ultimate outcome still remained uncertain. (Hoxie, Tr. 2693-94 (testifying that the outcome of the patent litigation could not be predicted after the claim construction); Figg, Tr. 2008). Indeed, the claim construction order posed potential problems for Endo's case. (Hoxie, Tr. 2668). The evidence shows that Endo may have faced difficulty defe

Hoxie testified that the district court's adoption of Endo's constr

The Proposed Finding is not supported by reliable evidence. Mr. Figg's opinions regarding what a reasonable litigant in Impax's position would have believed or done do not rest on a reliable or valid methodology. (*See* CCF ¶¶ 1370-74). Mr. Figg did not talk to anyone at Impax about the merits of the patent case between Endo and Impax. (Figg, Tr. 1992-93). Nor did Mr. Figg talk to Impax's outside counsel that represented Impax in the underlying patent case. (Figg, Tr. 1993). He did not consider or have access to the privileged materials or communications of Endo or Impax when he was forming his opinions. (Figg, Tr. 1994). Mr. Figg did not review the discovery record in the patent case between Impax and Endo that settled in June 2010. (CCF ¶ 1372). Respondent has offered no evidence of what Impax's actual views of the effect of the claim construction order were. The Proposed Finding is also inaccurate because the claim construction order posed potential problems for Endo's case. (Hoxie, Tr. 2668). The evidence shows that Endo may have faced difficulty defending against Impax's invalidity case. (CCF ¶¶ 1289-1300). The evidence shows that Endo may have faced difficulty proving infringement. (*See* CCF ¶¶ 1284-1288).

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder sh

The Proposed Finding is not supported by reliable evidence, inaccurate, and misleading for the reasons set forth in response to Proposed Finding No. 1033.

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).

Response to Proposed Finding No. 1035

Complaint Counsel objects to the phrase "more difficult" as vague. Complaint Counsel does not dispute the existence of the requirement that ANDA products be therapeutically equivalent to the NDA product and that this requirement may have an effect on how ANDA filers design their products to avoid the relevant patents. The Proposed Finding, however, does not explain to what it is comparing when it states that the therapeutic equivalence requirement makes the process of designing products in ways to avoid the relevant patents "more difficult."

The Proposed Finding is misleading to the extent that it equates therapeutic equivalence with patent infringement. Establishing therapeutic equivalence and establishing patent infringement are based on different legal standards for different purposes. (Hoxie, Tr. 2842-43). The Proposed Finding is also inaccurate to the extent that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Id*. at 2236.

1037. Brand companies must prove a patent is infringed by a "preponderance of the evidence." (Figg, Tr. 1851; Hoxie, Tr. 2831).

Response to Proposed Finding No. 1037

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 1038

The Proposed Finding is not supported by reliable evidence. Mr. Figg's opinions do not rest on a reliable or valid methodology. (*See* CCF ¶¶ 1370-1374). Mr. Figg did not talk to anyone at Impax about the merits of the patent case between Endo and Impax. (Figg, Tr. 1992-93). Nor did Mr. Figg talk to Impax's outside counsel that represented Impax in the underlying patent case. (Figg, Tr. 1993). He did not consider or have access to the privileged materials or communications of Endo or Impax when he was forming his opinions. (Figg, Tr. 1994). Mr. Figg did not review the discovery record in the patent case between Impax and Endo that settled in

Response to Proposed Finding No. 1039

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. The evidence indicates that the outcome of Impax-Endo patent litigation was uncertain. (Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644; *see also* CCF ¶ 1270). Despite having its claim construction adopted by the court, the claim construction order posed potential problems for Endo's case. (Hoxie, Tr. 2668; CCF ¶¶ 1284-1300). The evidence shows that Endo may have faced difficulty proving infringement. (CCF ¶¶ 1284-1288).

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1041

The Proposed Finding is misleading in that it implies that Impax was required to perform testing to meet the functional definition of "hydrophobic material." It was not Impax's burden to conduct the testing. Impax, rather, could rely on the results of Endo's testing, which showed that "MCC didn't perform the function that it was supposed to perform" to meet the functional definition adopted by the district court. (Hoxie, Tr. 2839).

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

for Endo's case. (Hoxie, Tr. 2668; *see* CCF ¶¶ 1284-1300). The evidence shows that Endo may have faced difficulty proving infringement. (*See* CCF ¶¶ 1284-1288).

The Proposed Finding is misleading in that it implies that Impax was required to perform testing to meet the functional definition of "hydrophobic material." It was not Impax's burden to conduct the testing. Impax, rather, could rely on the resu

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).

Response to Proposed Finding No. 1047

The Proposed Finding is misleading to the extent that it equates bioequivalence with patent infringement. Establishing bioequivalence and establishing patent infringement are based on different legal standards for different purposes. (Hoxie, Tr. 2842-43). Therapeutic equivalence relates to equivalence to the reference listed drug, while patent infringement relates to meeting each and every limitation of a claim of the patent. (Hoxie, Tr. 2843).

The Proposed Finding is also misleading to the extent that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agr

Response to Proposed Finding No. 1049

The Proposed Finding is misleading in that it implies that Impax was required to perform testing to meet the functional definition of "sustained release." It was not Impax's burden to establish infringement. (CX5007 at 033 (¶ 62, n.92) (Hoxie Report)).

The Proposed Finding is also misleading in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

1050. Mr. Figg testified that Endo consequently had the stronger position on "sustained release" infringement. (Figg, Tr. 1880-81).

Response to Proposed Finding No. 1050

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. The evidence indicates that the outcome of the Impax-Endo patent litigation was uncertain. (Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644; *see* CCF ¶ 1270). Despite having its claim construction adopted by the court, the claim construction order posed potential problems for Endo's case. (Hoxie, Tr. 2668; *see* CCF ¶¶ 1284-1300). The evidence shows that Endo may have faced difficulty proving infringement. (*See* CCF ¶¶ 1284-1288).

The Proposed Finding is misleading in that it implies that Impax was required to perform testing to meet the functional definition of "sustained release." It was not Impax's burden to establish infringement. (CX5007 at 033 (¶ 62, n.92) (Hoxie Report)).

The Proposed Finding is also misleading in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder sh

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The Proposed Finding is also misleading in that it suggests that the outcome of the underlying patent litigation is determinative of

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 1057

The Proposed Finding is misleading and incomplete. Endo's infringement argument that MCC served as the hydrophobic material in Impax's product opened the door to a number of prior art references that could have invalidated the relevant patents. MCC is a very commonly used excipient, and is present in many drug formulations and patents. By opening the door to more prior art, Endo was faced with the added difficulty of having to distinguish its patents over even more prior art references to avoid invalidation. (CCF ¶¶ 1292-93).

The Proposed Finding is also misleading in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged ag

having its claim construction adopted by the court, the claim construction order posed potential problems for Endo's case. (Hoxie, Tr. 2668; CCF ¶¶ 1284-1300). In particular, the claim construction of "hydrophobic material" posed potential problems for Endo's ability to rebut claims of invalidity by means of anticipation. (*See* CCF ¶¶ 1291-1293). Endo's arguments that MCC served as the hydrophobic material in Impax's product opened the door to a number of prior art references that could have invalidated the '933 and '456 patents because MCC is a very commonly used excipient, and is present in many drug formulations and patents. (Hoxie, Tr. 2679-80; CX5007 at 035-36 (¶¶ 66-67) (Hoxie Report)). There is a significant amount of literature, patents, and other information that could serve as prior art regarding its use. A patent can be invalidated by as little as one prior art reference. (Hoxie, Tr. 2681). By opening the door to more prior art, Endo was faced with the added difficulty of having to distinguish over even more prior art references to avoid invalidation of the '933 and '456 patents. (Hoxie, Tr. 2681).

To distinguish the claims of the patents over the numerous prior art references disclosing MCC, Endo argued that in the prior art, there was no experimental evidence to prove that MCC was hydrophobic. (RX-261 at 0027 (Endo's trial brief, in the *Endo v. Impax* patent litigation) (admitted for the fact of the assertion, not for truth of the matter asserted); Hoxie, Tr. 2679-80; CX5007 at 036-37 (¶ 68) (Hoxie Report)). This argument created inconsistencies in Endo's case. Thus, for purposes of assessing validity, Endo argued that the prior art did not show that MCC was hydrophobic. But for purposes of proving infringement, Endo insisted that that the MCC in Impax's product was hydrophobic without firm proof. (Hoxie, Tr. 2679-81; CX5007 at 036-37 (¶¶ 67-68) (Hoxie Report)).

The Proposed Finding is also misleading in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is

anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1059

The Proposed Finding is factually inaccurate and unsupported by the evidence cited. A prior art reference for purposes of patent validity need not be an existing patent, but can be any publicly available source of information. Mr. Figg never suggested that prior art was limited to existing patents. (Figg, Tr. 1897 ("Obviousness is . . . if a claimed invention is something that . . . would have been obvious over what the public already had . . .")).

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)).

Response to Proposed Finding No. 1060

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 1061

Complaint Counsel has no specific response.

On the basis of these arguments, Mr. Figg

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. The evidence indicates that the outcome of the Impax-Endo patent litigation was uncertain. (Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644; *see also* CCF ¶ 1270). Despite having its claim construction adopted by the court, the claim construction order posed potential problems for Endo's case. (Hoxie, Tr. 2668; CCF ¶¶ 1284-1300). In particular, the claim construction of "hydrophobic material" posed potential problems for Endo's ability to rebut claims of invalidity on the basis of obviousness. (*See* CCF ¶¶ 1295-1298).

To overcome Impax's obviousness claims, Endo argued that secondary indicia of nonobviousness (also known as "secondary considerations") supported the non-obviousness of the claimed formulations. (Hoxie, Tr. 2683-84; Figg, Tr. 1899; RX-548 at 0023 (¶ 51) (Figg Report); CX5007 at 037 (¶ 69) (Hoxie Report)). In particular, Endo relied on secondary considerations that included commercial success of the invention and findings that the invention satisfied a long-felt but unmet need. (Hoxie, Tr. 2683-84; Figg, Tr. 1899; RX-548 at 0023 (¶ 51) (Figg Report); CX5007 at 037 (¶ 69) (Hoxie Report)).

For secondary considerations to be relevant there needs to be a nexus between proven success of the product and the patented invention. But the patents do not mention oxymorphone, the active ingredient of Opana ER, and the patents do not address any special problems or long-felt, unmet needs with regard to the administration of oxymorphone. (Hoxie, Tr. 2684; CX5007 at 037-39 (¶¶ 70-71) (Hoxie Report)). The examples in the patent are directed to formulations of albuterol, a bronchodilator, which is chemically and therapeutically unrelated to oxymorphone, the active ingredient of Opana ER. (Hoxie, Tr. 2684-86; CX5007 at 038-39 (¶ 71) (Hoxie Report)).

As a result, Endo may have encountered problems trying to “successfully rely on secondary considerations or objective indicia of non-obviousness ba

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 1064

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 1065

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 1066

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. The evidence indicates that the outcome of the Impax-Endo patent litigation was uncertain. (Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644; *see also* CCF ¶ 1270). In particular, Endo may have faced difficulty in defending against Impax's invalidity case on the basis of lack of written description. (*See* CCF ¶¶ 1299-1300). Impax asserted that the '933 patent only disclose a single study regarding the use of albuterol in the formulation. (RX-260 at 0036-38 (Impax's pre-trial brief, in the *Endo v. Impax* patent litigation) (admitted for the fact of the assertion, not for truth of the matter asserted); CX5007 at 040 (¶ 75) (Hoxie Report); Hoxie, Tr. 2688-89; *see also* CX5007 at 28 (¶¶ 53 n.65 and 54 n.66) (Hoxie Report) (the '456 and the '933 patents were titled

Because the pharmacokinetics of active ingredients depends on many properties, there is no guarantee that non-albuterol active ingredients, including oxymorphone, would work in the same way. (CX5007 at 040-41 (¶ 75) (Hoxie Report); Hoxie, Tr. 2688-89).

The Proposed Finding is also misleading in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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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).

Response to Proposed Finding No. 1067

Complaint Counsel objects to the Proposed Finding as misleading, vague, and confusing. The District Court could only issue a permanent injunction if it found that one of the patent claims at issue was infringed *and* not invalid.

The Proposed Finding is also misleading in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

1068. But Endo was more likely than not to prevail on every claim. (Figg, Tr. 1884, 1904).

Response to Proposed Finding No. 1068

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. The evidence indicates that the outcome of the Impax-Endo patent litigation was uncertain. (Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644; *see also* CCF ¶ 1270). Despite having its claim construction adopted by the court, the claim construction order posed potential problems for Endo's case. (Hoxie, Tr. 2668; *see also* CCF ¶¶ 1284-1300). The evidence shows that Endo may have faced difficulty proving infringement and defending against Impax's invalidity claims. (*See* Complaint Counsel's Response to Proposed Finding Nos. 1039-1067; *see also* CCF ¶¶ 1284-1300).

The Proposed Finding is also misleading in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1069

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. The evidence indicates that the outcome of Impax-Endo patent litigation was uncertain. (Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644; *see also* CCF ¶ 1270). Despite having its claim

construction adopted by the court, the claim construction order posed potential problems for Endo's case. (Hoxie, Tr. 2668; *see also* CCF ¶¶ 1284-1300). The evidence shows that Endo may have faced difficulty proving infringement and defending against Impax's invalidity claims. (*See* Complaint Counsel's Response to Proposed Finding Nos. 1039-1067; *see also* CCF ¶¶ 1284-1300).

The Proposed Finding is also not supported by reliable evidence. Mr. Figg's opinions regarding what a reasonable litigant in Impax's position would have believed or done do not rest on a reliable or valid methodology. (*See* CCF ¶¶ 1370-74). Mr. Figg did not talk to anyone at Impax about the merits of the patent case between Endo and Impax. (Figg, Tr. 1992-93). Nor did Mr. Figg talk to Impax's outside counsel that represented Impax in the underlying patent case. (Figg, Tr. 1993). He did not consider or have access to the privileged materials or communications of Endo or Impax when he was forming his opinions. (Figg, Tr. 1994). Mr. Figg did not review the discovery record in the patent case between Impax and Endo that settled in June 2010. (Figg, Tr. 1991-92). Respondent has offered no evidence of Impax's actual views of the patent litigation merits. Further, Mr. Figg's opinions regarding the timing of the patent litigation and any appeals had Impax not settled are not reliable. (*See* CCF ¶¶ 1375-78). And Mr. Figg has no opinions about whether Endo paid Impax to accept the January 2013 entry date (Figg, Tr. 1998), and no opinion about the reasonableness of any other potential entry on which Endo and Impax could have agreed. (Figg, Tr. 2006).

The Proposed Finding is also misleading in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing

the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1070

The Proposed Finding is factually inaccurate, contrary to the weight of the evidence, not supported by reliable evidence, and misleading for the reasons set forth in response to Proposed Finding No. 1069. Mr. Figg did not offer an opinion about the reasonableness of any other potential entry dates. (Figg, Tr. 2006). **{**

} (CCF ¶ 1359 (*in camera*)).

d. All Other ANDA Filers Settled Similar Litigation

As discussed above, Endo also sued Acta

knowledge regarding the size, sophistication, and patent litigation experience of each of these pharmaceutical companies.

1073. Yet each ANDA filer settled its suit against Impax. (Snowden, Tr. 440; RX-441; RX-442; RX-443; CX3192).

Response to Proposed Finding No. 1073

The Proposed Finding is factually inaccurate. There is no evidence that Impax settled any lawsuits alleging infringement of the ’456 and ’933 patents with Actavis, Barr, Sandoz, Watson Labs, and Roxane Labs.

Assuming that Respondent is referring to settlements between Endo and the other ANDA filers, the Proposed Finding is misleading to the extent it implies that each company’s decision to settle its lawsuit with Endo is evidence that Impax’s decision to settle its lawsuit with Endo was “reasonable” or “prudent.” The other ANDA filers were positioned differently than Impax, and as a result had different considerations and motivations to take into account in deciding whether to settle. (Hoxie, Tr. 2857-58 (“[I]t's not a great result to clear the pathway for Impax, let Impax take all the profits, and then you come in 180 days later with five other generics, so the market opportunity for them was not -- was not great. So they didn't have the same motivation that

Impax and that introduction of a payment to Impax resulted in a settlement with a later entry date. (CCF ¶ 1455).

The Proposed Finding is also inaccurate in that it suggests that the reasonableness of Impax's decision to enter into the SLA and the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1074

The Proposed Finding is factually inaccurate for the reasons set forth in response to Proposed Finding No. 1073.

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).

Response to Proposed Finding No. 1075

The Proposed Finding is misleading and not supported by the weight of the evidence in that it states that if Impax and Endo had continued with the underlying patent litigation, it would not have concluded until 2013. Both Endo – prior to entering into the SLA – and Impax's patent

expert, Mr. Figg, estimated that the Federal Circuit could have ruled on an appeal in the patent litigation by November 2011 or even earlier (CX2576 at 001 (Feb. 2010 internal Endo e-mail) ("If [Impax] wait[s] for the appeal to play out, it will likely happen around June of next year."); Figg, Tr. 2033-34, 2044-45; CCF ¶ 371). Mr. Figg's opinions suggesting that the patent litigation and any appeals could have stretched into 20

2029-30). Mr. Figg has never litigated a Hatch-Waxman case through trial to judgment in the District of New Jersey. (Figg, Tr. 2031-32).

Mr. Figg also concedes that it is possible that the judge presiding over the Impax-Endo patent litigation could have ruled from the bench at the end of trial in mid-June 2010 (Figg, Tr. 2030), or issued an opinion in less than the estimated four to five months. (Figg, Tr. 1906-07; *see also* Hoxie, Tr. 2860).

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

1077. But as Mr. Hoxie explained, judges can take "their own sweet time" in releasing opinions in patent infringement cases. (Hoxie, Tr. 2860).

Response to Proposed Finding No. 1077

The Proposed Finding is misleading and incomplete. In the cited testimony, Mr. Hoxie testified that while district court judges can take time releasing opinions in patent infringement

anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1078

The Proposed Finding is misleading to the extent it implies that because it took a different judge nearly twelve months to issue an opinion in another case, that it would have taken a similar amount of time for the judge in the underlying patent litigation between Impax and Endo to issue an opinion. As Mr. Hoxie explained: "So it depends a lot on the case and it depends a lot on the judge, and I don't know that you can extrapolate from a case involving different patents, different parties and a different judge in a different court to draw conclusions about what would have happened or could have happened in this case." (Hoxie, Tr. 2870-71).

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1079

The Proposed Finding is inaccurate in that it

relevant question is whether the patent holder shared its monopoly profits to avoid the risk of

relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

1082. Indeed, the Federal Circuit is generous with briefing extensions, which increases the time it takes to receive a decision. (Figg, Tr. 1909-10).

Response to Proposed Finding No. 1082

The Proposed Finding is misleading insofar as it suggests that because the Federal Circuit may be generous with briefing extensions, that would have increased the time it would take the Federal Circuit to issue an opinion beyond November 2011. Mr. Figg explained that his November 2011 opinion is based "primarily on statistics that the Federal Circuit itself keeps." (Figg, Tr. 1908-09). Those statistics would necessarily incorporate any briefing extensions.

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1083

The Proposed Finding is incomplete. It is also possible that the Federal Circuit would have issued an opinion before November 2011, as Endo had estimated in contemporaneous documents. (CX2576 at 001 (Feb. 2010 internal Endo e-mail) ("If [Impax] wait[s] for the appeal to play out, it will likely happen around June of next year.")). Mr. Figg also testified that he could not exclude the possibility that the Federal Circuit decision could have been sooner than

the fourth quarter of 2011. (Figg, Tr. 2034). The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

1084. But the earliest Impax could theoretically have launched free from risk would have been some point in November 2011. (Figg, Tr. 1911).

Response to Proposed Finding No. 1084

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. Impax's patent expert, Mr. Figg, cannot exclude the possibility that the Federal Circuit decision could have been sooner than the fourth quarter of 2011. (Figg, Tr. 2034;

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).

Response to Proposed Finding No. 1085

The Proposed Finding is inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1086

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. In the event that Impax lost at the district court level, appealed, and prevailed on appeal, in the worst case scenario, the Federal Circuit may have remanded the case to the trial court for a full trial. (CX5007 at 044 (¶ 81) (Hoxie Report); Hoxie, Tr. 2700-01). But there is no basis for expecting that this worst case scenario would come to fruition. Remand is more likely when a case goes up on a narrow issue and the record is not fully developed or in a jury trial, where the factual findings and basis for the decision are not explicit. In a case like this, after a full bench trial, with detailed findings of fact and conclusions of law addressing validity and infringement, a remand would be unlikely because the appellate court should have all the information and would most likely be in a position to decide all the issues. (CX5007 at 044 (¶ 81) (Hoxie Report)).

Mr. Figg's opinion that a win for Impax in its hypothetical appeal of the district court decision would have likely resulted in a remand rather than a reversal is not reliable. He did not conduct any analysis in his report of the rate at which the Federal Circuit reverses claim construction proceedings and then remands the case. (Figg, Tr. 2035). For this opinion, Mr. Figg relied on the fact that a colleague at his law firm could not find a case in which the Federal Circuit reversed a claim construction decision and proceeded to decide the issues without a remand. (Figg, Tr. 2035-37). But there are examples of cases in which the Federal Circuit reversed a claim construction ruling and ordered entry of judgment without a remand for further proceedings. (Figg, Tr. 2037-42). Mr. Figg concedes that if there had been no remand, then there could have been a final decision in the patent litigation between Impax and Endo by November 2011. (Figg, Tr. 2044-45).

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1087

The Proposed Finding is inaccurate and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 1086.

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).

Response to Proposed Finding No. 1088

The Proposed Finding is inaccurate and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 1086.

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).

Response to Proposed Finding No. 1089

The Proposed Finding is inaccurate and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding Nos. 1075 and 1086. The Proposed Finding is also not supported by the evidence cited. In his testimony, Mr. Figg merely suggests that, even if Impax prevailed, it would not have been able to launch until "close" to January 2013. (Figg, Tr. 1973). He does not opine that, under such circumstances, Impax would not have launched "until after" January 1, 2013. (Figg, Tr. 1973).

The Proposed Finding is also not supported by reliable evidence. Mr. Figg acknowledges that "much of what [he's] opining about was fraught with uncertainty" and assessing the timing of litigation decisions involves an amount of unpredictability. (CX4045 (Figg, Dep. at 115, 222)). As such, Mr. Figg opined that a wide variety of litigation timelines would have been "reasonable" for Impax to expect for the remand proceedings, including an assumption that the proceedings would take as few as 6 months. (RX-548 at 0038-39 (¶¶ 83-84) (Figg Report); *see also 1089*

Federal Circuit remanded, it could have prevailed in the underlying litigation by May 2012. (RX-548 at 0038-39 (¶¶ 83-84) (Figg Report)).

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).

Response to Proposed Finding No. 1090

The Proposed Finding is inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*

did not review the discovery record in the patent case between Impax and Endo that settled in June 2010. (Figg, Tr. 1991-92). Respondent has offered no evidence of Impax's actual views of the patent litigation merits. Further, Mr. Figg's opinions regarding the timing of the patent litigation and any appeals had Impax not settled are not reliable. (*See* CCF ¶¶ 1375-78). And Mr. Figg has no opinions about whether Endo paid Impax to accept the January 2013 entry date (Figg, Tr. 1998), and no opinion about the reasonableness of any other potential entry date on which Endo and Impax could have agreed (Figg, Tr. 2006).

Second, the Proposed Finding makes no sense. If it were true that Impax could not have entered prior to January 2013, then it means that "Endo made a charitable contribution to Impax by paying Impax over $100 million AND allowing Impax to enter earlier than otherwise would have been likely." (CX5004 at 059-60 (¶ 125) (Noll Report); Noll, Tr. 1487-88; CCF ¶ 1310). It is also inconsistent with the facts. (CCF ¶¶ 1311-27). Mr. Figg does not explain why, if the settlement accelerated entry of generic oxymorphone ER, Endo paid so much to reach an agreement that reduced the duration of the period in which they could have profited from a continued patent monopoly. Nor does Mr. Figg address why Endo agreed to such a bad deal when it could have achieved a better outcome by spending a few million dollars more on litigating patent infringement claims against Impax. (CX5004 at 066-67 (¶ 141) (Noll Rebuttal Report); CCF ¶ 1330).

Quite simply, Mr. Figg has no answer to the question of why Endo paid so much to settle an infringement case on worse terms than Mr. Figg claims that Endo could have expected to achieve had they just continued to litigate the infringement case to conclusion. The answer is that the only plausible explanation for why Endo entered into a reverse-payment settlement that cost Endo over $100 million dollars is that the agreement enabled Endo to eliminate the possibility of

2234-37. Instead, the relevant question is whether Endo shared its monopoly profits with Impax to avoid the risk of competition. *Actavis,* 133 S. Ct at 2236.

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).

Response to Proposed Finding No. 1093

The Proposed Finding is misleading insofar as it suggests that Endo's acquisition of patents subsequent to entering into the Impax-Endo Settlement Agreement is determinative of whether such an agreement is anticompetitive unde

There are also various scenarios in which Endo could have been unable or unwilling to assert additional patents if Impax had won the underlying patent litigation. (CCF ¶¶ 1027, 1396).

The Proposed Finding is also misleading and incomplete insofar as it suggests that Endo's acquisition of patents subsequent to the Impax-Endo Settlement Agreement would have enjoined Impax from selling generic oxymorphone ER before January 2013. Undisputed evidence shows that it was possible that the underlying patent litigation between Endo and Impax would be resolved as early as the second half of 2011. (CCF ¶ 1026). Even Impax's experts agree that Impax could have launched free and clear of any patent risk in the second half of 2011, well before January of 2013. (CCF ¶ 1026). Since Impax would have made a "substantial portion" – perhaps even most – of its money during its initial six-month exclusivity period (Koch, Tr. 232-33), it could have withdrawn its product when these patents issued and faced no liability for damages. (Hoxie, Tr. 2707 ("[W]hat would have made sense for Impax would have been to launch before the new patents issued . . . if problems arose, then get off when problems arose, because they can't be sued for patent infringement before the patents issue.")).

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).

Response to Proposed Finding No. 1094

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1093.

The Proposed Finding is also misleading and incomplete insofar as it suggests that Impax definitively would not have launched generic oxymorphone ER at-risk. Impax's CEO, Dr. Hsu, was "absolutely" considering an at-risk oxymorphone ER launch in 2010. (CX4014 (Hsu, IHT at

130)). In fact, Impax wanted to launch its generic oxymorphone ER "as early as possible" to ensure that it would enjoy its first-filer exclusivity. (CCF ¶¶ 121-26). Impax was aware that delaying a launch beyond June 2010 could mean lost or delayed sales for oxymorphone ER. (CX0505 at 001 (May 14, 2010 Impax email chain) ("the cost of Jan '11 is lost/delayed sales—you know what they [s]ay about a bird in the hand. . . ")). There is no evidence to suggest that Endo's subsequent patent acquisitions would have altered Impax's financial incentives to maximize the value of its first-filer exclusivity.

The Proposed Finding is not supported by any reliable evidence to the extent it suggests that, in a world without the settlement, Endo would have acquired the Johnson Matthey patent earlier than it did in March 2012. The only support for this statement is Dr. Addanki's testimony, which is based on pure speculation. Moreover, because the Johnson Matthey patent was not owned by Endo at the time of the Impax-Endo Settlement Agreement, the patent could have later been acquired by Impax, Endo, or some third party. (*See* Hoxie, Tr. 2882; CCF ¶ 1027). Finally, the Johnson Matthey patent was partially invalidated in 2013 following interference proceedings with the '779 patent, owned by Mallinckrodt. (Snowden, Tr. 444). As such, it is unclear if the patent would or could have prevented Impax from launching generic oxymorphone ER. (*See* Figg, Tr. 1949-50 (the interference "resulted in the cancellation of the claims of the '482 patent")).

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).

Response to Proposed Finding No. 1095

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 1092.

The Proposed Finding is also misleading insofar as it suggests that the reverse payment was necessary for Impax to receive a license to patents that had not yet issued. It was not. This license was requested by, and had value for Impax. It would make no sense that the reverse payment was necessary to induce Impax to accept the license that it wanted and would benefit from. (CCF ¶¶ 1457-59).

The Proposed Finding is also incomplete. The license Impax received did not ensure freedom to operate. Instead, it left Impax exposed to considerable risk, uncertainty, and expense. (CCF ¶¶ 1415-30). In fact, on May 4, 2016, Endo filed a suit against Impax in New Jersey, alleging that Impax was in breach of the SLA with respect to three new patents – the ’122, the ’216 and the ’737 patents – all pending applications at the time Endo and Impax entered into the SLA. (CX2976 at 001, 009 (*Endo v. Impax*, complaint) (admitted for the fact the complaint was filed, not truth of the matter asserted)). On October 31, 2016, Endo provided Impax notice of termination of the SLA due to what Endo characterized as Impax’s material breach of the agreement. (CX2944 at 002 (Oct. 31, 2016 email chain attaching letter from Endo to Impax re: notice of termination of the license agreement)). Endo requested that Impax immediately cease sales of what it characterized as Impax’s infringing generic Opana ER product. (CX2944 at 003 (notifying Impax that “there is no legitimate dispute that Impax’s current Opana ER generic tablets infringe Endo’s patents” and demanding that “Impax should therefore honor Endo’s patent rights and immediately cease all sales of those infringing tablets”)).

The Proposed Finding is also incomplete because the U.S. District Court for the Southern District of New York's ruling is currently on appeal to the Federal Circuit. (JX-001 at 013 (¶ 62); Snowden, Tr. 493).

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)).

Response to Proposed Finding No. 1096

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1092 and 1095.

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).

Response to Proposed Finding No. 1097

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1092.

The Proposed Finding is also incomplete because there is no evidence that sellers of the subsequent patents would obtain the greatest value by selling exclusively to Endo. (CCF ¶ 1027). In fact, because the patent was not owned by Endo at the time of the Impax-Endo Settlement Agreement, the patent could have later been acquired by Impax, Endo, or some third party. (*See* Hoxie, Tr. 2882). Additionally, it is possible that the patent holder would obtain greater value by licensing the patents to both Endo and Impax, rather than to Endo alone. (CCF ¶ 1027). Moreover, if Endo was confident that it could keep Impax off the market with after-acquired patents, it would have had no reason to pay Impax $112 million under the Impax-Endo Settlement Agreement. (Noll, Tr. 1487-88).

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).

Response to Proposed Finding No. 1098

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1092 and 1097.

The Proposed Finding is also not supported by the evidence cited. Mr. Figg does not testify about any defendants’ stipulation in the ‘779 patent litigation. (Figg, Tr. 1965). Mr. Figg merely states that infringement “was not an issue” in the litigation and the Defendants, instead, argued that the patents were invalid. (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).

Response to Proposed Finding No. 1099

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1092 and 1097.

The Proposed Finding is also not supported by the evidence cited. Neither Ms. Snowden nor Mr. Figg offer an opinion on how the appeal regarding the ’779 patent will turn out. (Snowden, Tr. 451, 493; Figg, Tr. 1965-66, 2050). Like all on-going litigations, the outcome of this appellate litigation is uncertain. (*See* Hoxie, Tr. 2665).

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).

Response to Proposed Finding No. 1100

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1092, 1095, and 1097.

The Proposed Finding is also misleading and incomplete insofar as it suggests that Impax definitively would not have launched generic oxymorphone ER at-risk. Impax's CEO, Dr. Hsu, was "absolutely" considering an at-risk oxymorphone ER launch in 2010. (CX4014 (Hsu, IHT at 130)). In fact, Impax wanted to launch its generic oxymorphone ER "as early as possible" to ensure that it would enjoy its first-filer exclusivity. (CX4030 (Hsu, Dep. at 28); CCF ¶¶ 121-26). Impax was aware that delaying a launch beyond June 2010 could mean lost or delayed sales for oxymorphone ER. (CX0505 at 001 (May 14, 2010 email) ("the cost of Jan '11 is lost/delayed sales—you know what they [s]ay about a bird in the hand. . . .")). There is no evidence to suggest that Endo's subsequent patent acquisitions would have altered Impax's financial incentives to maximize the value of its first-filer exclusivity.

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).

Response to Proposed Finding No. 1101

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1092, 1095, 1097 and 1100.

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).

Response to Proposed Finding No. 1102

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1092, 1095, 1097 and 1100.

The Proposed Finding is also misleading and incomplete as Mr. Figg did not offer an opinion on how the appeals for the patent litigations will turn out. (Figg, Tr. 1965-66, 2050).

Like all on-going litigations, the outcome of this appellate litigation is uncertain. (*See* Hoxie,6m5g.

The Proposed Finding is also misleading and incomplete. Impax's expert, Mr. Figg, does not offer any opinions as to whether, in 2010, Endo's patents were valid or invalid. (Figg, Tr. 1995). Mr. Figg also does not offer any opinion on whether Impax was going to win or lose the patent case with Endo. (CX4045 (Figg, Dep. at 147)).

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).

Response to Proposed Finding No. 1108

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding No. 1106.

The Proposed Finding is also misleading and incomplete. Impax's expert, Mr. Figg, uses terms like "likely" and "more likely than not" in his expert report, but he does not assign any probability percentage to those words and did not have a specific percentage of probability in mind. (Figg, Tr. 2011-12).

1109. Nor did Mr. Hoxie opine that Impax would have won the patent litigation against Endo. (Hoxie, Tr. 2693).

Response to Proposed Finding No. 1109

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding Nos. 1106 and 1108.

1110. Mr. Hoxie does not offer an opinion regarding which party would have prevailed on issues of infringement. (Hoxie, Tr. 2841).

Response to Proposed Finding No. 1110

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding Nos. 1106 and 1108.

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).

Response to Proposed Finding No. 1111

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding Nos. 1106 and 1108.

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).

Response to Proposed Finding No. 1112

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding Nos. 1106 and 1108. In addition, Mr. Hoxie opined that the claim construction order raised issues for Endo's defense against Impax's invalidity case on the basis of obviousness. (CCF ¶¶ 1295-1298). Mr. Hoxie also opined that Endo may have faced difficulty in defending against Impax's invalidity case on the basis of lack of written description. (CCF ¶ 1300).

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).

Response to Proposed Finding No. 1113

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding No. 1106.

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).

