PUBLIC

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

02 13 2018
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In the Matter of:

IMPAX LABORATORIES, INC.,

a corporation.

Docket No. 9373

RESPONDENT IMPAX LABORATORIES, INC.'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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IMPAX'S GENERAL RESPONSES TO ALL PROPOSED FINDINGS OF FACT

1. Many of Complaint Counselôs proposed findings of fact are not facts but are instead a mixture of argument, legal conclusions, unsupported assertions, and mischaracterizations of the evidence. Respondent Impax Laboratories, Inc. objects to all such findings.

2. Very few of Complaint Counselôs proposed findings of fact reference the testimony elicited at trial. Of 1,492 proposed findings, 891 (or 60 percent) do not cite trial testimony in any way. Such findings should be accorded little or no weight.

3. Many of Complaint Counselôs proposed findings of fact rely solely on testimony from Investigational Hearings, a proceeding at which Respondent had no opportunity to cross-examine any of the witnesses. All such testimony should be accorded little or no weight, particularly in instances where the witness appeared at trial and testified differently or where Complaint Counsel chose not to elicit the same testimony from the witness at trial.

4. Many of Complaint Counselôs proposed findings of fact are basely solely on hearsay or on exhibits with no sponsoring witness. Other proposed findings are general in nature and refer only to groups of findings that are much narrower than the broad proposition which they supposedly support. These proposed findings should be disregarded.

5. Complaint Counselôs proposed findings based solely on the testimony or the report of an expert violate this Courtôs Order on Post-Trial Briefs, dated November 17, 2017, (ñOrder on Post-Trial Briefsò) to the extent that the findings address factual propositions that should be proven by fact witnesses or reliable exhibits. Respondent reserves the right to file a motion to strike.

6. Pursuant to the Courtôs Order on Post-Trial Briefs, Respondentôs replies ñuse the same outline headings as used by [Complaint Counsel] in its opening proposed findings of fact.ò

Order on Post-Trial Briefs at 4. Respondent does not endorse or adopt the positions taken by Complaint Counsel in those headings.

IMPAX'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT

I. Jurisdictional facts

1. Impax Laboratories, Inc. (ñImpaxò) is a for-profit corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California. (JX-001 at 001 (¶ 1); Koch, Tr. 251). Along with its Hayward headquarters, Impax operates out of its facilities in Middlesex, New Jersey, among other locations. (JX-001 at 001 (¶ 2)).

RESPONSE TO FINDING NO. 1:

Respondent has no specific response.

2. Impax engages in the business of, among other things, developing, manufacturing, and marketing pharmaceutical drugs. (JX-001 at 001, 02 (¶¶ 3, 6); Koch, Tr. 219-20).

RESPONSE TO FINDING NO. 2:

Respondent has no specific response.

3. Impax is a corporation as ñcorporationò is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44. (JX-001 at 001 (¶ 4)).

RESPONSE TO FINDING NO. 3:

Respondent has no specific response.

4. Impax has engaged, and continues to engage, in commerce and activities affecting commerce in each of the fifty states in the United States and the District of Columbia, as the term ñcommerceò is defined by Section 1 of the Federal Trade Commission Act, 15 U.S.C. § 44. (JX-001 at 001 (¶ 5)).

RESPONSE TO FINDING NO. 4:

Respondent has no specific response.

5. The Federal Trade Commission (ñFTCò) has jurisdiction over the subject matter of this proceeding and over Impax. (JX-001 at 002 (¶ 7)).

RESPONSE TO FINDING NO. 5:

Respondent has no specific response.

II. Competition between brand and generic drugs

A

9. The FDA assigns a generic drug a

the exclusivity period, the generic firm must enter the market at least six months before the challenged patents on the brand-name drug expireò)).

15. The 180-day exclusivity period can be ñvery valuableò to a generic company. (Koch, Tr. 232-33; *see also* Snowden, Tr. 414 (describing exclusivity period as a ñbenefitò)). First-filer exclusivity provides the generic company with ñsix months of runway before another entrant will be reviewed or approved.ò (Koch, Tr. 232). Generic companies, like Impax, ñcan make a substantial portion of their profitsò during that ñsix-month runway.ò (Koch, Tr. 232).

RESPONSE TO FINDING NO. 15:

Respondent has no specific response.

B. State law encourages substitution of AB-rated generic drugs for brand drugs

16. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate substitution of lower-cost AB-rated generic drugs for branded drugs. (CX5000 at 030 (¶ 66) (Noll Report) (citing summary from State Regulation of Generic Substitution); CX3162 at 018 n.83 (Impax White Paper) (quoting amicus brief in *Mylan Pharm. Inc. v. Warner Chilcott Public Ltd.*) (ñall states facilitate competition through laws that allow a pharmacist to substitute an AB-rated generic drug when presented with a prescription for its brand equivalentò); JX-003 at 011 (¶ 72)).

RESPONSE TO FINDING NO. 16:

Respondent has no specific response.

17. State substitution laws were enacted in part because the pharmaceutical market does not function well. (*See* RX-547 at 027 (¶ 50 n.64) (Addanki Report) (citing FDA Orange Book)). In a well-functioning market, a consumer selects and pays for a product after evaluating the productôs price and quality. In the prescription drug market, however, a patient can obtain a prescription drug only if the doctor writes a prescription for that particular drug. (JX-001 þ ÷ ę a l !

well. The cited footnote from Dr. Addankiôs report is a quotation from the FDAôs Orange Book describing the creation of the O

2140-42; Addanki, Tr. 2218). Accordingly, formulary placement can play a key role in doctorsô prescribing decisions when choosing between equally-safe and effective long-acting opioids. (Michna, Tr. 2148; CX4046 (Michna, Dep. at 115-16); CX4044 (Addanki, Dep. at 148); RX-549.0006-07, 21 (Michna Rep. ¶¶ 21, 51)).

In fact, Complaint Counselôs economic expert, Professor Noll, admitted that doctors make prescribing decisions based on price and formulary tiering, among other issues. (Noll, Tr. 1505-06). Dr. Savage, Complaint Counselôs medical expert, similarly admitted that ñthe copay is one variable that may be consideredò when making prescription choices ð ñclinical determinations are usually the first consideration and then copays.ò (CX4041 (Savage, Dep. at 138); *see* Savage, Tr. 772 (availability of insurance coverage for a medication would affect Dr. Savageôs clinical decision-making)).

Doctors are aware of drug prices when prescribing medications based on numerous sources of information. (Michna, Tr. 2122-23). For example, when they enter a ñdrug order in the system, as [they are] ready to print it or electronically send the prescription to the pharmacy, [they] will get an immediate feedback as to whether thatôs a covered medication for that insurance company, also what level of additional pay that the patient has to pay at the pharmacy.ò (Michna, Tr. 2122-23). Doctors also receive feedback directly from patients, pharmacists, and drug manufacturers regarding drug costs and formulary tiering. (Michna, Tr. 2123; CX4046 (Michna, Dep. at 115-16)). Dr. Savage personally is not aware of drug prices because formulary tiering and what patients pay in copays ñtruly is outside [her] experienceò since she is ña consultant in [her] practice areaò and does not ñdo the direct management of the patients [or] deal with insurance companies,ò which she leaves to ñthe staff physicians.ò (CX4041 (Savage, Dep. at 117-18)).

Finally, the citations to Dr. Michnaôs testimony are inaccurate and misleading. Dr. Michna did not testify that he is unaware of prices when prescribing medications; just the opposite. (Michna, Tr. 2122-23, 2148; CX4046 (Michna, Dep. at 115-16)). Dr. Michna made the same point in the cited portions of his testimony. (Michna, Tr. 2187-88 (discussing fluctuations in price and explaining ñIôd be aware of it if thereôs dramatic changesò); CX4046 (Michna, Dep. at 148-49) (ñI donôt trawl the daily cost of all the pharmaceutical products, but I have a general idea.ò)).

> 19. Instead, the patient, or in most cases a third-party payer such as a public or private health insurer, pays for the drug. (CX5000 at 031 (¶ 67) (Noll Report)). But these purchasers have little input over what drug is actually prescribed, because physicians ultimately select and prescribe appropriate drug therapies. (CX5002 at 063 (¶ 177) (Savage Report)).

RESPONSE TO FINDING NO. 19:

Respondent does not dispute that third-party payors often pay for drugs, but the first sentence of Complaint Counselôs Proposed Finding No. 19 is not supported by the cited evidence. The cited portion of Professor Nollôs report discusses policies to control drug costs, including ñrules about physician prescribing behavior and patient cost reimbursement by entities that pay for prescription drugs.ò (CX5000-031 (Noll Rep. ¶ 67)). The cited portion of the report does not discuss who pays for drugs in most instances.

The second sentence of Proposed Finding No. 19 is inaccurate, misleading, and not supported by the cited evidence. The exhibit cited, a paragraph from Dr. Savageôs report, does not discuss third-party payors or their input. (CX5002-063 (Savage Rep. ¶ 177)). The exhibit, moreover, actually notes that clinicians will ñconsciously consider costsò when they are ñaware that the patient will need to pay out of pocket.ò (CX5002-063 (Savage Rep. ¶ 177)). The second sentence is also inconsistent with the record. Dr. Michna ð who, unlike Dr. Savage, directly

manages patients, (CX4041 (Savage, Dep. at 117)) ð takes the costs of medications, including formulary placement, into account when choosing among equally safe and effective medication options. (*See* Michna, Tr. 2121-22, 2148; CX4046 (Michna, Dep. at 115-16); RX-549.0006-07, 21 (Michna Rep. ¶¶ 21, 51)). Other doctors do the same. (CX4046 (Michna, Dep. at 115-16); RX-549.0006-07, 021 (Michna Rep. ¶¶ 21, 51)).

> 20. State substitution laws are designed to correct this market imperfection by shifting the drug selection choice from physicians to pharmacists and patients who have greater financial incentives to make price comparisons. (CX5000 at 030 (¶¶ 65-66) (Noll Report); RX-547 at 027 (¶ 50 n.64) (Addanki Report) (quoting FDA Orange Book) (ñTo contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of products.ò)).

RESPONSE TO FINDING NO. 20:

Complaint Counselôs Proposed Finding No. 20 is inaccurate and mischaracterizes the cited exhibits. None of the cited exhibits provide that state substitution laws were designed to correct a market imperfection or to shift drug selection choices from one entity to another. Professor Nollôs report states that insurance companies and the government ñhave put in place three policies that increase the influence of price on drug choice and encourage use of generics,ò including generic substitution laws. (CX5000-030 (Noll Rep. ¶ 65)). Dr. Addankiôs report quotes the FDA Orange Book, which states only, ñTo contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of products.ò (RX-547.0027 (Addanki Rep. ¶ 50 n.64)).