Response to Proposed Finding No. 1114

The Proposed Finding is misleading and incomplete. At all times, Endo had the burden to prove infringement by a preponderance of the evidence. (CX5007 at 029, 033 (¶¶ 59, 62) (Hoxie Report)). If Endo was unable to prove infringement, then the Court could not issue an injunction.

The Proposed Finding is also misleading in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is

anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1115

The Proposed Finding is misleading and incomplete. Mr. Hoxie agrees that each of the individual steps in Mr. Figg's patent litigation timing is a reasonable estimate. But Mr. Hoxie opined that Mr. Figg's assessment is a worst case scenario, and disputes that each of those steps would be required. (Hoxie, Tr. 2860-61; CX 5007 at 42 (¶ 81) (Hoxie Report)). In particular, Mr. Hoxie questions Mr. Figg's assumption that, even if

anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1116

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding No. 1115.

The Proposed Finding is also incomplete because Mr. Figg testified that he could not exclude the possibility that receiving a decision from the Federal Circuit could also take less than one year, and thus could have been obtained in the Impax-Endo patent litigation sooner than the fourth quarter of 2011. (Figg, Tr. 2034).

1117. Mr. Hoxie also agreed that district court opinions can take even longer than the estimates advanced by Mr. Figg. (Hoxie, Tr. 2868).

Response to Proposed Finding No. 1117

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding No. 1115. The Proposed Finding is also incomplete because Mr. Figg concedes that the judge presiding over the Impax-Endo patent litigation could have ruled from the bench at the end of the trial in mid-June. (Figg, Tr. 2030).

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).

Response to Proposed Finding No. 1118

The Proposed Finding is misleading for the reasons stated in response to Proposed Finding Nos. 1115, 1116, and 1117.

The Proposed Finding is also factually inaccurate and contrary to the weight of the evidence. Mr. Hoxie testified that there are "lots of issues that could… influence the timing for [a patent litigation] decision positively or negatively," all of which were not addressed by Mr. Figg's timing estimates. (CX4043 (Hoxie, Dep. at 176); CCF ¶ 1375). Thus, Mr. Hoxie does not agree with Mr. Figg's timing assumption that the patent litigation would hold up a launch until, potentially, mid-2013. (Hoxie, Tr. 2863; *see also* CCF ¶¶ 1375-78).

1119. Mr. Hoxie admitted, however, that a remand "was a possibility." (Hoxie, Tr. 2864). Mr.

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).

Response to Proposed Finding No. 1122

The Proposed Finding is misleading and not relevant to the question of Mr. Hoxie's qualifications as a patent litigation expert for the reasons set forth in response to Proposed Finding No. 1121.

1123. Mr. Hoxie has never argued in a claim construction hearing. (Hoxie, Tr. 2744).

Response to Proposed Finding No. 1123

The Proposed Finding is misleading and not relevant to the question of Mr. Hoxie's qualifications as a patent litigation expert for the reasons set forth in response to Proposed Finding No. 1121. The Proposed finding is also incorrect. Mr. Hoxie testified that he argued a technical issue in a Markman hearing during a case related to a Novartis seeds litigation. (Hoxie, Tr. 2744, 2641).

1124. Mr. Hoxie has only been involved with a single at-risk launch in any capacity. (Hoxie, Tr. 2761-63).

Response to Proposed Finding No. 1124

The Proposed Finding is factually inaccurate. Mr. Hoxie spent about 13 years with the Novartis Group, a large multinational brand company, ultimately as Head of Global IP Litigation/Head of Patents, Global Pharma Markets. (CCF ¶ 1283). While the Novartis group has a generic business, it is primarily a branded pharmaceutical company. Mr. Hoxie testified that, while he has been involved with one at-risk launch from the generic side, he has also been involved from "the branded side where generic companies did at-risk launches." (Hoxie, Tr. 2762).

The Proposed Finding is also misleading and not relevant to the question of Mr. Hoxie's qualifications as a patent litigation expert for the reasons set forth in response to Proposed Finding No. 1121.

1125. And Mr. Hoxie has no experience litigating in front of the judge who presided over the Endo-Impax patent litigation. (Hoxie, Tr. 2871).

Response to Proposed Finding No. 1125

The Proposed Finding is misleading and not relevant to the question of Mr. Hoxie's qualifications as a patent litigation expert for the reasons set forth in response to Proposed Finding No. 1121.

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).

Response to Proposed Finding No. 1126

The Proposed Finding is misleading and incomplete insofar as it suggests that any launch prior to 2013 would have been at risk. The undisputed evidence shows that it was possible that the underlying patent litigation between Endo and Impax would be resolved as early as the second half of 2011. (CCF ¶ 1026). Even Impax's experts agree that Impax could have launched free and clear of any patent risk in the second half of 2011, well before January of 2013. (CCF ¶ 1026). Dr. Addanki's opinion that any launch before 2013 would have been at risk is unfounded speculation that Impax would have been blocked by subsequent patents Endo could obtain. (CCF ¶ 1027). There are various possible scenarios in which Endo would have been unable or unwilling to assert additional patents if Impax had won the underlying patent litigip e scenarios

litigation. (CCF ¶ 1026). The relevant patents asserted in the "second wave" litigation were not even issued until more than a year after Impax's potential free and clear launch. (RX-548 at 0049-50 (¶ 113) (Figg Report) (November 2012 for the '122 patent and December 2012 for the '216 patent); CCF ¶¶ 1395, 1397-98). Since Impax would have made a "substantial portion" – perhaps even most – of its money during its initial six month exclusivity period (Koch, Tr. 232-33), it could have withdrawn its product when these patents issued and faced no liability for damages. (Hoxie, Tr. 2707 ("[W]hat would have made sense for Impax would have been to launch before the new patents issued . . . if problems arose, then get off when problems arose, because they can't be sued for patent infringement before the patents issue.")).

The Proposed Finding is also misleading and incomplete insofar as it suggests that an alternative settlement with an earlier entry date was impossible. The evidence shows that Impax stopped negotiating for an earlier entry date once Endo agreed to pay the Endo Credit, which indicates that an alternative settlement with an earlier date and without a payment was a possibility. (CCF ¶¶ 1016, 1437-55).

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.

Response to Proposed Finding No. 1127

The Proposed Finding is unsupported by any evidence, factually inaccurate, and contrary to the weight of the evidence. Substantial evidence proves that Impax had financial incentives to launch oxymorphone ER as soon as possible (CCF ¶¶ 121-26), and Impax took many concrete steps to launch oxymorphone ER leading up to the settlement in June of 2010 (CCF ¶¶ 127-213). Impax (1) included a 2010 launch of oxymorphone ER as one of its "Company Key Goals" (CCF ¶¶ 127-30), (2) actively considered an at-risk launch (CCF ¶¶ 131-47), (3) continually projected oxymorphone ER entry dates as early as June 2010 (CCF ¶¶ 148-67), and (4) took additional

An at-risk launch is a "very serious risk." (Koch, Tr. 286-87; *see*

Impax also had a strong incentive to launch at risk because it believed doing so could give it a "head start" on the market before Endo could "get geared up and launch" an AG. (CX2920 at 001 (email discussing Mengler Board Slides)). Impax executives speculated that getting this type of "jump" on an Endo AG could give them at least 2-4 weeks on the market without facing any generic competition. (CX2920 at 001; *see also* CX0205 (email discussing Endo AG) ("Maybe Mengler is right after all when he says Endo won't be ready with an AG?")). Impax projected it would make higher profits during that time. (CX2753 at 014 (Impax launch

The Proposed Finding is misleading and incomplete insofar as it suggests that branded pharmaceutical companies are usually successful in recouping lost profits for infringement by generics. Complaint Counsel does not dispute the theoretical availability of lost profits damages. But the evidence shows that most generic companies that were found to have infringed paid less

patents, which would make treble damages unavailable. (Figg, Tr. 2014-15 (agreeing that Impax's non-infringement position was well-founded, and that its claim construction position was reasonable); Hoxie, Tr. 2697 ("Well, as I've said, I think Impax could well have won."); Hoxie, Tr. 2692-93 ("[U]nder the district court's claim construction ruling, Endo faced [substantial] difficulties in showing infringement and . . . Endo faced substantial difficulties in rebutting . . . Impax'[s] invalidity defenses.")).

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).

Response to Proposed Finding No. 1133

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 1134

The Proposed Finding is not supported by the evidence cited because Mr. Figg lacks the (c -0. 01 Tc -0us underlying patent litigse 0t3between Impax and Endo would likely have been confused r otherwise not understand the arguments presented. The Proposed Finding is also misleading insofar as it suggests that the patent holder does not bear the burden of proving its infringement case. (CX5007 at 033 (¶ 62) (Hoxie Report) ("[T]he burden of proving infringement clearly rested 0t3Endo . . .")).

Generic companies consequently risk far more in infringement liability than they earn

1135. 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 ariehe brand company than [generic] made")).

Response to Proposed Finding No. 1135

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1129, 1130, and 1132.

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)).

Response to Proposed Finding No. 1136

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1129 and 1130. Moreover, Mr. Smolenski's testimony on this point lacks foundation and is unreliable speculation. As he admitted, he is not a lawyer (CX4002 (Smolenski, IHT at 18)), and lacks a firm understanding of patent damages. His testimony is also inconsistent, underlining its speculative and unreliable nature. In his deposition he testified that the damages ratio could be one to "five or six," while in his investigational hearing he testified that it could be "one to ten." (CX4002 (Smolenski, IHT at 18-19); CX4037 (Smolenski, Dep. at 69)). No explanation is offered for the inconsistency, suggesting that Mr. Smolenski was just guessing at numbers. The Proposed Finding also uses the prospect of treble damages to inflate the damages ratio referred to by Mr. Smolenski. (CX4002 (Smolenski, IHT at 18-19); CX4037 (Smolenski, Dep. at 69)). The possibility of being found liable for treble damages was remote. (*See* Complaint Counsel's Response to Proposed Finding No. 1132).

The Proposed Finding is also misleading and incomplete insofar as it suggests an unreasonably high ratio between brand and generic prices. As the first-to-file generic, Impax projected that its oxymorphone ER would be introduced at 55% of the brand's WAC price. (CCF ¶¶ 585, 591). Thus, the ratio of Endo's lost profits to Impax's sales would be less than two.

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")).

Response to Proposed Finding No. 1137

The Proposed Finding is misleading and incomplete to the extent it suggests that potential patent damages would be uncontrolled and catastr

1138. Damages can be in the billions of dollars if the sales of the branded drug are high enough. (Hoxie, Tr. 2782).

Response to Proposed Finding No. 1138

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1130, 1132, and 1137.

1139. Mr. Figg testified that he could not "think of any situation where it would" be profitable

The Proposed Finding is also misleading and incomplete to the extent it suggests that any launch prior to 2013 would have been at risk. The undisputed evidence shows that it was possible that the underlying patent litigation between Endo and Impax would be resolved as early as the second half of 2011. (CCF ¶ 1026). Even Impax's experts agree that Impax could have launched free and clear of any patent risk in the second half of 2011, well before January of 2013. (CCF ¶ 1026). Dr. Addanki's opinion that any launch before 2013 would have been at risk is unfounded speculation that Impax would have been blocked by subsequent patents Endo could obtain. (CCF ¶ 1027). There are various possible scenarios in which Endo would have been unable or unwilling to assert additional patents if Impax had won the underlying patent litigation. (CCF ¶¶ 1027, 1396). Moreover, Endo did not undertake its "second wave" of patent litigation until December of 2012. (RX-548 at 0049 (¶ 113) (Figg Report); CCF ¶ 1402). This is more than

first-filer exclusivity unless it launched at risk. (CX5001 at 033 (¶ 62) (Bazerman Report)). Thus, launching at risk may have been the means for Impax to protect the "extremely valuable" first-filer exclusivity period. Indeed, the 180-day exclusivity period is an "important carrot[] that helps induce generic companies to file ANDAs." (Addanki, Tr. 2381).

Response to Proposed Finding No. 1141

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 1142

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1140.

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("[U]nder the district court's claim construction ruling, Endo faced [substantial] difficulties in showing infringement and . . . Endo faced substantial difficulties in rebutting . . . Impax'[s] invalidity defenses.")). Notably, Mr. Figg did not offer testimony that attorney's fees were likely to be awarded in the underlying patent litigation.

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")).

Response to Proposed Finding No. 1145

Complaint Counsel objects to the term "rare" as vague, ambiguous, and contrary to the weight of the evidence. The evidence shows that at-risk launches happen with some frequency. Between 2001 and 2015, at least forty eight generic pharmaceuticals launched at risk – an average of between three and four at-risk launches a year. (CCF ¶ 344). And such launches happen often enough that branded companies take at-risk launches very seriously in their planning. (CCF ¶ 345). The Proposed Finding is also unsupported by the evidence to the extent it takes Mr. Hoxie's statement out of context. Mr. Hoxie testified that at-risk launches are "not uncommon in situations where there is a strong economic incentive to launch at risk." (Hoxie, Tr. 2828). Impax had strong incentives to launch at risk. (*See* Complaint Counsel's Response to Proposed Finding No. 1129; *see also* CCF ¶¶ 121-26). The Proposed Finding is also misleading insofar as it suggests that the frequency of at-risk launches generally is relevant to whether Impax might have launched its generic oxymorphone ER product at risk. Impax was "absolutely" considering an at-risk launch in 2010 (CX4014 (Hsu, IHT at 130); CCF ¶¶ 338, 341), and Impax took many concrete steps to launch oxymorphone ER leading up to the settlement in June of 2010 (CCF ¶¶ 127-213).

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).

Response to Proposed Finding No. 1146

The Proposed Finding is misleading and incomplete to the extent it implies that at-risk launches in situations other than the "most common" described by Mr. Hoxie are uncommon. The situations in which generic companies have a strong motivation to launch at risk include an uncertain market opportunity generally – not just the possibility of multiple generics. (Hoxie, Tr. 2704-05). And, as Mr. Hoxie explained, Impax faced an uncertain market because it suspected Endo of switching the market to a new formulation of Opana ER, and because Impax was aware that Endo had pending patent applications that could cause problems down the road. (Hoxie, Tr. 2705-07). Thus, Impax had strong incentives to launch at risk. (CCF ¶¶ 121-26; *see also* Complaint Counsel's Response to Proposed Finding No. 1129).

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).

Response to Proposed Finding No. 1147

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1129, 1130, and 1137.

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).

Response to Proposed Finding No. 1149

The Proposed Finding is misleading and incomplete to the extent it implies that Teva alone was the main driver of at-risk launches. Teva partnered with other companies for five of those twenty-one at-risk launches, meaning that Teva alone was responsible for only about a third of at-risk launches during this time period. (CX5004 at 092-99 (Exhibit 4) (Noll Rebuttal Report)). One such partnership was with Impax, for the at-risk launch of generic Wellbutrin. (CX5004 at 094 (Exhibit 4) (Noll Rebuttal Report)). Notably, this at-risk launch by Impax and

Teva had a higher willingness to take risks than Impax, but he did not agree. (Hoxie, Tr. 2820-21).

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).

Response to Proposed Finding No. 1152

The Proposed Finding is misleading and incomplete to the extent it suggests that the size of the company is a causal factor in willingness to launch at risk. There is no evidence to support that assertion. (Noll, Tr. 1609 ("Although I don't think the size of the company has anything to do with it.")). Since the generic company launching at risk has control over how much product it sells, and how much liability it faces, there is no reason to assume that smaller companies are less able to launch at risk. (*See* Complaint Counsel's Response to Proposed Finding No. 1137). The Proposed Finding is also misleading and incomplete as it overlooks the importance of financial incentives to launch at risk – which does not depend on company size. In this case, Impax had strong incentives to launch at risk, regardless of its size. (CCF ¶¶ 121-26; *see also* Complaint Counsel's Response to Proposed Finding No. 1129).

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).

Response to Proposed Finding No. 1153

The Proposed Finding is factually inaccurate and unsupported by the evidence cited. Professor Noll testified that there were, in fact, some at-risk launches that were by a first to file company. (Noll, Tr. 1607-08). The Proposed Finding is also misleading and incomplete insofar as it suggests that comparing the number of at-risk launches to the total number of Hatch-Waxman cases is a meaningful analysis; it is not. (Noll, Tr. 1608 ("[T]hat's not the right denominator. . . . it's not all Hatch-Waxman cases, it's a subset of those."); Hoxie, Tr. 2826-27

("I wouldn't say that that percentage is a very meaningful percentage."); CX4039 (Noll, Dep. at 79-80) ("[T]he first relevant question is how many opportunities for at-risk launch are there in the sense that the FDA approval is granted, the litigation is still in progress, and the case isn't settled.")).

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).

Response to Proposed Finding No. 1154

The Proposed Finding is misleading and incomplete insofar as it suggests that comparing the number of at-risk launches to the total number of Hatch-Waxman cases is a meaningful analysis; it is not. (Noll, Tr. 1608 ("[T]hat's not the right denominator. . . . it's not all Hatch-Waxman cases, it's a subset of those."); Hoxie, Tr. 2826-27 ("I wouldn't say that that percentage is a very meaningful percentage."); CX4039 (Noll, Dep. at 79-80) ("[T]he first relevant question is how many opportunities for at-risk launch are there in the sense that the FDA approval is granted, the litigation is still in progress, and the case isn't settled.")).

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).

Response to Proposed Finding No. 1155

The Proposed Finding is unsupported by the evidence to the extent it takes Mr. Hoxie's agreement out of context. Mr. Hoxie testified that at-risk launches are "not uncommon in situations where there is a strong economic incentive to launch at risk." (Hoxie, Tr. 2828). Impax had strong incentives to launch at risk. (*See* Complaint Counsel's Response to Proposed Finding No. 1129; *see also* CCF ¶¶ 121-26). The Proposed Finding is also misleading and incomplete as the evidence shows that at-risk launches happen with some frequency. Between 2001 and 2015, at least forty-eight generic pharmaceuticals launched at risk – an average of between three and

four at-risk launches a year. (CCF ¶ 344). And such launches happen often enough that branded companies take at-risk launches very seriously in their planning. (CCF ¶ 345).

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).

Response to Proposed Finding No. 1156

The Proposed Finding is unsupported by reliable evidence. Respondent's citations to the record are simply Mr. Hoxie reading from a demonstrative exhibit that Respondent provided. Mr.

as soon as possible (CCF ¶¶ 121-26), Impax was "absolutely" considering an at-risk launch in

soon as possible (CCF ¶¶ 121-26), Impax was "absolutely" considering an at-risk launch in 2010 (CX4014 (Hsu, IHT at 130); CCF ¶¶ 338, 341), and Impax took many concrete steps to launch oxymorphone ER leading up to the settlement in June of 2010 (CCF ¶¶ 127-213). Impax (1) included a 2010 launch of oxymorphone ER as one of its "Company Key Goals" (CCF ¶¶ 127-30), (2) actively considered an at-risk launch (CCF ¶¶ 131-47), (3) continually projected oxymorphone ER entry dates as early as June 2010 (CCF ¶¶ 148-67), and (4) took additional concrete steps to be ready to launch oxymorphone ER as early as 2010 (CCF ¶¶ 168-73). These steps included working with federal agencies and outside parties to purchase the controlled-substance API needed for manufacturing (CCF ¶¶ 174-87), and manufacturing enough oxymorphone ER for a launch as early as June 2010 (CCF ¶¶ 188-202). Prior to the settlement with Endo, Impax had manufactured over four months' supply of 5mg tablets, over three months of 10mg tablets, over one month of 20mg tables, and two months of 40mg tablets. (CCF ¶ 202). But for the settlement, Impax would have been ready to launch on the day of ANDA approval in June 2010. (CCF ¶ 204). Because of its substantial launch preparations, Impax was forced to discard over $1.3 million of manufactured oxymorphone ER product following the settlement with Endo. (CCF ¶¶ 203-213). Moreover, the Proposed Finding is misleading because the relevant question is not whether Impax definitely would have launched oxymorphone ER at risk, but whether Endo paid to eliminate the *possibility*pax desr3,generic entry before January 1, 2013. (CX5000 at 011 (¶ 22) (Noll Report) ("Hence, the settlement agreement is anticompetitive because it eliminated the possibilitysr3competitionCX5000 over 30 months . . ."); *pax dessee also* tlement agreement imposes a social cost if it eliminates the rug."); Bazerman, Tr. 876). The evidence shows that Endo did, ilitysr3 generic entry. (CCF ¶¶ 321- 387).

1159. It "is very important for [Impax] to have a . . . risk-free launch" before it enters any market. (CX4014 (Hsu, IHT at 117)).

Response to Proposed Finding No. 1159

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding 1158. The Proposed Finding is also factually inaccurate and unsupported by the evidence cited. Dr. Hsu's testimony was that it was important for Impax to get a license to future Endo patents in the agreement with Endo to avoid the risk of facing additional patents later on. (CX4014 (Hsu, IHT at 116-17)). Dr. Hsu did not testify that it was Impax's policy to always pursue "risk-free" launches. That would be impossible. There is risk inherent in any

support that assertion. (Noll, Tr. 1609 ("Although I don't think the size of the company has anything to do with it.")). Since the generic company launching at risk has control over how much product it sells, and how much liability it faces, there is no reason to assume that smaller companies are less able to launch at risk. (*See* Complaint Counsel's Response to Proposed Finding No. 1137). The Proposed Finding is also misleading and incomplete as it overlooks the importance of financial incentives to launch at risk – which does not depend on company size. In

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")).

Response to Proposed Finding No. 1162

The Proposed Finding is misleading and unsupported by the evidence cited insofar as it takes Mr. Hoxie's words out of context. Mr. Hoxie's cited testimony concerned Impax's launch preparations for oxymorphone ER – his conclusion was that Impax would not have spent so much money preparing to launch unless there was a significant chance they would be making sales. (Hoxie, Tr. 2772). The Proposed Finding is also inaccurate and contrary to the weight of the evidence to the extent that it suggests that Impax was a small, cash-strapped company. In 2010, the year of the Endo settlement, its annual revenues were $879,509,000 and it held $348,401,000 in cash, cash equivalents, and short-term investments on its balance sheet. (CX3278 at 045 (Impax 2010 Annual Report)). The Proposed Finding is also misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1161.

The Proposed Finding is misleading and incomplete insofar as it ignores the uncontested evidence that Impax has previously launched products at risk. In 2005, Impax launched generic OxyContin at risk. (Koch, Tr. 275). In 2006 Impax partnered with Teva to launch generic Wellbutrin at risk. (CX5004 at 094 (Exhibit 4) (Noll Rebuttal Report)). And in 2014 Impax partnered with Perrigo to launch generic Astepro at risk. (CX2927 at 016-17 (Impax's Objections and Responses to Complaint Counsel's Second Set of Interrogatories); Snowden, Tr. 462, 464).

1163. Accordingly, Impax only "infrequently" considers the possibility of an at-risk launch. (Koch, Tr. 246-47).

Response to Proposed Finding No. 1163

The Proposed Finding is misleading and irrelevant because the frequency with which Impax considered launching products at risk has no bearing on the issues of this case. The

undisputed evidence shows that Impax considered launching oxymorphone ER at risk. (Koch, Tr. 247; CX4014 (Hsu, IHT at 130)). The relevant evidence proves that Impax had financial incentives to launch oxymorphone ER as soon as possible (CCF ¶¶ 121-26), and Impax took many concrete steps to launch oxymorphone ER leading up to the settlement in June of 2010 (CCF ¶¶ 127-213). Impax (1) included a 2010 launch of oxymorphone ER as one of its "Company Key Goals" (CCF ¶¶ 127-30), (2) actively considered an at-risk launch (CCF ¶¶ 131-47), (3) continually projected oxymorphone ER entry dates as early as June 2010 (CCF ¶¶ 148-67), and (4) took additional concrete steps to be ready to launch oxymorphone ER as early as 2010 (CCF ¶¶ 168-73). These steps in

actually launched one product at risk in 2013. (CX2927 at 016-17 (Impax's Objections and Responses to Complaint Counsel's Second Set of Interrogatories) (generic Astepro)). Moreover, in 2006 Impax partnered with Teva to launch generic Wellbutrin at risk. (CX5004 at 094 (Exhibit 4) (Noll Rebuttal Report)).

1165. That launch involved a generic version of oxycodone. (Koch, Tr. 274).

Response to Proposed Finding No. 1165

The Proposed Finding is misleading and incomplete insofar as it suggests that oxycodone is the only product that Impax either launched at risk, or had Board of Directors' approval to do so. See Complaint Counsel's Response to Proposed Finding No. 1164.

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).

Response to Proposed Finding No. 1166

The Proposed Finding is misleading and incomplete to the extent it suggests that the distinction of launching after a favorable district court decision is meaningful in this case. At the time of the settlement agreement with Endo, Impax had informed the district court that it would not launch during the trial. (Snowden, Tr. 471-72). Impax had not launched i(i)2e

The Proposed Finding is misleading and incomplete because it omits the approved launch of generic Solodyn in 2008. Impax's Board of Directors approved an at-risk launch of generic Solodyn in July of 2008. (CX2927 at 014-15 (Impax's Objections and Responses to Complaint Counsel's Second Set of Interrogatories)). Although Impax never actually launched this product, that was only because the anticipated market conditions and FDA approval did not materialize. (CX2927 at 015 (Impax's Objections and Responses to Complaint Counsel's Second Set of Interrogatories)). Thus Impax "pursued" the at-risk launch of generic Solodyn at least through approval by the Board of Directors.

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).

Response to Proposed Finding No. 1171

Complaint Counsel objects to the phrase "very limited" as vague, ambiguous, and unsupported by the evidence cited. In her testimony, Ms. Snowden noted that the launch was limited to 150,000 units, but did not characterize that as "very limited." (Snowden, Tr. 466). Similarly, Dr. Ben-Maimon described the launch as not unlimited, rather than "very limited."

Response to Proposed Finding No. 1173

The Proposed Finding is misleading and incomplete insofar as it implies that the lower risk associated with having a partner for the azelastine launch necessarily made it more attractive than the launch of oxymorphone ER. Any launch involves balancing risks against the potential upside. (CX4026 (Nguyen, Dep. at 50-51) ("In an at-risk launch there are pros and cons, and so you have to weigh that."); CX4030 (Hsu, Dep. at 43-44); Hoxie, Tr. 2704; CCF ¶ 134). In addition to sharing risk, Impax had to share profits with Perrigo, thus any lower risk was accompanied by lower potential for profits. (CX4021 (Ben-Maimon, Dep. at 153); Snowden, Tr. 462).

1174. In 2014, Perrigo notified Impax that it intended to launch azelastine at risk. (Snowden, Tr. 462).

Response to Proposed Finding No. 1174

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 1175

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 1176

The Proposed Finding is misleading and incomplete insofar as it implies that the lower risk associated with capping the number of units for the azelastine launch necessarily made it more attractive than the launch of oxymorphone ER. Any launch involves balancing risks against the potential upside. (CX4026 (Nguyen, Dep. at 50-51) ("In an at-risk launch there are pros and

cons, and so you have to weigh that."); CX4030 (Hsu, Dep. at 43-44); Hoxie, Tr. 2704; CCF ¶ 134). In addition to lowering risk, Impax had less potential upside in the azelastine launch because of the limited units. (*See* Complaint Counsel's Response to Proposed Finding No. 1173).

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)).

Response to Proposed Finding No. 1177

The Proposed Finding is misleading and irrelevant because Impax had no way of knowing that the azelastine launch would be so curtailed. The settlement occurred after the launch was already underway. (Snowden, Tr. 466-67). Thus the eventual settlement and withdrawal of the product did not play a role in Impax's decision to launch at risk.

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).

Response to Proposed Finding No. 1178

The Proposed Finding is misleading and incomplete because Ms. Snowden is not the person that seeks authorization from the Board of Directors to launch at risk – her role on the team that seeks authorization to launch at risk is to provide legal advice. (Snowden, Tr. 509-10). The Proposed Finding is also misleading and incomplete because it ignores the undisputed evidence that Impax considered launching oxymorphone ER at risk. (Koch, Tr. 247). The relevant evidence proves that Impax had financial incentives to launch oxymorphone ER as soon as possible (CCF ¶¶ 121-26), and Impax took many concrete steps to launch oxymorphone ER leading up to the settlement in June of 2010 (CCF ¶¶ 127-213). Impax (1) included a 2010 launch of oxymorphone ER as one of its "Company Key Goals" (CCF ¶¶ 127-30), (2) actively considered an at-risk launch (CCF ¶¶ 131-47), (3) continually projected oxymorphone ER entry

dates as early as June 2010 (CCF ¶¶ 148-67), and (4) took additional concrete steps to be ready to launch oxymorphone ER as early as 2010 (CCF ¶¶ 168-73). These steps included working with federal agencies and outside parties to purchase the controlled-substance API needed for manufacturing (CCF ¶¶ 174-87), and manufacturing enough oxymorphone ER for a launch as early as June 2010 (CCF ¶¶ 188-202). Prior to the settlement with Endo, Impax had manufactured over four months' supply of 5mg tablets, over three months of 10mg tablets, over one month of 20mg tables, and two months of 40mg tablets. (CCF ¶ 202). But for the settlement, Impax would have been ready to launch on the day of ANDA approval in June 2010. (CCF ¶ 204). Because of its substantial launch preparations, Impax was forced to discard over $1.3 million of manufactured oxymorphone ER product following the settlement with Endo. (CCF ¶¶ 203-213). Moreover, the Proposed Finding is misleading because the relevant question is not whether Impax definitely would have launched oxymorphone ER at risk, but whether Endo paid to eliminate the *possibility* of generic entry before January 1, 2013. (CX5000 at 011 (¶ 22) (Noll Report) ("Hence, the settlement agreement is anticompetitive because it eliminated the possibility of competition for over 30 months . . ."); *see also* CX5000 at 110 (¶ 252) (Noll Report) ("A settlement agreement imposes a social cost if it eliminates the possibility of entry by a generic drug."); Bazerman, Tr. 876). The evidence shows that Endo did, in fact, pay to eliminate the possibility of generic entry. (CCF ¶¶ 321- 387).

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)).

Response to Proposed Finding No. 1179

The Proposed Finding is misleading and incomplete insofar as it presents the Board of Directors decision as an additional obstacle once an at-risk launch decision had been made by

management. At the very least, a recommendation from management to launch would have been a significant factor in the Board's decision. In fact, the Impax Board has never rejected a formal at-risk launch recommendation by management. (CCF ¶ 342). Indeed, the Board of Directors' meeting minutes produced by Respondent indicate that the Board made its decision on at-risk launches at the same meeting at which the recommendation was made by management. (*See* CX2689 at 001-02; CX3223 at 002). These meeting minutes prove that the time from opening of the meeting to final decision by the Board was less than an hour. (CX2689 at 001-02 (8:03 am – 8:18 am); CX3223 at 001-02 (1:06 pm – 1:59 pm)).

In any case, the Impax Board of Directors never reached a decision to launch or not launch oxymorphone ER – it was not asked one way or the other. (CCF ¶ 343). The Proposed Finding is also unsupported by the evidence cited to the extent it relies on Dr. Hsu's deposition. Dr. Hsu's testimony concerns Board approval of the agreement with Endo, not at-risk launches. (CX4030 (Hsu, Dep. at 126-30)). Moreover, the relevant question is not whether Impax definitely would have launched oxymorphone ER at risk, but whether Endo paid to eliminate the *possibility* of generic entry before January 1, 2013. (CX5000 at 011 (¶ 22) (Noll Report) ("Hence, the settlement agreement is anticompetitive because it eliminated the possibility of competition for over 30 months . . ."); *see also* CX5000 at 110 (¶ 252) (Noll Report) ("A settlement agreement imposes a social cost if it eliminates the possibility of entry by a generic drug."); Bazerman, Tr. 875-76). The evidence shows that Endo did, in fact, pay to eliminate the possibility of generic entry. (CCF ¶¶ 321- 87).

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).

Response to Proposed Finding No. 1180

The Proposed Finding is misleading and incomple

The Proposed Finding is misleading and incomplete to the extent it suggests that the size of the company is a causal factor in willingness to launch at risk. There is no evidence to support that assertion. (Noll, Tr. 1609 ("Although I don't think the size of the company has anything to do with it.")). Since the generic company launching at risk has control over how much product it sells, and how much liability it faces, there is no reason to assume that smaller companies are less able to launch at risk. (*See* Complaint Counsel's Response to Proposed Finding No. 1137). Complaint Counsel also objects to the term "small" as vague. Although Complaint Counsel does not dispute that Impax's annual revenues are less than some other pharmaceutical manufacturers, Impax is hardly small. In 2010, the year of the Impax-Endo Settlement Agreement, its annual revenues were $879,509,000 and it held $348,401,000 in cash, cash equivalents, and short-term investments on its balance sheet. (CX3278 at 045 (Impax 2010 Annual Report)).

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).

Response to Proposed Finding No. 1183

Complaint Counsel has no specific response.

1184. Still, Impax's process for deciding whether to launch at risk is "the most significant effort" undertaken by the company. (Koch, Tr. 276).

Response to Proposed Finding No. 1184

The Proposed Finding is misleading and incomplete, as it takes Mr. Koch's language out of context. Mr. Koch testified that the at-risk launch decision-making process "was probably the most significant effort the company made *in making this evaluation*." (Koch, Tr. 276 (emphasis added)). The language does not indicate what exactly Mr. Koch meant, but it does not establish that such a decision was the most significant effort the company ever makes.

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).

Response to Proposed Finding No. 1185

The Proposed Finding is misleading and incomplete insofar as it implies that an at-risk launch of oxymorphone was never seriously considered because it ignores the fact that Impax senior management notified the Impax Board in May 2010 of a potential at-risk launch and planned to seek Board approval at a later date. Impax's settlement with Endo ultimately made such approval unnecessary. On May 14, 2010, upon receiving tentative FDA approval, Impax's CEO, Dr. Hsu, wanted to "alert BOD [board of directors] with potential oxymorphine [*sic*] launch," even though "we will have a special Board conference call *when we do decide to launch at risk on a later date*." (CX0008 at 002 (emphasis added); *see also* CCF ¶ 139). Impax's President of Generics, Chris Mengler, did just that in his May 2010 Board presentation, explaining that the "Current Assumption" was an

257), and entered a definitive settlement agreement on June 8, 2010 (CCF ¶ 317), a special Board conference call to approve an oxymorphone ER at-risk launch became unnecessary.