> 21. Under these laws, if a prescription is written for the branded product, a pharmacist could substitute the AB-rated generic for the brand. (CX5000 at 030 (¶ 66) (Noll Report); RX-547 at 026-27 (¶ 50) (Addanki Report); Reasons, Tr. 1219; JX-003 at 011 (¶ 72)).

RESPONSE TO FINDING NO. 21:

Respondent has no specific response.

22. An AB rating is fundamental to automatic substitution. If the generic drug is not AB-rated to the brand drug, a pharmacist cannot substitute the generic drug. (CX5000 at 030 (¶ 66) (Noll Report); JX-003 at 011 (¶ 72)).

RESPONSE TO FINDING NO. 22:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 22. The second sentence of Proposed Finding No. 22 is inaccurate and misleading. A pharmacist may substitute a non-AB-rated generic for a branded drug if the physician writes the chemical name of the drug, rather than the brand name, on the prescription. (JX-003-011 (¶ 72) (Second Set of Joint Stipulations)).

C. Competition from lower-priced generic drugs saves American consumers billions of dollars a year

23.

RESPONSE TO FINDING NO. 24:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 24 other than to note that while generic drugs generally are priced lower than branded drugs, that is not always the case. (Hoxie, Tr. 2795 (claiming generics do not always sell at a discount to the brand)).

The second sentence of Proposed Finding No. 24 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò

The third sentence of Proposed Finding No. 24 is incomplete and misleading. The first cited document (CX5000-048) is expert testimony inappropriately cited for a factual proposition. The second cited document (CX6055-010) is an FTC document advocating for Congressional legislation prohibiting all so-called ñpay-for-delayò agreements. The document cites no data or statistics in support of the proposition advanced by Complaint Counsel. (CX6055-010). Finally, the cited document acknowledges that the proposition advanced by Complaint Counsel is based on assumptions about demand and pricing meant to ñsimplif[y] the analysis,ò even though prices actually vary. (CX6055-014).

25. Generic drug entry before patent expiration can save consumers billions of dollars. (CX6055 at 005 (FTC study of reverse payments)).

RESPONSE TO FINDING NO. 25:

Complaint Counselôs Proposed Finding No. 25 is incomplete and misleading. The cited

ñpay-for-delayò agreements collectively. (CX6055-005). The document, moreover, cites no data, statistics, or other analysis in support of the proposition advanced by Complaint Counsel. (CX6055-005).

The Proposed Finding also ignores the uncertainty of the purported savings, as courts can enjoin generic companies from competing if they enter before patent expiration. (Snowden, Tr. 503-04; Figg, Tr. 1871, 1904-05). And the Proposed Finding ignores the risks to generic drug companies of entry before patent expiration, including billions of dollars in patent-infringement damages, (Hoxie, Tr. 2782), and bankruptcy (Koch, Tr. 287 (generic entry before patent expiration can be a ñbet-the-companyò undertaking and can ñtake the solvency of the company entirelyò); CX4030 (Hsu, Dep. at 43) (ñthe risk can be huge depending on the size of the product and depending on whether weôre first to fileò)).

26. Because of these price advantages and cost savings, many third-party payers of prescription drugs (e.g., health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. (CX5000 at 030-32 (¶¶ 65, 67-69) (Noll Report); CX6052 at 084-85 (FTC Authorized Generics Report)).

RESPONSE TO FINDING NO. 26:

Respondent has no specific response.

D. Competition from an authorized generic typically has a significant financial impact on the generic first filer

27. To offset some of the lost profits resulting from declining branded product sales after generic entry, brand companies frequently launch authorized generics. An authorized generic, or AG, is chemically identical to the brand drug, but is sold as a generic product, typically through either the brand companyôs subsidiary or through a third party. (JX-001 at 005 (¶ 31)). A brand company can market a generic version of its own brand product at any time, including during the first filerôs exclusivity period. (JX-001 at 005 (¶ 28)). For a brand company to market a generic version of its own brand product, no ANDA is necessary because the brand company already has approval to sell the drug under its NDA. (JX-001 at 005 (¶ 29)).

RESPONSE TO FINDING NO.

118-19); *see also* Bingol, Tr. 1337 (ñI donôt recall specific forecasts about an authorized generic.ò); Bingol, Tr. 1338-39 (an authorized generic ñwas never, to my knowledge . . . fully realized as a plan or an ideaò); CX4031 (Bradley, Dep. at 198) (ñI donôt recall having any conversation with any colleagues regarding the launch of an authorized generic.ò)). In fact, Endo intended to replace its original Opana ER product with a reformulated product ñand that would be the only product that we had on the market.ò (CX4019 (Lortie, Dep. at 117-18); *see* Bingol, Tr. 1338).

Respondent has no specific response to the second and third sentences of Proposed Finding No. 28.

> 29. Competition from an authorized generic has a significant financial impact on the first filer. (CX6052 at 047 (FTC Authorized Generics Report) (first filerôs revenues fall 40-52% when facing an AG); CX6055 at 007 (FTC study on reverse payments) (ñAG competition can substantially reduce the revenues a first-filer generic earns during its 180 days of marketing exclusivity.ò); CX4020 (Reasons, Dep. at 53) (as an additional competitor to the generic, an AG can result in lost market share and/or a lower price)).

RESPONSE TO FINDING NO. 29:

Complaint Counselôs Proposed Finding No. 29 is misleading and not supported by the cited evidence. The first exhibit cited in Proposed Finding No. 29 discusses ñwholesale expenditures,ò not actual first-filer revenue. (CX6052-047). The second exhibited cited in Proposed Finding No. 29 (CX6055-005) is an FTC document advocating for Congressional legislation prohibiting all so-called ñpay-for-delayò agreements. The document simply references an interim version of CX6052 and offers no other data, statistics, or analysis in support of the quoted language. (CX6055-007, 014). Finally, the third exhibit cited in Proposed Finding No. 29 does not mention ñsignificant financial impacts.ò (CX4020 (Reasons, Dep. at 53)).

30. Moreover, a first filerôs first-mover advantage can be undercut if it faces an AG at

rated ñdoesnôt impact the ability to sell. We -- Impax was still able to sellò); CX4037 (Smolenski, Dep. at 155)). The second sentence of Proposed Finding No. 32 is not supported by the cited evidence. The cited document does not discuss whether any form of financial impact is well known in the pharmaceutical industry. (CX6052-159-60).

III. Opana ER was a successful and rapidly growing brand drug

33. In 2010, Endo was ñwas really a company based on two products . . . Lidoderm and Opana.ò (CX4011 (Holveck, IHT at 11-12, 16)). Together, Lidoderm and the Opana franchise accounted for 63% of Endoôs revenues. (CX3214 at 148 (Endo 2010 10-K)). Behind Lidoderm, Opana ER was Endoôs ñsecond biggest selling product.ò (Bingol, Tr. 1263).

RESPONSE TO FINDING NO. 33:

Respondent has no specific response.

34. Oxymorphone is in a class of drugs known as opioids, which have long been used to relieve pain. (JX-001 at 006 (¶ 2)). Oxymorphone is a semi-synthetic opioid, originally developed over 100 years ago and first approved by the FDA in 1960. (JX-001 at 006 (¶ 1); CX5002 at 037 (¶ 104) (Savage Report); CX3247 (NDA No. 011738 ñNumorphanò); CX6050 at 004 (FDA presentation: Regulatory History of Opana ER)).

RESPONSE TO FINDING NO. 34:

Respondent has no specific response.

35. Opana ER is an extended-release formulation of oxymorphone. (JX-001 at 006 (¶ 3)). Unlike immediate-release drugs, extended-release medications like Opana ER have special coatings or ingredients that control how fast the active ingredient is released from the pill into the patientôs body. (CX5002 at 034 (¶ 96) (Savage Report)). Compared to an immediate-release oxymorphone formulation, Opana ER provides longer-lasting, 12-hour pain relief that allows the patient to take fewer pills each day. (CX3163 at 008 (¶ 8) (Impax Answer); CX5002 at 038 (¶ 106) (Savage Report)).

RESPONSE TO FINDING NO. 35:

Respondent has no specific response.

36. The FDA approved Opana ER (NDA No. 021610) in June 2006 ñfor the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid

treatment for an extended period of time.ò (JX-001 at 006 (¶ 4)). It is used to treat pain for a wide variety of conditions, ranging from chronic back problems to cancer. (JX-001 at 006 (¶ 5)).

RESPONSE TO FINDING NO. 36:

Respondent has no specific response.

37. In July 2006, Endo launched Opana ER as the only extended-release version of oxymorphone on the market. (JX-001 at 006 (¶¶ 6, 8); CX6050 at 006, 08 (FDA Regulatory History of Opana ER)). Endo ultimately sold Opana ER in seven dosage strengths (5, 7.5, 10, 15, 20, 30, and 40 mg). (JX-001 at 006 (¶ 7)).

RESPONSE TO FINDING NO. 37:

Respondent has no specific response.

38. Opana ER was originally launched in four dosage strengths (5, 10, 20 and 40 mg). (CX3273 at 002 (¶ 4) (Bingol Decl.)). In April 2008, Opana ER was launched in three additional dosage strengths (7.5, 15, and 30 mg). (CX3273 at 002 (¶ 4) (Bingol Decl.)). The most commercially significant strengths for Opana ER were the 5 mg, 10 mg, 20mg, 30 mg, and 40 mg strengths, which in 2010 accounted for approximately 94% of the unit sales of Opana ER. (CX3273 at 002-03 (¶ 4) (Bingol Decl.)).

RESPONSE TO FINDING NO. 38:

Respondent has no specific response.

39. As Endoôs second best-selling drug, Opana ER was Endoôs ñflagship branded product.ò (CX2607 at 005 (¶ 16) (Lortie Decl.); Bingol, Tr. 1263). After a modest start of $5 million in sales in 2006, sales grew to $172 million in 2009. (CX2607 at 004 (¶ 13) (Lortie Decl.)). Endoôs 2009 sales of Opana ER amounted to 12% of its total annual revenue. (CX3160, Endo Pharmaceuticals Holdings Inc. SEC 2009 Form 10-K (Feb. 26, 2010), at 052).

RESPONSE TO FINDING NO. 39:

Respondent has no specific response other than to clarify that Mr. Lortieôs declaration

was written in = ª ŮMאg T l ή e! ɹ pM ’ ‘ M

40. Sales reached approximately $240 million in 2010 (CX2607 at 004 (¶ 13) (Lortie Decl.), the earliest year that generics could have entered and the year of the Endo-Impax settlement agreement. (RX-364 (SLA); RX-365 (DCA); JX-001 at 007 (¶ 16)).

RESPONSE TO FINDING NO. 40:

Respondent has no specific response.

41. In 2011, sales for Opana ER were approximately $384 million. (CX2607 at 004 (¶ 13) (Lortie Decl.)). Endo had expected that upward sales trend to continue into 2012. (CX2607 at 005 (¶¶ 15-16) (Lortie Decl.)).