The relevant evidence proves that Impax had financial incentives to launch oxymorphone ER as soon as possible (CCF ¶¶ 121-26), and Impax took many concrete steps to launch oxymorphone ER leading up to the settlement in June of 2010 (CCF ¶¶ 127-213). Impax (1) included a 2010 launch of oxymorphone ER as one of its "Company Key Goals" (CCF ¶¶ 127-30), (2) actively considered an at-risk launch (CCF ¶¶ 131-47), (3) continually projected oxymorphone ER entry dates as early as June 2010 (CCF ¶¶ 148-67), and (4) took additional concrete steps to be ready to launch oxymorphone ER as early as 2010 (CCF ¶¶ 168-73). These steps included working with federal agencies and outside parties to purchase the controlled-substance API needed for manufacturing (CCF ¶¶ 174-87), and manufacturing enough oxymorphone ER for a launch as early as June 2010 (CCF ¶¶ 188-202). Prior to the settlement with Endo, Impax had manufactured over four months' supply of 5mg tablets, over three months of 10mg tablets, over one month of 20mg tables, and two months of 40mg tablets. (CCF ¶ 202). But for the settlement, Impax would have been ready to launch on the day of ANDA approval in June 2010. (CCF ¶ 204). Because of its substantial launch preparations, Impax was forced to discard over $1.3 million of manufactured oxymorphone ER product following the settlement with Endo. (CCF ¶¶ 203-213). Moreover, the Proposed Finding is misleading because the relevant question is not whether Impax definitely would have launched oxymorphone ER at risk, but whether Endo paid to eliminate the *possibility* of generic entry before January 1, 2013. (CX5000 at 011 (¶ 22) (Noll Report) ("Hence, the settlement agreement is anticompetitive because it eliminated the possibility of competition for over 30 months . . ."); *see also* CX5000 at 110 (¶ 252) (Noll Report) ("A settlement agreement imposes a social cost if it eliminates the

possibility of entry by a generic drug."); Bazerman, Tr. 876). The evidence shows that Endo did, in fact, pay to eliminate the possibility of generic entry. (CCF ¶¶ 321- 387).

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).

Response to Proposed Finding No. 1186

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1185.

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

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1185.

also misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1185.

1194. The Board presentation would also include any recommendations about limitations on at-risk sales in order to mitigate potential damages. (Koch, Tr. 278).

Response to Proposed Finding No. 1194

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1185.

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).

Response to Proposed Finding No. 1195

The Proposed Finding is misleading and incomplete to the extent it suggests that an at-risk launch is only risk, with no potential reward. Were that the case, no company would ever launch at risk. To the contrary, the evidence shows that at-risk launches happen with some frequency. Between 2001 and 2015, at least forty-eight generic pharmaceuticals launched at risk. (CCF ¶ 344). And such launches happen often enough that branded companies take at-risk launches very seriously in their planning. (CCF ¶ 345). Moreover, there is risk inherent in any pharmaceutical launch, and any launch involves balancing those risks against the potential upside. (CX4026 (Nguyen, Dep. at 50-51) ("In an at-risk launch there are pros and cons, and so you have to weigh that."); CX4030 (Hsu, Dep. at 43-44); Hoxie, Tr. 2704; CCF ¶ 134). In some cases, the risks of launching and facing patent damages can be outweighed by the risks of losing a market opportunity. (Hoxie, Tr. 2704; CX4026 (Nguyen Dep. at 51-52) ("So, that's a big incentive for launching a product . . . We don't make any money until we launch a product.")). Because Impax suspected that Endo would try to reformulate Opana ER, forgoing an at-risk launch would carry risks for Impax – in that the market could decline or disappear entirely. (CCF

¶¶ 124-26, 356; Mengler, Tr. 527 ("[T]he biggest concern [is] that Opana ER somehow in its original form disappears . . . if there's no substitute, I get nothing.")). Another risk was that Endo was in the process of getting additional patents, so it may have made sense for Impax to launch before the new patents issued and before the product switch, make its money, and get off the market if problems arose. (Hoxie, Tr. 2707). Because generic drugs make a "substantial portion" of their profits during initial 180-day exclusivity periods (Koch, Tr. 232-33), that would be a viable strategy. The Proposed Finding is also misleading and incomplete as it conflates launches before and after a district court decision. Launches following a favorable district court decision for the generic company are lower risk. (Hoxie, Tr. 2810-11).

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).

Response to Proposed Finding No. 1196

The Proposed Finding is misleading and incomplete insofar as it presents the Board of Directors decision as an additional obstacle once an at-risk launch decision had been made by management. At the very least, a recommendation from management to launch would have been a significant factor in the Board's decision. In fact, the Impax Board has never rejected a formal at-risk launch recommendation by management. (CCF ¶ 342). Indeed, the Board of Directors meeting minutes produced by Respondent indicate that the Board made its decision on at-risk launches at the same meeting at which the recommendation was made by management. (*See* CX2689 at 001-02; CX3223 at 002). These meeting minutes prove that the time from opening of the meeting to final decision by the Board was less than an hour. (CX2689 at 001-02 (8:03 am – 8:18 am); CX3223 at 001-02 (1:06 pm – 1:59 pm)). The Proposed Finding is also misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1185.

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).

Response to Proposed Finding No. 1197

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1185 and 1196.

1198. Once all of the Board's questions and concerns are addressed, the Executive Committee returns to the Board of Directors for a fu

Margaret Snowden, Impax’s in-house attorney responsible for Intellectual Property, made a formal presentation and recommendation regard

possibility of generic entry before January 1, 2013. (CX5000 at 011 (¶ 22) (Noll Report) ("Hence, the settlement agreement is anticompetitive because it eliminated the possibility of competition for over 30 months . . ."); *see also* CX5000 at 110 (¶ 252) (Noll Report) ("A settlement agreement imposes a social cost if it eliminates the possibility of entry by a generic drug."); Bazerman, Tr. 876). The evidence shows that Endo did, in fact, pay to eliminate the possibility of generic entry. (CCF ¶¶ 321- 387).

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)).

Response to Proposed Finding No. 1203

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 1204

The Proposed Finding is misleading and irrelevant for the reasons set forth in response to Proposed Finding No. 1202.

1205. Impax never launched dutasteride because the district court ruled against Impax. (Snowden, Tr. 470; CX4021 (Ben-Maimon, Dep. at 157)).

Response to Proposed Finding No. 1205

The Proposed Finding is misleading and irrelevant because the fact that Impax did not launch dutasteride in the face of an adverse district court ruling has no bearing on whether or not it would have launched oxymorphone ER at risk. Moreover, the relevant question is not whether Impax definitely would have launched oxymorphone ER at risk, but whether Endo paid to

possibility of competition for over 30 months . . ."); *see also* CX5000 at 110 (¶ 252) (Noll Report) ("A settlement agreement imposes a social cost if it eliminates the possibility of entry by a generic drug."); Bazerman, Tr. 876). The evidence shows that Endo did, in fact, pay to eliminate the possibility of generic entry. (CCF ¶¶ 321- 387).

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).

Response to Proposed Finding No. 1206

The Proposed Finding is misleading and incomplete in that it ignores that Impax was preparing to obtain Board approval for a potential at-risk launch, but that such Board approval became unnecessary after Impax entered the settlement with Endo. On May 14, 2010, upon receiving tentative FDA approval, Impax's CEO, Dr. Hsu, wanted to "alert BOD [board of directors] with potential oxymorphine [*sic*] launch . . . even though we will have a special Board conference call *when we do decide to launch at risk on a later date*." (CX0008 at 002 (emphasis added); *see also* CCF ¶ 139). Impax's President of Generics, Chris Mengler, did just that in his May 2010 Board presentation, explaining that the "Current Assumption" was an oxymorphone ER at-risk launch, with expected revenues beginning in Q2'2010. (CX2662 at 012, 015). Per the official Board of Directors meeting minutes, Mr. Mengler expressed the view that oxy5(i)-1h0 Board 94-0.g29.T

and Endo reached agreement in principle on June 3, 2010 (CCF ¶ 257), and entered a definitive settlement agreement on June 8, 2010 (CCF ¶ 317), a special Board conference call to approve an oxymorphone ER a-risk launch became unnecessary.

Though a Board vote became unnecessary, it is worth noting that the Impax Board has never rejected a formal at-risk launch recommendation by management. (CCF ¶ 342).

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).

Response to Proposed Finding No. 1207

The Proposed Finding is misleading and incomplete in that it ignores that Impax senior management notified the Impax Board in May 2010 of a potential at-risk launch and planned to seek Board approval at a later date, but Impax's settlement with Endo made such approval unnecessary. (*See* Complaint Counsel's Response to Proposed Finding No. 1206).

a.

Impax dedicated significant resources to preparing for a potential at-risk launch of oxymorphone ER. (CCF ¶¶ 168-213). Impax's Operations division had the 2010 objective of launching oxymorphone ER "on the day of ANDA approval." (CX2899 at 002 (2010 Operations MBOs); CCF ¶ 169). To reach that objective, Impax dedicated "an inordinate amount of both labor and plant capacity" to the production of oxymorphone ER product at the expense of other Impax products. (CX4023 (Hildenbrand, Dep. at 43-44); CCF ¶ 172). Impax worked to obtain the needed quota from the DEA to be able to procure adequate oxymorphone API to sustain a mid-2010 at-risk launch, (CCF ¶¶ 174-87). Impax manufactured enough oxymorphone ER for launch as early as June 2010. (CCF ¶¶ 188-202). Once the settlement rendered Impax's launch preparations moot, Impax had to discard over $1.3 million of manufactured oxymorphone ER product and was left with $1.6 million in oxymorphone API with a 2011 expiration date, a "big amount" for Impax. (CCF ¶¶ 203-213). Dr. Hsu explained the opportunity cost of preparing oxymorphone for an at-risk launch: "[I]f we decide to launch this product, something else is going to have to delay." (CX4014 (Hsu, IHT at 129)).

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).

Response to Proposed Finding No. 1209

The Proposed Finding is not supported by the testimony cited and is misleading. In the transcript pages cited by Impax, Ms. Snowden – who serves in a legal rather than a business capacity at Impax (Snowden, Tr. 343-46; Snowden, Tr. 509-10 (agreeing that her role was to provide legal advice)) – was responding to a hypothetical question in the present tense. (Snowden, Tr. 503 ("Q. Would it be a good business strategy for Impax to risk its very valuable first-to-file exclusivity with a limited launch of Opana ER? A. I don't think so.")). Impax cites

no contemporaneous documents or any testimony of what Impax or its executives actually thought at the time.

Furthermore, the Proposed Finding is contrary to the weight of the evidence. Prior to entering the settlement agreement with Endo, Impax executives were "absolutely" considering an at-risk oxymorphone launch. (CX4014 (Hsu, IHT at 130); CCF ¶¶ 131, 139, 145-47). At the May 2010 Board meeting, Impax's generic division president "expressed the view that Oxymorphone was a good candidate for an at-risk launch." (CX2663 at 001 (Minutes of the Impax Board of Directors Meetings of May 25 and 26, 2010)). Everyone at the meeting agreed that oxymorphone ER was a "great market opportunity" and it was understood that the Executive Committee might "come back to the Board seeking an at-risk launch." (CCF ¶ 146).

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).

Response to Proposed Finding No. 1210

Response to Proposed Finding No. 1211

The Proposed Finding is not supported by the testimony cited and is incomplete. Beyond Ms. Snowden's vague description of an example involving Mylan, no factual evidence of this "example" is in the record, including what the product was, when the favorable district court decision or injunction occurred, or which court or courts heard the matter. (Snowden, Tr. 504-06).

Furthermore, the Proposed Finding is irrelevant, as an unspecified, undated example that has no nexus with Impax's plans or preparations to launch oxymorphone at risk prior to entering the settlement with Endo.

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

At his deposition, Mr. Koch testified that senior management "scoped out the opportunity for the directors. We never reached a decision to ask them to consider an at-risk launch." (CX4018 (Koch, Dep. at 103-04)). Mr. Koch clarified that Impax senior management neither reached a decision to proceed nor a decision not to proceed. (CX4018 (Koch, Dep. at 103)).

In his trial testimony, Mr. Koch acknowledged that, in 2010, Impax was considering whether to launch Opana ER at risk (Koch, Tr. 247), and that Impax's current assumption as of May 25/26, 2010 and prior to the settlement with Endo was an oxymorphone ER at-risk launch. (Koch, Tr. 337-38). That was consistent with the testimony of Impax's CEO that, prior to the Endo settlement, Impax was "absolutely" considering the possibility of an at-risk launch. (CX4014 (Hsu, IHT at 130)).

The cherry-picked trial testimony from Mr. Koch in the Proposed Finding is also contradicted by a wealth of contemporaneous documents, including the Minutes of the Meeting of the Board of Directors of Impax Laboratories, Inc. of May 25 and 26, 2010, prepared and signed by Mr. Koch in his capacity as Secretary of the Board. (CX2663 at 001, 004; *see also* CCF ¶¶ 127-213). In that official corporate record, Mr. Koch recounted the presentation of Mr. Mengler, Impax's President of Generics, to the Board in which Mr. Mengler "expressed the view that Oxymorphone was a good candidate for an at-risk launch." (CX2663 at 001). At trial, Mr. Koch acknowledged that he had seen – and would have seen at the time – Mr. Mengler's May presentation to the Board (Koch, Tr. 336-37), in which senior management's current assumption for oxymorphone ER was an at risk launch in Q2'2010. (CX2662 at 012, 015 (May 2010 Mengler Board Presentation)). Mr. Koch further testified that everyone at the meeting agreed that oxymorphone ER was "a great market opportunity" for Impax, and that it was understood

that the Executive Committee might "come back to the Board seeking an at-risk launch." (CCF ¶ 146).

The Proposed Finding is misleading, in that it suggests that waiting for a court decision on a preliminary injunction would be inconsistent with an at-risk launch. To the contrary, Endo moved for a preliminary injunction on May 21, 2010, after learning of Impax's grant of tentative

make a launch decision based on the preliminary injunction decision. (Koch, Tr. 310; CX2929 at 001). The only contemporaneous document cited in support of the Proposed Finding counters the proposition. In the May 14, 2010, email from Dr. Hsu following the news of FDA tentative approval, Dr. Hsu stated: "I think we should alert BOD with potential oxymorphine [*sic*] launch in this meeting even though we will have a special Board conference call when we do decide to launch at risk on a later date." (CX0008 at 002). The email thread never mentions delaying launch until receiving a favorable court ruling in the patent suit. (CX0008).

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).

Response to Proposed Finding No. 1216

The Proposed Finding is misleading in that it suggests that Impax having not yet made a launch decision is akin to Impax having affirmatively decided not to launch. The May 17, 2010 email from Todd Engle to Impax sales personnel simply instructed the sales team that they did not have additional information to disclose to inquiring customers at that time. (RX-323). This e-mail is consistent both with Impax's concern that disclosing its marketing intentions to customers would put Impax at a competitive disadvantage to Endo (CCF ¶ 183), and with Impax "absolutely" considering an at-risk launch. (CX4014 (Hsu, IHT at 130)).

The Proposed Finding is also incomplete as it does not cover the range of communications with potential customers. At the time, Impax was also soliciting and obtaining Letters of Intent ("LOIs"), which are written statements from pharmaceuticals customers that "prove to the DEA that the Impax customers will order the Oxymorphone [requested by Impax] in quantities that exceed the Procurement Quota already granted." (CCF ¶ 182). In the spring of 2010, Impax obtained LOIs with commitments from four customers comprising 88% of the total generic oxymorphone ER demanded Impax expected in 2010. (CCF ¶¶ 185-86).

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)).

Response to Proposed Finding No. 1217

The Proposed Finding is misleading and incomplete. Impax informed the court that it would not launch its generic oxymorphone ER product "through and including the last trial day as presently scheduled" (RX-251). The trial was scheduled to conclude on June 17, 2010 (CX2769 at 020 (Patent Litigation Docket Entry No. 218)), which was only three days after Impax would be eligible for final FDA approval. (JX-001 at 007 (¶¶ 15-16)). Thus, Impax's representation to the court did not indicate that it would not launch at risk shortly following final approval of its product.

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)).

Response to Proposed Finding No. 1218

The Proposed Finding is misleading. Impax's senior management made a presentation in May 2010 to the Impax Board of Directors identifying an oxymorphone ER at-risk launch as the "Current Assumption" with projected 2010 profits in excess of $28 million (CX2662 at 012, 015), and Mr. Mengler, Impax's President of Generics, informed the Board of Directors at the same May 2010 meeting that oxymorphone ER was "a good candidate for an at-risk launch." (CX2663 at 001 (Minutes of the Impax Board of Directors Meetings of May 25 and 26, 2010)).

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).

Response to Proposed Finding No. 1219

The Proposed Finding is not supported by the testimony cited and is counter to the weight of the evidence, including the contemporaneous documents. In the transcript pages cited, Mr.

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")).

Response to Proposed Finding No. 1221

Complaint Counsel has no specific response.

1222.

(CX2662-012).

Response to Proposed Finding No. 1222

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. Mr. Mengler, Impax's President of Generics, first presented a potential 2010 oxymorphone ER at-risk launch no later than November 2009, when he identified a July 2010 launch as a "2010 Plan Upside." (CX2628 at 017) (Nov. 2009 Mengler presentation to the Board of Directors)). In February 2010, Mr. Mengler again notified the Board that a mid-June 2010 oxymorphone ER launch was a "Possible Upside" with an impact of $10 to $12 million per month. (CX2662 at 010

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).

Response to Proposed Finding No. 1224

Complaint Counsel has no specific response to the statement that senior management "did not ask the Board to approve an at-risk launch" at the May 2010 Board meeting. The remainder of the Proposed Finding is factually inaccurate. Mr. Mengler notified the Board in May 2010 that the " huno specn

dedicated slide that walked through the status of Impax's application and launch readiness (CX2662 at 013). The substantive discussion of a potential at-risk oxymorphone ER was noted in the second paragraph of the official corporate minutes of the May 2010 Board meeting. (CX2663 at 001 (Minutes of the Impax Board of Directors Meetings of May 25 and 26, 2010)).

Finally, Mr. Koch acknowledged that he wrote in the official corporate minutes that Mr. Mengler "'expressed the view that oxymorphone was a good candidate for an at-risk launch,'" which he characterized as Mr. Mengler "thought it was a great market opportunity." (Koch, Tr. 294). At his deposition, Mr. Koch testified that, "[a]s far as I know, everyone agreed it was a great market opportunity." (CX4018 (Koch, Dep. at 121)). The trial testimony of Mr. Koch cited by the Proposed Finding is at odds with the clear and unambiguous language of the Board meeting minutes – minutes that form part of the permanent corporate record of Impax, and that Mr. Koch would not have signed if he believed they were not accurate at the time. (Koch, Tr. 255-56).

1226. The discussion about oxymorphone ER was instead used to put oxymorphone ER "on the radar" of the Board. (Mengler, Tr. 548).

Response to Proposed Finding No. 1226

The Proposed Finding is misleading. Mr. Mengler needed to "put oxymorphone ER 'on the radar'" because Dr. Hsu instructed Mr. Mengler to "alert BOD [board of directors] with potential oxymorphine [*sic*] launch . . . even though we will have a special Board conference call *when we do decide to launch at risk on a later date*." (CX0008 at 002 (emphasis added); *see also* CCF ¶ 139).

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).

Response to Proposed Finding No. 1227

The Proposed Finding is misleading for the reasons set forth in Complaint Counsel's Response to Proposed Finding No. 1226. Complaint Counsel also objects to the use of the term "mentioned." As discussed above in Complaint Counsel's Response to Proposed Finding No. 1225, Mr. Mengler's May 2010 presentation to the Board discussed a potential at-risk oxymorphone ER launch at four different points (CX2662 at 010, 012, 013, 015), including a dedicated slide that walked through the status of Impax's application and launch readiness. (CX2662 at 013).

Larry Hsu, Impax's CEO at the time, explained that senior management "want to alert the

Response to Proposed Finding No. 1233

The Proposed Finding is incomplete, misleading, and contrary to the actual presentation Mr. Mengler gave to the Boar

for oxymorphone ER. (CX2662 at 012, 015). Mr. Mengler presented this plan to the Board in accordance with the instructions of Impax CEO Dr. Hsu. (CX0008 at 002 (May 14, 2010 Hsu email to Mengler)).

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 oxymor

Endo. (CCF ¶¶ 219-29). Impax was not eligible for final FDA approval until June 14, 2010 (JX-001 at 007 (¶¶ 15-16)), and had represented to the district court that it would not launch at-risk until June 18, 2010, at the earliest. (CCF ¶ 142). Given that Impax and Endo reached agreement in principle on June 3, 2010 (CCF ¶ 257), and entered a definitive settlement agreement on June 8, 2010 (CCF ¶ 317), a special Board conference call to approve an oxymorphone ER a-risk launch became unnecessary.

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).

Response to Proposed Finding No. 1238

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1237.

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)).

Response to Proposed Finding No. 1239

The Proposed Finding is not supported by the evidence cited and is contrary to the weight of the evidence. Dr. Hsu's cited testimony merely explains that Impax generally aimed to be ready to launch if and when Impax's management made a launch decision. (CX4030 (Hsu, Dep. at 85-86)). Dr. Hsu does not reference or otherwise link Impax's launch-ready date to the Hatch Waxman Act or FDA regulatory processes. (CX4030 (Hsu, Dep. at 85-86)). In the portion cited, Mr. Hildenbrand testifies only that the estimated launch date provided by marketing "generally" was the date of FDA approval. In other portions of his deposition, Mr. Hildenbrand makes clear

that he was not responsible for deciding the date for a new product launch (CX4023 (Hildenbrand, Dep. at 23-24)); that he didn't know "[w]hether there were other factors, other than ANDA approval" that went into the launch date provided by marketing (CX4023 (Hildenbrand, Dep. at 29)); and that he "can't re

Complaint Counsel objects to the phrase "in order to do so" to the extent that it suggests that Impax intends to be "launch ready" for every product at the earliest date allowed by the Hatch-Waxman Act. (*See* Complaint Counsel's Response to Proposed Finding No. 1239).

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)).

Response to Proposed Finding No. 1241

The Proposed Finding is misleading to the extent it suggests that Impax begins the prelaunch preparation activities for every product eighteen months before the expected date of FDA approval. While the "earliest theoretical launch date" is often the date of FDA approval (Impax FOF 1242), the evidence shows that Impax's target launch dates and launch ready dates "may or may not be" the date of FDA approval, depending on other product-specific circumstances. (CX4028 (Camargo, Dep. at 59-60, 68-69); *see also* Complaint Counsel's Response to Proposed Finding No. 1239). In fact, the timing of many pre-launch preparations depends on case-by-case evaluation of a product's particular circumstances and specifications. (CX4028 (Camargo, Dep. at 48-49 (discussing timing for API purchasing); CX4023 (Hildenbrand, Dep. at 144) (discussing wide range of time needed to complete validation for different products); *see also*

Response to Proposed Finding No. 1243

Complaint Counsel has no specific response.

1244. The Supply Chain Group uses those forecasts to begin routine launch planning. (Camargo, Tr. 958; CX4023 (Hildenbrand, Dep. at 79)).

Response to Proposed Finding No. 1244

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 1245

Complaint Counsel has no specific response.

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

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).

Response to Proposed Finding No. 1249

The Proposed Finding is unsupported by the evidence cited insofar as it suggests a particular order of steps. Mr. Camargo's cited testimony did not identify requesting quota as the first step, and Impax's Product Launch Checklist identifies many tasks that Impax must complete to prepare for a product launch. There is no evidence that the first task on this list is to "request quota from the DEA." (*See, e.g.* CX3078 at 001, 003 (email attaching updated Product Launch Checklist for the May 11, 2010 launch coordination meeting)).

1250. Second, the Supply Chain Group purchases the active pharmaceutical ingredients and other unique materials necessary to produce the finished product. (Camargo, Tr. 964).

Response to Proposed Finding No. 1250

The Proposed Finding is unsupported by the evidence cited insofar as it suggests a particular order of steps. Mr. Camargo's cited testimony did not identify purchasing API as the second step, and Impax's Product Launch Checklist identifies many tasks that Impax must complete to prepare for a product launch. There is no evidence that the second task on this list is to "purchase the active pharmaceutical ingredients and other unique materials." (*See, e.g.* CX3078 at 001, 003 (email attaching updated Product Launch Checklist for the May 11, 2010 launch coordination meeting)).

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).

Response to Proposed Finding No. 1251

The Proposed Finding is unsupported by the evidence cited insofar as it suggests a particular order of steps. Mr. Camargo's cited testimony did not identify process validation as the third step, and Impax's Product Launch Checklist identifies many tasks that Impax must

complete to prepare for a product launch. There is no evidence that the third task on this list is to "conduct[] 'process validation.'" (*See, e.g.* CX3078 at 001, 003 (email attaching updated Product Launch Checklist for the May 11, 2010 launch coordination meeting)).

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).

Response to Proposed Finding No. 1252

The Proposed Finding is unsupported by the evidence cited insofar as it suggests a particular order of steps. Mr. Camargo's cited testimony did not [illegible]

assumptions for necessary safety stock)). A first-to-file drug has a “higher selling margin” and can require larger resource requirements. (CX4028 (Camargo, Dep. at 68); CX4023

Complaint Counsel's Response to Proposed Findings Nos. 1239, 1240, and 1241). The cited testimony from Mr. Koch refers to Impax's 2010 Annual Report, which *specifically* states that Impax will "generally" begin to schedule process validation when the company expects FDA approval within the next six months. (CX3278 at 101). Indeed, the Annual Report makes clear that the Impax's launch preparation timetable considers not only the expected FDA approval date, but also whether "such action is appropriate to increase the commercial opportunity" and/or whether "litigation will be resolved in the Company's favor." (CX3278 at 101).

The Proposed Finding is also inconsistent with testimony from Impax's former Vice President of Manufacturing & Materials Management, Joe Camargo. Mr. Camargo explained that Impax's launch ready dates are not set, as a matter of course, to the anticipated FDA approval date: "It may or may not be. . . . But there are other factors that could be considered that are relevant to that particular product." (CX4028 (Camargo, Dep. at 59-60); Camargo, Tr. 982). He specifically identified on-going litigation as one of those factors. (CX4028 (Camargo, Dep. at 60) ("I know there were other products [where this] was the case.")). Because Impax's first-to-market products, such as oxymorphone ER, are typically subject to litigation, the launch-ready date may be more likely to depart from the FDA approval date. (CX4028 (Camargo, Dep. at 68-69) ("If you weren't using the first-to-market term, I could say that generally we were trying to launch around the FDA approval date. But when you just narrow it down to first-to-market w8.1 products, .4(droc 101).)]TJ0.0002 Tc -0.00319 Tw 8.93sskelend(ati 0 he)4-by-hearlutigrket-0nirto that 0

CX4028 (Camargo, Dep. at 48-49 (discussing timing for API purchasing); *see also* CX4023 (Hildenbrand, Dep. at 26-27) (discussing "frequent changes" to launch-ready plans)).

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).

Response to Proposed Finding No. 1261

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1260.

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).

Response to Proposed Finding No. 1262

Complaint Counsel has no specific response.

relationships. (CX4014 (Hsu, IHT at 129); *see also* CCF ¶¶ 170, 172-173 (discussing manufacturing capacity decisions made by Impax management); CX4038 (Engle, Dep. at 191-93) (discussing choice to reduce production on a product because of capacity constraints); Camargo, Tr. 954-55 (noting Impax has needed to take products off the production plan because of capacity constraints.); CX4023 (Hildenbrand, Dep. at 43-44) (highlighting particular opportunity costs associated with manufacturing first-to-file products)). Thus, Impax's real-world launch-ready timeline for oxymorphone ER reflected product specific Impax management priorities, not simply a pro forma approach to product preparation. (CCF ¶¶ 127-28, 130, 168-73; *see also* CCF ¶ 199) (the period for manufacturing the post-process validation launch inventory build for oxymorphone ER, for instance, required only two weeks); CX4028 (Camargo, Dep. at 48-49 (discussing timings for API purchasing); (CX4023 (Hildenbrand, Dep. at 144) (discussing

This Proposed Finding is misleading for the

regulations, and other risks on a decision to begin product manufacturing. (Koch, Tr. 271-72; Camargo, Tr. 1007). Mr. Koch merely confirmed that Impax is generally aware that there are risks to expending capital on unapproved pre-launch inventory. (Koch, Tr. 272). Mr. Camargo merely confirmed that the Supply Chain Group was aware that some products in the production window are also subject to li

If Impax does not take these predicate steps,

d. The Regular Discarding of Products and Materials as a Result of

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).

Response to Proposed Finding No. 1275

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 1263, 1264, and 1274.

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).

Response to Proposed Finding No. 1276

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 1263, 1264, and 1274.

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).

Response to Proposed Finding No. 1277

The Proposed Finding is misleading to the extent it suggests that discarding $1.4 million of sellable product is "a matter of course." (*See* Complaint Counsel's Response to Proposed Finding No. 1274; CCF ¶¶ 206-13).

1278. Impax's CFO at the time of settlement, Arthur Koch, similarly testified that writing off

1279. Impax, for example, discarded pre-launch methylphenidate products because Impax never received FDA approval. (CX4023 (Hildenbrand, Dep. at 95-96)).

Response to Proposed Finding No. 1279

The Proposed Finding is misleading to the extent it suggests that discarding methylphenidate product (which could not be sold because it had not received FDA approval) is analogous to discarding $1.4 million of oxymorphone ER product (which could be sold because it had received FDA approval). (*See also* Complaint Counsel's Response to Proposed Finding No. 1274).

1280. In April 2010, Impax wrote off over $1 million worth of non-oxymorphone products. (CX2905-003; Camargo, Tr. 1023).

Response to Proposed Finding No. 1280

The Proposed Finding is not confirmed by the evidence cited. Inventory that is listed as "at risk for destruction" is not necessarily destroyed. Impax routinely reclassified the inventory it listed as "at risk" for disposal to be "No Longer At Risk." (*See, e.g.* CX2922 at 004, 10 (calculating over $650,000 worth of reclassified materials and finished goods in March 2011)). In fact, in the document cited, over $61,000 of the April 2010 losses are marked "to be reversed" or "will be reversed." (CX2905 at 003).

The Proposed Finding is also misleading in that it suggests that discarding $1.4 million of a single, sellable product is a routine practice. (*See* Complaint Counsel's Response to Proposed Finding No. 1274; CCF ¶¶ 206-13). In the cited document, the non-oxymorphone ER products cannot be sold, and are being scrapped for production reasons, such as "projected [polymer] expiration," "use of wrong setting," and "missing seal." (*See* CX2905 at 002-03). In contrast, the oxymorphone ER product could be sold, and was being scrapped for a non-production reason – "delayed launch." (CX2922 at 009). Moreover, the total value of the discarded oxymorphone product ($1.4 million) was approximately $400,000 more than the value of all of the other

inventory losses that Impax incurred during April 2010 (before any reversals), and was far greater than the combined losses for the first five months of 2010. (CCF ¶ 212). Additionally, after the Impax-Endo Settlement Agreement, Impax was left with more than $1.6 million in oxymorphone API with a 2011 expiration date. (CCF ¶ 209). It is unclear what, if anything, Impax did with this remaining oxymorphone API. (CX2928 at 015 (Impax Response to Interrogatory No. 20); CCF ¶ 209).

1281. In June 2010, Impax wrote off roughly $560,000 worth of non-oxymorphone ER product. (CX2896-002-03; Camargo, Tr. 1023-24).

Response to Proposed Finding No. 1281

The Proposed Finding is not supported by the evidence cited. Inventory that is listed as "at risk for destruction" is not necessarily destroyed. Impax routinely reclassified inventory listed at risk for disposal to be "No Longer At Risk." (*See, e.g.* CX2922 at 004, 010 (calculating over $650,000 worth of reclassified materials and finished goods in March 2011)). In fact, in the document cited, $53,000 of the June 2010 losses are marked "to be reversed." (CX2896 at 003).

The Proposed Finding is also misleading to the extent it suggests that discarding $1.4 million of a single, sellable product is a routine practice. (*See* Complaint Counsel's Response to Proposed Finding No. 1274; CCF ¶¶ 206-13). In the cited document, the non-oxymorphone ER product cannot be sold and is being scrapped for production reasons, including a "contamination" and "cleaning issue." (*See* CX2896 at 002-03). In contrast, the oxymorphone ER product could be sold, and was being scrapped for a non-production reason – "delayed launch." (CX2922 at 009). Moreover, the total value of the discarded oxymorphone product ($1.4 million) was approximately $840,000 more than the value of all of the other inventory losses that Impax incurred during June 2010 (before any reversals), and was far greater than the combined losses for the first five months of 2010. (CCF ¶ 212). Additionally, after the Endo-

Impax Settlement Impax was left with more than $1.6 million in oxymorphone API with a 2011 expiration date. (CCF ¶ 209). It is unclear what, if anything, Impax did with this remaining oxymorphone API. (CCF ¶ 209).

Moreover, the June 2010 calculation explicitly makes an exception for the "1.4M hit [of oxymorphone ER] materials which became obsolete by virtue of [the Endo-Impax] settlement on Oxymorphone." (CX2896 at 002). The Operations group was only able to meet its 2010 goals regarding rejected product by excluding the oxymorphone ER product from the normal calculations. (CX2896 at 002; CCF ¶ 213).

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).

Response to Proposed Finding No. 1282

The Proposed Finding is misleading to the extent it suggests that discarding $1.4 million of a single, sellable product is a routine practice. (*See* Complaint Counsel's Response to Proposed Finding 1274; CCF ¶¶ 206-13). The Proposed Finding is also misleading to the extent that it suggests that discarding non-sellable product is the same as discarding sellable product. In the cited document, the non-oxymorphone ER products cannot be sold and are being scrapped for production reasons, such as "contamination," "broken tablets," equipment "malfunction," 295 Td(Pron(a) 29

The Proposed Finding is further misleading because inventory that is listed as "at risk for destruction" is not necessarily destroyed. Impax routinely reclassified inventory listed at risk for disposal to be "No Longer At Risk." (*See, e.g.* CX2922 at 004, 010). In fact, in the document cited, over $650,000 of goods are marked "No Longer At Risk." The total value of material actually discarded in March 2011 was about $400,000 – far less than $2 million of product "at risk." (CX2922 at 004-05, 008, 010).

1283. And in 2017, Impax had to discard roughly $25 million in finished product. (Engle, Tr. 1786).

Response to Proposed Finding No. 1283

The Proposed Finding is misleading and incomplete in that the cited testimony does not specify what product or groups of products were discarded, or the reason(s) why the product(s) were discarded. Discarding product that is unsellable because of regulatory, manufacturing or other reasons is different from discarding sellable product because of a reverse-payment settlement.