RESPONSE TO FINDING NO. 41:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 41. The second sentence of Proposed Finding No. 41 is inaccurate and not supported by the cited evidence. The cited declaration actually states that ñ[n]et sales for Opana ER decreased in 2012 b¾ p c] t ts]

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RESPONSE TO FINDING NO. 47:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

> 48. The size of the branded product is ñobviouslyò an important factor in determining whether to develop a generic product. (CX4021 (Ben-Maimon, Dep. at 17-18)). Indeed, when Impax assesses the value of potential market opportunity for a new generic drug, the size of the corresponding branded productôs sales provides the ñbestò and ñmost accurateò estimate. (Reasons, Tr. 1219-20).

RESPONSE TO FINDING NO. 48:

The first sentence of Complaint Counselôs Proposed Finding No. 48 is not supported by the cited evidence. Dr. Ben-Maimon testified that ñ[o]bviously *market size*ò was one of many factors considered when selecting a generic to develop. (CX4021 (Ben-Maimon, Dep. at 17-18) (emphasis added)). She said nothing about the ñsize of the bra Ţ M
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a single patent, No. 5,128,143 (the ñô143 patentò), in the Orange Book covering Opana ER. (CX3242 at 003 (2007 Endo letter to the FDA)). The ô143 patent was not a

52. On October 2, 2007, Endo listed Patent No. 7,276,250 (the ñô250 patentò) relating to a mechanism for controlling the release of a drugôs active ingredient over an extended period of time. (JX-001 at 006 (¶ 9); CX3520 (U.S. Patent No. 7,276,250 Abstract)). That patent expires in 2023 (JX-001 at 006 (¶ 10); CX3208 at 006, 07 (Smolenski/Camargo email)).

RESPONSE TO FINDING NO. 52:

Respondent has no specific response.

53. On October 19, 2007, Endo listed in the Orange Book two additional patents pertaining to a controlled release mechanism ð No. 5,662,933 (the ñô933 patentò) and No. 5,958,456 (the ñô456 patentò). (JX-001 at 006 (¶ 9); CX3249 (U.S. Patent No. 5,662,933 Abstract); CX0303 at 35 (U.S. Patent No. 5,958,456 Abstract)). The ô933 and ô456 patents expired in September 2013. (JX-001 at 006 (¶ 10)).

RESPONSE TO FINDING NO. 53:

Respondent has no specific response.

54. Those patents had been issued by the U.S. Patent and Trademark Office up to a decade earlier ð in 1997 and 1999, respectively. (CX0303 at 006 (¶¶ 22, 23) (*Endo v. Impax* complaint)).

RESPONSE TO FINDING NO. 54:

Respondent has no specific response.

55. Endo failed to list the ô456 and ô933 patents in the Orange Book within 30 days of

RESPONSE TO FINDING NO. 56:

Respondent has no specific response.

57. Eventually, at least eight companies submitted ANDAs seeking approval to market a generic version of Opana ER, including Impax and Actavis. (CX2607 at 008-09 (Lortie Decl. ¶ 24)). Each compa

approval for Impaxôs ANDA would expire in June 2010. (JX-001 at 005, 07 (¶¶ 15-16, 26)); *see also* CCF ¶¶ 94-118, below).

RESPONSE TO FINDING NO. 59:

Respondent has no specific response.

60. Endo was aware of this key date and had long forecasted the possibility of generics launching in the middle of 2010. (CX4025 (Bingol, Dep. at 24-26) (as early as 2008, Endo had identified and was planning around the possibility that Impax could launch a generic at risk in mid-2010); CX2573 at 004 (Feb. 2010 EN3288 Commercial Update) (noting that Impax could launch at risk any time after June 2010); CX2564 at 094 (Mar. 2010 Endo 10-year outlook) (projecting July 2010 generic entry)).

RESPONSE TO FINDING NO. 60:

Respondent has no specific response.

61. By May 2010, Endo was repeatedly forecasting that a generic version of Opana ER would launch in July 2010. (CX3017 at 001-03, 05-06 (May 2010 Endo internal email thread and attached Opana ER P&L model scenarios); CX3009 at 003 (May 2010 Endo Opana ER P&L model scenarios)). The FDA tentatively approved Impaxôs ANDA on May 13, 2010, and Impax could launch as soon as it got final approval from the FDA, which was generally a formality after getting tentative approval (JX-001 at 007 (¶ 17); Snowden, Tr. 417-18 (ñImpax was almost certain to get final approval at the conclusion of the 30-month stayò); Koch, Tr. 340-41 (ñitôs pretty routine and rubber stamp from the time of tentative approval to final approvalò); CX5007 at 022 (¶ 42) (Hoxie Rebuttal Report)).

RESPONSE TO FINDING NO. 61:

The first sentence of Complaint Counselôs Proposed Finding No. 61 is inaccurate and misleading. None of the cited documents indicate that a generic version of Opana ER ñwould launch in July 2010.ò The forecasts were based on ñmanyò assumptions and Endo was looking at ñany possible scenario.ò (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 (ñWe have to consider all scenariosò)). They were ñbased on scenarios that we had created, I mean, the accuracy of which are always debatable.ò (Bingol, Tr. 1303). And many of the assumptions were actually total unknowns. (Bingol, Tr. 1307 (ñJUDGE CHAPPELL: Okay. Well, I donôt

want you to guess[], so according to this document, whatever those claims were you didnôt know. THE WITNESS: Well, we would be -- thatôs correct.ò); Cuca, Tr. 662-63).

In the case of Opana ER, Endoôs ñbase caseò and ñlatest best estimateò did not assume generic entry in 2010. (CX4035 (Cuca, Dep. at 62) (discussing CX3009)). Indeed, in the spring of 2010, Endo knew ñthere had been ANDAs filed for generic versions of Opana ER,ò but believed ñthere was not imminently at that point going to be a generic.ò (Cuca, Tr. 643; *see* RX-086 at 9-10 (Impax was ñnot likely to launch at riskò)). But Endo still forecast different scenarios regarding the future of its Opana ER product to ñanalyze the full range of potential outcomes.ò (Cuca, Tr. 663-64).

While respondent does not dispute that the FDA tentatively approved Impaxôs ANDA on May 13, 2010, or that final approval was likely after that point, the claim in the second sentence of Proposed Finding No. 61 that Impax could launch as soon as it got final approval is inaccurate and not supported by the cited evidence. While Impax would be permitted by the FDA to launch as soon as it received final approval, the FDAôs approval is only one of numerous factors affecting whether Impax ñcould launchò at any given time, including patent litigation, manufacturing readiness, and Impax internal approvals. (Koch, Tr. 276-77; Snowden, Tr. 426; CX4021 (Ben-Maimon, Dep. at 34); Engle, Tr. 1783-85).

62. Even if Impax did not launch as soon as it received final FDA approval in June 2010 following expiration of the 30-month stay, Endo identified other key dates for a potential generic launch ranging from later in 2010 to, at the

the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

> 63. For example, Endo expected that a decision in the patent litigation would probably occur in August/September 2010 and that Impax could launch at risk ahead of an appellate decision. (CX2576 at 001 (Bingol/Kelnhofer email) (district court decision would ñlikely be rendered in the August/September [2010] time frameò)).

RESPONSE TO FINDING NO. 63:

Complaint Counselôs Proposed Finding No. 63 is inaccurate and misleading. The estimate of an August/September 2010 decision was in response to a question asking about ñthe *earliest* dateò a competitor could ñstart shipping the generic.ò (CX2576 (emphasis added); CX4025 (Bingol, Dep. at 175-76) (discussing CX2576 and explaining there were ña lot of scenarios, and that one scenario is that it could be as earl[y] as June.ò ñSo we donôt know, but these are some potential stakes in the ground that we put to monitorò)).

> 64. The other date that Endo frequently forecasted for generic Opana ER entry was mid-2011. (CX1106 at 005 (July 2009 Endo presentation re 2010 Opana Brand Strategic Plan) (ñGeneric OPANA ER may not be available until early to mid-2011ò); CX1320 at 007 (Feb. 2010 Endo Three-Year Plan) (Opana ER ñKey Assumptionò of ñGeneric entrant July 2011ò)).

RESPONSE TO FINDING NO. 64:

Complaint Counselôs Proposed Finding No. 64 is incomplete and misleading in its suggestion that Endo ñfrequentlyò forecast a particular date. The Proposed Finding cites only two documents, one of which is marked ñDRAFT Not Approved by Management.ò (CX1106-003; *see* Bingol, Tr. 1298-99 (discussing identical ñdraftò language: ñJUDGE CHAPPELL: . . . it says itôs a draft. Why would he have presented a draft to a

65. Endo expected that an appellate decision on the infringement case would be issued by June 2011. (Feb. 2010 Bingol/Kelnhofer email) (ñIf [Impax] wait[s] for the appeal to play out, it will likely happen around June of next year.ò)).

RESPONSE TO FINDING NO. 65:

Complaint Counselôs Proposed Finding No. 65 is inaccurate and misleading to the extent it intended to cite CX2576. The estimate of a June 2011 Federal Circuit decision was in response to a question asking about ñthe *earliest* dateò a competitor could ñstart shipping the generic.ò (CX2576 (emphasis added); CX4025 (Bingol, Dep. at 175-76) (discussing CX2576 and explaining there were ña lot of scenariosò and that Mr. Bingol was ñsimply looking at numbers of scenarios that could play out and the influencing factors in those scenarios . . . But as I point out below, there are many scenarios to play out, and we really donôt knowò)).

66. The middle of 2011 was also when Endo had licensed another generic company, Actavis, which was the first-to-file generic on two dosage strengths of generic Opana ER, to begin selling generic Opana ER. (CX2607 at 009 (¶ 25) (Lortie Decl.); CX0309 at 002 (Analyst update discussing Actavis settlement)). Actavis was the first-to-file generic on those two dosage strengths and could launch in July 2011. (CX2607 at 009 (¶ 25) (Lortie Decl.); CX0309 at 002). But Impax had first-filer exclusivity on the remaining five dosages, so Actavis had to wait until Impax had used first-filer exclusivity before it could launch those dosages. (JX-001 at 007 (¶ 14); CX2607 at 009 (¶ 25) (Lortie Decl.); *see also* CCF ¶¶ 99-102, below).

RESPONSE TO FINDING NO. 66:

Respondent has no specific response.

67. For Endo, Impaxôs entry was paramount because Impax held first-filer exclusivity for the five dosage strengths of Opana ER that comprised over 95% of Endoôs Opana ER sales. (JX-001 at 007 (¶¶ 13, 14)). Impaxôs impending launch therefore presented a substantial risk to Endoôs Opana ER monopoly.