The Proposed Finding is also misleading to the extent it suggests discarding approximately $1.4 million of a product is routine. (*See* Complaint Counsel's Response to Proposed Finding 1274; CCF ¶¶ 206-13). While it was typical for Impax to discard some product or materials in inventory every month, a disposal of this "big amount" of manufactured oxymorphone ER product was not a common practice. (CX4004 (Engle, IHT at 133-34)). Indeed, directly after the cited testimony, Mr. Engle confirms that throwing away $1.5 million in product is a "large enough amount to attract attention from management." (Engle, Tr. 1786-87; *see also* CCF ¶ 206).

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

(Camargo, Dep. at 60) ("I know there were other products [where this] was the case.")). Because Impax's first-to-market products, such as oxymorphone ER, are typically subject to litigation, the launch-ready date may be more likely to depart from the FDA approval date. (CX4028 (Camargo, Dep. at 68-69) ("If you weren't using the first-to-market term, I could say that generally we were trying to launch around the FDA approval date. But when you just narrow it down to first-to-market opportunities, I don't know if I could generally say that's true or not.")).

1285. In the case of generic Opana ER, that was June 14, 2010. (Mengler, Tr. 558).

Response to Proposed Finding No. 1285

Complaint Counsel had no specific response.

1286. To meet the June 2010 "launchable" date, Impax began planning oxymorphone ER production in 2009. (Camargo, Tr. 969, 1004).

Response to Proposed Finding No. 1286

Complaint Counsel had no specific response.

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).

Response to Proposed Finding No. 1287

Complaint Counsel had no specific response.

1288. The Supply Chain Group also put oxymorphone ER on its product launch checklist to coordinate all launch-related activities. (Camargo, Tr. 1006).

Response to Proposed Finding No. 1288

Complaint Counsel had no specific response.

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).

Response to Proposed Finding No. 1289

The Proposed Finding is misleading and incomplete to the extent it suggests that, as of June 2009, Impax was not considering launching oxymorphone ER upon FDA approval. Instead,

the cited email recognizes the substantial upside of an oxymorphone ER launch, and states that, in June 2009, Impax still "need[ed] to figure out what we want to plan for" regarding the oxymorphone ER product. (RX-181 at 0001). In the end, Impax decided to plan for a launch as early as June 2010, and took substantial concrete steps to be ready to launch. (CCF ¶¶ 168-202).

(Camargo, Tr. 1006-07). Neither source discusses any analysis of why Impax ultimately undertook launch preparations for oxymorphone ER. (*See* RX-181.0001; Camargo, Tr. 1007).

In addition, the Proposed Finding is misleading, factually inaccurate, and contrary to the weight of the evidence to the extent it suggests that Impax would take the steps necessary to be ready to launch oxymorphone ER in mid-2010, even if there was no possibility that Impax would actually do so. (*See* Complaint Counsel's Response to Proposed Finding Nos. 1263 and 1284.)

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).

Response to Proposed Finding No. 1292

The Proposed Finding is misleading, factually inaccurate, and contrary to the weight of the evidence to the extent it suggests that Impax would take the steps necessary to be ready to launch oxymorphone ER in mid-2010, even if there was no possibility that Impax would actually do so. (*See* Complaint Counsel's Response to Proposed Finding Nos. 1263, 1284, and 1289.)

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).

Response to Proposed Finding No. 1293

Complaint Counsel has no specific response.

1294. Impax made several requests for an oxymorphone quota in 2010 because its first request was denied by the DEA. (Camargo, Tr. 974-75).

Response to Proposed Finding No. 1294

The Proposed Finding is incomplete. Quota can be requested and granted for different purposes, including for research and development and commercial manufacturing purposes. (CCF ¶ 175; CX4027 (Anthony, Dep. at 37, 39)). Quota granted for one purpose (such as research and development) cannot be used for a different purpose (such as commercial

manufacturing). (CCF ¶ 175; CX4027 (Anthony, Dep. at 37, 39)). Only Impax's request for 2010 commercial manufacturing quota was denied. (CCF ¶ 176; CX2874 at 003 (Dec. 23, 2009 letter from the DEA); CX4027 (Anthony, Dep. at 93-95)). The DEA denied Impax's request for 2010 commercial manufacturing because Impax's submission did not properly justify the need for the requested quota. (CX2874 at 005 (Dec. 23, 2009 letter from the DEA); CX4027 (Anthony, Dep. at 95); CCF ¶ 176). To justify subsequent DEA requests, Impax's included additional supporting documentation, including customer commitments to purchase oxymorphone ER from Impax in 2010. (CX2882 at 001, 003 (Apr. 2010 email chain and LOI); CCF ¶¶ 185-86).

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)).

Response to Proposed Finding No. 1295

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 1297

Complaint Counsel has no specific response.

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")).

Response to Proposed Finding No. 1298

The Proposed Finding is misleading to the extent it suggests that Impax did not have enough quota to complete a launch inventory build by June 2010. Impax purchased all of the API it was authorized to purchase under the March 2010 DEA quota allotment. (CCF ¶ 181). This oxymorphone API was enough to manufacture product sufficient for an initial launch of oxymorphone ER in 2010. (CCF ¶ 181; CX2898 at 001 (Impax had enough API for the inventory build lots after the process validation lots were completed); CX2563 (indicating Impax was "launch ready" in June 2010)). Impax did, however, need to request more quota and purchase more API to sustain the oxymorphone ER product after its launch. (CCF ¶ 181). Impax requested and ultimately received this additional quota. (CCF ¶¶ 182-87).

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)).

Response to Proposed Finding No. 1299

Complaint Counsel has no specific response, except to clarify that this quota request was for commercial manufacturing quota. (CCF ¶ 178). To support this quota request, Impax's request included customer commitments to purchase oxymorphone ER from Impax in 2010.

(CX2882 at 001, 003 (Apr. 2010 email chain and LOI); CCF ¶¶ 185-86). These commitments represented 88% of the total generic oxymorphone ER demand Impax expected in 2010. (CX2882 at 001 (Apr. 2010 email chain and LOI); CCF ¶ 185).

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)).

Response to Proposed Finding No. 1300

Complaint Counsel has no specific response, except to clarify that the Impax-Endo Settlement Agreement had nullified Impax's plans to use this 2010 oxymorphone quota. (CCF ¶ 187; CX2865).

1301. In total, the DEA's quota decisions ensured Impax had enough oxymorphone quota to complete process validation. (Camargo, Tr. 975-76).

Response to Proposed Finding No. 1301

The Proposed Finding is misleading and incomplete because the March, 2010 quota was enough to allow Impax to manufacture product sufficient for an initial launch of oxymorphone ER. The DEA ultimately granted Impax all of the oxymorphone quota it requested in anticipation of a June 2010 launch. (*See* Complaint Counsel's Response to Proposed Finding Nos. 1296 and 1298).

b. Process Validation

1302. Impax also conducted process validation for oxymorphone ER. (Camargo, Tr. 1011-12).

Response to Proposed Finding No. 1302

Complaint Counsel has no specific response.

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)).

Response to Proposed Finding No. 1303

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 1304

Response to Proposed Finding No. 1307

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 1308

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 1309

Complaint Counsel has no specific response except to note the contradiction within Impax's Proposed Findings suggesting oxymorphone ER is both a "relatively expensive" product and a "small cost item." (*See* Complaint Counsel's Responses to Proposed Finding Nos. 1267-68).

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.

left with more than $1.6 million in oxymorphone API with a 2011 expiration date. (CCF ¶ 209). It is unclear what, if anything, Impax did with this remaining oxymorphone API. (CX2928 at 015 (Impax Response to Interrogatory No. 20); CCF ¶ 209).

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).

Response to Proposed Finding No. 1312

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 1274. Indeed, directly after the cited testimony, Mr. Engle confirms that throwing away $1.5 million in product is a "large enough amount to attract attention from management." (Engle, Tr. 1786-87; *see also* CCF ¶ 206). In previous testimony, Mr. Engle had stated that while it was typical for Impax to discard small amounts of product or materials in inventory every month (such as $50,000), a disposal of this "big amount" of manufactured oxymorphone ER product was not a common practice. (CX4004 (Engle, IHT at 133-34) (testifying that throwing away a million dollars of product "never happened")). Impax's Senior Vice President of Operations for seven years, Chuck Hildenbrand, could not recall any other instance where the Operations team successfully manufactured product for a launch date, the product received FDA approval, and yet the product had to be destroyed because the company decided not to launch. (CCF ¶ 211).

1313. In June 2010, Impax also possessed oxymorphone API that had not been incorporated into any finished products. (Camargo, Tr. 1022).

Response to Proposed Finding No. 1313

Complaint Counsel has no specific response.

1314. Impax did not discard the API, and eventually used it to manufacture other finished products. (Camargo, Tr. 1022).

Response to Proposed Finding No. 1314

The Proposed Finding is inconsistent with other, more reliable, evidence. Impax submitted its response to an interrogatory which specifically asked what happened to any product or material related to oxymorphone ER that Impax had on hand as of June 8, 2010. With respect to the $1.6 million worth of oxymorphone API, Impax stated: "It is unclear based on available documentation whether Impax was able to process this API" to support Impax's later launches for oxymorphone ER. (CX2928 at 015 (Impax Response to Interrogatory No. 20); CCF ¶ 209). This interrogatory response is the sworn, binding testimony of the company, and cannot be contradicted by self-serving testimony of a paid witness at trial. (Camargo, Tr. 947-48). Mr. Camargo's trial testimony is also suspect because he testified at deposition that he didn't know if the oxymorphone API was ever used. (CX4028 (Camargo, Dep. at 198-99) ("I don't know specifically, no.")).

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).

Response to Proposed Finding No. 1315

The Proposed Finding is misleading and incomplete. By mid-June 2010, Impax had validated its manufacturing process for oxymorphone ER and had manufactured launch quantities, including almost $1.4 million worth of inventory in both finished goods and brite stock (which is product bottled, but not yet labeled). (CCF ¶¶ 196-202, 208). Although Impax would need additional inventory to sustain its sale of oxymorphone ER after launch, Impax was "Launch ready" as of June 15, 2010. (CX2563 at 002; *see also* CX2899 at 002; CX4028 (Camargo, Dep. at 205-06)).

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).

Response to Proposed Finding No. 1316

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 1317

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1315.

a. Additional Oxymorphone ER Necessary

1318. [redacted] (CX2662-013; *see* Engle, Tr. 1776, 1779).

Response to Proposed Finding No. 1318

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1231 and 1315.

1319. In fact, "the process validation batches weren't sufficient to meet the market demand for a full launch." (Koch, Tr. 292-93).

Response to Proposed Finding No. 1319

The Proposed Finding is incomplete for the reasons set forth in response to Proposed Finding Nos. 1231 and 1315.

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).

Response to Proposed Finding No. 1320

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 1315.

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).

Response to Proposed Finding No. 1321

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1315.

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).

Response to Proposed Finding No. 1322

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1315. Moreover, Impax's former Vice President of Supply Chain testified that Impax had between one and four months' worth of supply for each dosage strength of oxymorphone ER. (CCF ¶ 202).

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).

Response to Proposed Finding No. 1323

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1315 and 1322.

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).

Response to Proposed Finding No. 1324

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1315 and 1322. Mr. Engle is responsible for forecasting; he does not make the launch-readiness decision. (Engle, Tr. 1784). That responsibility falls to the Operations group. According to the Operations group, Impax was "Launch ready" for oxymorphone ER as of June 15, 2010. (CX2563 at 002; *see also* CX2899 at 002; CX4028 (Camargo, Dep. at 205-

06)). The Proposed Finding is also not supported by the evidence cited. In his trial testimony, Mr. Engle does not explain why he wants twice as much oxymorphone as necessary. But in previous testimony, Mr. Engle explained that he "always" tries to be "aggressive" in his forecasts because he can't get in "trouble if I forecast too much" (CX4004 (Engle, IHT at 132) ("I want to over forecast on production-wise.")); and that he requests 200% of what he thinks Impax will sell during launch so that customers can stock their shelves with additional inventory. (CX4004 (Engle, IHT at 145-46)).

b.

suggests that Impax never expected to launch oxymorphone ER in 2010. In fact, prior to the Impax-Endo settlement negotiations, Impax took many substantial and concrete steps to be ready to launch in June 2010. (CCF ¶¶ 168-202).

1327. Mr. Camargo responded that he had already "advised the team that it was unlikely that we would make the Oxymorphone." (CX2904-001).

Response to Proposed Finding No. 1327

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1325 and 1326.

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).

Response to Proposed Finding No. 1328

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1325 and 1326.

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).

Response to Proposed Finding No. 1329

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Findings Nos. 1325 and 1326. The Proposed Finding is also not supported by the testimony cited because Mr. Camargo, in his deposition testimony, made clear that he did not have any responsibility for, or involvement in, the decision to launch at risk, which was made by

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1325 and 1326.

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).

Response to Proposed Finding No. 1331

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1325 and 1326. Complaint Counsel also notes that as a "standard practice," the Supply Chain Group would "hold off on beginning a launch inventory build until the PV summary report was signed off on." (Camargo, Tr. 979). The Supply Chain Group did not expect the PV summary report to be signed off on until May 18, 2010. (Camargo, Tr. 978). If the Supply Chain Group "received the go-ahead from senior management for oxymorphone ER once the process validation summary report was signed off on" then it was prepared to commence with the remainder of the launch inventory build. (Camargo, Tr. 979). In fact, as of May 13, 2010, Impax was still considering the possibility of launching oxymorphone ER at-risk.

mg tablets, and two months for the 40 mg tablets. (CCF¶ 202). According to the Operations group, Impax was "Launch ready" for oxymorphone ER as of June 15, 2010. (CX2563 at 002; *see also* CX2899 at 002; CX4028 (Camargo, Dep. at 205-06)).

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)).

DEA, Mr. Engle requested letters of intent from its customers to purchase oxymorphone ER from Impax in 2010. (Engle, Tr. 1788; CCF ¶¶ 182-185). To secure these letters of intent, Impax informed its customers that "Impax is preparing the launch" of oxymorphone ER in 2010. (CCF ¶ 184). By April 2010, Impax had received purchase commitments from four customers representing 88% of the total generic oxymorphone ER demand Impax expected in 2010. (CCF ¶ 185).

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")).

Response to Proposed Finding No. 1335

The Proposed Finding is misleading and incomplete to the extent it suggests that Impax was not ready to launch oxymorphone ER as of mid-June 2010. (*See* Complaint Counsel's Responses to Proposed Findings Nos. 1315 and 1332).

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).

Response to Proposed Finding No. 1336

The Proposed Finding is misleading in that it suggests that Impax had no communications with its customers about a potential 2010 oxymorphone ER launch. (*See* plaint Counsel 001;

commitments from these four customers (Walgreens, AmeriSource Bergen, Cardinal, and McKesson) represented 88% of the total generic oxymorphone ER demand Impax expected in 2010. (CCF ¶ 185; CX2864; CX3882). Impax provided these purchase commitments to the DEA as support for its request for additional oxymorphone ER quota, which the DEA then granted. (CCF ¶¶ 186-87). There is no reason to believe that, despite these purchase commitments, the customers would not in fact buy from Impax, particularly since Impax would be the only approved seller of a generic oxymorphone ER product. Indeed, Impax would have had a reasonable period of time to arrange any necessary pricing contracts in the event of an oxymorphone ER launch decision. (*See, e.g.,* RX-364 at 0007 (SLA § 3.2) (defining a reasonable time to make offers to sell a product as 30 days or less)).

1338. Impax had engaged in no preselling activities in an effort to generate market demand for generic Opana ER. (Engle, Tr. 1782).

Response to Proposed Finding No. 1338

The Proposed Finding is misleading in that it suggests that Impax generally engages in preselling activities to generate market demand for its generic products. But Mr. Engle previously testified that, "[a]s a generic sales and marketing guy, I don't really do an awful lot of marketing." (CX4004 (Engle, IHT at 48-49)). As Mr. Engle explained: "I don't think I create markets. I don't create, really awareness, and I don't drive prescriptions. I'm just following behind a brand and filling needs of the market. I don't create the market. . . . I'm really counting on the prescriptions being generated by the brand's marketing efforts with physicians. . . and as a generic person, as a marketer, I'm really taking advantage of the ability of pharmacies to substitute a generic for a brand product." (CX4004 (Engle, IHT at 49-50)).

Response to Proposed Finding No. 1339

The Proposed Finding is not supported by the evidence cited and is contradicted by more reliable evidence. RX-086 is a presentation by Fuld & Company, an unknown third-party. Fuld & Company provided no testimony about the document's creation, and the document has no independent indicia of reliability. To the contrary, it contains multiple levels of hearsay and

The Proposed Finding is misleading and incomplete. By April 2010, Impax had secured good faith commitments from four customers to purchase Impax's oxymorphone ER. (CCF ¶ 185). The commitments from these four customers (Walgreens, AmeriSource Bergen, Cardinal, and McKesson) represented 88% of the total generic oxymorphone ER demand Impax expected in 2010. (CCF ¶ 185; CX2864; CX3882). Impax provided these purchase commitments to the DEA as support for its request for additional oxymorphone ER quota, which the DEA then granted. (CCF ¶¶ 186-87). Although these commitments do not obligate the customers to buy from Impax, there is no reason to believe that the customers would not do

The Proposed Finding is misleading in that it suggests that Impax maintained multiple versions of its five-year plan. As Mr. Engle testified in his deposition, Impax maintained a single "five-year plan file" that was the "main piece or main file that we use for everything." (CX4038 (Engle, Dep. at 48, 51)). The five-year plan is updated quarterly. (Engle, Tr. 1719). At Impax, the five-year plan was a "critical" document, with implications for "future planning, resource planning, especially capital expenditures that may be needed to support that plan." (CX4022 (Mengler, Dep. at 26); *see also* CCF ¶ 165).

The Proposed Finding is also misleading in that it suggests that Impax's five-year plan included a scenario in which Impax would launch oxymorphone ER later than July 2011. To the contrary, prior to entering the settlement with Endo, Impax's five-year plan consistently forecasted two possibilities: Under the "upside" case, Impax would begin selling oxymorphone ER in June 2010, while under the "base" case it would launch oxymorphone ER in July 2011. (CX2825 at 012 (Feb. 2010 Smolenski email to Sica attaching 5-year plan); CX0004 at 014-15 (Feb. 2010 Sica email to Mengler attaching 5-year plan); CX0514 at 001, 004 (May 16, 2010

year plans were “critical” documents relied upon by senior management for “business forecasting purposes” and long-range business planning. (CX4022 (Mengler, Dep. at 26, 146); Engle, Tr. 1719-20; *see also* CCF ¶ 165).

The Proposed Finding is misleading and incomplete. In the document cited, Kevin Sica sends a five-year forecast to Mr. Mengler. (CX0004 at 001). Consistent with all five-year plans prior to Impax's settlement with Endo, it forecasts an oxymorphone ER launch in June 2010 under the "Upside" scenario and July 2011 under the "Base" scenario. (CX0004 at 014-15; *see also* CX2825 at 012 (Feb. 2010 Smolenski email to Sica attaching 5-year plan); CX0514 at 004 (May 16, 2010 Mengler email to Hsu et al. attaching "final, final" 5-year plan)). In the testimony cited, Mr. Engle does not call the five-year plan a "one-off forecast[]." Though Mr. Engle prepared the five-year plan with Mr. Sica (Engle, Tr. 1729), he testified that he did not recall "who developed the assumptions that were used in the forecast." (Engle, Tr. 1768). As such, Mr. Engle did not testify that he selected June 2010 as the oxymorphone ER upside launch date.

The Proposed Finding is also misleading insofar as it suggests that a June 2010 entry date assumption for oxymorphone ER was included only in a "one-off" forecast. Impax's internal projections and forecasts consistently assumed a generic oxymorphone ER entry as early as June 2010 and prior to January 2013. These forecasts included (1) monthly demand forecasts used by the Operations group to plan for the eventual launch of generic products; (2) forecasts used at the Quarterly launch planning meetings; and (3) five-year forecasts. (CCF ¶¶ 148-67).

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).

Response to Proposed Finding No. 1349

contemplating and preparing for a potential at-risk launch prior to entering the settlement with Endo. (CCF ¶¶ 127-213). Mr. Engle and Mr. Sica prepared the five-year plan at the request of Mr. Mengler, who needed the information for a presentation he was preparing. (Engle, Tr. 1767-68). Consistent with all five-year plans prior to Impax's settlement with Endo, the five-year plan Mr. Sica and Mr. Engle provided to Mr. Mengler forecasted an oxymorphone ER launch in June 2010 under the "Upside" scenario and July 2011 under the "Base" scenario. (CX0004 at 014-15; *see also* CX2825 at 012 (Feb. 2010 Smolenski email to Sica attaching 5-year plan); CX0514 at 004 (May 16, 2010 Mengler email to Hsu et al. attaching "final, final" 5-year plan)).

1350. That forecast, moreover, did not account for regulatory, legal, or any other risk associated with launch. (Engle, Tr. 1770-71; CX0004).

Response to Proposed Finding No. 1350

The Proposed Finding is misleading and not supported by the evidence. The five-year plan was a "critical" document that "we use for everything." (CX4038 (Engle, Dep. at 48); CX4022 (Mengler, Dep. at 26)). While Mr. Engle stated that *he* did not account for legal or regulatory risks in preparing the five-year forecast provided to Mr. Mengler in February 2010, he also stated that he did not know "who developed the assumptions that were used in the forecast." (Engle, Tr. 1768). Thus, Mr. Engle's testimony does not support the conclusion that the critically important five-year forecast does not account for regulatory, legal, or other risks associated with launch.

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).

Response to Proposed Finding No. 1351

The Proposed Finding is misleading and incomplete. On May 16, 2010, following the FDA's tentative approval of Impax's ANDA, Mr. Mengler circulated the "final, final current five

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).

Response to Proposed Finding No. 1353

Complaint Counsel has no specific response, but notes that the Proposed Finding is not supported by the testimony cited. (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).

Response to Proposed Finding No. 1354

The Proposed Finding is misleading, irrelevant, and not fully supported by the testimony cited. The Launch Planning Committee, the Marketing and Operations divisions, and Impax's senior management all were forecasting and preparing for a June 2010 at-risk launch.

The Quarterly Launch Planning Meetings brought together representatives from various Impax groups, including Legal, Regulatory, Marketing, and Operations, to discuss and plan for

(CX0008 at 002; *see also* CCF ¶ 139). Mr. Mengler did just that at the May 25-26, 2010 meeting of the Board of Directors, explaining that a June 2010 at-risk launch had gone from a possible "Upside" in February 2010 to a "Current Assumption" in May 2010. (CX2662 at 010, 012, 015; *see also* CCF ¶ 145). Mr. Mengler's presentation informed the Board that Impax expected to earn $28.8 million from oxymorphone ER sales in 2010. (CX2662 at 015; CCF ¶ 145). Mr. Mengler "expressed the view that Oxymorphone was a good candidate for an at-risk launch." (CX2663 at 001 (May 25-26, 2010 Minutes of the Meeting of the Board of Directors of Impax Laboratories, Inc.); CCF ¶ 146). Impax's Operations group was prepared to launch oxymorphone ER on June 14, 2010 – the day the FDA granted final approval. (CCF ¶¶ 169-71).

Finally, in the testimony cited in the Proposed Finding, Mr. Engle explained that it was his "recommendation that Impax should prepare to launch on June 14 and consider obtaining board approval." (Engle, Tr. 1755; *see also* CX3347 at 002).

1355. Its sole purpose is to ensure Impax is able to launch identified products. (Engle, Tr. 1754-55).

Response to Proposed Finding No. 1355

The Proposed Finding is misleading and not supported by the testimony cited because Mr. Engle did not offer testimony as to the committee's "sole purpose." He merely testified that the committee did not make the ultimate launch decision – instead being tasked with preparing for launch. (Engle, Tr. 1754-55). The Proposed Finding is also misleading for the reasons set forth in response to Proposed Finding No. 1354.

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)).

Response to Proposed Finding No. 1356

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 1357

Complaint Counsel has no specific response.

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).

Response to Proposed Finding No. 1358

The Proposed Finding is misleading to the extent it suggests that Impax's projected launch date was set, as a matter of course, to the end of the thirty-month stay. (CX4028 (Camargo, Dep. at 59-60, 66-69); Camargo, Tr. 982; *see also* Complaint Counsel's Response to Proposed Finding No. 1284). Impax's projected launch timeline for oxymorphone ER reflected product-by-product Impax management priorities. (CCF ¶¶ 127-28, 130, 168-73). In accordance with these priorities, Impax took concrete steps to be ready to launch oxymorphone ER as early as June 2010 instead of allocating resources to other Impax products. (CCF ¶¶ 174-213; CX4023 (Hildenbrand, Dep. at 43-44)).

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)).

Response to Proposed Finding No. 1359

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding Nos. 1284 and 1358.

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).

Response to Proposed Finding No. 1360

The Proposed Finding is incomplete and misleading. The Quarterly Launch Planning Committee itself was comprised of representatives from a range of functions at Impax, including Legal and Regulatory. (CCF ¶ 163). The documents Mr. Engle prepared and circulated in advance of the committee's meetings also covered the "Regulatory Status" and "Legal Status" of the drug (those sections were redacted in Impax's production as privileged, suggesting they conveyed legal advice). (CX3347 at 002-03; CX3348 at 003-04). Members of senior management sitting on the committee, such as CEO Dr. Hsu, were also privy to all relevant litigation and settlement issues. (*See* Engle, Tr. 1773-74).

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).

Response to Proposed Finding No. 1361

The Proposed Finding is incomplete and misleading. Senior managers, including Impax's CEO, Dr. Hsu, sat on the Quarterly Launch Planning Committee (Engle, Tr. 1773-74), and the documents are consistent with senior management's thinking prior to entering the settlement with Endo. (*Compare* CX3348 at 003 (May 20, 2010 Quarterly Launch Planning Meeting projecting oxymorphone ER launch date of June 14, 2010) *with* CX2662 at 012 (May 25-26, 2010 presentation to Impax Board of Directors showing a June 2010 oxymorphone ER at-risk launch)). Specifically, the Quarterly Launch Planning documents are consistent with the "Upside" scenario in the five-year plans relied upon by senior management and with senior management's presentation to the Board of Directors on May 25-26, 2010, of an oxymorphone ER at-risk launch in June 2010 as the "Current Assumption." (CX2662 at 012; CCF ¶¶ 145, 165-66). Everyone at the May 2010 Board meeting agreed that an at-risk launch of oxymorphone ER was a "great market opportunity" for Impax. (Koch, Tr. 259; CCF ¶ 146).

1362. In any event, Mr. Engle's thoughts on logical next steps never proceeded beyond the Quarterly Launch Planning Committee. (Engle, Tr. 1777).

Response to Proposed Finding No. 1362

The Proposed Finding is misleading and incomplete. The work of Mr. Engle and the Quarterly Launch Planning Committee was shared with senior management and – prior to the settlement with Endo – senior management was also proceeding with the "Current Assumption" of a June 2010 oxymorphone ER at-risk launch. (CX2662 at 012). At the May 25-26, 2010,

analyses of potential liability for an at-risk launch of oxymorphone of which you're aware that do not contain privileged legal advice? A. No, not that I'm aware of."); CX4026 (Nguyen, Dep. at 85) ("Q. And would you be looking at brand lost profits to assess potential damages? Ms. Fabish: Objection. I'm going to instruct the witness not to answer. It's privileged and redacted information.")). Even in the cited testimony, Dr. Addanki does not state what Impax actually thought or expected its potential damages could be at the time of the settlement, but rather opines on potential damages on a general basis of generic and brand prices. (Addanki, Tr. 2379-80). Impax cannot hide its actual estimates of potential damages behind the attorney-client privilege and then attempt to establish those potential damages through the general musings of an expert.

Moreover, Dr. Addanki's opinion that it is never financially beneficial for a generic to launch is inconsistent with the facts in this case. Impax invested millions of dollars and dedicated

concerned about a potential switch to some new version of Opana ER." (CCF ¶ 121; RX-547 at 0064 (¶ 121) (Addanki Report)). Impax was acutely aware that it risked making no money if Endo reformulated Opana ER and Impax's product was not substitutable. (CCF ¶¶ 123-24; Mengler, Tr. 527 ("[I]f there's no substitute, I get nothing.")). Thus, Impax had strong incentives to launch before Endo would have the opportunity to switch the market to its reformulated product. (CCF ¶¶ 121-26).

1364.

} (CX2662-015).

Response to Proposed Finding No. 1364

Complaint Counsel has no specific response, except to note that it is unclear from the face of the document whether Impax forecasted $28.8 million in revenues or net sales in 2010. (CX2662 at 015). The five-year plan Mr. Mengler circulated on May 14, 2010, indicates that Impax expected to earn at least that amount in net sales in 2010. (CX0514 at 004 (May 14, 2010 Mengler email to Hsu et al. attaching five-year plan) (projecting $30.8 million in 2010 oxymorphone ER net sales)).

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

Professor Noll all agree that it was possible that the underlying patent litigation between Endo and Impax would be resolved in the second half of 2011. (CCF ¶ 1026; CX5004 at 079-80 (¶¶ 166-67) (Noll Rebuttal Report); RX-547 at 0082 (¶ 152) (Addanki Report); RX-548 at 0036-37 (¶ 80) (Figg Report)). Even Impax's experts agree that Impax could have launched free and clear of any patent risk in the second half of 2011, well before January 2013. (CCF ¶ 1026; RX-547 at 0082 (¶ 152) (Addanki Report); RX-548 at 0036-37 (¶ 80) (Figg Report)). The fact that Impax was spending money challenging the patent demonstrates that Impax recognized there was some probability it would ultimately win the infringement case and be able to launch oxymorphone ER free and clear of legal risk. (CCF ¶ 1026; Noll, Tr. 1438-39).

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).

Response to Proposed Finding No. 1366

The Proposed Finding is incomplete and misleading and not supported by any contemporaneous documents or fact witness testimony. Impax held first-to-file exclusivity for the five dosages representing 95% of Opana ER sales. (CCF ¶ 101). Regardless of Impax's date of entry, the relevant FDA law prohibited Actavis from launching until 180 days after Impax entered the market. (CCF ¶¶ 14, 66, 102).

1367. Finally, had Impax launched at risk, it would have jeopardized Impax's 180-day exclusivity. (Addanki, Tr. 2381).

Response to Proposed Finding No. 1367

The Proposed Finding is incomplete, misleading and not supported by any contemporaneous documents or fact witness testimony. As stated above, Impax held first-to-file exclusivity for the five dosages representing 95% of Opana ER sales. (CCF ¶ 101). Regardless of Impax's date of entry, the relevant FDA law prohibited Actavis from launching until 180 days

after Impax entered the market. (CCF ¶¶ 14, 66, 102). In fact, Impax risked the entire value of its exclusivity if it did not launch at risk. As Dr. Addanki himself opined, "Impax was concerned about a potential switch to some new version of Opana ER." (CCF ¶ 121; RX-547 at 0064 (¶ 121) (Addanki Report)). Impax was acutely aware that it risked making no money if Endo reformulated Opana ER and Impax's product was not substitutable. (CCF ¶¶ 123-24; Mengler, Tr. 527 ("[I]f there's no substitute, I get nothing.")). Because of the uncertain market opportunity due to Endo's suspected reformulation, waiting for several years to launch would carry significant risks for Impax. Thus, Impax had strong incentives to launch before Endo would have the opportunity to switch the market to its reformulated product. (CCF ¶¶ 121-26).

The Proposed Finding is also misleading and incomplete insofar as it presumes that Impax would have launched prior to receiving a decision from the district court on the merits. Impax could have waited until it received a favorable district court judgment before launching, which would substantially reduce the risk of facing an injunction. (CCF ¶ 120 ("An at risk launch involves . . . significantly less risk after the generic receives a favorable decision . . ."); Noll, Tr. 1603-04 ("[I]t's far more likely that [Impax] would have launched at risk if they had received a favorable decision."); CX5007 at 024 (¶ 44) (Hoxie Rebuttal Report) ("If Impax had received a favorable decision at the district court level, a launch prior to the appellate decision could be a reasonable risk . . .")). In fact, Impax had previously done just that, and launched oxycodone at risk following a favorable district court decision. (Snowden, Tr. 425-26).

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")).

Response to Proposed Finding No. 1368

The Proposed Finding is contrary to the contemporaneous documents and fact witness testimony, and Dr. Addanki's expert opinion cannot be used to establish a factual proposition. As discussed above, Impax consistently withheld all estimates of potential liabilities from an at-risk launch as protected by the attorney-client privilege and/or work-product doctrine, and Impax's counsel did not allow any fact witnesses to testify on the subject on the same basis. (CX2636 at 003 (Mar. 11, 2010 Engle email to Mengler attaching Zorn model); CX2635 at 003, (Mar. 12, 2010 Sica email to Smolenski attaching Zorn model); CX3155 at 003-04, 007, 010, 013, 027 (Mar. 23, 2010 Engle email to Mengler and Snowden attaching Zorn model); CX2753 at 004-05, 008, 011, 014, 028 (May 14, 2010 Engle email to Hsu, Mengler, and Snowden attaching Zorn model); CX4032 (Snowden, Dep. at 227-28) ("Q. Are there any analyses of potential liability for an at-risk launch of oxymorphone of which you're aware that do not contain privileged legal advice? A. No, not that I'm aware of."); CX4026 (Nguyen, Dep. at 85) ("Q. And would you be looking at brand lost profits to assess potential damages? Ms. Fabish: Objection. I'm going to instruct the witness not to answer. It's privileged and redacted information.")). Impax cannot now offer its expert's opinion in lieu of the actual facts.

10

The actual facts show that just before Impax entered the settlement agreement with Endo, Endo 22(o

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).

Response to Proposed Finding No. 1369

The Proposed Finding is misleading. The relevant question is not what an expert did or did not do in 2017; rather, it is whether Impax was a risk to enter with its generic oxymorphone

Cuca attaching Opana ER Combined P&L scenarios)). And Mr. Cuca was notifying Endo CFO Alan Levin that the expected July 2010 Impax generic launch would cause Endo to "lose $71.2M in branded ER sales." (CX1314 (June 1, 2010 Cuca email to Levin)). To counter the expected loss in branded sales, Endo prepared to launch an authorized generic as soon as Impax entered. (CCF ¶¶ 84-92). Endo began its authorized generic preparations in late 2009 and was ready to launch by June 2010. (CCF ¶¶ 86-89).