RESPONSE TO FINDING NO. 67:

Respondent does not dispute that the five dosages of Opana ER for which Impax held first-filer exclusivity comprised over 95 percent of Endoôs Opana ERôs sales. The remainder of

69. In terms of Endoôs revenues for Opana ER, which had been growing prior to 2010, generic entry threatened to cut dollar sales drastically. In 2010, Endo projected that generic entry would cut sales from $215 million in the year before generic launch to $34.8 million in the year after. (CX1320 at 003, 05, 07 (Feb. 2010 Endo Three-Year Plan); CX2564 at 016, 94 (Mar. 2010 Endo 10 Year Outlook and Valuation)). At a different point, Endo projected lost sales at approximately $20 million per month when generics launched. (CX4025 (Bingol, Dep. at 48, 187-88); CX1106 at 005 (July 2009 Endo Opana Brand Strategic Plan) (ñEach month that generics are delayed beyond June 2010 is worth $20 million in net sales per month.ò)). Loss of sales to a generic product made generic entry a ñworst-case scenarioò for Endo for Opana ER. (CX4025 (Bingol, Dep. at 74-76)).

RESPONSE TO FINDING NO. 69:

The first sentence of Complaint Counselôs Proposed Finding No. 69 is not supported by any record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 69 is incomp e] omp ъ Ќcee] M A ӟ ӓ

The fourth sentence of Proposed Finding No. 69 is incomplete and misleading. Mr. Bingol testified that when conducting projections in order to estimate the future performance of Opana ER, ñan entry of a generic is -- we would consider that to be a fairly negative impact to the overall business and somewhat of a worst-cast scenario. So you want to plan for that and show that potential impact. Whether or not it comes to pass is another question. . . . [F]orecasts, especially these types of assumptions, arenôt always probability based. You canôt really know.ò (CX4025 (Bingol, Dep. at 74-76)).

> 70. The revenue declines would be primarily driven by loss of branded unit sales. In fact, Endo expected to lose 80ï85% of its market share volume once a generic version of Opana ER launched. (CX3273 at 008 (Bingol Decl.) (forecasting a loss of 80% market share); CX1320 at 007 (Feb. 2010 Endo Three-Year Plan.) (Opana ER ñKey Assumptionò that ñ15% brand volume remains after 3 monthsò following generic entry); CX4025 (Bingol, Dep. at 28) (ñGenerics will typically erode the brand significantly, often within the first two to three months.ò)). Endo believed that prescriptions of Opana ER would fall from 200,500 prescriptions in the full quarter before generic entry to 29,100 in the full quarter after generic launch. (CX1320 at 007 (Feb. 2010 Endo Three-Year Plan)).

RESPONSE TO FINDING NO. 70:

The first sentence of Complaint Counselôs Proposed Finding No. 70 is not supported by any record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 70 is incomplete and misleading. Mr. Bingol was referring to a decline in Endoôs 3.4 percent market share in the ñLong Acting Opioid

(describing ñassumptionsò)). It was Endoôs practice to forecast different scenarios regarding the future of its Opana ER product to ñanalyze the full range of potential outcomes.ò (Cuca, Tr. 663-64). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted ña number of different potential outcomes over the course of years,ò the accuracy of which were ñalways debatable.ò (Bingol, Tr. 1292, 1303).

71. The substantial economic effect that generics would have on Opana ER sales was expected to negatively impact Endoôs business in a number of ways beyond just revenue loss. For example, Endo heavily relied on Opana ER revenues to fund significant R&D efforts, and Endo projected the dramatic reduction in Opana ER revenues could force it to reduce its research and development programs. (CX3273 at 009 (¶ 20) (Bingol Decl.)). After loss of Opana ER sales due to an Impax launch, Endo planned to scale back and possibly abandon some ongoing development efforts. (CX2607 at 021-22 (¶ 51) (Lortie Decl.)). Reduced Opana ER revenues from an Impax launch could also lead to workforce reductions, unused business units, and idle capacity. (CX3273 at 009 (¶ 21) (Bingol Decl.); CX2607 at 021 (¶ 51) (Lortie Decl.)).

RESPONSE TO FINDING NO. 71:

Complaint Counselôs Proposed Finding No. 71 is incomplete and misleading. Mr. Lortieôs declaration states unequivocally that ñgeneric sales have had a relatively small effect on Opana ER.ò (CX2607-010-11 (ñEndo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mildò)).

C. To protect its franchise, Endo planned to reformulate Opana ER, but needed time to do so

72. With the threat of generic entry looming, Endo wanted to protect and extend its Opana franchise, including the substantial profits from Opana ER. (CX1002 at 004 (Mar. 2010 Endo presentation re Corporate Development & Strategy Departmental Offsite) (Endo planned to aggressively protect the Opana ER franchise)). Endo planned to use several tactics, including introducing a new version of Opana ER and an authorized generic, to ensure it retained market share. *See* CCF ¶¶ 73-90, below; (CX2564 at 099 (Mar. 2010 Endo 10-Year Outlook and Valuation); CX3007 at 003 (June 2010 Endo pricing proposal for authorized generic version of Opana ER)); CX2573 at 005 (Feb. 2010 Endo presentation re EN3288 Commercial Update)). To successfully execute its

plan, Endo needed to introduce the new Opana ER before generic entry ð which could ensure that the new drug product would capture sales potentially lost to generics. *See* CCF ¶¶ 73, 75-80, below.

RESPONSE TO FINDING NO. 72:

The first sentence of Complaint Counselôs Proposed Finding No. 72 is incomplete and misleading. The cited document (CX1002) states only that Endo would ñ[a]ppropriately protect the Opana and Lidoderm franchises, including by aggressively defending against paragraph IV challenges.ò (CX1002-004).

The second sentence is incomplete and misleading because it ignores the testimony of Demir Bingol, Endoôs Senior Director of Marketing and the person responsible for marketing Endoôs Opana ER products. Mr. Bingol testified that an authorized generic ñwas never, to my knowledge . . . fully realized as a plan or an idea.ò (Bingol, Tr. 1338-39; *see* Bingol, Tr. 1337 (ñI donôt recall specific forecasts about an authorized generic.ò); CX4019 (Lortie, Dep. at 118-19) (ñwe never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didnôt want to.ò); CX4031 (Bradley, Dep. at 198) (ñI donôt recall having any conversation with any colleagues regarding the launch of an authorized generic.ò)). Endo had no intention of launching both an authorized generic and a reformulated version of Opana ER. (Bingol, Tr. 1338; CX4019 (Lortie, Dep. at 117-18) (Endo ñintended to replace one product with the other, and that would be the only product that we had on the market.ò)).

The third sentence of Proposed Finding No. 72 in not supported by any record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). To the extent the Proposed Finding

support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

73. Since 2007, Endo had been working on a reformulated ñcrush resistantò version of Opana ER (ñReformulated Opana ERò) to replace the original version. (CX3214 at 015 (Endo SEC Form 10-K for 2011); CX3199 at 046 (Opana Brand Single Strategy Plan)). Reformulated Opana ER was also referred to in planning as EN3288 and Revopan. (RX-007 at 0001 (Endo Narrative for 3X .

Finally, the seventh sentence

reformulated Opana ER, he worked in marketing, and there is no evidence that Mr. Bingol had any role in deciding whether or when to launch a product. (Bingol, Tr. 1308 (JUDGE CHAPPELL: . . . Youôre a marketing person; right? THE WITNESS: Correct.ò)). In fact, the evidence is clear that Endo actually intended to transition to a reformulated version of Opana ER at the very end of 2012. (CX4017 (Levin, Dep. at 99-101, 131) (Endoôs Chief Financial Officer); RX-094.0003 (planned launch in roughly September 2012, with conversion by end of the year)). And Endoôs original budget for 2012 projected original Opana ER sales into the fourth quarter of 2012. (RX-108.0002 at 10; RX-094.0006 (ñPrior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012.ò)). Professor Noll admitted that such a strategy would have permitted Endo to carry out the ñlate switchò plan and avoid any payments to Impax under the SLA. (*See* CX4039 (Noll, Dep. at 124) (testifying that zero-payment outcome ñwould have required entry along about the 1st of September of 2012ò)).

Respondent has no specific response to the second sentence of Proposed Finding No. 78. The third sentence of Proposed Finding No. 78 is misleading and not supported by the cited evidence. The cited document (CX2575) does not state that Endo ñexpectedò to file an application at any time. The document instead included a ñrecommendationò that Endo ñtarget filing date 3Q2010.ò (CX2575-005). The document moreover, was still being revised and had not been forwarded to senior management. (CX2575-001).

The fourth sentence of Proposed Finding No. 78 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endoôs Senior Director of Marketing and the author of the cited exhibit (CX2575). Mr. Bingol testified that ñEN3288

(Bingol, Tr. 1303). Endo always forecast ña number of different potential outcomes over the course of years.ò (Bingol, Tr. 1292).

Respondent has no specific response to the fifth sentence of Proposed Finding No. 78. The sixth sentence of Proposed Finding No. 78 is incomplete and misleading because Mr. Bingol testified ñfor this asset it was important to try to have your follow-on formulations, products, improvements, whatever would separate this product from potential generics *or* with a reasonable amount of time to make the conversion.ò (CX4025 (Bingol, Dep. at 64) (emphasis added); *see also* CX2578-009 (a ñdraftò document from 2007, just after original Opana ER launched); Bingol, Tr. 1298-99 (discussing ñdraftò language: ñJUDGE CHAPPELL: . . . it says itôs a draft. Why would he have presented a draft to anybody?ò)).

> 79. Endo not only wanted to begin this transition between formulations as soon as possible, but also to make the transition as ñsmooth a[s] possible.ò (CX4019 (Lortie Dep. at 33). Endoôs desire for a smooth transition was driven in part by an understanding that patients cannot be switched immediately from one long-acting opioid to another because

RESPONSE TO FINDING NO. 80:

looking at ñany possible scenario.ò (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 (ñWe have to consider all scenariosò)). They were ñbased on scenarios that we had created, I mean, the accuracy of which are always debatable.ò (Bingol, Tr. 1303). And many of the assumptions were actually total unknowns. (Bingol, Tr. 1307 (ñJUDGE CHAPPELL: Okay. Well, I donôt want you to guess[], so according to this document [CX2724], whatever those claims were you didnôt know. THE WITNESS: Well, we would be -- thatôs correct.ò); Cuca, Tr. 662-63).

In the case of Opana ER, Endoôs ñbase caseò and ñlatest best estimateò did not assume generic entry in 2010. (CX4035 (Cuca, Dep. at 62) (discussing CX3009)). Indeed, in the spring of 2010, Endo knew ñthere had been ANDAs filed for generic versions of Opana ER,ò but believed ñthere was not imminently at that point going to be a generic.ò (Cuca, Tr. 643; *see* RX-086 at 9-10 (Impax was ñnot likely to launch at riskò)). Endo still forecast different scenarios regarding the future of its Opana ER product to ñanalyze the full range of potential outcomes.ò (Cuca, Tr. 663-64).

The second sentence of Proposed Finding No. 82 is not supported by the cited evidence. (RX-364; CX2583-032 (stating only that ña phased withdrawal of Opana ER and launch of Revopan . . . was facilitated by the Impax settlement and Penwest transactionò)).

> 83. In July 2010, Endo filed a supplemental New Drug Application (No. 201655) for a Reformulated Opana ER. (JX-001 at 011 (¶ 48)). Endo originally expected final FDA approval in January 2011 (CX2528 at 009) (Endo presentation re Revopan Launch Readiness Review)), but approval was delayed due to certain deficiencies in the methods used in the bioequivalence studies (RX-011 (Jan. 7, 2011 FDA complete response letter)). The FDA ultimately approved the application in December 2011. (JX-001 at 011 (¶ 48)). Endo began selling Reformulated Opana ER in February 2012. (CX1107 at 006 (¶ 19) (Lortie Decl.)).

RESPONSE TO FINDING NO. 83:

Respondent has no specific response other than to clarify that Mr. Lortie testified that any dates regarding FDA approval were merely ñassumptions at that point,ò but that ñ[t]here was some subsequent work that need

Mr. Cuca explained that Endo forecast diffe ar

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with any colleagues regarding the launch of an authorized generic.ò (CX4031 (Bradley, Dep. at 198)).

The cited evidence does not reflect that ñEndoò ñintendedò to do anything. The exhibits include (1) a single statement by an ñaccount executive on our managed markets team,ò (CX4025 (Bingol, Dep. at 174, 179) (discussing CX2576, testifying that he did not ñknow what their conversation meant or why they wrote those thingsò)); (2) a statement about authorized generics in the context of *crush-resistant Opana ER*, (CX2581 (discussing EN3288); CX4025 (Bingol, Dep. at 183) (discussing CX2581, explaining language meant that ñmentally we have all options on the table to be commercially successful, and this is one of these levers we could pull if we had to, and at this point no steps were taken, and I donôt recall that any ever were.ò)); (3) a draft document, (CX2573-004 (ñDRAFT Not Approved by Managementò); Bingol, Tr. 1298-99 (discussing identical ñdraftò language: ñJUDGE CHAPPELL: . . . it says itôs a draft. Why would he have presented a draft to anybody?ò)); and (4) a ñproposal,ò (CX3007-003). Finally, all of the hypothetical scenarios at issue in these documents discuss a possible authorized generic in response to what would necessarily be an at-risk generic launch in 2010. No documents or testimony address whether, let alone suggest that, Endo would launch an authorized generic under other circumstances, such as in response to Impax (or another generic) launching pursuant to a settlement license.

> 86. By late 2009, Endo began preparing for an authorized generic launch in summer 2010. Endo designed AG oxymorphone ER tablets in October and November 2009, and received labels for its AG by May 4, 2010. (CX2998 at 001 (October 2009 Endo email chain) (ñWe have $ in the budget to buy tooling this year for potentially bringing generic Opana ER to the market sometime in the future. Iôd like to spend that money this year, but we need to decide on the tablet design quickly ï like the end of the month.); CX2999 at 001 (November 2009 Endo email chain) (ñI would like a decision before Thanksgiving on design for potential generic Opana ER.ò); CX3005 (May 2010 Endo email attaching oxymorphone ER labels)).

RESPONSE TO FINDING NO. 86:

Complaint Counselôs Proposed Finding No. 86 is inaccurate and misleading in its suggestion that Endoôs actions reflected a decision or intention to launch an authorized generic, much less in summer 2010. In fact, the cited documents reflect the exact opposite. (CX2998-001 (ñWe have $ in the budget to buy tooling this year for potentially bringing generic Opana ER to the market sometime in the future. Iôd like to spend that money this year.ò); CX2999-002 (same); CX3005 (saying nothing about an authorized generic, launch, or timing)).

87. In February 2010, Endo informed drug wholesalers that Endo would launch an AG immediately upon Impaxôs launch. (CX2576 at 003 (Feb. 2010 email from Endo National Account Executive Kayla Kelnhofer) (ñWe will launch on word/action of first generic competitor. We are hearing as early as June this year (not confirmed) let me ask around and verify.ò)).

RESPONSE TO FINDING NO. 87:

Complaint Counselôs Proposed Finding No. 87 is incomplete and misleading. The Proposed Finding is based on a single document, which included a single email exchange with a single Endo customer by a single ñaccount executive on our managed markets team.ò (CX4025 (Bingol, Dep. at 174) (discussing CX2576)). There is no evidence suggesting that the single account executive had any role in deciding whether or when a product would launch. Demir Bingol, Endoôs Senior Director of Marketing, testified that he did not ñknow what their conversation meant or why they wrote those things.ò (CX4025 (Bingol, Dep. at 179)).

Indeed, Mr. Bingol testified that an authorized generic ñwas never, to my knowledge . . . fully realized as a plan or an idea.ò (Bingol, Tr. 1338-39; *see* Bingol, Tr. 1337 (ñI donôt recall specific forecasts about an authorized generic.ò)). Brian Lortie, Endoôs Senior Vice President for Pain Solutions, similarly testified that Endo ñnever seriously considered taking any further steps to prepare for or to do [an authorized generic of Opana ER] because we really didnôt want to.ò

(CX4019 (Lortie, Dep. at 118-19); *see* CX4031 (Bradley, Dep. at 198) (ñI donôt recall having any conversation with any colleagues regarding the launch of an authorized generic.ò)).

Finally, the hypothetical scenario at issue in this document discusses a theoretical authorized generic in response to what would necessarily be an at-risk generic launch in 2010. No documents or testimony address, let alone suggest, whether Endo would launch an authorized generic under any other circumstance.

88. Endo created new SKUs for its generic oxymorphone ER and, as of May 26, 2010, had made one batch of each strength of oxymorphone ER. (CX3002 at 001, 05 (May 2010 Endo email chain and Change Control Report); CX3003 (May 2010 Endo email chain) (ñWe made 1 batch of each strength.ò)).

RESPONSE TO FINDING NO. 88:

Respondent has no specific response other than to clarify that Endo did not create new SKUs; rather, Novartis, Endoôs agent, created new SKUs as a result of an ñunrecoverable errorò in its own SAP software. (CX3002-001, 05).

89. Endo personnel reported that Endo had manufactured enough generic oxymorphone ER to support a June 2010 AG launch. (CX3003 (ñ[I]f we launch in June we would be able to support the current generic ER forecast. We would make an additional batch of both the 20 mg and the 40 mg in July.ò)).

RESPONSE TO FINDING NO. 89:

Complaint Counselôs Proposed Finding No. 89 is misleading. The hypothetical scenario at issue in this document discu

what market share they have across specific customers . . . I am trying to assess as part of the customer targeting exercise, which customers Impax and Sandoz value the most and will be less willing to lose so we can prioritize customers appropriately.ò); CX3007 at

RESPONSE TO FINDING NO. 91:

To the extent Complaint Counselôs Proposed Finding No. 91 purports to rely on expert testimony, it violates this Courtôs Order on Post-Trial Briefs by improperly citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò

Proposed Finding No. 91, moreover, is not supported by the cited evidence. The only

Koch, Tr. 287), and it ñis very important for [Impax] to have a . . . risk-free launchò in the vast majority of cases, (CX4014 (Hsu, IHT at 117)) ð as Impaxôs meager track record of actually launching at-risk reflects, (*see* Snowden, Tr. 424, 426 (aside from limited oxycodone launch after favorable district court decision, in a single dose, and with a cap on sales, Impax had not pursued any other at-risk launches at the time of Endo-Impax settlement)).

Had Impax seriously considered launching oxymorphone ER at-risk, it would have sought Board approval ð a prerequisite at Impax for any at-risk launch (Koch, Tr. 276-77 (ñevery at-risk launch is a board-level decisionò); Snowden, Tr. 426; CX4030 (Hsu, Dep. at 128); CX4021 (Ben-Maimon, Dep. at 160)) ð well before tentative FDA approval of its ANDA. (Koch, Tr. 333-34, 341). Yet Impaxôs senior management never even recommended an at-risk launch of oxymorphone ER to the Impax Board of Directors regarding, nor was the Impax Board of Directors ever asked to vote on such an at-risk launch. (Koch, Tr. 299; Snowden, Tr. 470-71; CX4030 (Hsu, Dep. at 85); JX-001-009 (¶ 29) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

Finally, to the extent Proposed Finding No. 93 purports to summarize and incorporate other findings, it should be disregarded because the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

A. Impax's generic application

94. In June 2007, Impax filed an Abbreviated New Drug Application (ñANDAò) (No. 79-087) for a generic version of Original Opana ER (ñgeneric oxymorphone ERò). (JX-001 at 007 (¶ 11)).

RESPONSE TO FINDING NO. 94:

Respondent has no specific response.

95. Impaxôs ANDA included a Paragraph III certification for Patent Number 5,128,143 (ñthe ô143 patentò). A Paragraph III certification meant that Impaxôs ANDA would be eligible for FDA approval upon the ô143 patentôs expiration in September 2008. (CX2967 at 017 (July 2007 Impax letter to FDA)).

RESPONSE TO FINDING NO. 95:

Respondent has no specific response.

96. As of June 2007, the ô143 patent was the only patent listed in the Orange Book as covering Opana ER. (CX2967 at 014, 017 (July 2007 Impax letter to FDA); CCF ¶ 50, above).

RESPONSE TO FINDING NO. 96:

Respondent has no specific response.

97. In October of 2007, however, Endo listed three additional patents in the Orange Book as covering Opana ER: U.S. Patent Nos. 7,276,250 (ñthe ô250 patentò), 5,662,933 (ñthe ô933 patentò), and 5,958,456 (ñthe ô456 patentò). Endo listed the ô250 patent in the Orange Book on October 2, 2007, and the ô933 and ô456 patents on October 19, 2007. The ô933 and ô456 patents expired in September 2013. The ô250 patent expires in February 2023. (JX-001 at 006 (¶¶ 9-10)).

RESPONSE TO FINDING NO. 97:

Respondent has no specific response.

98. The ô250, ô933, and ô456 patents all pertain to the controlled-release mechanism of the oxymorphone formulation. (JX-003 at 002 (¶ 6) (discussing the ô456, ô933, and ô250 patents)).

RESPONSE TO FINDING NO. 98:

Respondent has no specific response.

99. On November 23, 2007, the FDA accepted Impaxôs ANDA with an amendment to include Paragraph IV certifications for the ô250, ô933, and ô456 patents. (CX3163 at 010 (¶ 37) (Impax Answer); JX-001 at 007 (¶ 12)).

RESPONSE TO FINDING NO. 99:

Respondent has no specific response.