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)).

Response to Proposed Finding No. 1371

The Proposed Finding is misleading and incomplete. An Endo lawyer posturing during negotiations signifies nothing more than negotiating bluster. Impax's attorney backed up her claim, offering at least one example of when Impax had in fact launched at risk. (CX4032 (Snowden, Dep. at 26-31)). Even more importantly, Mr. Donatiello's bluster was at odds with Endo's internal expectation that Impax would launch at risk (CCF ¶¶ 58-71), Endo's preparations to launch an authorized generic in response to an Impax at-risk launch (CCF ¶¶ 84-92), and Endo's (unsuccessful) motion for a preliminary injunction to bar Impax from launching at risk (CCF ¶¶ 140-43, CX2759 at 021 (Patent Litigation Docket Entry No. 233) (Order terminating Endo's motion for preliminary injunction)).

1372. Endo's lawyer responded that "Impax never launches at risk. . . . That's not a realistic date." (Snowden, Tr. 424).

Response to Proposed Finding No. 1372

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1370 and 1371.

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")).

Response to Proposed Finding No. 1373

The Proposed Finding is misleading and incomplete. The single document Impax cites to support the proposed finding is a presentation prepared by the outside vendor Fuld & Company that is dated the same day as the settlement (June 8, 2010), with no cover email. (RX-086). Fuld & Company provided no testimony about the document's creation, and the document has no independent indicia of reliability. To the contrary, it contains multiple levels of hearsay and repeatedly refers to "Low Confidence Rumor[s]." (RX-086 at 0016, 0017). Endo's actual internal documents show that they had reached the "consolidated view" that Impax would launch at risk by July 2010 (CX3009 at 001, 003 (June 1, 2010 Hogan email to Cuca attaching Opana ER Combined P&L scenarios); *see also* CCF ¶¶ 58-71), and that by June 2010 Endo was prepared to launch an authorized generic in response to an at-risk launch by Impax. (CCF ¶¶ 84-92; *see* Complaint Counsel's Response to Proposed Finding No. 1363).

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).

Response to Proposed Finding No. 1374

The Proposed Finding is misleading and incomplete. The single document Impax cites to support the proposed finding is a presentation prepared by the outside vendor Fuld & Company that is dated the same day as the settlement (June 8, 2010), with no cover email. (RX-086). Fuld & Company provided no testimony about the document's creation, and the document has no independent indicia of reliability. To the contrary, it contains multiple levels of hearsay and repeatedly refers to "Low Confidence Rumor[s]." (RX-086 at 0016, 0017). Furthermore, what outside prognosticators believed is

launch at risk as soon as June 2010 (CCF ¶¶ 127-213), and Endo also believed that Impax was preparing to launch at risk by July 2010. (CCF ¶¶ 58-71; *see* Complaint Counsel's Response to Proposed Finding No. 1363).

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).

Response to Proposed Finding No. 1375

The Proposed Finding is misleading and incomplete. In the testimony cited, Impax's counsel was not asking Mr. Cuca about any spec

"consolidated view" was July 2011 Impax entry); *see also* Complaint Counsel's Response to Proposed Finding No. 1374).

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).

Response to Proposed Finding No. 1377

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1374, 1375, and 1376.

The scenarios in those forecasts, however, were created by Endo's marketing teaed by

credibility in the marketplace and to the realization of the value from our diversification strategy." (CX3042 at 035).

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).

Response to Proposed Finding No. 1379

The Proposed Finding is misleading and misr

Opana ER product. (Bingol, Tr. 1310). In the second transcript page cited, Mr. Bingol was responding to general questions from Impax's counsel "about various forecasts and scenarios" and the "purpose of creating large numbers of forecasts and scenarios." (Bingol, Tr. 1328). Mr. Bingol explained that "part of [his] job of being a marketing director is to try to understand what's happening not only today but, you know, two, three, seven years from now and trying to anticipate what those changes are going to be and to create a scenario to reflect that so that you can make better business decisions." (Bingol, Tr. 1328).

This Proposed Finding is also misleading insofar as it implies that there are myriad "forecasts" with a broad range of "scenarios" of when Endo expected Impax to launch its generic oxymorphone ER product. But Impax has not pointed to any Endo forecast (dated prior to the settlement with Impax) that projected the expected Impax entry date outside of the narrow range of June 2010 to July 2011. That is because, prior to the settlement with Impax, Endo did not forecast Impax to launch later than July 2011 and, in fact, had reached the "consolidated view" by June 1, 2010 that Impax would launch at risk in July 2010. (*See* Complaint Counsel's Response to Proposed Finding Nos. 1373-76).

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).

Response to Proposed Finding No. 1381

The Proposed Finding is incomplete. Mr. Hoxie further opined that at-risk launches are not uncommon in situations where the generic company is at risk of losing its market opportunity if launch is delayed and that Impax faced such a risk with oxymorphone ER. (CCF ¶¶ 355-57; CX5007 at 022-24 (¶¶ 41-44) (Hoxie Rebuttal Report)). Impax's economic expert also

acknowledged that "Impax was concerned about a potential switch to some new version of Opana ER." (CCF ¶ 121; RX-547 at 0064 (¶ 121) (Addanki Report)).

Importantly, Impax itself understood that it had financial incentives to launch at risk. As a fundamental business principle, Impax understood that the cost of delaying its oxymorphone ER

1382. But Mr. Hoxie does not opine that Impax actually would have launched at risk at any time. (Hoxie, Tr. 2910).

Response to Proposed Finding No. 1382

The Proposed Finding is misleading and mischaracterizes the relevant inquiry. The hypothetical question of what Impax actually would have done absent the settlement – a question on which Impax's experts also did not opine (*see generally* RX-547 (Addanki Report); RX-548 (Figg Report); *see also* CX4045 (Figg, Dep. at 208) ("I don't know what Impax would have done, and I tried to stay away from what Impax would have done."); CX4044 (Addanki, Dep. at 177-78) ("I did not assess the likelihood that Impax would launch at risk.")) – is not the relevant inquiry. Under *Actavis*, the relevant inquiry is whether Endo paid Impax to eliminate the risk of competition until January 2013. (Complaint Counsel's Proposed Conclusions of Law ¶ 7).

The Proposed Finding is misleading and mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding Nos. 1381 and 1382.

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).

Response to Proposed Finding No. 1384

The Proposed Finding is misleading and mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding Nos. 1381 and 1382.

1385. It also means that Mr. Hoxie did not calculate the odds of an at-risk launch by Impax.

No. 1384

The Proposed Finding is misleading and mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding Nos. 1381 and 1382. Furthermore, as detailed above in response to Proposed Finding No. 1363, Impax consistently withheld all financial estimates of potential liabilities from an at-risk launch as protected by the attorney-client privilege and/or work-product doctrine. (CX2636 at 003 (Mar. 11, 2010 Engle email to Mengler attaching Zorn model); CX2635 at 003, (Mar. 12, 2010 Sica email to Smolenski attaching Zorn model); CX3155 at 003-04, 007, 010, 013, 027 (Mar. 23, 2010 Engle email to Mengler and Snowden attaching Zorn model); CX2753 at 004-05, 008, 011, 014, 028 (May 14, 2010 Engle email to Hsu, Mengler, and Snowden attaching Zorn model); CX4032 (Snowden, Dep. at 227-28) ("Q. Are there any analyses of potential liability for an at-risk launch of oxymorphone of which you're aware that do not contain privileged legal advice? A. No, not that I'm aware of."); CX4026 (Nguyen, Dep. at 85) ("Q. And would you be looking at brand lost profits to assess potential damages? Ms. Fabish: Objection. I'm going to instruct the witness not to answer. It's privileged and redacted information.")). Impax cannot hide its actual estimates of potential damages behind the attorney-client privilege and then attempt to admonish Mr. Hoxie for "not quantify[ing] the risk to Impax from an at-risk launch." (Impax FOF ¶ 1387).

Finally, Impax's experts also did not "quantify the risk to Impax from an at-risk launch" or "conduct a risk-benefit analysis for an at risk launch by Impax." (*See generally* RX-547 (Addanki Report); RX-548 (Figg Report); *see also* CX4045 (Figg, Dep. at 208); CX4044 (Addanki, Dep. at 177-78)).

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).

The Proposed Finding is misleading and mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding Nos. 1381 and 1382. The Proposed Finding also misrepresents the scope of Mr. Hoxie's analysis with regard to a potential at-risk launch. Mr. Hoxie responded to Mr. Figg's failure to address that "the risk of damages does not mean that generic companies never launch at risk" by analyzing the motivations for a generic to launch at risk generally, the specific financial incentives for Impax to launch oxymorphone ER at risk, and the concrete steps Impax was taking to plan and prepare for a potential oxymorphone ER at-risk launch. (CX5007 at 021-27 (¶¶ 39-50) (Hoxie Rebuttal Report)).

Finally the approach described in the Proposed Finding is the same approach taken by Impax's patent and economic experts. (RX-548 at 039-43 (¶¶ 85-92) (Figg Report); RX-547 at 073-77 (¶¶ 137-43) (Addanki Report)).

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).

Response to Proposed Finding No. 1389

The Proposed Finding is misleading and mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding Nos. 1381 and 1382. As set forth above in response to Proposed Finding No. 1387, the Proposed Finding also misrepresents the scope of Mr. Hoxie's analysis with regard to a potential at-risk launch. Consistent with addressing why generic companies may elect to launch at risk, Mr. Hoxie concluded the statement quoted in the Proposed Finding by testifying that "not launching carries risks in this case of its own." (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).

Response to Proposed Finding No. 1390

The Proposed Finding is misleading and mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding Nos. 1381 and 1382. Furthermore, as detailed above in response to Proposed Finding Nos. 1363 and 1387, Impax consistently withheld all

The Proposed Finding is misleading. As discussed above in response to Proposed Finding

Exhibit 4) (Noll Rebuttal Report)). His analysis revealed that "[n]ot one firm paid triple damages," that "nearly all that were found to have infringed a valid patent

and "is based on comparing consumer welfare under the settlement with consumer welfare if the parties did not settle." (CX5004 at 058 (¶ 122) (Noll Rebuttal Report)). The first prong is "did the settlement agreement eliminate the possibility of entry during some period after the date on which the FDA gave final approval to the ANDA?" (CX5000 at 013 (¶ 29) (Noll Report)).

1399. Step one can be satisfied by an entry-date-only settlement, even when there is no reverse payment. (Noll, Tr. 1615-16).

Response to Proposed Finding No. 1399

The Proposed Finding is incomplete. When asked if a settlement with only an entry date and no payment could eliminate the risk of competition, Professor Noll explained that is

emphasized, all three prongs of the test must be satisfied to be anticompetitive: "this is one of the three parts of the test. You have to – you have to pass all three parts. The fact that the payment is large doesn't mean by itself it's anticompetitive. . . . You have to satisfy all three conditions." (Noll, Tr. 1618-19). Furthermore, in addition to satisfying the three-part test specific to reverse payments, you also must establish market power as in any other rule-of-reason case. (CX5000 at 012 (¶ 27) (Noll Report)).

1406. Professor Noll's three-part test has never been published or peer-reviewed. (Noll, Tr. 1642).

Response to Proposed Finding No. 1406

The Proposed Finding is misleading. As Professor Noll explained, "other experts have written similar things in their articles in journals," and the approach is consistent with the Supreme Court's decision in *Actavis*. (Noll, Tr. 1617-18, 1642; CX4039 (Noll, Dep. at 30-31)). Professor Noll clarified that any dispute in academic literature "is not about how you model it," but rather "about what it means." (Noll, Tr. 1643).

1407. Nor has Professor Noll's three-part test ever been accepted or utilized by any court. (Noll, Tr. 1642).

Response to Proposed Finding No. 1407

The Proposed Finding is factually incorrect and not supported by the testimony cited. Professor Noll testified that his framework is consistent with the Supreme Court's decision in *Actavis*. (Noll, Tr. 1617-18, 1642; CX4039 (Noll, Dep. at 30-31)).

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).

Response to Proposed Finding No. 1408

Complaint Counsel objects to the term "so-called," and the Proposed Finding misrepresents Professor Noll's testimony. Professor Noll stated that "[r]everse payment settlements and excessive litigation with respect to patent infringement" are problems related to the Hatch-Waxman Act. (Noll, Tr. 1493-94). Professor Noll does believe that the "the conduct at issue in reverse-payment settlements causes anticompetitive harm if some purchasers of the brand-name drug were denied the possibility that a generic substitute would be available to them prior to the date at which the generic was permitted to enter under the settlement agreement"—in other words if "the settlement agreement preserved and extended the market power of the

Eleventh Circuit erred is consistent with the Supreme Court's view, which abrogated the Eleventh Circuit's approach in a subsequent case, *FTC v. Actavis*. (Noll, Tr. 1617-18, 1642; CX4039 (Noll, Dep. at 30-31)).

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).

Response to Proposed Finding No. 1414

The Proposed Finding is misleading and not supported by the testimony cited. Professor Noll specifically rejected this statement: "it's not the right way to describe it. I actually – the reason for the change in wording is because of extensions of the model, but yes, I did – I did relate what the conclusions of the model were to the words that were used in the *Actavis* decision, because they didn't use exactly the same words that I did." (Noll, Tr. 1501).

Professor Noll did not have to change his three-part test because, as Professor Noll explained at his deposition, "[i]n my view, the Actavis decision by the Supreme Court pretty much straight down the middle adopts this three-part test." (CX4039 (Noll, Dep. at 30-31)).

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).

Response to Proposed Finding No. 1415

The Proposed Finding is misleading and mischaracterizes the issue. Professor Noll's chart has some distinct differences – namely, the charts used by the FTC were rudimentary approximations, while Professor Noll chart is an actual visual representation of his formula, resulting in different values and labeling. (*See* RXD-003; RXD-004; Noll, Tr. 1538). But more importantly, these charts should be "conceptually identical." The charts illustrate the consumer harm reverse-payment settlements create: the brand and generic companies make more money by sharing the brand firm's monopoly profits than by competing, but their increased profits come at

the expense of consumer savings. (RXD-003; RXD-004). This basic concept is and has always been at the heart of why large, unjustified reverse-payment settlements are anticompetitive.

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).

Response to Proposed Finding No. 1416

The Proposed Finding is incomplete and misleading. In the testimony cited, Professor Noll rejected Impax counsel's assertion that his "opinion is that the relevant analysis in a rule of reason case does not require a showing of actual anticompetitive effects." (Noll, Tr. 1661). Professor Noll explained that the elimination of the possibility of generic entry prior to the settlement's entry date is an "actual anticompetitive effect[s]" and that he considered actual effects in his analysis. (Noll, Tr. 1660-62). Professor Noll explained that he did not need to attempt to model what would have happened in the market absent the agreement because "you can put a boundary on what would happen in the market by looking at the value of the settlement." (Noll, Tr. 1661).

This is because a large, unexplained reverse payment acts as an insurance policy for the brand-name firm against the generic entering any time before the agreed-upon entry date. (CCF ¶ 1022). A brand-name firm will only make such a payment if it extends its monopoly profits, which come at the expense of consumer welfare. (CCF ¶ 1022). That extension of monopoly profits at the expense of consumer welfare is anticompetitive. (CCF ¶ 1022). Thus, it is not necessary to demonstrate an alternative, earlier, entry date upon which Impax would have entered.

Professor Noll's sole focus when considering

("the reverse payment itself is a reliable index of the welfare loss of consumers due to a reverse-payment settlement")).

Response to Proposed Finding No. 1417

The Proposed Finding is misleading and incomplete in that it suggests that Professor Noll opined that all reverse payments are anticompetitive. Throughout his expert reports and testimony, Professor Noll was clear that a large reverse-payment settlement is anticompetitive only if it is unjustified and the brand company is using the large payment to protect its market power. (Noll, Tr. 1619 ("Q. If the payment received by the generic is greater than the sum of the litigation costs, didn't you testify it's necessarily anticompetitive? A. Not – you have to do the third part, which is it's unjustified. The size of the payment alone is insufficient."); CX5000 at 007-11, 13 145-46 (¶¶ 11-22, 29, 333) (Noll Report); CX5004 at 007-08 (¶ 11) (Noll Rebuttal Report)).

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).

Response to Proposed Finding No. 1418

The first sentence of the Proposed Finding is misleading and incomplete in that it suggests that Professor Noll opined that all reverse payments are anticompetitive. (*See* Complaint Counsel's Response to Proposed Finding No. 1417). A brand-name firm will not make a large and unjustified payment to a generic firm unless the agreement increases the brand-name firm's expected monopoly profits. (CX5000 at 105 (¶ 242) (Noll Report); *see* CCF ¶¶ 1005-07). As a result, the existence of a large and unjustified payment shows that the brand-name firm expects the payment to allow it to recover monopoly profits that it otherwise would not earn if the litigation continued. (CX5000 at 105 (¶ 242) (Noll Report)).

1419. But from an economic perspective, large payments do not make an agreement

payment is not large; and (3) if it includes a reasonable payment for goods, services, or assets that are provided by the generic firm, meaning that the payment is justified. (CCF ¶ 1020).

The Proposed Finding is also factually and legally inaccurate. A settlement that contains a large, unjustified reverse payment from a branded firm with market power to a generic firm is anticompetitive. (CX5000 at 007-11, 13, 145-46 (¶¶ 11-22, 29, 333) (Noll Report)). A brand-name firm will not make a large, unjustified payment to a generic company unless it is securing the agreement of the generic company on a later entry date than it would agree to otherwise. (CCF ¶ 1005). As Professor Noll summarized in his rebuttal:

> Dr. Addanki and Mr. Figg have no answer to the question why Endo paid so much to settle an infringement case on worse terms than the *Addanki Report* and the *Figg Report* claim that Endo could have expected to achieve had they just continued to litigate the infringement case to conclusion. . . . The answer . . . is that the only plausible explanation for why Endo entered into a reverse-payment settlement that cost Endo over $100 million dollars is the one given in the *Noll Report*: the agreement enabled Endo to eliminate the possibility of generic entry until eight months before the expiration of the patents at issue in the infringement case.

(CX5004 at 066-67 (¶ 141) (Noll Rebuttal Report)).

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).

Response to Proposed Finding No. 1421

The Proposed Finding is incomplete and misleading. The exact amount of the payment is not needed to determine whether it was large enough to induce Impax to abandon its patent challenge and accept the 2013 entry date. More importantly, the Endo Credit was a "make-whole" provision that guaranteed Impax would receive the value of the No-AG provision either through additional profits from being the exclusive generic for 180 days or from a cash payment. (CCF ¶¶ 270-78).

Furthermore, the factors for determining the Endo Credit were known at the time of settlement and explicitly incorporated into the SLA. (CCF ¶¶ 326-27). The precise numerical

potential financial impact of the Endo Credit provision on Endo by using "the most recent forecast for Opana sales" and "an assumption about what the triggering event for the provision could look like." (CX4035 (Cuca, Dep. at 83-84)).

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).

Response to Proposed Finding No. 1423

The Proposed Finding is misleading and incomplete insofar as it suggests that calculation of the expected value of all or part of the SLA was possible or necessary to determine that the payments at issue in this case were large. As Professor Noll explained, calculating an expected value of these provisions is not practically possible because it is not possible to (1) identify every conceivable event; (2) determine the present value of each event; and then (3) assign an accurate probability to each event. (Noll, Tr. 1478 (expected value is the "probability-weighted sum of every conceivable event"), 1577-78, 1652 ("[The Noll Report] does not contain an expected value because that would require multiplying all the possible outcomes by their probabilities, and that's not possible.")).

Although Dr. Addanki criticized Professor Noll for not calculating expected values for the payments to Impax, he agreed with Professor Noll that calculating such expected values would not be "in any practical sense doable." (CX4044 (Addanki, Dep. at 114); CCF ¶ 479). Moreover, it was not necessary to calculate the expected value of the SLA payments to determine that they were large. Professor Noll used historical Opana ER sales data and Impax's own contemporaneous documents to calculate the value of the No-AG agreement and Endo Credit to Impax in every reasonable scenario. (CCF ¶¶ 461-72). His analysis shows that, in any such scenario, the combination of these provisions would result in a payment of at least $16.5 million to Impax, and likely far more. (CCF ¶¶ 467-72). Of course, the actual value of the Endo

Credit turned out to be $102 million. (CCF ¶¶ 444, 479). Impax does not challenge or rebut any of Professor Noll's calculations.

Because the actual outcome resulted in an enormous payment, and because the vast majority of the other possible scenarios would result in payments of tens of millions of dollars, the expected value of the No-AG agreement and Endo Credit is greater than saved litigation costs unless the scenario in which Impax would receive no value was overwhelming likely to result. (CCF ¶ 488; Noll, Tr. 1479-80 ("The probability of that event happening has to be over 90 percent to get the expected value of the agreement to Impax to be less than the saved litigation costs.")).

In other words, the outcome that the lead negotiator for Impax – Mr. Mengler – felt was "so unlikely it wasn't worth worrying about" would need to have been almost certain to occur. (CX0219 at 001 (Smolenski email to Hsu); CCF ¶¶ 480, 488). Dr. Addanki offers no evidence that this outcome was likely, let alone almost certain. (CCF ¶¶ 476, 488). Indeed, there is simply no credible record evidence to suggest that there was any meaningful possibility of both the No-AG and Endo Credit provisions being worthless to Impax. (CCF ¶¶ 482, 492-94). To the contrary, substantial contemporaneous evidence proves that the combination of the Endo Credit and No-AG provision had substantial value to Impax. (CCF ¶¶ 428-29, 431, 434-38, 482-87, 489-91).

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).

Response to Proposed Finding No. 1424

The Proposed Finding is factually inaccurate and contrary to the weight of the evidence. The fact that neither Complaint Counsel's nor Impax's economic expert calculated an expected value does not mean that there is "no economic evidence" of a large, unjustified payment at the

The amount to be paid under the Endo Credit was determined by a mathematical formula; implementing a product switch in accordance with Endo's plan to cause sales of Original Opana ER to fall to zero prior to the fourth quarter of 2012 would necessarily trigger a substantial payment under the provision. (CCF ¶¶ 326-27, 463, 484; CX2610 at 027 (Dec. 2010 Endo Revopan Playbook); CX2738 at 008 (Oct. 12, 2011 Endo ELC 2012 Budget Review of Branded Pharmaceuticals)).

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).

Response to Proposed Finding No. 1426

The Proposed Finding is misleading and not supported by any contemporaneous documents. The testimony of Dr. Addanki on which the Proposed Finding relies is a hypothetical view that ignores the facts of the case— namely, that both before and after the settlement, Endo

pharmaceutical products. Dr. Addanki did not study how many months it would have taken Endo to switch patients from Original to Reformulated Opana ER, and he acknowledged that such a switch typically takes months. (CCF ¶ 478).

4. Professor Noll's Analysis Ignores Real World Outcomes

Professor Noll considers any event that occurs after execution of the settlement

are if I can say that I know they're positive." (Noll, Tr. 1664). Thus, Professor Noll did "not put a dollar sign on the actual anticompetitive harm," but rather "put a lower bound on them." (Noll, Tr. 1664-65). Because the "welfare loss to consumers is greater than the payment," the lower bound of the consumer harm is $102 million. (Noll, Tr. 1664-65).

By reaching a settlement with the first-filer, the brand company not only eliminates the possibility of entry by the first-filer during the period before the generic entry date in the agreement, but also eliminates the possibility of entry for six months beyond this period by other potential generic competitors. (CCF ¶ 981). Such a settlement converts the possibility of substantial loss of monopoly profits into the certainty that monopoly profits will be retained until the date of generic entry in the agreement. (CCF ¶ 981). The payment represents a portion of the monopoly profits the brand-name firm is preserving by entering into the settlement. (CCF ¶ 982). Those monopoly profits are taken directly from the savings customers otherwise would enjoy from generic entry. (CCF ¶ 982). Thus, the amount of the payment represents at least a lower bound of the amount of consumer harm resulting from the reverse-payment agreement. (CCF ¶ 982).

1429. Professor Noll has not assessed whether actual, post-settlement outcomes comported with any *ex ante* expectations. (Noll, Tr. 1668).

Response to Proposed Finding No. 1429

The Proposed Finding is incomplete. Professor Noll explained that what matters is "what the payment was, what the value – what the transaction was. The actual transaction was what matters." (Noll, Tr. 1668). The "actual transaction" was heavily negotiated and contained clear terms of payment: Endo provided Impax with a six-month No-AG provision, the value of which was insured by the Endo Credit provision, and $10 million cash up front. (CCF ¶¶ 214-320, 390-497). The "only plausible explanation" for Endo to make such a large, unjustified payment to

Impax is that "the agreement enabled Endo to eliminate the possibility of generic entry until eight months before the expiration of the patents at issue in the infringement case." (CX5004 at 066-67 (¶ 141) (Noll Rebuttal Report); CCF ¶ 1331).

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).

Response to Proposed Finding No. 1430

The Proposed Finding is misleading. Both Complaint Counsel's and Impax's experts agree—and the parties have stipulated (JX-001 at 008 (¶ 20))—that the outcome of the patent litigation was uncertain at the time of the settlement. (Figg, Tr. 2008; Noll, Tr. 1644-45; Hoxie, Tr. 2693-94). As Professor Noll explained, that uncertainty is "the entering wedge of the analysis" (Noll, Tr. 1645); the only plausible explanation for why Endo entered into a reverse-payment settlement that cost Endo over $100 million dollars is that the agreement enabled Endo to eliminate the possibility of generic entry until eight months before the expiration of the patents at issue in the infringement case. (CCF ¶ 1331). Independent valuation of the patent's strength is also not necessary because it is incorporated into the size of the payment: "the weaker the patent, the bigger the payment will be." (Noll, Tr. 1441).

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

The anticompetitive nature of a large reverse payment does not depend on the probability that the patent holder (i.e., the brand-name fi

The Proposed Finding is misleading. Both Complaint Counsel's and Impax's experts agree—and the parties have stipulated (JX-001 at 008 (¶ 20))—that the outcome of the patent litigation was uncertain at the time of the settlement. (Figg, Tr. 2008; Noll, Tr. 1644-45; Hoxie, Tr. 2693-94).

Moreover, if who would have won the Endo-Impax patent litigation was known or knowable, one of the parties would have little reason to enter the settlement; it is the uncertainty of who would prevail that resulted in the reverse-payment agreement. (CCF ¶¶ 1006-08). If Endo believed it would win the underlying patent case, it has very little incentive to settle with the generic. (CCF ¶ 1006). Endo would save some in litigation costs, but those would be very small compared to the potential profits from extending a monopoly. (CCF ¶ 1006). Thus, the fact that Endo was willing to make a payment to Impax in excess of litigation costs indicates that Endo extended its monopoly longer than it expected to if the litigation had continued. (CCF ¶ 1006).

The Proposed Finding is also inaccurate in that it suggests that the outcome of the underlying patent litigation is determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. 133 S. Ct. at 2234-37. Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. *Actavis*, 133 S. Ct. at 2236.

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).

Response to Proposed Finding No. 1434

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1427 and 1433.

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).

Response to Proposed Finding No. 1435

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1427 and 1433.

1436. The three-part test consequently does not calculate the average period of competition that would have resulted absent the settlement. (Noll, Tr. 1624).

Response to Proposed Finding No. 1436

The Proposed Finding misrepresents the testimony cited. Professor Noll actually stated: "I did take into account the possibilities of competition in the absence of a settlement. Did I predict exactly what that would be? No." (Noll, Tr. 1624). The Proposed Finding also is misleading and not relevant to determining whether the agreement is anticompetitive for the reasons set forth in response to Proposed Finding Nos. 1427 and 1433.

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).

Response to Proposed Finding No. 1437

The Proposed Finding is misleading and misrepresents the testimony cited. In the testimony cited, Professor Noll was not addressing whether Impax was capable of or legally permitted to launch generic oxymorphone ER prior to September 2013. Impax was prepared to potentially launch at risk upon final FDA approval, which it received on June 14, 2010. (CCF ¶¶ 127-47). And Professor Noll's analysis does assess whether "the settlement agreement eliminate[d] the possibility of entry during some .

In the testimony cited, Professor Noll was actually addressing the reasons why it was not necessary to determine who would have prevailed in the patent suit had Impax and Endo not settled to conduct his economic analysis. (Noll, Tr. 1643). As discussed above in response to Proposed Finding Nos. 1427 and 1430, who would prevail was uncertain at the time of the settlement, so "what the settlement agreement buys and is about is eliminating some adverse consequences that could happen to you in the future but that are not certain." (Noll, Tr. 1625-26).

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).

Response to Proposed Finding No. 1438

The Proposed Finding is misleading and misrepresents the cited testimony. Professor Noll testified that he "did not attempt to measure that particular thing. What I did is put a lower bound on it." (Noll, Tr. 1666). Professor Noll confirmed that a large, unjustified reverse-payment settlement rules out the possibility that the settlement could benefit consumers. (Noll, Tr. 1666-67; *see also* Complaint Counsel's Response to Proposed Finding Nos. 1427 and 1430).

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).

Response to Proposed Finding No. 1439

The Proposed Finding is incomplete, misleading, and mischaracterizes the relevant inquiry. The license is immaterial to any discussion of the reverse payment that Endo made to Impax. (CCF ¶¶ 1405-07, 1459). The reverse payment was not necessary for Impax to receive such a license to patents that had not yet issued. This license was requested by and had value for Impax. (CCF ¶ 1457). It would make no sense that the reverse payment was necessary to induce

Impax to accept the license that it wanted and that would benefit Impax. (CCF ¶ 1457). Indeed, Sandoz obtained an option to license Orange Book patents that Endo might obtain in the future relating to Opana ER, and the Sandoz settlement—signed the same day as Impax—did not include a reverse payment. (CCF ¶ 1457).

Finally, a patent license to future patents is not unique in the pharmaceutical industry (CCF ¶¶ 1408-11), and the subsequent contract breach and infringement litigation demonstrates that the license did not unambiguously provide Impax with certain freedom to operate. (CCF ¶¶ 1415-30).

The SLA guaranteed Impax entry on January 2013 as well as protection against any

the patents. (CCF ¶¶ 1423-24). Endo then provided Impax notice of termination of the SLA requesting that Impax immediately stop selling what Endo characterized as Impax's infringing generic Opana ER product. (CCF ¶¶ 1425). In the notice, Endo stated "there is no legitimate dispute that Impax's current Opana ER generic tablets infringe Endo's patents" and demanded "Impax should therefore honor Endo's patent rights and immediately cease all sales of those infringing tablets." (CX2944 at 003 (Oct. 31, 2016 email chain attaching letter from Endo to Impax re: notice of termination of the license agreement); CCF ¶ 1425). Impax continued to disagree with Endo's interpretation of the SLA as it applied to the later-issued patents. (CCF ¶ 1425). If the parties had not settled their lawsuit, Impax could have been liable for damages and possibly even required to withdraw its generic oxymorphone ER product from the market. (CCF ¶ 1430).

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).

Response to Proposed Finding No. 1442

The Proposed Finding is incomplete, misleading, and mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding Nos. 1439 and 1441.

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 ric -2.3 Tepate2teand 2(thed pateny Endo, no)]TJ0 Tc 0 Tw 121-0.212 72 2554. its generi

1445. The Proposed Finding is incomplete, misleading, and mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding Nos. 1439 and 1441. 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).

Response to Proposed Finding No. 1445

The Proposed Finding is factually inaccurate, as Endo did ultimately sue Impax for infringement of the '122 and '216 patents with respect to Original Opana ER. (CCF ¶ 1421). The Proposed Finding is also incomplete, misleading, and mischaracterizes the relevant inquiry for the same reasons set forth in response to Proposed Finding Nos. 1439 and 1441.

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).

Response to Proposed Finding No. 1446

The Proposed Finding is incomplete. Endo sued Impax for both breach of the SLA for failing to negotiate with Endo in good faith a royalty for the '122, the '216 and the '737 patents (which were pending applications at the time Endo and Impax entered into the SLA) *and* infringement of the same patents. (CCF ¶ 1421). The Proposed Finding is also incomplete, misleading, and mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding No. 1439 and 1441.

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).

Response to Proposed Finding No. 1447

The Proposed Finding is misleading and incomplete. Though Endo did not file for an injunction, on October 31, 2016, Endo provided Impax notice of termination of the SLA and requested that Impax immediately cease sales of what it characterized as Impax's infringing generic Opana ER product. (CCF ¶ 1425). The Proposed Finding is also incomplete, misleading,

and mischaracterizes the relevant inquiry for

(CX3455 at 022-23 (Sep. 19, 2013 *Endo v. Actavis* transcript)); (4) Endo or the generic company would prevail in any hypothetical future patent litigation involving patents that may or may not issue (CCF ¶¶ 1431-32); and (5) the FDA would determine that Endo should remove its reformulated version of Opana ER from the market. (*See* CX3189 at 001-02 (Endo's application for reformulated Opana ER was not even file

The Proposed Finding is also incomplete in that it omits that Impax likely is the only oxymorphone ER product available to consumers because Impax {[redacted]} (CCF ¶¶ 1485-92 (*in camera*)). {[redacted]} (CCF ¶¶ 1487-88 (*in camera*)). {[redacted]} (CCF ¶ 1490 (*in camera*)).

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)).

Response to Proposed Finding No. 1450

The Proposed Finding is incomplete, misleading, and mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding Nos. 1439, 1446 and 1449.

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).

Response to Proposed Finding No. 1451

The Proposed Finding is factually incorrect and contrary to the weight of the evidence. Dr. Addanki's opinion relies on an incorrect methodology that ignores the economics of how reverse payments work. (CCF ¶¶ 1012-20). A brand-name firm will not make a large and unjustified payment to a generic firm unless the agreement increases the brand-name firm's expected monopoly profits. (CCF ¶ 1014). As a result, the existence of a large and unjustified

payment shows that the brand-name firm expects the payment to allow it to recover monopoly profits that it otherwise would not earn if the litigation continued. (CCF ¶ 1014).