100. With respect to the amendment for the ô250, ô933 and ô456 patents, Impaxôs Paragraph IV notice asserted that its ANDA product did not infringe these patents and/or that the patents were invalid. (JX-001 at 007 (¶ 12); CX2714 at 002 (Impaxôs Paragraph IV Notice)). As a matter of routine, Impax made sure that the information it included in the Paragraph IV notification was ñtruthful.ò (CX4026 (Nguyen, Dep. at 31)).

RESPONSE TO FINDING NO. 100:

Respondent has no specific response of the first sentence of Complaint Counselôs Proposed Finding No. 100. The second sentence of Proposed Finding No. 100 is incomplete because it ignores the fact that while Impax believes ñin its opinion and to the best of its knowledgeò that patents identified in Paragraph IV notifications are invalid, unenforceable, or will not be infringed, (JX-003-002 (¶7) (Second Set of Joint Stipulations)), courts can disagree with 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).

101. Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosages of Opana ER. Thus, Impax was eligible for first-filer exclusivity (a ñ180-day exclusivity periodò) for these dosages. (JX-001 at 007 (¶¶ 13-14)). These dosages were the most profitable dosages for Endo, comprising over 95% of Endoôs Opana ER sales. (JX-001 at 007 (¶ 13)).

RESPONSE TO FINDING NO. 101:

Respondent has no specific response.

102. Because Impax was eligible for first-filer exclusivity, the FDA could not grant final approval for other companiesô generic oxymorphone ER ANDAs in those dosage strengths until 180 days after Impax started selling its generic product. In other words, no other generic company could compete with its own oxymorphone ER product for those dosage strengths until 180 days after Impax began selling its generic product. (JX 001 at 002 (¶ 7); Mengler, Tr. 522-23; CCF ¶¶ 14-15, above).

RESPONSE TO FINDING NO. 102:

The Complaint Counselôs Proposed Finding No. 102 is incomplete and inaccurate. First-filer exclusivity can be forfeited, and the FDA can therefore approve other ANDA generic

products sooner than 181 days after the first filer enters the market, if, for example, a first-filer does not launch its product within a certain timeframe or it does not receive tentative approval from the FDA. (Snowden, Tr. 414-15, 417; JX-003-002 (Second Set of Joint Stipulations ¶ 7); CX5000 at 033 (Noll Rep. ¶ 73) (explaining that to ñtake advantage of the exclusivity period, the generic firm must enter the market at least six months before the challenged patents on the brand-name drug expireò)).

To the extent Proposed Finding No. 102 purports to summarize and incorporate other findings, it should be disregarded because the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

103. Impaxôs first-to-file exclusivity was very valuable because, as a generic company, Impax can make ña substantial portion of their profitsò during the six months of first-filer exclusivity. (Koch, Tr. 232).

RESPONSE TO FINDING NO. 103:

Respondent has no specific response.

104. Impax did not forfeit its 180-day exclusivity rights for generic oxymorphone ER at any point, either during or subsequent to the patent litigation. (Snowden, Tr. 484; *see also* CX1107 at 009 (¶ 25) (Lortie Decl.)).

RESPONSE TO FINDING NO. 104:

Respondent has no specific response.

105. Although no other ANDA filer for generic oxymorphone ER could enter during Impaxôs 180-day exclusivity, as the holder of the approved NDA for Opana ER, Endo could market an authorized generic (ñAGò) version of Opana ER during Impaxôs exclusivity period. (Mengler, Tr. 523; CX4003 (Snowden, IHT at 27); JX-001 at 5 (¶ 28)).

RESPONSE TO FINDING NO. 105:

Respondent has no specific response.

106. In December 2007, Impax sent Endo a not Þ Į M ˍ ϰ m t ʻ , Im ò I002 t Ŏ Mŧ ž Ů

110. Impax desired an early trial date for the patent litigation and sought to transfer the patent litigation to the District of New Jersey. (Snowden, Tr. 357-58). The court granted Impaxôs request and transferred the patent litigation case to the District of New Jersey. (Snowden, Tr. 357-58).

RESPONSE TO FINDING NO. 110:

Respondent has no specific response.

111. On May 13, 2010, near the end of the 30-month stay, the FDA granted tentative approval of Impaxôs ANDA for all dosage strengths of generic ox

115. On June 8, 2010, before the end of trial, Impax and Endo entered the Impax-Endo Settlement Agreement, which settled the patent litigation. (JX-001 at 007 (¶ 18)). As part of this agreement, the parties executed a Settlement and License Agreement (ñSLAò) and a Development and Co-Promotion Agreement (ñDCAò). (JX-003 at 005 (¶ 26); RX-364 (SLA); RX-365 (DCA)).

RESPONSE TO FINDING NO. 115:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 115. The second sentence of Proposed Finding No. 115 is misleading. The Settlement and License Agreement settled the patent litigation. (RX-364.0001; JX-001-007-09 (¶¶ 19, 33) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)). The

determine that the launch infringed a valid patent. (RX-548.0039-40 (Figg Rep. ¶¶ 85-86)). The second sentence of Proposed Finding No. 119 is incomplete because it ignores the fact that an at-risk launch can occur outside the context of active litigation, including any time a generic company launches a product, without a license, before relevant patents expire. (Bingol, Tr. 1282). An at-risk launch can also occur when relevant patents are pending, but not yet approved or the subject of litigation. (CX4014 (Hsu, IHT at 116) (every Impax license ñagreement has to cover all the patent[s], not just the patent [at issue] today, but cover all future patent[s] as well,ò ñotherwise you end up with [a] launch [of] the product and still have to be under [patent] risk, and that doesnôt really help usò); Figg, Tr. 1938).

120. An at-risk launch can occur any time after FDA final approval, including (1) before a district court decision, (2) after a district court decision but before an appellate decision by the Federal Circuit, or (3) even after a Federal Circuit opinion if the case is remanded or otherwise continues. (Hoxie, Tr. at 2810-11; CX4021 (Ben-Maimon, Dep. at 133-34); Nguyen, Dep. at 47-48)). An at-risk launch involves more risk prior to a district court decision and significantly less risk after the generic receives a favorable decision from either the district court or the Federal Circuit. (Hoxie, Tr. at 2810-11; CX4021 (Ben-Maimon, Dep. at 133-34)).

RESPONSE TO FINDING NO. 120:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 120. The second sentence of Proposed Finding No. 120 is misleading and not supported by the cited evidence. The cited testimony of Dr. Ben-Maimon does not state that companies face ñsignificantly less riskò when launching a product at-risk following a court decision, but rather that ñrisk goes down *to some extent*.ò (CX4021 (Ben-Maimon, Dep. at 134) (emphasis added)).

C. Impax had financial incentives to launch as soon as possible

121. In the absence of its settlement with Endo, Impax had strong financial incentives to launch oxymorphone ER as soon as possible to prevent Endo from destroying the

market opportunity for generic oxymorphone ER. (CCF ¶¶ 122-26; *see also* RX-547 at 0064 (¶ 121) (Addanki Report) (ñImpax was concerned about a potential switch to some new version of Opana ERò); CX5001 at 033-34 (¶ 62) (Bazerman Report) (discussing Impaxôs financial incentives fo

RESPONSE TO FINDING NO. 122:

The first sentence of Complaint Counselôs Proposed Finding No.

Board presentation (CX2685) does not discuss oxymorphone ER or the impact of delaying a launch of the same. (CX2685-003).

Respondent has no specific response to the third sentence of Proposed Finding No. 122.

123. Impax was also concerned about a decrease in Impaxôs profits if Endo switched the Opana ER market to a reformulated product. (Mengler, Tr. 526-27, 568

Finding No. 123 (CX4022) does not support the Proposed Finding because it does not discuss reformulation, risks, substitution, or anything else in the Proposed Finding. (CX4022 (Mengler, Dep. at 104)).

Respondent has no specific response to the third sentence of Proposed Finding No. 123.

124. If Endo successfully converted the market from Original Opana ER to Reformulated Opana ER before Impax could enter with its generic version, Impax might get ñnothingò in terms of generic Opana ER sales. (Mengler, Tr. 527 (if Endo launched Reformulated Opana ER before Impax launched generic Opana ER the market for generic Opana ER could disappear); *see also*

RESPONSE TO FINDING NO. 125:

Respondent has no specific response.

126. Thus, but for the Impax-Endo Settlement Agreement, Impax would have been financially motivated to launch as soon as possible to ensure it would enjoy its first-filer exclusivity ahead of Endoôs planned switch to a new formulation. (*See* CCF ¶¶ 121-25, above).

RESPONSE TO FINDING NO. 126:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

D. Prior to the Impax-Endo Settlement Agreement, Impax was preparing for a launch of generic oxymorphone ER as early as June 14, 2010

1. One of Impax's Company Goals for 2010 was to successfully manage a launch of generic oxymorphone ER

127. Each year, Impax sets ñCompany Key Goals.ò (CX4030 (Hsu, Dep. at 22-23); Koch, Tr. 249). These goals are based on ña lot of discussionò and meetings with the Impax management teams and ultimately received approval from Impaxôs CEO. (CX4030 (Hsu, Dep. at 22-23)). Impax Division Heads would use the Company Key Goals to ensure they had the plans and resources to accomplish their particular part of the Key Goals. (Koch, Tr. 249; CX4018 (Koch, Dep. at 110)). The Company Key Goals would then be circulated to company management and used to set yearly Management By Objective (ñMBOsò). (CX2562 at 001 (2010 Company Key Goals); Koch, Tr. 251).

RESPONSE TO FINDING NO. 127:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 127. The second sentence of Proposed Finding No. 127 is inaccurate and misleading. Dr. Hsu testified that ñ[t]hereôs no official approval process,ò but rather ñas the CEO, I have to agree with the key goal we put together.ò (CX4030 (Hsu, Dep. at 23)).

Respondent has no specific response to the third and fourth sentences of Proposed Finding No. 127.

128. MBOs are an important tool in setting executive compensation, determining bonus calculations, and corporate planning. (Koch, Tr. 249-51; Camargo, Tr. 1000-01; CX4023 (Hildenbrand, Dep. at 197-98); CX2562 at 002 (2010 Company Key Goals) (Hsu instructing management to use the goals in setting ñquantitative targets and to map out executive plans for achieving themò); *see, e.g.* CX3069 at 002 (2010 Supply Chain MBOs) (tying achievement of each goal to targeted and obtained salary percentages)). MBOs are more quantitative and division-oriented than the Company Key Goals. (*Compare* CX2562 at 001-02 (2010 Company Key Goals) *with* CX3069 at 002 (2010 Supply Chain MBOs)).

RESPONSE TO FINDING NO. 128:

Respondent has no specific response.

129. In February 2010, Impaxôs CEO, Larry Hsu, widely distributed Impaxôs 2010 Company Key Goals to management personnel. (CX2562 at 001 (2010 Company Key Goals)).