Neither Dr. Addanki nor Mr. Figg explains why, if the settlement accelerated entry of generic oxymorphone ER as they claim, Endo paid so much to reach an agreement that reduced the duration of the period in which Endo could have profited from a continued patent monopoly. (CCF ¶ 1330). Nor do they have an explanation for why Endo paid so much to settle an infringement case on worse terms than Dr. Addanki and Mr. Figg claim that Endo could have expected to achieve had Endo just continued to litigate the infringement case to conclusion. (CCF ¶ 1331). Endo did not make "a charitable contribution to Impax by paying Impax over $100 million AND allowing Impax to enter earlier than otherwise would have been likely." (CCF ¶ 1310). Endo paid Impax over $100 million because it guaranteed that generic entry for the five best-selling dosages of Opana ER would not occur until approximately eight months prior to the expiration of the asserted patents. (CCF ¶¶ 1311-12).

Dr. Addanki's opinion also relies on the uns

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).

Response to Proposed Finding No. 1453

The Proposed Finding is factually incorrect, is contrary to the weight of the evidence, and mischaracterizes the relevant inquiry. The license Impax obtained is immaterial to any discussion of the reverse payment that Endo made to Impax. (CCF ¶¶ 1405-07, 1459). The reverse payment was not necessary for Impax to receive such a license to patents that had not yet issued. This license was requested by and had value for Impax. (CCF ¶ 1457). It would make no sense that the reverse payment was necessary to induce Impax to accept the license that it wanted and that would benefit Impax. (CCF ¶ 1457; *see* Complaint Counsel's Response to Proposed Finding No. 1439).

Moreover, the anticompetitive harm occurred between June 2010 and January 2013 when Impax's agreement with Endo guaranteed no generic competition until 2013. (CCF ¶ 1394). Subsequent decisions from other patent litigations do not change that harm to consumers. (CCF ¶ 1394).

Finally, at the time Impax and Endo entered into the Impax-Endo Settlement Agreement, there were myriad future outcomes. Impax may have launched at risk. (CCF ¶¶ 127-213, 1431). Impax may have proceeded with the litigation, won, and entered the market. (CCF ¶¶ 361-77, 1431). Endo may have faced different incentives in pursuing patent approvals and acquiring patents. (CCF ¶¶ 1431-35). It is not possible to know what the market would look like today if Impax and Endo had not settled. (CCF ¶ 1431).

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).

Response to Proposed Finding No. 1454

The Proposed Finding mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding No. 1453.

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")).

Response to Proposed Finding No. 1455

The Proposed Finding mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding No. 1453.

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).

Response to Proposed Finding No. 1456

The Proposed Finding mischaracterizes the relevant inquiry for the reasons set forth in response to Proposed Finding No. 1453.

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")).

Response to Proposed Finding No. 1457

The first sentence of the Proposed Finding is factually inaccurate and not supported by any citation to the evidence. The remainder of the Proposed Finding is misleading and misrepresents both Mr. Hoxie's role and opinion. Mr. Hoxie is an expert in pharmaceutical patent licensing, pharmaceutical patent litigation, and pharmaceutical patent prosecution. (Hoxie, Tr. 2663). He has no expertise in industrial economics or antitrust law. Thus, it would be inappropriate for Mr. Hoxie to opine on the competitive effects of the reverse-payment settlement between Impax and Endo.

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).

Response to Proposed Finding No. 1458

The Proposed Finding is misleading and incomplete, as Professor Noll testified that he was "sure there could have been" an alternative settlement. (Noll, Tr. 1648; CCF ¶¶ 1438-52). But Professor Noll did not try to identify a specific alternative settlement or offer an opinion about alternative settlements because it is not necessary to determine the specific date on which a generic would have entered in order to conclude that a reverse-payment agreement is anticompetitive. (CCF ¶ 986 (citing CX5004 at 76-77 (¶ 160) (Noll Rebuttal Report)); CX4039 (Noll, Dep. at 58-59); Noll, Tr. 1648). Professor Noll explained that if the brand company is willing to make a large payment to the generic that exceeds saved litigation costs and/or the reasonable costs of goods, services, or assets exchanged by the generic company, then the brand company believed there was a means—an alternative settlement, an at-risk launch, a court victory, etc.—through which the generic could have gotten in earlier than the licensed entry date; that shows the reverse-payment settlement is anticompetitive. (CCF ¶¶ 986-87, 1019-20). Moreover, as Impax's economic expert acknowledged, determining Impax's and Endo's reservation dates cannot be determined from their positions in negotiations. (CCF ¶¶ 1017-18). Thus, a framework that requires proof of specific alternative entry dates in a no-payment settlement is unworkable. (CCF ¶ 1018).

The Proposed Finding is also misleading to the extent that it assumes Complaint Counsel must prove that a settlement with an earlier entry date would have occurred. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the

underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. (*See* Complaint Counsel's Pretrial Brief at 43 (citing *Actavis*, 133 S. Ct. at 2236)). Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. (*See* Complaint Counsel's Pretrial Brief at 43; Complaint Counsel's Proposed Conclusions of Law, ¶ 7).

1459. Instead, Professor Noll opined that the feasibility of an alternative settlement was irrelevant to his analysis. (Noll, Tr. 1484, 1597).

Response to Proposed Finding No. 1459

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1458.

1460. Complaint Counsel consequently proffered Professor Max Bazerman as an expert in

Complaint Counsel objects to the word "purportedly," which was not in Professor Bazerman's testimony. (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).

Response to Proposed Finding No. 1463

Complaint Counsel objects to the word "purportedly," which was not in Professor Bazerman's testimony. (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).

Response to Proposed Finding No. 1464

Complaint Counsel objects to the word "theoretically," because Professor Bazerman opined that the payment logically pushes back the expected entry date and that there are reasons to expect that the parties could have settled without payment. (*See* Complaint Counsel's Response to Proposed Finding No. 1465).

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.

Response to Proposed Finding No. 1465

The Proposed Finding is factually inaccurate, and Respondent does not even attempt to cite evidence to support the Proposed Finding.

Professor Bazerman testified that he assesses each reverse-payment settlement based "on the specific facts of that case," and that is what he did in this case. (Bazerman, Tr. 895). Professor Bazerman reviewed hundreds of documents, including the settlement agreement between Endo and Impax, documents from the negotiation of the settlement agreement, Endo's settlements for generic Opana ER with other generic companies, and deposition and

investigational hearing transcripts of Endo's and Impax's employees. (Bazerman, Tr. 860-61; CX5001 at 064-69 (List of Materials Considered) (Bazerman Report); CX5005 at 015 (List of Additional Materials Considered) (Bazerman Rebuttal Report)). Professor Bazerman used these numerous sources and his expertise in negotiation theory to provide very specific reasons how the reverse payments in this case were linked to the licensed entry date and how economics and logic dictate that the effect of such payments would be to push back the entry date compared to a settlement without payments. (CCF ¶¶ 994 (reverse payments expand the range of settlement negotiations), 999 (No-AG Provision), 1005 (Endo Credit), 1067-68 (DCA), 1076 (DCA); Bazerman, Tr. 863-77). Professor Bazerman further offered specific reasons why he opined that a settlement without reverse payments and an earlier entry date for Impax was possible. (CCF ¶ 1441; Bazerman, Tr. 873-74).

Not only did Professor Bazerman provide numerous sources of evidence to support his opinions, he also assessed the primary sources of Respondent's experts to determine if they offered any facts that would impact his analysis. (Bazerman, Tr. 861-62). Respondent's experts offered no facts to change his opinion. (Bazerman, Tr. 862). Indeed, those experts' reports strengthened Professor Bazerman's opinions because he found that Respondent's experts could not come up with a "coherent story" that considered the facts of the case. (Bazerman, Tr. 862 ("I was struck by a few pieces, one the lack of a coherent story of what – of what happened in this story between Endo and Impax that would account for all the facts")). Professor Bazerman further noted inconsistencies between the stories being told by Respondent's experts. For example, with respect to the payments, Professor Bazerman observed that Respondent's economic expert and patent expert differed on the u

the reverse payment had no effect. (Bazerman, Tr. 862). Professor Bazerman's opinion is, thus, based on analysis of the actual facts in this case and the specific effects of Endo's payments to Impax.

Complaint Counsel also objects to the term "categorical opposition to reverse-payment settlements" as factually inaccurate for the reasons set forth in response to Proposed Finding No. 1466.

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).

Response to Proposed Finding No. 1466

The Proposed Finding is factually inaccurate and not supported by the evidence cited. Professor Bazerman testified that he is suspicious of reverse-payment settlements because there is generally no reason for a brand company to pay a generic company to reach a settlement, and the dynamics of the pharmaceutical industry give rise to the potential for parasitic value creation, a concept that Professor Bazerman developed in 1997, long before he worked on any reverse-payment case. (Bazerman, Tr. 853-54, 872). Parasitic value creation occurs when the negotiating parties benefit by taking value from parties not at the negotiating table. (Bazerman, Tr. 855-56). There is the potential for parasitic value creation in reverse-payment settlements because the brand company makes more from being able to sell the branded product without generic competition than the generic company makes from selling an equivalent generic, as branded products have higher prices. (Bazerman, Tr. 871-72). Having a brand company pay the generic not to enter the market could be a way for both companies to financially enrich themselves, but take value from consumers. (Bazerman, Tr. 872).

But finding reverse-payment settlements to be suspicious does not mean Professor Bazerman finds every reverse-payment to be automatically negative. Contrary to the Proposed

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).

Response to Proposed Finding No. 1470

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1466.

1471. In each of those cases, Professor Bazerman testified that the terms in the settlement agreements were linked. (Bazerman, Tr. 886-87).

Response to Proposed Finding No. 1471

The Proposed Finding is misleading and incomplete to the extent that it implies Professor Bazerman opposes all reverse-payment settlements. Professor Bazerman assesses each reverse-payment settlement based on the facts of that case and bases his opinions on those facts. (Bazerman, Tr. 895).

1472. And in each case, Professor Bazerman opinioned that the linkage served to delay generic entry. (Bazerman, Tr. 887).

Response to Proposed Finding No. 1472

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1471.

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).

Response to Proposed Finding No. 1473

The Proposed Finding is misleading, incomplete, and not supported by the evidence cited. Professor Bazerman testified only that his views "*as a matter of legislative opportunities* have not changed substantially" since his testimony in Schering-Plough. (Bazerman, Tr. 895)

(emphasis added). He then reiterated that he assesses each reverse-payment case on "the specific facts of that case." (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).

Response to Proposed Finding No. 1474

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1471.

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).

Response to Proposed Finding No. 1475

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1471.

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).

Response to Proposed Finding No. 1476

The Proposed Finding is factually inaccurate and not supported by the evidence cited. Professor Bazerman testified that he has never been employed as an expert witness by a drug company, but did not provide any reasons. (Bazerman, Tr. 906). The Proposed Finding is pure speculation about Professor Bazerman's reasoning. Respondent offers no evidence—and Complaint Counsel finds none in the record—that Professor Bazerman has ever even been asked

The Proposed Finding is also factually inaccurate and not supported by the evidence insofar as it suggests that Professor Bazerman is biased against pharmaceutical companies. Professor Bazerman testified that he "love[s] pharmaceutical companies" and believes "they're one of the most important industries in the U.S." (Bazerman, Tr. 932). Indeed, Professor Bazerman has consulted more with the pharmaceutical industry than any other industry, including companies such as AstraZeneca, Pfizer, Abbott, Biogen, Bristol-Myers, and Johnson & Johnson. Professor Bazerman's consulting work for these companies span a "wide range of topics from procurement to sales to business development to advising firms in the midst of litigation." (Bazerman, Tr. 840-41).

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).

Response to Proposed Finding No. 1477

The Proposed Finding is misleading in that it suggests Professor Bazerman would not work for any company that had ever considered a reverse-payment settlement. Professor Bazerman suggested nothing of this sort. He testified that he would not be inclined to work in a consulting role for a specific negotiation in

The Proposed Finding is misleading and factually inaccurate for the reasons set forth in response to Proposed Finding Nos. 1476 and 1477.

1479. Any such work would violate Professor Bazerman's personal set of ethics. (Bazerman, Tr. 899-900).

Response to Proposed Finding No. 1479

The Proposed Finding is misleading and factually inaccurate for the reasons set forth in response to Proposed Finding Nos. 1476 and 1477.

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).

Response to Proposed Finding No. 1480

The Proposed Finding is factually inaccurate and not supported by the evidence cited, which makes no reference to Professor Bazerman's code of ethics applied in practice or in relation to contingency contracts. (Bazerman, Tr. 926-28).

1481. Ordinarily, Professor Bazerman loves contingency contracts. (Bazerman, Tr. 926).

Response to Proposed Finding No. 1481

Complain Counsel has no specific response.

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).

Response to Proposed Finding No. 1482

The Proposed Finding is factually inaccurate, as Professor Bazerman testified that he "would edit that [language] to say 'can create value.'" (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).

Response to Proposed Finding No. 1483

The Proposed Finding is incomplete to the extent that it omits Professor Bazerman's testimony that such agreements "can"—but don't necessarily—create value. (Bazerman, Tr. 927; *see also* Complaint Counsel's Response to Proposed Finding No. 1482).

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).

Response to Proposed Finding No. 1484

The Proposed Finding is misleading and incomplete by failing to differentiate between contingency contracts that exchange value between the negotiating parties and contingency contracts that create value for the negotiating parties by taking it from those who are not part of the negotiations. Professor Bazerman calls the latter type of agreement parasitic value creation. (Bazerman, Tr. 855-56). Impax and Endo discussed a contingency contract that would exchange value between those parties, specifically, an acceleration provision that would allow Impax to sell generic Opana ER before January 1, 2013 if the market for generic Opana ER eroded by a certain percentage (e.g., if Endo started to move the market to a reformulated product). (CCF ¶ 1050 (citing CX5001 at 027-28 (¶ 53) (Bazerman Report))). The parties rejected that type of contingency contract. (CCF ¶¶ 1050-51). Instead, Endo and Impax agreed to the Endo Credit, which in essence paid Impax for the value of

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).

Response to Proposed Finding No. 1485

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1484.

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).

Response to Proposed Finding No. 1486

The Proposed Finding is misleading and incomplete by suggesting that an entry-only settlement and a reverse-payment settlement create the same type of value for a generic company. Professor Bazerman testified that in typical patent settlement negotiations, the parties have reservation values based on factors such as the patent merits and the costs of litigation. (CX4040 (Bazerman, Dep. at 60-61)). Settlements can be valuable if they align with each party's reservation value and save both parties the costs of litigation. (CX5001 at 006 (¶ 10) (Bazerman Report)). A reverse payment can artificially expand a generic company's reservation value and induce it to accept a date later than it would otherwise accept. (CCF ¶ 994 (citing CX5001 at 035 (¶ 66) (Bazerman Report))). Having a brand company pay a generic to push back the entry date can benefit both pharmaceutical companies, but at the expense of consumers not at the table. (CCF ¶ 994 (citing CX5001 at 035 (¶ 66) (Bazerman Report))). Reverse-payment settlement agreements can therefore be parasitic value creation, whereas an entry-date only settlement would not be parasitic.

1487. Entry-date only settlements similarly eliminate the risk of competition from the generic company. (Bazerman, Tr. 882).

Response to Proposed Finding No. 1487

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1486.

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).

Response to Proposed Finding No. 1488

The Proposed Finding is misleading, incomplete, and not supported by the evidence cited. Professor Bazerman testified that Impax could have negotiated an entry date earlier than January 2013 without reverse payments and that Impax "should have known that they could have

Moreover, the cited sources do not support the Proposed Finding, as the cited sources relate to Professor Bazerman's discussion of how a reverse payment logically can push back the entry date, not about the likelihood that Endo and Impax could have reached an earlier entry date in a settlement without payments.

1489. In forming his opinions, Dr. Bazerman did not speak to any individual employed by Endo or Impax. (Bazerman, Tr. 880).

Response to Proposed Finding No. 1489

Response to Proposed Finding No. 1493

The Proposed Finding is misleading and incomplete to the extent that it uses "parasitic" separate from the context of Professor Bazerman's discussion of "parasitic value creation." (*See* Complaint Counsel's Response to Proposed Finding No. 1466).

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).

Response to Proposed Finding No. 1494

Complaint Counsel has no specific response.

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.")).

Response to Proposed Finding No. 1495

Complaint Counsel objects to the term "antic

the challenged agreement. (*See* Complaint Counsel's Pretrial Brief at 43 (citing *Actavis*, 133 S. Ct. at 2236)). Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. (*See* Complaint Counsel's Pretrial Brief at 43; Complaint Counsel's Proposed Conclusions of Law, ¶ 7).

Professor Bazerman did discuss how the Impax-Endo Settlement Agreement would be expected to harm consumers through parasitic value creation. Professor Bazerman opined that, based on the negotiation history, Impax would not have accepted an entry date of January 1, 2013 without payment from Endo. (CX 5001 at 029-30 (¶ 55) (Bazerman Report)). But because Endo made more from selling the branded product without generic competition than Impax would make from selling an equivalent generic, Endo could profitably pay Impax not to enter the market until January 1, 2013, such that both companies found the reverse-payment settlement to be more profitable than an alternative settlement without a reverse payment or an at-risk launch by Impax. (Bazerman, Tr. 870-71; CX 5001 at 023-24 (¶¶ 46-48) (Bazerman Report)). But consumers would not have access to a generic until January 1, 2013, versus an earlier entry date that would be expected in a settlement without a reverse payment. (CX5001 at 035 (¶ 66) (Bazerman Report)).

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).

Response to Proposed Finding No. 1497

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 1496.

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).

Response to Proposed Finding No. 1498

The Proposed Finding is factually inaccurate, as Professor Bazerman testified in the relevant section that he had assessed the alternative settlement and "offered an opinion about the direction of [the benefits to consumers under each settlement]." (Bazerman, Tr. 897). Indeed, Professor Bazerman opined that an entry-date-only settlement between Endo and Impax was possible and that the entry date without payments would be earlier than January 1, 2013. (CCF ¶ 1441; Bazerman, Tr. 873-74). The benefit that consumers would have received under an entry-date-only settlement was access to generic Opana earlier than January 1, 2013. And that entry-date-only settlement could have included a license to pending patents similar to the SLA, as the scope of the license was not tied to the entry date in the Impax-Endo Settlement Agreement. (CCF ¶ 1405 (citing CX5001 at 030 (¶ 56) (Bazerman Report))).

Specifically relating to the Endo Credit, Professor Bazerman also testified about the difference of including an acceleration provision instead of the Endo Credit. He testified that the difference for consumers was that "an acceleration trigger would be much more likely to bring the generic product to market earlier than the Endo Credit." (Bazerman, Tr. 874-75).

Finally, the Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 1496. The Proposed Finding is also misleading to the extent that it assumes Complaint Counsel must prove that a settlement with an earlier entry date w4.8-0./..

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).

Response to Proposed Finding No. 1499

The Proposed Finding is factually inaccurate and misleading for the reasons set forth in response to Proposed Finding No. 1498.

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).

Response to Proposed Finding No. 1500

The Proposed Finding is misleading for the reasons set forth in response to Proposed Finding No. 1496.

1501. Professor Bazerman admits, moreover, that if Impax continued to litigate against Endo and lons

negotiating reverse payments as part of the settlement, the negotiated entry date would be expected to be later than an entry date in a settlement in which Impax did not get paid, because there is no other reason for Endo to be making a payment. (Bazerman, Tr. 846; CCF ¶¶ 994-95). Further, Professor Bazerman testified that to determine the value requested by Respondent's counsel in the cited passage, he "would probably need more data that I didn't have access to do that kind of work." (Bazerman, Tr. 898). There is no indication that the types of data Professor Bazerman would need have even been provided

the risk of competition. (*See* Complaint Counsel's Pretrial Brief at 43; Complaint Counsel's Proposed Conclusions of Law, ¶ 7).

1505. Professor Bazerman cannot even identify the zone of possible entry-date agreements for Endo and Impax. (Bazerman, Tr. 913-14).

Response to Proposed Finding No. 1505

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1504.

1506. In fact, Professor Bazerman cannot say with certainty that an alternative settlement was possible in this case. (Bazerman, Tr. 914).

Response to Proposed Finding No. 1506

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1504.

1507. Professor Bazerman admits that Impax asked for earlier entry dates and Endo rejected them. (Bazerman, Tr. 907).

Response to Proposed Finding No. 1507

The Proposed Finding is misleading and incomplete, as it focuses only on Impax's request for one specific entry date, July 2011. Professor Bazerman observed that there were no discussions or proposals between Endo and Impax with entry in 2011 after July or any point in 2012. (CX5005 at 009-10 (¶ 15) (Bazerman Rebuttal Report)). As Professor Bazerman testified, if Endo would not accept entry in July 2011, "[t]hey could have continued to negotiate" for other dates earlier than January 2013. (Bazerman, Tr. 916). Instead, the parties negotiated a settlement with reverse payments.

The Proposed Finding is also misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1504.

1508. Impax also asked for a date-only settlement with entry in 2011, which Endo rejected. (Bazerman, Tr. 915-16).

("such an early entry date for Actavis would create a precedent and anchor for Endo's subsequent negotiations with Impax as first filer for all of the other dosages")). Indeed, after the Endo-Actavis settlement, both Impax and Endo assume a July 2011 entry date for all dosage strengths of generic Opana ER in internal documents and forecasts. (CX5005 at 012-13 (¶¶ 20-21) (Bazerman Rebuttal Report)). Thus, the psychological effect created by the Actavis settlement would therefore be to make the entry date much *earlier* than January 2013, Impax's entry date. But unlike with Actavis, Impax received a reverse payment in its settlement for generic Opana ER. (CX5001 at 034-35 (¶ 65) (Bazerman Report) ("The Endo-Actavis settlement included no branded-to-generic payments, and it is

The Proposed Finding is misleading, incomplete, and unnecessary to determining the effect of including a reverse payment in a settlement for the reasons set forth in response to Proposed Finding No. 1510.

1517. Professor Bazerman also pointed to the settlement agreement between Endo and Actavis as an example of an earlier entry date. (Bazerman, Tr. 877).

Response to Proposed Finding No. 1517

Complaint Counsel has no specific response.

1518. But Professor Bazerman has not done any analysis of the Actavis settlement. (Bazerman, Tr. 916-17).

Response to Proposed Finding No. 1518

The Proposed Finding is factually inaccurate and not supported by the evidence cited. Although Professor Bazerman testified that he "didn't do a thorough analysis of that negotiation process or agreement," he "read about [the] pieces," "understood the context and how it differs from this case," and understood "contextual issues." (Bazerman, Tr. 917). Respondent does not indicate what additional analysis is required to determine that Actavis negotiated an entry date approximately 18 months before Impax's entry date and that Actavis did not receive a payment. Further, Respondent does not appear to contest either of these facts.

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).

Response to Proposed Finding No. 1519

The Proposed Finding is factually inaccurate and not supported by the evidence cited. Professor Bazerman testified that he agreed with Respondent's counsel that one reason Endo might settle with Actavis was because of the dosage strengths for which Actavis was the first to file. (Bazerman, Tr. 917). Professor Bazerman does not, however, talk about Endo's actual reasons for settling. Moreover, Professor Bazerman opined that, if Endo was thinking along the

CX5005 at 004, 015 (¶ 5, List of Additional Materials Considered) (Bazerman Rebuttal Report)). Professor Bazerman also relied upon Impax's document and testimony, which shows that Impax structured the Endo Credit to replicate the value of the No-AG provision if Endo reformulated Opana ER and expected to profit from either the No-AG provision or the Endo Credit. (Bazerman, Tr. 867, 873; CX5001 at 028-29 (¶ 54) (Bazerman Report)).

1522. Nor has Professor Bazerman seen any analysis in which Impax valued the Endo Credit prior to settlement. (Bazerman, Tr. 912).

Response to Proposed Finding No. 1522

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1521.

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).

Response to Proposed Finding No. 1523

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1521.

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).

Response to Proposed Finding No. 1524

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1521.

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).

Response to Proposed Finding No. 1525

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1521. Whether Impax got value from the No-AG provision or from the

Endo Credit would be governed by post-settlement events over which Impax did not have

The Proposed Finding is misleading and incomplete in that it implies that Professor Bazerman believes Endo could have avoided making an Endo Credit payment if the Novartis plant did not shut down. To the contrary, Professor Bazerman testified that it would have been very difficult for Endo to time reformulation in

payment. (CCF ¶ 994). Indeed, there would generally be no reason for Endo to make a reverse payment except to push back the entry date Impax would accept. (Bazerman, Tr. 863; CX5001 at 029-30 (¶ 55) (Bazerman Report)). Professor Bazerman therefore concluded that the reverse payments increased Endo's and Impax's total profits—by allowing Endo to maintain a monopoly until the pushed-back entry date and to provide Impax with sufficient compensation—at the expense of consumers. (CCF ¶ 994).

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).

Response to Proposed Finding No. 1531

The Proposed Finding is misleading and incomplete. Professor Bazerman testified that the No-AG provision and the Endo Credit worked together to ensure Impax got value and it is not possible to analyze one without the other. (Bazerman, Tr. 867, 873, 908-09, 911-12). Further, he testified that "the value of the combined no-AG agreement plus Endo credit is worth, even at the point of signing, worth many tens of millions of dollars on an expected value basis." (CX4040 (Bazerman, Dep. at 58)). This is consistent with analysis done by Professor Noll in his expert report, which Professor Bazerman considered in forming his opinions. (CCF ¶¶ 469-72; CX5005 at 004, 015 (¶ 5, List of Additional Materials Considered) (Bazerman Rebuttal Report)). Professor Bazerman also relied upon Impax's document and testimony, which shows that Impax insured the value of the No-AG provision with the Endo Credit in case Endo reformulated Opana ER, such that Impax expected to profit from either the No-AG provision or the Endo Credit. (Bazerman, Tr. 867, 873; CX5001 at 028-29 (¶ 54) (Bazerman Report)).

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).

Response to Proposed Finding No. 1532

The Proposed Finding is misleading, incomplete, and contrary to the weight of the evidence for the reasons set forth in response to Proposed Finding No. 1531.

1533. Professor Bazerman has not seen any analysis prior to settlement where Impax valued the no-Authorized Generic provision. (Bazerman, Tr. 912).

Response to Proposed Finding No. 1533

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1531. Moreover, Professor Bazerman reviewed forecasts from Impax that show months in which Impax predicts Endo does not sell an authorized generic in competition with Impax and how Impax's revenues are affected by being the only generic. (CCF ¶¶ 413-14 (citing, for example, CX2825 at 008-17); CX5001 at 064-65 (List of Materials Considered) (Bazerman Report) (list includes CX2825 with a Bates number of IMPAX-OPANA-CID00007096)).

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).

Response to Proposed Finding No. 1534

The Proposed Finding is factually inaccurate and not supported by the evidence cited for the reasons set forth in response to Proposed Finding No. 1530.

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).

Response to Proposed Finding No. 1535

The Proposed Finding is misleading and incomplete. Professor Bazerman described the range of Endo's payment to Impax under the DCA as $10-40 million, with $10 million provided

upfront. The payments to Endo were negotiated without Endo knowing what rights it was getting or even what product was the subject of the agreement. (CX5001 at 018-19 (¶ 37) (Bazerman Report)). Across all of his experience consulting with pharmaceutical firms, Professor Bazerman has never encountered a brand company negotiating how much they would pay without knowing what they were paying to obtain. (CX5001 at 018-19 (¶ 37) (Bazerman Report)). Professor Bazerman opined that Endo did know what it was paying for, specifically, Impax staying out of the market until January 2013. (Bazerman, Tr. 845; CX5001 at 018-19 (¶ 37) (Bazerman Report)). Professor Bazerman observed numerous other factors linking the settlement agreement and the DCA, including that (1) the DCA is incorporated into the settlement agreement; (2) the settlement and DCA were negotiated together in fall 2009 and then again in May/June 2010 and analyzed in the same documents; (3) the two agreements were held in escrow to ensure that both took effect at the same time, even though one is dated a day earlier; and (4) Impax and Endo did not have a relationship conducive to a value-creating agreement relating to a different product for which Impax owned a competing product. (Bazerman, Tr. 865-69; CCF ¶¶ 1067-68, 1074, 1076-81; CX5001 at 016-22 (¶¶ 34-43) (Bazerman Report)).

1536. This means that Professor Bazerman did not calculate the value of the profit-sharing rights Endo received under the DCA. (Bazerman, Tr. 925).

Response to Proposed Finding No. 1536

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1535.

Despite failing to value the rights Endo

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).

Response to Proposed Finding No. 1538

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1535.

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).

Response to Proposed Finding No. 1539

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1535. Specifically, Professor Bazerman opined that Endo made the payment under the DCA in return for Impax's agreement not to sell generic Opana ER before January 2013. (CX5001 at 018-19 (¶ 37) (Bazerman Report)). Thus, there is no reason to believe that the DCA would be entered into years after settlement. Indeed, even after paying $10 million upfront, Endo preferred to terminate the agreement five years later rather than switch to a new compound when the compound referenced in the DCA failed in testing. (CCF ¶ 1246). This is consistent with Professor Bazerman's opinion that Endo and Impax did not have a relationship conducive to a value-creating development agreement and that the focus of the DCA was Endo obtaining Impax's agreement not to sell generic Opana ER until January 2013. (Bazerman, Tr. 845; CX5001 at 020-22 (¶¶ 41-44) (Bazerman Report)).

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).

Response to Proposed Finding No. 1540

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1535 and 1539.

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).

Response to Proposed Finding No. 1541

The Proposed Finding is factually inaccurate and not supported by the evidence cited. Professor Bazerman testified that the combination of the No-AG provision, the Endo Credit, and the Development and Co-Promotion Agreement would have the effect of "moving the entry date later," even if he could not specify "the number of days, week or months" by which the entry date was pushed back. (Bazerman, Tr. 910-11). Professor Bazerman testified that those payments to Impax in the Impax-Endo Settlement Agreement would push back the entry date by expanding the range of settlement negotiations that Impax would accept and allow the parties to agree to a settlement with an entry date for Impax beyond what would have been expected without the payment. (CCF ¶ 994). Indeed, there would generally be no reason for Endo to make a reverse payment except to push back the entry date Impax would accept. (Bazerman, Tr. 863; CX5001 at 029-30 (¶ 55) (Bazerman Report)). Professor Bazerman therefore concluded that the reverse payments increased Endo's and Impax's total profits—by allowing Endo to maintain a monopoly until the pushed-back entry date and to provide Impax with sufficient compensation—at the expense of consumers. (CCF ¶ 994).

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).

Response to Proposed Finding No. 1542

The Proposed Finding is misleading in that it suggests that ex-post events are determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent

not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement (*See* Complaint Counsel's Pretrial Brief at 43 (citing *Actavis*, 133 S. Ct. at 2236)).

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).

Response to Proposed Finding No. 1545

The Proposed Finding is misleading in that it suggests that ex-post events are determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. (*See* Complaint Counsel's Pretrial Brief at 43 (citing *Actavis*, 133 S. Ct. at 2236)). Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. (*See* Complaint Counsel's Pretrial Brief at 43; Complaint Counsel's Proposed Conclusions of Law, ¶ 7).

1546. Yet Professor Bazerman has not done any analysis regarding which settlement agreement has been better for consumers. (Bazerman, Tr. 918-20).

Response to Proposed Finding No. 1546

The Proposed Finding is misleading and incomplete because it suggests that the Impax-Endo Settlement Agreement was better for consumers than the Actavis settlement based on events that occurred years after the two settlements were entered. But ex-post events are not determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. (*See* Complaint Counsel's Pretrial Brief at 43 (citing *Actavis*, 133 S. Ct. at 2236)). Instead, the relevant question is whether the patent holder shared its monopoly

profits to avoid the risk of competition. (*See* Complaint Counsel's Pretrial Brief at 43; Complaint Counsel's Proposed Conclusions of Law, ¶ 7).

Moreover, the Proposed Finding is factually inaccurate in that Professor Bazerman testified that he was able to review "features of those two settlements in a comparative way and talk about how features would [ ] comparatively affect consumers." (Bazerman, Tr. 919-20). The payments to Impax would be expected to push back the date of Impax's entry compared to an entry date-only agreement. (Bazerman, Tr. 846). The Actavis settlement had no payment to Actavis and allowed generic entry in July 2011, approximately 18 months before Impax's entry date. (Bazerman, Tr. 877).

1547. Professor Bazerman has not done an analysis of the expected value of the Actavis settlement to consumers. (Bazerman, Tr. 919).

Response to Proposed Finding No. 1547

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1546.

1548. And Professor Bazerman has not calculated an expected value for consumers of the Imp12.ta.T ment. (Bazerman, Tr. 919).

Response to Proposed Finding No. 1548

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1546.

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).

Response to Proposed Finding No. 1549

Complaint Counsel has no specific response.

To identify a best alternative to negotiate

Impax's economic expert agreed that he lacked the information necessary to determine Impax's or Endo's reservation date (or BATNA). (CCF ¶¶ 1443, 1445-46).

1551. This process requires a probabilistic assessment of the different possible scenarios Impax was facing. (Bazerman, Tr. 903).

Response to Proposed Finding No. 1551

The Proposed Finding is misleading and incomplete for the reason set forth in response to Proposed Finding No. 1550.

1552. Professor Bazerman did not perform the decision tree analysis to determine Impax's best alternative to negotiated agreement. (Bazerman, Tr. 903).

Response to Proposed Finding No. 1552

The Proposed Finding is misleading and incomplete for the reason set forth in response to Proposed Finding No. 1550.

1553. Professor Bazerman did not calculate the expected values of the possible outcomes facing Impax. (Bazerman, Tr. 903).

Response to Proposed Finding No. 1553

The Proposed Finding is misleading and incomplete for the reason set forth in response to Proposed Finding No. 1550.

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).

Response to Proposed Finding No. 1554

The Proposed Finding is misleading and incomplete for the reason set forth in response to Proposed Finding No. 1550.

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).

Response to Proposed Finding No. 1555

Complaint Counsel has no specific response.

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")).

Response to Proposed Finding No. 1556

The Proposed Finding is misleading and incomplete in that it erroneously suggests Professor Bazerman's expert opinions require proof that Impax would have launched at risk. They do not. Professor Bazerman describes the many steps that Impax took to prepare for an at-risk launch, including validating its manufacturing process, getting DEA quota, buying API, producing finished products for launch, and making the Impax Board aware of the potential for an at-risk launch. (Bazerman, Tr. 875-76; CX5001 at 031-33 (¶ 60-61) (Bazerman Report)). But Professor Bazerman's opinion is not that Impax would definitely have launched at risk; instead, he opines that Impax posed a credible threat to Endo and that Endo overcame that competitive threat by paying Impax. (Bazerman, Tr. 876). Indeed, Endo—which planned to launch Reformulated Opana ER in late 2010 or early 2011 but was concerned about a generic launch before then—would have no reason to pay Impax unless it viewed an at-risk launch as a realistic threat. (CX5001 at 034 (¶ 64) (Bazerman Report)). Even if Impax never actually launched at risk, the possibility of an at-risk launch (and the corresponding threat to Endo's branded sales) would improve Impax's potential negotiated outcomes and may have ultimately influenced whether Endo would agree to an entry-date-only settlement. (Bazerman, Tr. 921; CX4040 (Bazerman, Dep. at 41 (Endo's BATNA affected by potential for Impax entering at risk"))). But Endo paid Impax rather than face this risk of competition. (Bazerman, Tr. 876 (discussing the credible risk of Impax entering); CX5001 at 034 (¶ 64) (Bazerman Report)).