RESPONSE TO FINDING NO. 129:

Respondent has no specific response other than to note that the cited evidence does not support the proposition that Dr. Hsuôs distribution was ñwideò in comparison to any other communication or any other Company Key Goals document.

2. Prior to the Impax-Endo Settlement Agreement, Impax considered an at-risk launch

131. Consistent with the Company Key Goals, Impax was actively considering whether to launch its oxymorphone ER product in 2010, either upon final FDA approval or after a district court de

assumed launch date does not ñimply or mean that any legal decision ha[d] been made to clear the way for a launch.ò); Koch, Tr. 299-300 (Impax merely tried to ñlook[] at different various scenariosò and attempt ñvery hard to . . . describe the possible outcomes under any number of different assumptions.ò)). Indeed, in the case of oxymorphone ER, Impax modelled a set of assumptions involving a June 2010 launch date even when that date remained an ñobvious[] controversial element.ò (CX0514-001).

The testimony cited in the Proposed Finding reflects that Impax ñconsideredò an at-risk launch only as part of this general decision-making process and routine forecasting. Mr. Koch testified that Impax considered an at-risk launch in the sense that it ñevaluatedò it. (Koch, Tr. 247). Elsewhere in Mr. Kochôs testimony, he confirmed that Impax never intended to launch oxymorphone ER at-risk. (Koch, Tr. 324-25 (ñJUDGE CHAPPELL: Are you a hundred percent certain you would be aware of whether or not Impax planned an at-risk launch of Opana ER? WITNESS: Absolutely. I would have a key role in that. JUDGE CHAPPELL: Do you know in fact whether Impax intended an at-risk launch of Opana ER? . . . THE WITNESS: I do know. JUDGE CHAPPELL: Did they intend to do an at-risk launch of Opana ER? THE WITNESS: No.ò); *see also* Koch, Tr. 310 (Impax would only consider an at-risk launch after a favorable court ruling)).

And in the cited testimony of Dr. Hsu, Impaxôs founder and CEO at the time the SLA was executed, Dr. Hsu explained that evaluating an at-risk launch was part of a larger process that looks at all options in making a launch decision, in order to be able to defend any potential course of action to Impaxôs Board of Directors later on. (CX4041 (Hsu, IHT at 129-30) (ñWe could settle, we could launch at risk, we could do many other things, and as the job of CEO, I just have to, you know, lay out everything, get prepared so I don't get accused by the board and

say, well, wait a minute, how come you didn't prepare for plan B?ò); CX4041 (Hsu, IHT at 130) (ñQ: So, as of May 13th, 2010, Impax was at least considering the possibility of an at-risk launch for Oxymorphone ER? A. Yes, thatôs one of the options, absolutely.ò)). Moreover, contemporaneous documents make clear that such ñevaluationò of all possible ñoptionsò does not suggest an at-risk launch was likely to occur, or that Impax intended to launch oxymorphone ER at risk. To the contrary, in contemporaneous documents, Dr. Hsu noted that ñitôs unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reason[s]).ò (RX-297.0002; *see* CX2929-001 (Dr. Hsu further explained that that ñmostly likely we will make launch decision based on court decision on the PI.ò)).

With respect to at-risk launches generally, the decision-making process is especially involved, because Impax is ñincredibly conservative,ò (CX4021 (Ben-Maimon, Dep. at 34); *see* Koch, Tr. 287), and it ñis very important for [Impax] to have a . . . risk-free launchò in the vast majority of cases, (CX4014 (Hsu, IHT at 117)) ð as Impaxôs meager track record of actually launching at-risk reflects, (*see* Snowden, Tr. 424, 426 (aside from limited oxycodone launch after favorable district court decision, in a single dose, and with a cap on sales, Impax had not pursued any other at-risk launche

the Hatch-Waxman Act. (Camargo, Tr. 952-53, 958; CX4023 (Hildenbrand, Dep. at 79)). This process is routine, consistent with industry practice, and is the same for all products. (CX4023 (Hildenbrand, Dep. at 30); Koch, Tr. 271; CX3278-101).

Forecasting a launch date as part of this process does not mean that Impax has decided whether or when to launch a product. Todd Engle, Impaxôs Vice President of Sales and Marketing, would forecast potential launch dates based on the earliest possible date allowed by the Hatch-Waxman Act. (Engle, Tr. 1767, 1769, 1772-73). Mr. Engle and the teams on which he worked did not make a decision regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impaxôs Board of Directors. (Engle, Tr. 1754-55).

The New Products Committee, moreover, does not decide whether or when Impax will launch a product, including whether or when Impax will launch a product at risk. Impaxôs Board of Directors makes that decision; it must approve any at-risk launch management recommends. (Koch, Tr. 276-77, 286). Even if the Board approves a potential at-risk launch, it may do so with limitations on the extent of the launch, and senior management may decline to act on the Boardôs approval based on changes in market dynamics or the underlying patent litigation. (Koch, Tr. 276-77, 286; CX4026 (Nguyen, Dep. at 56) (ñeven after Board approval, senior management still has the decision to pull the trigger or notò)).

Respondent has no specific response to the third sentence of Proposed Finding No. 133.

134. Management team members would also formulate a risk analysis profile for at-risk launches. (Koch, Tr. 276). This risk analysis profile, also called a risk-launch analysis, included a legal analysis involving the status and merits of the patent litigation and potential risk of patent damages. (CX2704 at 010-11 (Impax Objection and Response to Interrogatory No. 9); CX3274 at 001 (Oct. 13, 2010 email chain)). The risk-launch analysis would also consider the potential rewards of an at-risk launch, such as estimated potential profits that might be earned from the launch. (CX2704 at 011 (Impax Objection

and Response to Interrogatory No. 9); *see, e.g.,* CX2695 at 009 (Impax Risk Scenarios for Avodart)).

RESPONSE TO FINDING NO. 134:

Respondent has no specific response to Complaint Counselôs Proposed Finding No. 134 other than to note that Mr. Koch testified that he and ñdivision headsò of certain operations would formulate a risk analysis profile. (Koch, Tr. 276). Mr. Koch did not mention Impax

He did not account for risk in any way, and specifically did not consider any regulatory or legal risk associated with a potential launch of oxymorphone ER. (Engle, Tr. 1770-71). The expiration of the thirty-month stay is the target launch date Impax routinely uses in its launch-preparedness efforts for its products. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)).

Mr. Engle did not make decisions regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impaxôs Board of Directors. (Engle, Tr. 1754-55, 1771). Nor does Mr. Engle and the Marketing department make risk assessments regarding a launch on the forecasted date, or otherwise take into account the status of related litigation. (Engle, Tr. 1774-77). Marketingôs forecasting and planning work helps assess ñwhat it would take to be in a position to launch,ò so that Impax can work towards that goal and keep all options open for management (or, in the case of an at-risk launch, the Board and management) to select a launch date. (CX4037 (Smolenski, Dep. at 116); Koch, Tr. 299-300; *see* Engle, Tr. 1754-55; CX4002 (Smolenski, IHT at 120); CX4038 (Engle, Dep. at 197-98)).

138. Upon receiving tentative FDA approval on May 13, 2010, Chris Mengler, Impaxôs President of Generics, instructed the head of Operations and to ñmove on with our next step of preparation for launch.ò (CX2929 (May 2010 email chain)).

RESPONSE TO FINDING NO. 138:

Complaint Counselôs Proposed Finding No. 138 is incomplete and misleading. The full statement found in the cited evidence is, ñLetôs move on with our next step of preparation for launch . . . *the court stuff[] should occur timely enough for us to build inventory*.ò (CX2929-001 (emphasis added; ellipsis in original)). The document also states that Impax ñlikely [] will make launch decision based on court decision on the PI.ò (CX2929-001). These omitted portions

Tr. 547). Todd Engle, a senior member of Impaxôs Sales and Marketing team, then provided Dr. Hsu and Mr. Mengler a risk-launch analysis for oxymorphone ER that he prepared in conjunction with Meg Snowden, Impaxôs most senior in-house counsel. (CX2753 at 001, 004-28 (May 14, 2010 Engle email and attached Risk Analysis); CX3274 at 001 (May 13, 2010 Impax email chain)). The analysis projected that in its first six months on the market, Impax would earn $53 million in profit if it did not face an AG or between $23.4 million and $28.5 million if it did face an AG. (CX2753 at 004).

RESPONSE TO FINDING NO. 139:

The first sentence of Complaint Counselôs Proposed Finding No. 139 is incomplete and

for a potential launch. (CX3309 at 016 (*Endo v. Impax*, transcript of May 14, 2010 teleconference with court) (arguing Impax was ñgoing down that roadò)). Endo proposed that, even after Impax obtained final FDA approval, Impax should agree to refrain from launching until a district court ruling. (CX3309 at 015-16 (*Endo v. Impax*, transcript of May 14, 2010 teleconference with court)).

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plaintiffôs counsel and see what we can work out with respect t

RESPONSE TO FINDING NO. 143:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 143. The second sentence of Proposed Finding No. 143 is inaccurate, misleading, and not supported by the cited evidence. The cited exhibit states in relevant part that a particular declarant had ñbee

testified that Endo forecast ña number of different potential outcomes over the course of years. As a brand leader . . . you have to plan for all the contingencies.ò (Bingol, Tr. 1292).

144. On the same day, Ted Smolenski, Impaxôs Director of Portfolio Management,

associated with a potential launch of oxymorphone ER. (Engle, Tr. 1770-71). Mr. Engle, moreover, does not make the decision regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impaxôs Board of Directors. (Engle, Tr. 1754-55, 1771). Forecasting and planning work helps assess ñwhat it would take to be in a position to launch,ò so that Impax can work towards that goal and keep all options open for management (or, in the case of an at-risk launch, the Board and management) to select a launch date. (CX4037 (Smolenski, Dep. at 116); Koch, Tr. 299-300; *see* Engle, Tr. 1754-55; CX4002 (Smolenski, IHT at 120); CX4038 (Engle, Dep. at 197-98)). The limited significance of launch dates assumed in such routine forecasts is reflected in the fact that the date chosen for Impaxôs oxymorphone ER was an ñobvious[] controversial elementò of the forecast. (CX0514-001; *see* Koch, Tr. 301 (management updated the Board of Directors on various scenarios so the Board was not caught off guard regarding any future course)).

145. By the May 2010 Board of Direct

going to be successful.ò (Koch, Tr. 295). There is no evidence indicating that oxymorphone ERôs opportunity had anything to do with an at-risk launch, as Proposed Finding No. 146 attempts to imply.