The potential for Impax to launch at-risk also relates to Impax's agreement to stay out of the market until January 2013. Impax's at-risk launch preparations created expectations within Impax about Opana ER sales. For example, the president of Impax's generics division told Impax's CEO that he was concerned about postponing Impax's launch of generic Opana ER because that would result in lost sales for Impax. (CCF ¶ 224). Having undertaken preparations Thalso rest sbyn

brand-name company. (CCF ¶ 1025). The Proposed Finding is also misleading and incomplete insofar as it suggests that Endo's lost profits might be up to ten times as much as Impax's profits. As the first-to-file generic, Impax projected that its oxymorphone ER would be introduced at 55% of the brand's WAC price. (CCF ¶¶ 585, 591). Thus, the ratio of Endo's lost profits to Impax's sales would be less than two.

1561. Such penalties mean that any generic company deciding whether to launch at risk must make its decision with care. (Bazerman, Tr. 922).

Response to Proposed Finding No. 1561

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding Nos. 1556 and 1560.

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).

Response to Proposed Finding No. 1562

The Proposed Finding is misleading in that it suggests that ex-post events are determinative of whether the Impax-Endo Settlement Agreement is anticompetitive under the rule of reason. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. (*See* Complaint Counsel's Pretrial Brief at 43 (citing *Actavis*, 133 S. Ct. at 2236)). Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. (*See* Complaint Counsel's Pretrial Brief at 43; Complaint Counsel's Proposed Conclusions of Law, ¶ 7).

The Proposed Finding is also incomplete in that both Impax's patent expert and Complaint Counsel's patent expert agree that the outcome of Impax-Endo patent litigation was uncertain (CCF ¶ 1270 (citing Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644)).

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).

Response to Proposed Finding No. 1563

The Proposed Finding is misleading and incomplete because it erroneously suggests that Impax was undertaking launch preparations fo

July 2011 (when another generic, Actavis, was licensed to enter on other dosage strengths and Endo could be prepared for generic sales). (CCF ¶ 1320). Impax's desire to maintain secrecy is consistent with an actual intention to launch, rather than mere bluffing. (CCF ¶ 183).

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).

Response to Proposed Finding No. 1564

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1563.

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.

Response to Proposed Finding No. 1565

The Proposed Finding is factually inaccurate and ignores the reverse payments in the Impax-Endo Settlement Agreement. There are various economic reasons why a no-payment settlement between Impax and Endo was feasible. First, as Professor Bazerman explains, most patent litigations, including pharmaceutical patent litigations, settle because of efficiencies in terms of legal costs and expenditure of executive time. (CX5005 at 007 (¶ 10) (Bazerman Rebuttal Report); CX5001 at 010-11 (¶¶ 20-21) (Bazerman Report)). Indeed, since 2004, nearly 77% of pharmaceutical patent litigations settled without a reverse payment. (CCF ¶ 1440). In this case, through the No-AG/Endo Credit payment and the DCA, Endo would be expected to pay Impax tens of millions of dollars under the Impax-Endo Settlement Agreement. (CCF ¶¶ 448-51, 466-72; CX5001 at 024-29 (¶ 49-54) (Bazerman Report)). Economics and simple negotiation logic dictate that Endo would have been willing to accept some earlier entry date if it did not have to make such a large payment to Impax. (CCF ¶ 995; Bazerman, Tr. 874). Professor

Bazerman discusses potential earlier entry dates that the evidence suggests would have been economically acceptable. For example, Professor Bazerman noted that Endo settled with numerous other generics without reverse payments for entry dates in September 2012, including a settlement with Sandoz that was finalized on the same day as the Impax-Endo Settlement Agreement. (CX5005 at 010 (¶ 17) (Bazerman Rebuttal Report) (citing September 2012 entry date in other settlements and concluding "these other settlements show that Endo was willing to settle Opana ER patent litigation with entry dates earlier than January 2013"); CCF ¶ 1009). At the time of the Impax-Endo Settlement Agreement, Endo expected to begin selling its reformulated product by mid-2011, so there is reason to think that Endo would have been willing to give Impax the same date if it did not need to make reverse payments, which ended up costing Endo $112 million between the Endo Credit payment and upfront payment in the DCA. (Bazerman, Tr. 873-74; CX5001 at 016, 028-29 (¶¶ 34, 54) (Bazerman Report)).

The Proposed Finding is also misleading to the extent that it assumes Complaint Counsel must prove that a settlement with an earlier entry date would have occurred. As the Supreme Court explained in *Actavis*, proving anticompetitive effect does not require litigating the underlying patent claims or reconstructing the hypothetical world absent the challenged agreement. (*See* Complaint Counsel's Pretrial Brief at 43 (citing *Actavis*, 133 S. Ct. at 2236)). Instead, the relevant question is whether the patent holder shared its monopoly profits to avoid the risk of competition. (*See* Complaint Counsel's Pretrial Brief at 43; Complaint Counsel's Proposed Conclusions of Law, ¶ 7).

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).

Response to Proposed Finding No. 1566

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).

Response to Proposed Finding No. 1568

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1567. The Proposed Finding is also misleading and incomplete in suggesting that the brand firm and generic firm-mpd firm Tadt9(esponse tom4ry9(e)5iJTw daipel f6-0.irm)]{e3i-43 Tu 64

threat to the brand company and impact its willingness to enter a specific settlement. (Bazerman, Tr. 920-21; CX4040 (Bazerman, Dep. at 41 (Endo's BATNA affected by potential for Impax entering at risk"))). Indeed, when the generic company suspects that future demand may decrease because of product reformulation, the generic may have increased incentives to launch at risk to realize value from its investment in the generic product. (CX5001 at 033-34 (¶ 62) (Bazerman Report)). The chances of an at-risk launch—and the related risk to the brand company from lost branded sales—may therefore expand acceptable entry dates for the brand company and align the entry dates each party deems acceptable, rather than driving a wedge between them.

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).

Response to Proposed Finding No. 1570

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1569.

Complaint Counsel also object to the term "refusal to confirm" as vague and not supported by the evidence cited. Endo did not just refuse to comment on reformulation plans, it flatly denied such plans. (CX4010 (Mengler, IHT at 41-42 (quoting Endo representative as saying "We are absolutely not switching this product. I promise you"))).

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).

Response to Proposed Finding No. 1571

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1569.

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).

Response to Proposed Finding No. 1572

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1569.

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).

Response to Proposed Finding No. 1573

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1569.

1574. This renders the prospect of any term-split agreement unlikely. (RX-547.0066).

Response to Proposed Finding No. 1574

The Proposed Finding is misleading and incomplete for the reasons set forth in response to Proposed Finding No. 1569. The Proposed Finding is also not supported by the evidence cited, as the cited materials do not discuss the likelihood of a term-split agreement. (RX-547 at 0066).

COMPLAINT COUNSEL'S RESPONSE TO RESPONDENT IMPAX'S PROPOSED

to show that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.") (internal quotation omitted).

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 regard of eby sndega21

antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."); *id.* at 2237 ("[O]ne who makes such a payment may be unable to explain and to justify it."); *Lamictal*, 791 F.3d at 412 ("Second, the burden shifts to the defendant to show that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.") (internal quotation omitted).

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.").

Response to Proposed Conclusion No. 5

Complaint Counsel has no specific response, but notes that *Actavis* itself was decided under § 5 of the FTC Act. *Actavis*, 133 S. Ct. at 2229-30.

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"].

Response to Proposed Conclusion No. 6

Complaint Counsel has no specific response.

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).

Response to Proposed Conclusion No. 7

Complaint Counsel has no specific response, but notes that *Actavis* reaffirmed the principle set forth in *California Dental Ass'n v. FTC*, 526 U.S. 756, 780 (1999), that in rule of reason cases "[t]here is always something of a sliding scale in appraising reasonableness" and

that "the quality of proof required should vary with the circumstances." 133 S. Ct. at 2237-38 (internal quotation marks and citations omitted). Accordingly, the rule of reason analysis in a reverse-payment case does not require Complaint Counsel to "present every possible supporting fact" or "theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences." *Actavis*, 133 S. Ct. at 2237-38.

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"*

The Proposed Conclusion is incorrect and should be rejected. Impax cites no case holding that *Actavis* imposes on Complaint Counsel a threshold burden of proving that a payment is large and unjustified before application of the rule of reason. Impax's argument has been specifically rejected. *See King Drug Co. of Florence, Inc. v. Cephalon, Inc*., 88 F. Supp. 3d 402, 414 (E.D. Pa. 2015) ("[N]owhere in the *Actavis* opinion does the Supreme Court state that plaintiffs bear a 'threshold burden' of demonstrating that the reverse payment was large and unjustified."). And every court to address burdens of proof under *Actavis* has held that the plaintiff must establish a "large" payment as part of its *prima facie* case under the rule of reason—not as a threshold burden—and the defendant then bears the burden to show a sufficient justification for the payment. *See, e.g*., *In re Lipitor Antitrust Litig*., 868 F.3d 231, 256-57 (3d Cir. 2017) (*Actavis* "clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants*.") (emphasis in original). Impax's approach would require a court to inquire into these very same elements twice, the difference being that in the first iteration, the plaintiff is forced to anticipate and negate possible justifications that the defendant might or might not actually offer. Such an unprecedented and inefficient approach to application of the rule of reason makes no sense. If the Supreme Court had intended such a dramatic departure from standard rule-of-reason analysis, it surely would have said so.

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.").

Response to Proposed Conclusion No. 10

The Proposed Conclusion is incorrect and should be rejected. Under *Actavis*, Impax has the burden of proof to explain or justify its reverse payments. *Actavis*, 133 S. Ct. at 2236 (2013) ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are

present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."); *id.* at 2237 ("[O]ne who makes such a payment may be unable to explain and to justify it."); *see also Lamictal*, 791 F.3d at 412 ("Second, the burden shifts to the defendant to show that legitimate justifications are present, thereby explaining the presence of the challenged term and showing th

same elements twice, the difference being that in the first iteration, the plaintiff is forced to anticipate and negate possible justifications that the defendant might or might not actually offer. Such an unprecedented and inefficient approach to application of the rule of reason makes no sense. If the Supreme Court had intended such a dramatic departure from standard rule-of-reason analysis, it surely would have said so.

B. "Large" and "Unjustified" Are Separate And Discrete Requirementsual.2s 8ementsual.2s 8

has held that the plaintiff must establish a "large" payment as part of its *prima facie* case under the rule of reason and the defendant then bears the burden to show a sufficient justification for the payment. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d at 256-57 (*Actavis* "clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants*.") (emphasis in original). Impax's approach, however, would require a court to inquire into these very same elements twice, the difference being that in the first iteration, the plaintiff is forced to anticipate and negate possible justifications that the defendant might or might not actually offer. Such an unprecedented and inefficient approach to application of the rule of reason makes no sense. If the Supreme Court had intended such a dramatic departure from standard rule-of-reason analysis, it surely would have said so.

15. *Actavis* provides a "safe harbor" for small reverse payments. *In re Aggrenox Antitrust Litig.*

Supp. 3d 704, 718 (N.D. Ill. 2016) ("A 'large' payment is anything more than the value of the avoided litigation costs plus any other services provided from the generic to the brand manufacturer."); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d at 417 ("[A] reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim."); *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc*., 74 F. Supp. 3d 1052, 1071 (N.D. Cal. 2014) (lower bound for "large payment" is likely "anything more than the value of the avoided litigation costs plus any other services provided from the generic to the brand manufacturer").

Moreover, not all payments that exceed litigation costs

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."

Response to Proposed Conclusion No. 20

The Proposed Conclusion is incorrect and should be rejected to the extent that it suggests that Complaint Counsel must calculate a precise mathematical value for the payment. *See Actavis*, 133 S. Ct. at 2237-38 (FTC need not "present every possible supporting fact" or "theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences"). The Proposed Conclusion is also incorrect and should be rejected to the extent it suggests that Impax does not bear the burden of justifying the payments. *See Actavis*, 133 S. Ct. at 2236 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."); *id.* at 2237 ("[O]ne who makes such a payment may be unable to explain and to justify it."); *Lamictal*, 791 F.3d at 412 ("Second, the burden shifts to the defendant to show that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.") (internal quotation omitted).

21. Complaint counsel has not met its burden with regard to the DCA.

Response to Proposed Conclusion No. 21

The Proposed Conclusion is incorrect and should be rejected. First, this Proposed Conclusion is not "supported by applicable legal authority" as required by the mandatory rules for post-trial briefs. Order on Post-Trial Briefs (Nov. 17, 2017) at 2 ("All legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be

supported by applicable legal authority."). Second, Complaint Counsel showed that the DCA

testimony about whether the deal was consistent with industry standards as not only relevant but also sufficient to rebut a defendant's justification. (*See* CC Reply Br. at Argument, II.A.2).

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.

Response to Proposed Conclusion No. 25

The Proposed Conclusion is incorrect and should be rejected. First, the Proposed Conclusion is misleading because it appears to attribute opinions to Dr. Geltosky that are in fact quotations from *In re Schering-Plough Corp.* In *Schering-Plough*, neither this Court nor the Eleventh Circuit found the testimony of the parties' pharmaceutical business development experts irrelevant. And the DCA is nothing like the side deal in *Schering-Plough*: in *Schering-Plough*, the Court of Appeals found that 1) the brand company acquired a late-stage drug, not an unformulated concept as in this case; 2) the brand evaluated clinical research results showing that the drug was an improvement over existing therapies; 3) the valuation was conducted by employees who were unaware of the patent case and was corroborated by a separate valuation done on a similar product outside the context of any patent settlement; and 4) the payment and deal structure were similar to deals the brand had done before. *Schering-Plough v. FTC*, 402 F3d 1056, 1059, 1068-70 (11th Cir. 2005). None of these four features are present in this case. Second, Dr. Geltosky's unrebutted opinions that the DCA was negotiated in a small fraction of the time it would normally take, that Endo failed to follow its own documented diligence process, and that the structure of the DCA is highly unusual for an early-stage product are corroborated by contemporaneous Endo business documents and witness testimony. Courts

a finding that Endo was not actually paying it to obtain the profit-sharing rights in the DCA. (CCF ¶¶ 1220-22).

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.

Response to Proposed Conclusion No. 27

The Proposed Conclusion is incorrect and should be rejected. First, it is Impax's burden to justify the payment by showing that it was exchanged for the services in the DCA. *Actavis*, 133 S. Ct. at 2236, 2237; *Lamictal*, 791 F.3d at 412. There is no threshold burden of proof to trigger "antitrust scrutiny" prior to the rule of reason analysis. None of the cases cited by Impax hold that *Actavis* imposes a threshold burden of proof before application of the rule of reason, and Impax's argument has been specifically rejected elsewhere. Every court to address burdens of proof under *Actavis* has held that the plaintiff must establish a "large" payment as part of its *prima facie* case under the rule of reason and the defendant then bears the burden to show a sufficient justification for the payment. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d at 256-57 (*Actavis* "clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants*.") (emphasis in original). Second, Impax has failed to meet its burden to show that the profit-sharing rights Endo received under the DCA explain or justify its $10 million payment. The "relevant antitrust question" under *Actavis* is the reason for the reverse payment. 133 S. Ct. at 2237. Where a reverse payment "reflects traditional settlement considerations," such as a payment for independent business services, "there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement," and the parties "may have provided for a reverse payment without having sought or brought about the anticompetitive consequences" the Court identified. *Actavis*, 133 S. Ct. at 2236. Here, the record evidence demonstrates that the $10 million payment was not made

The Proposed Conclusion is incorrect and should be rejected to the extent that it suggests

time of settlement, the DCA payment was a least $10 million and the value of the No-AG/Endo Credit was at least $16.5 million. (CCF ¶¶ 329, 466-72, 1226).

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").

Response to Proposed Conclusion No. 32

The Proposed Conclusion is incorrect and should be rejected to the extent that it equates uncertainty about *what* the precise value of a contingent liability is with uncertainty about *whether* that contingency will have value. (*See* CC Reply Br. at Argument, II.B.2). A contingent obligation like a lottery ticket, with an extremely low chance of being worth a lot and an enormous chance of being worth nothing, has a small expected value. But a contingent obligation with many possible values, most of them large, has a large expected value. For example, if a scratch-off has a 5% chance of no payment, a 20% chance of $20 million, a 30% chance of $30 million, a 25% chance of $40 million, a 15% chance of $50 million, and a 5% chance of $100 million, the expected value is enormous ($35 million), even though therpecteuth mdid0015 0e/a

uncertainty about

Credit were triggered, Impax would make *at least* $62 million. (CCF ¶ 470). In all of these scenarios, the value of the No-AG provision and Endo Credit was at least three times larger than saved litigation costs. The scenario in which Impax did not receive a payment under either the No-AG provision or the Endo Credit was "so unlikely it wasn't worth worrying about." (CCF ¶ 480). Professor Noll's analysis, therefore, confirms what Impax's own documents and testimony demonstrate: that the No-AG provision and Endo Credit is a large payment. (*See* CC Reply Br. at Argument, II.B).

Finally, the Proposed Conclusion is also incorrect and should be rejected to the extent it suggests that Impax does not bear the burden of justifying the payments. *See Actavis*, 133 S. Ct. at 2236 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."); *id.* at 2237 ("[O]ne who makes such a payment may be unable to explain and to justify it."); *Lamictal*, 791 F.3d at 412 ("Second, the burden shifts to the defendant to show that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.") (internal quotation omitted).

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

The Proposed Conclusion is incorrect and should be rejected to the extent it suggests that either Complaint Counsel or Professor Noll "relied on the ultimate amount" of the Endo Credit payment ($102 million) to prove that the No-AG provision and Endo Credit was a large payment as of June 2010. Complaint Counsel established this payment was large with unrebutted contemporaneous documents and testimony showing that, at the time of the agreement, Impax expected to make more than $20 million in additional sales due to not facing an AG or receive an "approximation of th[ose] profits" under the Endo

or near saved litigation costs, the possibility of that scenario would have to be enormous. (*See* CC Br. at Argument, II.B.2). But Impax itself viewed this outcome as extremely unlikely. (*See* CC Br. at Argument, II.B.2).

Complaint Counsel's economic expert's analysis of the alleged "payment" terms is

demonstrate: that the No-AG provision and Endo Credit is a large payment. (*See*

421, 435 (3d Cir. 2016) (quoting *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 307 (3d Cir. 2007).

Response to Proposed Conclusion No. 39

Complaint Counsel has no specific response.

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).

Response to Proposed Conclusion No. 40

Complaint Counsel has no specific response, but notes that "reasonable interchangeability" is determined by high cross-elasticity of demand. *See Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 612 n.31 (1953) (antitrust product market must "be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross elasticities of demand' are small"); *Telecor Comm'cns Inc. v. Sw. Bell Tel. Co.*, 305 F.3d 1124, 1131 (10th Cir. 2002) (reasonable interchangeability "may be measured by, and is substantially synonymous with, cross-elasticity" (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962))). Products that are functionally interchangeable or even identical may not be in the same relevant antitrust market. *See U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 996 (11th Cir. 1993) (excluding functionally similar products where there was insufficient evidence of cross-elasticity); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988) (functionally interchangeable sweeteners in separate markets because "a small change in the price of [one] would have little or no effect on demand for [the other]"); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 327 (D.R.I. 2017) ("Products are not reasonably interchangeable merely because they share similar forms or functions, but rather '[s]uch limits

are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes.'") (quoting *In re Nexium*, 968 F. Supp. 2d 367, 387-88 (D. Mass. 2013)); *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc*. ("*Lidoderm"*), 2017 WL 5068533, at *19 (N.D. Cal. Nov. 3, 2017) ("Consistent with the bulk of the case law, something *more* than mere therapeutic equivalency is required to define the relevant antitrust product market. There must be some showing of cross-elasticity.").

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.").

Response to Proposed Conclusion No. 41

Complaint Counsel has no specific response, but notes that "reasonable interchangeability" is determined by high cross-elasticity of demand. *See Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 612 n.31 (1953) (antitrust product market must "be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross elasticities of demand' are small"); *Telecor Comm'cns Inc. v. Sw. Bell Tel. Co.*, 305 F.3d 1124, 1131 (10th Cir. 2002) (reasonable interchangeability "may be measured by, and is substantially synonymous with, cross-elasticity" (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962))). Products that are functionally interchangeable or even identical may not be in the same relevant antitrust market. *See U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 996 (11th Cir. 1993) (excluding functionally similar products where there was insufficiL 50ngea25e

(functionally interchangeable sweeteners in separate markets because "a small change in the price of [one] would have little or no effect on demand for [the other]"); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d at 327 (D.R.I. 2017) ("Products are not reasonably interchangeable merely because they share similar forms or functions, but rather '[s]uch limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes.'") (quoting *In re Nexium*, 968 F. Supp. 2d 367, 387-88 (D. Mass. 2013); *Lidoderm*, 2017 WL 5068533, at *19 ("Consistent with the bulk of the case law, something *more* than mere therapeutic equivalency is required to define the relevant antitrust product market. There must be some showing of cr

inquiry, regardless of the method used, is to assess the likely competitive effects of the conduct at issue. *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004)

Response to Proposed Conclusion No. 47

Complaint Counsel has no specific response.

48. This requires an evaluation of "the nature of the commercial entities involved and by the

counterparts. They are essentially copies of the branded drug, with the same active ingredient in the same dose, and are therefore generally the closest functional substitute for the corresponding brand product. (CCF ¶¶ 9, 549-50). Given these commercial realities, the unique competitive role of generics "cannot be seriously debated." *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003).

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).

Response to Proposed Conclusion No. 50

ER and other LAOs. A SSNIP test is one way to assess cross-elasticity of demand. (CCF ¶¶ 518-19, 526, 898-99 (describing how the SSNIP test establishes cross-elasticity); CCRF ¶ 750). Professor Noll did not specifically conduct a SSNIP test, but he used a related technique to assess cross-elasticity to analyze whether other LAOs were in the same product market as Opana ER: He observed what happened to the price and sale of one LAO when a lower-priced generic version of another LAO was introduced. By observing a product's reacti

legally cognizable way." Whether or not patients *could* substitute another long acting opioid for oxymorphone ER in response to a price increase only establishes functional interchangeability between the products. The relevant antitrust question is whether enough patients actually *would* switch to another LAO in response to a small but significant price increase for an oxymorphone ER product to make that price change unprofitable—i.e., whether there is high cross-elasticity of demand between oxymorphone ER products and other LAOs. *See Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 612 n.31 (1953) (antitrust product market "must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross elasticities of demand' are small"); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 996 (11th Cir. 1993) (excluding functionally similar products where there was insufficient evidence of cross-elasticity); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988) (functionally interchangeable sweeteners in separate markets because "a small change in the price of [one] would have little or no effect on the demand for [the other]"); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 327 (D.R.I. 2017) ("Products are not reasonably interchangeable merely because they share similar forms or functions, but rather 'such limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes.'" (quoting *In re*

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).

Response to Proposed Conclusion No. 55

The Proposed Conclusion is incorrect and should be rejected to the extent it suggests that the context of business documents is not important. "[T]he mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes." *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1075 (D.D.C. 1997).

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).

Response to Proposed Conclusion No. 56

The Proposed Conclusion is incorrect and should be rejected to the extent it suggests that the context of business documents is not important. "[T]he mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes." *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1075 (D.D.C. 1997).

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.").

Response to Proposed Conclusion No. 57

The Proposed Conclusion is incorrect and should be rejected. Business documents from Endo and other LAO manufacturers use the terms "competitor" and "market" in a general business sense—not in an economics or antitrust sense. But "the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes." *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1075 (D.D.C. 1997). When examined in context, these Endo business documents show that LAO manufacturers were generally not concerned with the price of LAOs based on different molecules. Endo's documents, for example, rarely even mention the relative price of other LAOs. Instead, those documents make clear that Endo's primary marketing goal was to *differentiate* Opana ER from other LAOs so that it did not have to compete with them on price. (CCF ¶¶ 724-25). Endo's marketing goal was to "effectively communicate why [its] product is different and why it would be needed by certain patient types." (CCF ¶ 728). To this end Endo repeatedly emphasized that Opana ER had "distinct pharmacologic properties compared with most other opioids," (CCF ¶¶ 726, 729-32, 769-70). Such product differentiation increases brand loyalty and make it *less* likely consumers will switch brands in response to small price changes. *See* CC Reply Br. at Argument, III.A.3.

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).

Response to Proposed Conclusion No. 58

Complaint Counsel has no specific response.

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).

Response to Proposed Conclusion No. 59

The Proposed Conclusion is incomplete and misleading. The essence of product market definition is cross-elasticity, which is based on whether enough consumers switch to another product in response to a change in relative prices to make that price change unprofitable. *See* CC Reply Br. at Argument, III.A.

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.

Response to Proposed Conclusion No. 60

The Proposed Conclusion is incorrect and should be rejected. Impax has not provided any evidence that consumers switched among LAOs of different molecules in response to price changes. The analysis of LAO formulary placement by Impax's economic expert does not show

price competition, let alone cross-elasticity of demand. Dr. Addanki admitted that he did not analyze or even know why any LAOs were put in certain formulary positions or whether it had anything to do with price. (CCF ¶ 944; CCRF ¶ 836). Third, Dr. Addanki's analysis entirely ignored generic oxymorphone ER and all other generic LAOs, which he acknowledge would "be on tier one uniformly or virtually uniformly." (CCF ¶ 946). By excluding generics, the most direct competitors for these products, Dr. Addanki paints a misleading picture of the level of competition between Opana ER and other LAOs. (CCF ¶ 947); *see also* CC Reply Br. at Argument, III.A.3.

Impax also offers anecdotal evidence that Endo offered rebates to secure formulary placement, but that is neither unusual nor inconsistent with market power. *See Lidoderm*, 2017 WL 5068533, at *17, *20 ("[E]vidence that physicians and MCOs were concerned about the 'high' price of Lidoderm and prescribed more or made more available where prices were lower or significant rebates were provided does not mean that the *other* products on the market . . . constrained the price of Lidoderm. It simply shows that, in order to grow the market for what defendants repeatedly characterize as a unique product, price concessions and rebates for Lidoderm were necessary."). The fact that Endo provided discounts to payers to sell more Opana ER does not answer the market definition question because it does not shed any light on the cross-elasticity of demand *between* Opana ER and other products. The fact that Endo decreased its sale price of Opana ER provides no indication of whether Opana ER was *relatively* cheaper than other LAOs. If payers were receiving similar discounts from other LAO manufacturers, then changes in formulary placement would not indicate anything about cross-elasticity of demand. Alternately, if those products were *already* significantly more expensive than Opana ER—or

significantly cheaper—the need for further discounting would not indicate price competition with them. *See* CC Reply Br. at Argument, III.A.3.

61. What little price-switching evidence Complaint Counsel has offered in response does not support Complaint Counsel's proposed market definition.

Response to Proposed Conclusion No. 61

The Proposed Conclusion is incorrect and should be rejected. Complaint Counsel provided an analysis of the cross-elasticity of demand between Opana ER and other LAOs. Professor Noll analyzed what happened to the price and sale of one LAO when a lower-priced generic version of another LAO is introduced. *See* CC Reply Br. at Argument, III.C.3. By observing a product's reaction to changes in the price of another product, the fact finder can draw conclusions about the degree of cross-elasticity between two drugs and whether they are close substitutes. (CCF ¶ 899 (describing how the SSNIP test establishes cross-elasticity)). For example, if Opana ER and morphine sulfate were close economic substitutes, a launch of generic morphine sulfate should result in users of Opana ER switching to generic morphine sulfate. (CCF ¶ 899 (citing Noll, Tr. 1374-75)). Dr. Addanki does not use this method for defining a relevant product market. (CCF ¶ 899). Professo

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.

Response to Proposed Conclusion No. 62

The Proposed Conclusion is incorrect and should be rejected. Professor Noll analyzed what happened to the price and sale of one LAO when a lower-priced generic version of another LAO is introduced. By observing a product's reaction to changes in the price of another product, the fact finder can draw conclusions about the degree of cross-elasticity between two drugs and whether they are close substitutes. (CCF ¶ 899 (describing how the SSNIP test establishes cross-elasticity)). Professor Noll's analysis determined that lower-price generic oxymorphone ER products took substantial sales from Opana ER, but not from any other LAOs. Similarly, he determined that lower cost generic versions of other LAOs did not take sales from Opana ER. These results allowed Professor Noll to draw the conclusion that there is high cross-elasticity of demand between brand and generic versions oxymorphone ER products, but low cross-elasticity between oxymorphone ER products and other, non-oxymorphone LAOs. Dr. Addanki does not offer any criticism of this analysis. (*See* CCF ¶¶ 897-903); *see* CC Reply Br. at Argument, III.C. Impax does not offer any citation or support for its Proposed Conclusion that Professor Noll's analysis 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).

Response to Proposed Conclusion No. 63

Complaint Counsel has no specific response, but notes that, although product differentiation does not establish market power, it can contribute to market power. *See* Lawrence A. Sullivan, et al., The Law of Antitrust: An Integrated Handbook 69 (3d ed. 2015) (noting that

product differentiation is an entry barrier

Response to Proposed Conclusion No. 66

The Proposed Conclusion is incorrect and should be rejected. Complaint Counsel has not alleged a relevant market based on "targeted customers," and therefore the Proposed Conclusion is irrelevant. Moreover, the Proposed Conclusion incorrectly suggests that the relevant market definition question is based on functional interchangeability. Whether or not patients *could* substitute another long acting opioid for oxymorphone ER in response to a price increase only establishes functional interchangeability between the products. The relevant antitrust question is whether patients actually *would* switch to another LAO in response to a small but significant price increase for an oxymorphone ER product—i.e., whether there is high cross-elasticity of demand between oxymorphone ER products and other LAOs. *See Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 612 n.31 (1953) (antitrust product market "must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross elasticities of demand' are small"); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 996 (11th Cir. 1993) (excluding functionally similar products where there was insufficient evidence of cross-elasticity); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988) (functionally interchangeable sweeteners in separate markets because "a small change in the price of [one] would have little or no effect on the demand for [the other]"); *In re Loestrin*, 261 F. Supp. 3d at 327 ("Products are not reasonably interchangeable merely because they share similar forms or functions, but rather 'such limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes.'" (quoting *In re Nexium*, 968 F. Supp. 2d at 387-88)); *Lidoderm*, 2017 WL 5068533, at *19 ("Consistent with the bulk of the case law, something *more*

than mere therapeutic equivalency is required to

bulk of the case law, something *more* than mere therapeutic equivalency is required to define the relevant antitrust product market. There must be some showing of cross-elasticity."); CC Reply Br. at Argument, III.A. & C.

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.*

Professor Noll's analysis is confirmed by real-world evidence about the effect of generic oxymorphone entry. When Impax's generic oxymorphone ER entered the market, **{** [redacted] **}** (CCF ¶¶ 629-37) (*in camera*). **{** [redacted] **}** (CCF ¶ 653; CX4038 (Engle Dep., at 122-23) (*in camera*)). This difference cannot be explained by state substitution laws: Impax's generic oxymorphone ER was not AB-rated to Endo's reformulated Opana ER and therefore could not be automatically substituted. If oxymorphone ER were interchangeable with other LAOs, Impax's cheaper product should have taken sales from them as well. The fact that it did not shows that other LAOs are not in the same relevant market as oxymorphone ER products. *See* CC Reply Br. at Argument, III.A. Moreover, if non-oxymorphone LAOs had high cross-elasticity of demand with oxymorphone ER, then Opana ER would have already been constrained to a competitive price when Impax's generic product launched: "[I]f competitive prices were being charged before the patented drug had a generic competitor, then the entry of new competitors would not result in a substantial change in price." *In re Aggrenox*, 199 F. Supp. 3d at 667. The fact that Impax's generic product entered at a lower price and took substantial sales from Endo's branded product confirms that competition from other LAOs was not sufficient to keep Endo's price at a competitive level.

69. The relevant market in which Opana ER competed was the market for long acting opioids.

Response to Proposed Conclusion No. 69

The Proposed Conclusion is incorrect and should be rejected. First, this Proposed Conclusion is not "supported by applicable legal authority" as required by the mandatory rules for post-trial briefs. Order on Post-Trial Briefs (Nov. 17, 2017) at 2 ("All legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be

supported by applicable legal authority."). Second, the relevant market in which to assess the challenged conduct is brand and generic oxymorphone ER products. Professor Noll's unrebutted analysis of substitution between oxymorphone ER and other LAOs answers the market definition question. Professor Noll analyzed what happened to the price and sale of one LAO when a lower-priced generic version of another LAO is introduced. By observing a product's reaction to changes in the price of another product, the fact finder can draw conclusions about the degree of cross-elasticity between two drugs and whether they are close substitutes. (CCF 899 (describing

Response to Proposed Conclusion No. 72

Complaint Counsel has no specific response.

a. Indirect Method

73. "Proving the existence of monopoly power through indirect evidence requires a definition of the relevant market." *Broadcom*, at 307.

Response to Proposed Conclusion No. 73

Complaint Counsel has no specific response.

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

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.").

Response to Proposed Conclusion No. 77

The Proposed Conclusion is inaccurate and should be rejected. The relevant market is limited to brand and generic oxymorphone ER products. Impax does not appear to dispute that, when the market is defined in this way, Endo had 100% of the market at the relevant time and therefore had market power. *See* CC Reply Br. at Argument, III.A. and B.

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.

Response to Proposed Conclusion No. 78

The Proposed Conclusion is inaccurate and should be rejected. Complaint Counsel showed that the relevant market is limited to brand and generic oxymorphone ER products. *See* Reply Br. at Argument, III.A. Impax does not appear to dispute that, when the market is defined in this way, Endo had 100% of the market at the relevant time and therefore had market power. *See* CC Reply Br. at Argument, III.B.

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).

Response to Proposed Conclusion No. 79

Complaint Counsel has no specific response.

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)).

Response to Proposed Conclusion No. 80

Complaint Counsel has no specific response.

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 w -21r I e1dc 0W0e0018 T05.7rlishg monopoly powe

Response to Proposed Conclusion No. 10

The Proposed Conclusion is incorrect and should be rejected. First, Complaint Counsel showed restricted output by showing that the entry of generic oxymorphone ER expanded output in the relevant market. *See* CC Reply Br. at Argument, III.C. Second, Complaint Counsel showed supracompetitive prices through (1) an extremely high Lerner Index, (2) Endo's ability to increase its net price, and (3) the effect of entry of lower-priced generic oxymorphone ER, which shows that Opana ER had not previously been sold at a fully competitive price. *See* CC Reply Br., Argument, III.A. and C.

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).

Response to Proposed Conclusion No. 85

Complaint Counsel has no specific response.

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.").

Response to Proposed Conclusion No. 86

The Proposed Conclusion is incorrect and should be rejected to the extent it suggests that the rule of reason requires Complaint Counsel to show an actual injury in a hypothetical but-for world. A central teaching of *Actavis* is that "the relevant anticompetitive harm" in a reverse payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s] and [] share[s] patent-generated monopoly profits." 133 S. Ct. at 2236-37. As *Actavis* recognizes, a large payment to induce the generic to

agree to forestall entry harms the competitive pro

while the interest of the government is "to prevent and restrain violations of the antitrust laws along with the attendant social costs such violations can cause." *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016); *see also id*. at 59.

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)

Response to Proposed Conclusion No. 87

Complaint Counsel has no specific response, but notes that "the relevant anticompetitive harm" in a reverse payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s] and [] share[s] patent-generated monopoly profits." 133 S. Ct. at 2236-37. As *Actavis* recognizes, a large payment to induce the generic to agree to forestall entry harms the competitive process, because it distorts the bargaining process that ordinarily would be expected to protect consumer interests.

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.

Response to Proposed Conclusion No. 88

Complaint Counsel has no specific response, but notes that *Actavis* explains that "the anticompetitive consequence that underlies the claim of antitrust unlawfulness" in a reverse payment case arises from the sharing of monopoly profits to eliminate "the risk of competition." 133 S. Ct. at 2236. (*See* CC Reply Br. at Argument, IV.A).

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).

Response to Proposed Conclusion No. 89

Complaint Counsel has no specific response, but

effects under a rule of reason analysis, and once this showing is made Realcomp must offer

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.

Response to Proposed Conclusion No. 92

The Proposed Conclusion is incorrect and should be rejected. The Commission's decision made clear that it was not deciding whether and which post-settlement effects are relevant under the *Actavis* rule of reason inquiry and that its decision was not establishing any law of the case. As the Commission stated, "Without the facts before us, and an understanding of how the parties intend to marshal those facts, a formulation that unnecessarily establishes law of the case risks straight-jacketing the proceeding in ways that impede effective inquiry and appropriate resolution." *See* Comm'n Decision at 11. Thus, the Commission stated multiple times that it was not "in a position *at this time*" to "shut off" arguments. *See* Comm'n Decision at 11-12 ("We are not willing to shut off all such argument at this time."). Thus, the Commission did not hold that post-settlement effects are relevant under the rule of reason, only that they may be. In any event, to the extent post-settlement effects are relevant, the most relevant effect is that before the settlement, there was a risk of generic competition to Opana ER; after the reverse payment agreement, there was no risk of generic entry on the most popular dosages until January 1, 2013. (CCF ¶¶ 332-87).

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).

Response to Proposed Conclusion No. 93

Complaint Counsel has no specific response, but notes that "the relevant anticompetitive harm" in a reverse payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s] and [] share[s] patent-generated monopoly profits." 133 S. Ct. at 2236-37. As far back as *Board of Trade of City of Chicago v.*

United States, it has been clear that to determine whether a challenged restraint amounts to a rule of reason violation, courts look to "the nature of the restraint and its effect, *actual or probable*." 246 U.S. 231, 238 (1918) (emphasis added). An anticompetitive effect *can* be established by demonstrating an actual increase in prices or decrease in output. *See, e.g., United States v. Brown Univ. in Providence in State of R.I.*, 5 F.3d 658, 668 (3d Cir. 1993); *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1097 (1st Cir. 1994). But that is not the only way to prove the requisite effect. "[A] demonstration of defendant's market power, which when combined with the anticompetitive nature of the restraints, provides the necessary confidence to predict the likelihood of anticompetitive effects." *In the Matter of Realcomp II Ltd.*, No. 9320 2009 FTC LEXIS 250 at *90, aff'd *Realcomp II, Ltd v. FTC*, 635 F.3d 815, 827 (2011) ("Market power and the anticompetitive nature of the restraint are sufficient to show the potential for anticompetitive effects under a rule of reason analysis, and once this showing is made Realcomp must offer procompetitive justifications."). In effect, Impax's "actual" anticompetitive effects argument seeks to impose on Complaint Counsel additional proof requirements that are required only of private plaintiffs, who must prove injury in-fact to establish standing under the Clayton Act. *See* CC Br. 26. But as the First Circuit explained, the distinction between government law enforcement and private antitrust suits rests on an important difference in the respective role of the public and private plaintiffs: The interest of a private plaintiff is to "remediate an injury," while the interest of the government is "to prevent and restrain violations of the antitrust laws along with the attendant social costs such violations can cause." *In re Nexium (Esomeprazolej00009yc,.0008 11 T*

along with the attendant social costs such violations can cause." *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d at 60; *see also id*. at 59.

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).

Response to Proposed Conclusion No. 95

The Proposed Conclusion is incorrect and should be rejected to the extent it suggests that the rule of reason requires Complaint Counsel to show an actual injury through reconstruction of a but-for world. Under *Actavis*, "the relevant anticompetitive harm" in a reverse payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s] and [] share[s] patent-generated monopoly profits." 133 S. Ct. at 2236-37. As far back as *Board of Trade of City of Chicago v. United States*, it has been clear that to determine whether a challenged restraint amounts to a rule of reason violation, courts look to "the nature of the restraint and its effect, *actual or probable*." 246 U.S. 231, 238 (1918) (emphasis added). An anticompetitive effect *can* be established by demonstrating an actual increase in prices or decrease in output. *See, e.g., United States v. Brown Univ. in Providence in State of R.I.*, 5 F.3d 658, 668 (3d Cir. 1993); *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1097 (1st Cir. 1994). But that is not the only way to prove the requisite effect. "[A] demonstration of defendant's market power, which when combined with the anticompetitive

seeks to impose on Complaint Counsel additional proof requirements that are required only of private plaintiffs, who must prove injury in-fact to establish standing under the Clayton Act. *See* CC Br. 26. But as the First Circuit explained, the distinction between government law enforcement and private antitrust suits rests on an important difference in the respective role of the public and private plaintiffs: The interest of a private plaintiff is to "remediate an injury," while the interest of the government is "to prevent and restrain violations of the antitrust laws along with the attendant social costs such violations can cause." *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d at 60; *see also id*. at 59.

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.").

Response to Proposed Conclusion No. 96

The Proposed Conclusion is incorrect and should be rejected. *Actavis* instructs that "the relevant anticompetitive harm" in a reverse payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s] and [] share[s] patent-generated monopoly profits." 133 S. Ct. at 2236-37. None of the cases cited by Impax support the Proposed Conclusion. *King Drug* repeatedly defined "payment for delay" as "payment to prevent the risk of competition." 791 F.3d at 412; *see also id.* at 402 ("a reverse payment inducing delay—i.e., a 'payment in return for staying out of the market'") (quoting *Actavis*, 133 S. Ct. at 2234-35); *id.* at 411 (antitrust laws likely forbid "payment *for delay* (or,

that is, to eliminate the risk of patent invalidity or noninfringement)") (emphasis in original). Moreover, *King Drug* explained that "the antitrust problem [in *Actavis*] was that, as the Court inferred, entry *might have been earlier*, and/or the risk of competition not eliminated, had the reverse payment not been tendered," and held that, "to prove anticompetitive effects" under the rule of reason, a plaintiff need only prove "payment to prevent the risk of competition." 781 F.3d at 408, 412 (emphasis added); *see also id.* at 404 ("prevention of that risk of competition. . . constitutes the relevant anticompetitive harm") (internal quotation marks omitted). Similarly, *Cipro* makes clear that the rule-of-reason analysis focuses on the payment—not any actual or hypothetical subsequent events—to determine whether it "eliminates competition beyond the point at which competition *would have been expected* in the absence of the agreement." *In re Cipro Cases I & II*, 348 P.3d 845, 865-69 (Cal. 2015) (emphasis added); *see also* CC Reply Br. at Argument, I.C.1.

97. Courts may not infer anticompetitive effects—including delayed entry—"from the mere presence of a reverse payment." Comm'n Decision at 8.

Response to Proposed Conclusion No. 97

The Proposed Conclusion is inaccurate and should be rejected to the extent it suggests that Complaint Counsel must prove "delayed entry" to establish anticompetitive effects. *Actavis* instructs that "the relevant anticompetitive harm" in a reverse-payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s] and [] share[s] patent-generated monopoly profits." 133 S. Ct. at 2236-37. In addition, Complaint Counsel notes that a reverse payment does not give rise to anticompetitive effects unless it is large and unless the parties have market power. Nor does a large reverse payment give rise to anticompetitive effects when it is supported by traditional settlement

considerations rather than a desire to share monopoly profits to induce the challenger to stay out of the market. *See Actavis*, 133 S. Ct. at 2235.

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)).

Response to Proposed Conclusion No. 98

Complaint Counsel has no specific response.

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.*

Response to Proposed Conclusion No. 99

Complaint Counsel has no specific response.

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).

Response to Proposed Conclusion No. 100

The Proposed Conclusion is incorrect and should be rejected. Professor Noll's analysis is precisely the approach underpinning the Supreme Court's decision in *Actavis.* Just as cases following *Actavis* have found, Professor Noll finds, as an economic matter, that a reverse payment agreement creates an anticompetitive effect by preventing the risk of competition if: (1) the brand had market power; and (2) the brand made a large, unjustified reverse payment to the generic as part of an agreement for the generic not to enter. (CCF ¶¶ 498-501, 828-42, 966-87);

see also King Drug of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402, 416 (E.D. Pa. 2015);

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).

Response to Proposed Conclusion No. 103

The Proposed Conclusion is incorrect and shoul

has often been thought to be a hallmark of a so-called "full" rule-of-reason analysis. *See* CC Reply Br. at Argument, I.E. Courts applying the framework outlined by Complaint Counsel and Professor Noll have held that it is consistent with a full rule-of-reason analysis, not a quick look or *per se* analysis. *See* CC Br. at 27.

Indeed, Professor Noll's analysis is precisely the approach underpinning the Supreme Court's decision in *Actavis*. Just as cases following *Actavis* have found, Professor Noll finds, as an economic matter, that a reverse payment agreement creates an anticompetitive effect by preventing the risk of competition if: (1) the brand had market power; and (2) the brand made a large reverse payment to the generic as part of an agreement for the generic not to enter. (CCF ¶¶ 498-501, 828-42, 966-87); *see also Cephalon*, 88 F. Supp. 3d 402 (E.D. Pa. 2015), *Lamictal*, 791 F.3d 388 (E.D. Pa. 2015); *In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015); CC Reply Br. at Argument, I.E. Further, *Actavis* explains that "the very anticompetitive consequence that underlies the claim of antitrust unlawfulness" in a reverse payment case arises from the sharing

reason analysis. *See* CC Reply Br. at Argument, I.E. Courts applying the framework outlined by Complaint Counsel have held that it is consistent with a full rule of reason analysis, not a quick look or *per se* analysis. *See* CC Br. at 27; CC Reply Br. at Argument, I.E.

106. Complaint Counsel's proposed per se framework conflicts with the Supreme Court's guidance in *Actavis*.

Response to Proposed Conclusion No. 106

The Proposed Conclusion is incorrect and should be rejected. Complaint Counsel's proposed framework is not a *per se* analysis. *See* CC Br. at 27; CC Reply Br. at Argument, I.E. Complaint Counsel's proposed framework is consistent not only with *Actavis*, but also with courts interpreting *Actavis* and applying the rule of reason. *See* CC Br. at 23-34; CC Reply Br. at Argument, I.E. To Complaint Counsel's knowledge, no court has ever adopted Impax's proposed rule-of-reason framework.

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.").

Response to Proposed Conclusion No. 107

Complaint Counsel has no specific response, but notes that "the relevant anticompetitive harm" in a reverse-payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s] and [] share[s] patent-generated monopoly profits." *Actavis*, 133 S. Ct. at 2236-37. As *Actavis* recognizes, a large payment to induce the generic to agree to forestall entry harms the competitive process, because it distorts the bargaining process that ordinarily would be expected to protect consumer interests. 133 S. Ct. at 2236-37.

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.

Response to Proposed Conclusion No. 108

The Proposed Conclusion is inaccurate and should be rejected because it misstates the rule-of-reason burden-shifting framework. Once Complaint Counsel satisfies its *prima facie* showing of harm to competition, the burden falls on the defendant to justify the large payment. *Actavis*, 133 S. Ct. at 2236 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."). If Respondent were to justify the large payment, then the burden would shift back to Complaint Counsel to offer a less-restrictive alternative to achieve the asserted procompetitive objective. *See* CC Br. At 21. Thus, Impax's purported justifications would only be balanced against anticompetitive harms if Impax meets its burden of showing that the challenged term—the payment—actually served those justifications and no less-restrictive alternative was available.

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.").

Response to Proposed Conclusion No. 109

The Proposed Conclusion is incorrect and should be rejected. Under *Actavis*, "the relevant anticompetitive harm" in a reverse-payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s]" and "share[s] patent-generated monopoly profits." 133 S. Ct. at 2236-37. Complaint Counsel "prove[d] anticompetitive effects" by proving a large "payment to prevent the risk of

competition” and market power.

for world as opposed to an anticompetitive effect

635 F.3d 815, 834-35 (6th Cir. 2011) (rejecting free rider justification because Realcomp had not demonstrated the necessary connection between the challenged restraint—a rule barring certain discount, limited-service agency listings from the Realcomp's website—and the prevention of free-riding); *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 368-70 (5th Cir. 2008) (rejecting an organization's asserted justification that its business model fostered higher quality care because there was "no logical nexus between better performance by NTSP physicians and NTSP's dissemination of polling results or its other challenged practices"); 7 Areeda, ¶ 1505a ("An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint.").

115. In other words, "an antitrust defendant may show in the antitrust proceeding that legitimate justifications are present." *Actavis*, 133 S. Ct. at 2236.

Response to Proposed Conclusion No. 115

Complaint Counsel has no specific response.

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.

Response to Proposed Conclusion No. 116

Complaint Counsel has no specific response, but notes that the Commission expressly stated it was not deciding whether the additional patents were relevant to the rule of reason analysis. *See* Comm'n Decision at 11-12 ("We are not willing to shut off all such argument *at this time*.") (emphasis added)).

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).

Response to Proposed Conclusion No. 117

The Proposed Conclusion is incorrect and should be rejected. First, the Commission's decision made clear that it was not deciding whether entry prior to patent expiration was relevant under the *Actavis* rule-of-reason inquiry and that its decision was not establishing any law of the case. As the Commission stated, "[w]ithout the facts before us, and an understanding of how the

Argument, IV.C. Second, comparing the entry date to patent expiration improperly assumes the patents are valid and infringed. *See Actavis*, 133 S. Ct. at 2231 ("The patent here may or may not be valid, and may or may not be infringed."). Even when a license entry date is earlier than patent expiration, "the antitrust problem [is] that . . . entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered." *Lamictal*, 791 F.3d at 408; *see also* CC Br. at 25; CC Reply Br. at Argument, I.C.1.

119. The SLA was procompetitive because it allowed generic entry over ten years before the expiration of the '122 and '216 patents.

Response to Proposed Conclusion No. 119

The Proposed Conclusion is incorrect and should be rejected. "An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint." 7 Areeda, ¶ 1505a; *see also 1-800 Contacts*, Initial Decision at 166 ("Cognizable justifications ordinarily explain how specific restrictions enable the defendants to increase output or improve product quality, service, or innovation.") (internal quotations omitted). Impax eventually obtained a license to the '122 and '216 patents through the patent license provisions of the SLA, but Impax has not provided any logical explanation, let alone any evidence, to explain why it would need to be paid to accept a broader license than Endo had originally proposed. To the contrary, the factual record shows that the payment terms were already fully negotiated before Impax raised the scope of the license. (CCF ¶ 1458). Impax thus cannot establish that the payments it received from Endo served to achieve consumer benefits arising from the license to future Endo patents provided in the settlement. *See* CC Br. at 67-71; CC Reply Br. at Argument, IV.C. In addition, comparing the entry date to patent expiration improperly assumes the patents are valid and infringed. *See Actavis*, 133 S. Ct. at 2231 ("The patent here may or may not be valid, and may or may not be infringed."). Even when a license entry date is earlier than patent

expiration, “the antitrust problem [is] that . . . entry might have been earlier, and/or the risk of

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").

Response to Proposed Conclusion No. 121

The Proposed Conclusion is incorrect and should be rejected. "An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint." 7

Response to Proposed Conclusion No. 123

The Proposed Conclusion is incorrect and should be rejected. Impax's purported justifications would only be balanced against anticompetitive harms if Impax meets its burden of showing that the challenged term—the payment—

objective is, of course, entirely immaterial unless it is served by the challenged restraint." 7 Areeda, ¶ 1505a; *see also 1-800 Contacts*, Initial Decision at 166 ("Cognizable justifications ordinarily explain how specific restrictions enable the defendants to increase output or improve product quality, service, or innovation.") (internal quotations omitted). Impax cannot establish that the payments it received from Endo served to achieve consumer benefits arising from the license to future Endo patents provided in the settlement. *See* CC Br. at 68-71; CC Reply Br. at Argument, IV.C. Indeed, Impax has not provided any logical explanation, let alone any evidence, to explain why it would need to be paid to accept a broader license than Endo had originally proposed. To the contrary, the factual record shows that the payment terms were already fully negotiated before Impax raised the scope of the license. (CCF ¶ 1458). Moreover, the competitive effect of a challenged agreement must be evaluated as of the time it entered. Whether Impax's "five years of sustained sales" would have occurred without the payment depends entirely on a series of unpredictable events occurring after the settlement. *See*counpredictabll 15.77 0 Cl

ordinarily explain how specific restrictions enable the defendants to increase output or improve product quality, service, or innovation.") (internal quotations omitted). Impax thus cannot

that the payments it received from Endo served to achieve consumer benefits arising from the license to future Endo patents provided in the settlement. *See* CC Br. at 68-71; CC Reply Br. at Argument, IV.C. Indeed, Impax has not provided any logical explanation, let alone any evidence, to explain why it would need to be paid to a

the challenged restraint."). As the Supreme Court noted in *Actavis*, companies may "settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, *without* the patentee paying the challenger to stay out prior to that point." 133 S. Ct. at 2237 (emphasis added); *see also id.* at 2234 ("We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition . . . . But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels . . . while dividing [the] return between the challenged patentee and the patent challenger.").

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)).

Response to Proposed Conclusion No. 128

The Proposed Conclusion is incorrect and should be rejected. The "specific restraint at issue" in a reverse-payment case is "payment in return for staying out of the market." *Actavis*, 133 S. Ct. at 2234. And *Actavis* requires a defendant to justify "the challenged term"—i.e., the payment. 133 S. Ct. at 2236; *see also 1-800 Contacts*, Initial Decision at 166 ("Cognizable justifications ordinarily explain how specific restrictions enable the defendants to increase output or improve product quality, service, or innovation.") (internal quotations omitted); 7 Areeda, ¶ 1505a ("An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint."). Nothing in any of the cases Impax cites suggests that defendants are relieved of their burden to justify the challenged restraint by showing that the restraint itself furthers some procompetitive objective. As the Supreme Court noted in *Actavis*, companies may "settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's

market prior to the patent's expiration, *without* the patentee paying the challenger to stay out prior to that point." 133 S. Ct. at 2237 (emphasis added); *see also id.* at 2234 ("We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition . . . . But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels . . . while dividing [the] return between the challenged patentee and the patent challenger.").

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").

Response to Proposed Conclusion No. 129

The Proposed Conclusion is incorrect and should be rejected. The "specific restraint at issue" in a reverse-payment case is not the payment on its own but "payment in return for staying out of the market." *Actavis,* 133 S. Ct. at 2234; *see also id.* at 2235 (reverse payment provides strong evidence that "the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market"). And *Actavis* requires a defendant to justify "the challenged term"—i.e., the payment—and show "the lawfulness of *that term* under the rule of reason." 133 S. Ct. at 2236 (emphasis added); *see also 1-800 Contacts,* Initial Decision at 166 ("Cognizable justifications ordinarily explain how specific restrictions enable the defendants to increase output or improve product quality, service, or innovation.") (internal quotations omitted); 7 Areeda, ¶ 1505a ("An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint."). As the Supreme Court noted in *Actavis*, companies may "settle in other ways, for example, by

allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, *without* the patentee paying the challenger to stay out prior to that point." 133 S. Ct. at 2237 (emphasis added); *see also id.* at 2234 ("We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition . . . . But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels . . . while dividing [the] return between the challenged patentee and the patent challenger.").

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.

Response to Proposed Conclusion No. 130

The Proposed Conclusion is incorrect and should be rejected. The "specific restraint at issue" in a reverse-payment case is not the payment on its own but "payment in return for staying out of the market." *Actavis*, 133 S. Ct. at 2234; *see also id.* at 2235 (reverse payment provides strong evidence that "the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market"). And *Actavis* requires a defendant to justify "the challenged term"—i.e., the payment—and show "the lawfulness of *that term* under the rule of reason." 133 S. Ct. at 2236 (emphasis added); *see also 1-800 Contacts*, Initial Decision at 166 ("Cognizable justifications ordinarily explain how specific restrictions enable the defendants to increase output or improve product quality, service, or innovation.") (internal quotations omitted); 7 Areeda, ¶ 1505a ("An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint."). As the Supreme Court noted in *Actavis*, companies may "settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, *without* the patentee paying the challenger to stay out prior to that point." 133 S. Ct. at 2237

(emphasis added); *see also id.* at 2234 ("We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition . . . . But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels . . . while dividing [the] return between the challenged patentee and the patent challenger.").

131. Complaint Counsel's approach would also permit it to cherry-pick value-conveying terms (alleged "payments") that it considers objectionable, while ignoring others.

Response to Proposed Conclusion No. 131

The Proposed Conclusion is incorrect and should be rejected. Complaint Counsel's approach is a direct application of *Actavis*, which teaches that the "specific restraint at issue" in a reverse-payment case is not the payment on its own but "payment in return for staying out of the market." *Actavis*, 133 S. Ct. at 2234; *see also id.* at 2235 (reverse payment provides strong evidence that "the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market"). And *Actavis* requires a defendant to justify "the challenged term"—i.e., the payment—and show "the lawfulness of *that term* under the rule of reason." 133 S. Ct. at 2236 (emphasis added); *see also 1-800 Contacts*, Initial Decision at 166 ("Cognizable justifications ordinarily explain how specific restrictions enable the defendants to increase output or improve product quality, service, or innovation.") (internal quotations omitted); 7 Areeda, ¶ 1505a ("An allegedly legitimate

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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).

Response to Proposed Conclusion No. 134

Complaint Counsel has no specific response, but notes that the *Actavis* Court held that "[t]here is always something of a sliding scale in appraising reasonableness" and that "the quality of proof required should vary with the circumstances." *Actavis*, 133 S. Ct. at 2237-38.

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).

Response to Proposed Conclusion No. 135

Complaint Counsel has no specific response, but notes that the *Actavis* Court held that "[t]here is always something of a sliding scale in appraising reasonableness" and that "the quality of proof required should vary with the circumstances." *Actavis*, 133 S. Ct. at 2237-38.

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)).

Response to Proposed Conclusion No. 136

Complaint Counsel has no specific response, but notes that the *Actavis* Court held that "[t]here is always something of a sliding scale in appraising reasonableness" and that "the quality of proof required should vary with the circumstances." *Actavis*, 133 S. Ct. at 2237-38.

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

paying the challenger to stay out prior to that point." 133 S. Ct. at 2237 (emphasis added); *see also id.* at 2234 ("We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition . . . . But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels . . . while dividing [the] return between the challenged patentee and the patent challenger."). A settlement with an entry date and broad license but not including the No-AG provision, Endo Credit, or DCA was indisputably an available option. *See* CC Reply Br. at Argument, IV.E.

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).

Response to Proposed Conclusion No. 139

The Proposed Conclusion is inaccurate and should be rejected. A less-restrictive alternative is one that eliminates the restraint and still provides the asserted procompetitive benefits, such as an NCAA television plan without the provisions the Supreme Court held were the tepeti5(ly ke

the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels . . . while dividing [the] return between the challenged patentee and the patent challenger."). A settlement with an entry date and broad license but not including the No-AG provision, Endo Credit, or DCA was indisputably an available option. *See* CC Reply Br. at Argument, IV.E.

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)).

Response to Proposed Conclusion No. 140

Complaint Counsel has no specific response, but notes that Section 5 of the FTC Act mandates that, upon determination that a challenged practice is an unfair method of competition, the Commission "***shall*** issue . . . an order requiring such person . . . to cease and desist from using such method of competition or such act or practice." 15 U.S.C. § 45(b) (emphasis added); *see also FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957) (confirming the Commission's power to issue cease and desist order). Complaint Counsel further notes that "it is well settled that once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor." *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 170-71 (2004) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 334 (1960)).

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).

Response to Proposed Conclusion No. 141

Complaint Counsel has no specific response, but notes that it is entirely proper for a court to order "fencing in" relief that bars otherwise legal conduct when it is "necessary to preclude the revival of the illegal practices." *In re Toys "R" Us, Inc.*, 126 F.T.C. 695, 697 (1998) (internal quotations omitted); *see also FTC v Nat'l Lead Co.*, 352 U.S. at 431 ("[T]hose caught violating the Act must expect some fencing in.").

142. A remedy is impermissibly overbroad if it lacks limits reasonably related to violation. *See Fanning*, 821 F.3d at 177.

Response to Proposed Conclusion No. 142

Complaint Counsel has no specific response, but notes that it is entirely proper for a court to order "fencing in" relief that bars otherwise legal conduct when it is "necessary to preclude the revival of the illegal practices." *In re Toys "R" Us*, 126 F.T.C. at 697 ; *see also FTC v Nat'l Lead Co.*, 352 U.S. at 431 ("[T]hose caught violating the Act must expect some fencing in.").

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.

Response to Proposed Conclusion No. 143

The Proposed Conclusion is inaccurate and should be rejected. First, the 2003 decision in *Asahi Glass* is "not persuasive." *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1068 (N.D. Cal. 2014) ("*Lidoderm*"). "It was decided ten years before *Actavis* , and no longer applies current antitrust law." *Lidoderm*, 74 F. Supp. 3d at 1068. Second, *Actavis* recognizes that some provisions that provide "value"—an entry date before patent expiration, payment for avoided litigation costs, or payment for services—are not on their own cognizable as reverse payments. 133 S. Ct. at 2236-37; *see also Lamictal*, 791 F.3d at 407-08 (explaining

distinction between early entry date on its own and an entry date combined with a large payment). Complaint Counsel's proposed order e

some fencing in."). Third, Complaint Counsel's proposed order is not "expansive"; it is narrowly tailored to prevent Impax from engaging in future similar anticompetitive conduct. *See* CC Reply Br. at Argument, V.

145. Complaint Counsel's proposed remedies are inappropriate because there is no proof of

is no warrant for injunctive relief." *U.S. v. Uniroyal, Inc.*, 300 F. Supp. 84, 88 (S.D.N.Y. 1969).

Response to Proposed Conclusion No. 146

The Proposed Conclusion is inaccurate and should be rejected. The Proposed Conclusion conflates government enforcement actions with private parties' claims for injunctive relief. A private plaintiff must show a "real or immediate threat that the plaintiff will be wronged again" to obtain an injunction. *City of Los Angeles v. Lyons*, 461 U.S. 95, 103, 111 (1983). But "[a] Government plaintiff, unlike a private plaintiff, must seek to obtain the relief necessary to protect the public from further anticompetitive conduct and to redress anticompetitive harm." *Hoffmann-La Roche*, 542 U.S. at 170. Thus, "it is well settled that once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor." *Hoffmann-La Roche*, 542 U.S. at 170-71 (internal quotations omitted). An injunction is necessary and appropriate unless there is no "cognizable danger" that Respondent will engage in future violations of the same type. *W.T. Grant Co.*, 345 U.S. at 633.

The proposed order's provisions are reasonably tailored to the violation that occurred and appropriate to prevent a recurrent violation. Indeed, Impax offers nothing to undermine the conclusion that, absent the proposed relief, it has the incentive, desire, and opportunity to enter similar agreements in the future. (CCF ¶¶ 1460-84). Impax's current CEO has made clear his intention to "always" seek a No-AG provision in any patent litigation settlement. (CCF ¶¶ 1481-84). The proposed relief is necessary to prevent such anticompetitive behavior in the future.

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.

Response to Proposed Conclusion No. 147

The Proposed Conclusion is inaccurate and should be rejected. First, Impax's math is verifiably wrong. There are 13 federal Courts of Appeals, and only three even arguably had adopted the standard Impax describes. Two other circuits had indicated they would reach a different result. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001). Prior to *Actavis*, the Third Circuit held that reverse payments were not only actionable but presumptively unlawful. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 216 (3d Cir. 2012). And the FTC was vigorously challenging reverse-payment agreements throughout this time period. Thus, the state of the law in 2010 was unsettled.

Second, as Impax concedes, *Actavis* applies to agreements entered before the Supreme Court's June 2013 decision. Impax Br. at 30 n.10. To suggest that a court must apply *Actavis* to pre-2013 agreements but cannot order any remedy in such cases makes no sense. And it would render the general principle of retroactivity of Supreme Court decisions, and the remand in *Actavis* itself, meaningless.

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 .6(lieis22BmTw edie1 Tc -0.01g CoTJ0 Tc 0 Tw 12 0 0 12 72 243.42 Tm(148.)ird Circ 6l7 Bio to Propo

of the proposed order, which prohibits Impax from enforcing certain provisions in its 2017 oxymorphone ER settlement agreement with Endo. *See* Impax Br. at 135-36. But this order is appropriate fencing-in relief. The violation in this case is Impax's agreement to preserve Endo's oxymorphone ER monopoly in exchange for a share of Endo's monopoly profits. The 2017 Agreement is the mirror image: the parties agreed to preserve Impax's current oxymorphone ER monopoly and share the resulting profits. It is well-settled that "those caught violating the Act must expect some fencing in." *FTC v Nat'l Lead Co.*, 352 U.S. at 431; *In re Toys "R" Us*, 126 F.T.C. at 697 (quoting same). Indeed, the order in *Toys "R" Us*, barred the company from certain refusals to deal that would ordinarily be permissible unilateral conduct. *Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 940 (7th Cir. 2000). Impax's 2017 Agreement with Endo is likewise a revival of the same means the parties used in 2010 to accomplish the violation here: the sharing of monopoly profits to prevent the risk of competition. Thus, the prohibition in Paragraph II.C is appropriate fencing-in relief based on the underlying violation established in this case.

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"

the remedy are to be resolved in its favor." *Hoffmann-La Roche Ltd.*, 542 U.S. at 170 (quoting *E.I. du Pont de Nemours,* 366 U.S. at 334). Second, it is entirely proper for a court to order "fencing in" relief that bars otherwise legal conduct when it is "necessary to preclude the revival of the illegal practices." *In re Toys "R" Us*, 126 F.T.C. at 697 (internal quotations omitted); *see also FTC v National Lead Co.*, 352 U.S. at 431 ("[T]hose caught violating the Act must expect some fencing in.").

Actavis recognizes that some provisions that provide "value"—an entry date before patent expiration, payment for avoided litigation costs, or payment for services—are not on their own cognizable as reverse payments. 133 S. Ct. at 2236-37; *see also Lamictal*, 791 F.3d at 407-08 (explaining distinction between early entry date on its own and an entry date combined with value from a large payment). Complaint Counsel's proposed order expressly carves out these types of "explained" payments. It excludes entry-date only settlements, as well as payments representing avoided litigation costs up to $7 million and independent business transaction entered outside of a 45-day window before and after settlement. Revised Proposed Order, I.W. To the extent that these narrowly-tailored exclusions would still bar some conduct that might otherwise be lawful, it is well-established that the Commission may bar certain conduct that would be permitted if engaged in by someone not found to have violated the law. CC Br. at 71-72. The fencing-in relief here is reasonably related to the violation found, and thus entirely proper.

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.

Response to Proposed Conclusion No. 150

The Proposed Conclusion is inaccurate and should be rejected. Section 5 of the FTC Act mandates that, upon determination that a challenged practice is an unfair method of competition, the Commission "***shall*** issue . . . an order requiring such person . . . to cease and desist from using such method of competition or such act or practice." 15 U.S.C. § 45(b) (emphasis added); *see also FTC v. Nat'l Lead Co.*, 352 U.S. at 428. "[I]t is well settled that once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor." *Hoffmann-La Roche Ltd.*, 542 U.S. at 170 (quoting *E.I. du Pont de Nemours*, 366 U.S. at 334). Second, it is entirely proper for a court to order "fencing in" relief that bars otherwise legal conduct when it is "necessary to preclude the revival of the illegal practices." *In re Toys "R" Us*, 126 F.T.C. at 697 (internal quotations omitted); *see also FTC v Nat'l Lead Co.*, 352 U.S. at 431 ("[T]hose caught violating the Act must expect some fencing in."). The fencing-in relief here is reasonably related to the violation found, and thus entirely proper.

Moreover, the challenged provision restricts Impax's ability to enter into *future* agreements involving extended-release oxymorphone that threaten competition in that market. This limited, narrowly-tailored restriction is neither unreasonably ambiguous nor overbroad. *See* CC Reply Br. at Argument, V.

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.

Response to Proposed Conclusion No. 151

The Proposed Conclusion is inaccurate and should be rejected. These provisions are standard in Commission orders. *See* CC Br. at 77.

Dated: February 14, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

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CERTIFICATE FOR ELECTRONIC FILING

I 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.

February 14, 2018

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