The third sentence of Proposed Finding No. 146 is inaccurate, misleading, and misrepresents the cited evidence. Mr. Koch actually testified that Mr. Mengler shared information about oxymorphone ER with the Board because ñ*we were unsure of what direction we were to ultimately take* and we didnôt want the case -- we didnôt want to come back to the board seeking an at-risk launch with them never having heard of it before, so almost at the earliest time we can think of, we would scope out for them the market profile. And this -- and that was what Chris was doing here.ò (Koch, Tr. 301 (emphasis added)). Mr. Koch did not testify what ñeveryone at the meetingò understood or whether the Executive Committee would come back to the board with any recommendation.

147. The discussion about the oxymorphone ER opportunity was memorialized by Arthur Koch, Impaxôs CFO, in the Board of Directors meeting minutes. (Koch, Tr. 257-59; CX2663 at 004 (May 2010 board of directors meeting minutes)). Mr. Koch takes notes during the Board meeting with a view to prepare the meeting minutes. Based on these notes, Mr. Koch prepares a draft, which he circulates to the CEO. When he is comfortable that the minutes þ ǒ ŏ ¸ ȳ ẍ ȷ ȵ ṗ ɐ ˇ Íl Š ˆ ă Ǒ ˚ ṃ ṅ ˂ ṗ a n m þ ẋ ɪ ˝ M ȥ ˙ a x b £ Ċ

projections and forecasts were built off of the best information available to Impax at that

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154. When a new product entered the 18-month planning window, the Operations group would kick off its pre-launch preparation activities. (Camargo, Tr. 958-59). To start, the Operations group would take information about the new product from the monthly forecasts, including the intended launch date, and enter the information into Impaxôs enterprise resource planning system (ñERPò). (Camargo, Tr. 959-61).

RESPONSE TO FINDING NO. 154:

Respondent has no specific response other than to note that the phrase ñintended launch dateò is derived from Complaint Counselôs question at trial. Impaxôs Operations group referred instead to a ñlaunch-readyò date. (*See, e.g.*, CX2914-003).

155. ERP is a computer system that allows a company, like Impax, to plan the many aspects of a product launch. (Camargo, Tr. 959-61). During the 2009-2010 time-frame, Impaxôs enterprise resource planning system was called PRMS. (Camargo, Tr. 959-60).

RESPONSE TO FINDING NO. 155:

Respondent has no specific response.

156. PRMS assisted Impaxôs Operations group with the planning necessary to be ready to launch on the target launch date, the date of each productôs planned actual product launch. (Camargo, Tr. 960-61, 982; CX4023 (Hildenbrand, Dep. at 17, 27)).

RESPONSE TO FINDING NO. 156:

Complaint Counselôs Proposed Finding No. 156 is incomplete and misleading because the use of a target launch date by Operations does not mean that the particular product is slated for an ñactual product launchò on that date. (CX4023 (Hildenbrand, Dep. at 39-40, 84-85); Engle, Tr. 1754-55, 1771).

Instead, the record indicates that Impax strives to have every product in its generic pipeline ñlaunch readyò at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86); Camargo, Tr. 982; CX4028 (Camargo, Dep. at 59)). This ensures that Impax has the ability meaningfully to consider all options for a product. (CX4014 (Hsu, IHT at 86)). In order to accomplish this, Impax begins

working towards launch preparedness eighteen-months before the earliest possible launch date. (Camargo, Tr. 952-53, 958; CX4023 (Hildenbrand, Dep. at 79)). This process is routine, consistent with industry practice, and is the same for all products. (CX4023 (Hildenbrand, Dep. at 30); Koch, Tr. 271; CX3278-101)). The target launch dates used in this process do not reflect a decision regarding whether or when to launch a product. Instead, Todd Engle, Impaxôs Vice President of Sales and Marketing, would forecast potential launch dates based on the earliest possible date allowed by the Hatch-Waxman Act. (Engle, Tr. 1767, 1769, 1772-73). Mr. Engle and the teams on which he worked did not make a decision regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impaxôs Board of Directors. (Engle, Tr. 1771, 1754-55). The date of a ñproductôs planned actual product launch,ò if at risk, would only be decided by Impax senior management after approval from the Board of Directors. (Koch, Tr. 276-77, 286; CX4026 (Nguyen, Dep. at 56)).

157. For example, Impax used PRMS to plan for the purchasing of raw materials, to allocate labor and plant capacity necessary to manufacture the product, and to assess the safety stock needed to launch a product. (Camargo, Tr. 958-59, 964-65).

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CX5000 at 165-67, 231-38 (¶ 371 & App. D) (Noll Report) (summarizing 27 key forecasts); Camargo Tr. 953-54, 958-59, 964-65 (discussing Operation and Supply Chainôs use of monthly forecasts)).

RESPONSE TO FINDING NO. 158:

Complaint Counselôs Proposed Finding No. 158 is incomplete and misleading because it ignores the actual language in the initial forecast cited, which set out Impaxôs assumptions and noted that any estimate of a mid-2010 launch of oxymorphone ER was ñthe best case scenario; therefore we should not plan on being ready 3 months early.ò (CX2819-001).

Todd Engle, Impaxôs Vice President of Sales and Marketing, created the forecasts. In the case of oxymorphone ER, Mr. Engle used June 2010 as an upside assumption simply because

159. Using the planned launch date fro

RESPONSE TO FINDING NO. 162:

Respondent does not dispute Complaint Counselôs Proposed Finding No. 162, but notes that the Proposed Finding is incomplete and misleading. Impax strives to have every product in its generic pipeline ñlaunch readyò at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)). Joseph Camargo, Impaxôs Vice President of Supply Chain, testified that despite using that estimated launch-ready date, the ñodds of launching [in June 2010] when the 30-month stay expires may be low.ò (RX-181.0001; *see* Camargo, Tr. 1009-10 (ñit didnôt seem likely to me that we would actually launchò in mid-2010 because the company ñtended to shy away fromò at-risk launches)). As of May 25, 2010, the Operations team had stopped their oxymorphone ER preparation efforts completely and shifted capacity to other projects. (CX2904-001 (May 25, 2010, email chain in which Chuck Hildenbrand tells Joe Camargo and others, ñI donôt see the OXM happening in June, lets replace it with more MDDò)). And, by June 2010, the date on which Impax anticipated to be fully ñLaunch Readyò still remained ñTBD.ò (CX2914-003; CX4023 (Hildenbrand, Dep. at 209)).

> 163. Other Impax forecasts also projected an oxymorphone ER launch on June 14, 2010. For example, Impax conducted quarterly launch planning meetings. (Mengler, Tr. 556-58). The quarterly launch planning meetings were generally chaired by a representative from Marketing, and brought together representatives from various Impax groups, including Legal, Regulatory, Marketing, and Operations, to discuss and plan for product launches. (CX4023 (Hildenbrand, Dep. at 68-69); *see, e.g.*

(CX2831). Mr. Engle testified that the document was ña first draftò and he tried ñto give a good range of possibilities and recognizing the fact that I donôt know everything and . . . senior management may have other information I donôt have, s¾M m ‘ MM m mH ‘ Ţ l M ä p

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The third sentence of Proposed Finding No. 167 is inaccurate and not supported by the

RESPONSE TO FINDING NO. 168:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

169. Operations and Supply Chainôs MBO goals for 2010 included achieving a ñnew product launch on the day of ANDA approvalò for the oxymorphone ER product. (CX2899 at 002 (2010 Operations MBOs); CX3069 at 002 (2010 Supply Chain MBOs); Camargo, Tr. 1001-02). Operations oversees the planning, manufacturing, and packaging of products that Impax produces internally to ensure that Impax is ñlaunch-ready.ò (Camargo, Tr. 961-62). The Supply Chain group fell within Operations (collectively ñOperations groupò) and was responsible for coordinating with the Marketing group the resources necessary to meet customer demand for Impax products. (CX4023 (Hildenbrand, Dep. at 10-11); Camargo, Tr. 951, 961-62).

RESPONSE TO FINDING NO. 169:

The first sentence of Complaint Counselôs Proposed Finding No. 169 is incomplete, inaccurate, and misleading. The full quotation from the cited evidence actually reads, ñAchieve new product launch on the day of ANDA approval *without putting Company into unnecessary financial or legal risks*.ò (CX2899-002; CX3069-002 (emphasis added)). Joseph Camargo, Impaxôs Vice President of Supply Chain, testified that achieving the stated objective meant receiving sign off on a process validation report and being ready to execute a launch inventory build if management so instructed. (Camargo, Tr. 1033-34). The stated objective was also consistent with Impaxôs efforts to have every product in its generic pipeline ñlaunch readyò at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)).

not launch oxymorphone ER until 2013, due to the Impax-Endo Settlement Agreement. (Camargo, Tr. 1001-02; CX4028 (Camargo, Dep. at 208-11); CCF ¶¶ 203-04, 208-09, below).

RESPONSE TO FINDING NO

of both labor and plant capacity, that could cause, therefore, disruption to other products requiring adjustments in planning.ò (CX4023 (Hildenbrand, Dep. at 43-44)). In fact, Mr. Hildenbrand rejected Complaint Counselôs suggestion that the specific production of oxymorphone ER required ña substantial amount of resources,ò stating only that it would require ñ[n]ot insignificantò resources. (CX4023 (Hildenbrand, Dep. at 140)).

Respondent has no specific response to the second sentence of Proposed Finding No. 172.

> 173. As a small, resource-constrained company, Impax had to make difficult decisions about how to allocate its manufacturing capacity. (CX4038 (Engle, Dep. at 189-91, 192)). Despite the potential impact on the production of other products, the Operations group began preparations for the launch of generic oxymorphone ER in June 2010. (Camargo, Tr. 969).

RESPONSE TO FINDING NO. 173:

The first sentence of Complaint Counselôs Proposed Finding No. 173 is not supported by the cited evidence. Mr. Engle did not testify that Impax was a small, resource-constrained company, or that Impax had to make ñdifficult decisionsò about manufacturing capacity. Mr. Engle actually testified that ñI think they [Impax] do that [make decisions about how to allocate resources] every day. I think itôs a constant process of making judgments, what to make, when to make it. . . . Itôs just the nature of demand planning and production scheduling, equipment availability, people availability.ò (CX4038 (Engle, Dep. at 192)).

The second sentence of Proposed Finding No. 173 is incomplete, misleading, and not supported by the cited evidence. Mr. Camargo did not testify that preparing oxymorphone ER had a potential impact on the production of other products. He testified only that in 2009, the supply chain group began planning for the launch of oxymorphone ER because it had entered Impaxôs eighteen-month planning window, (Camargo, Tr. 969), just as Impax does for all

products when they enter the eighteen-month planning window. (CX4023 (Hildenbrand, Dep. at 30)). Moreover, contemporaneous operational documents make clear that, for form ñbeg[inning] preparations for the launch of generic oxymorphone ER in June 2010,ò by May 25, 2010, the Operations team had *stopped* their oxymorphone ER preparedness efforts completely and shifted capacity to other projects. (CX2904-001 (May 25, 2010, email chain in which Mr. Hildenbrand tells Mr. Camargo and others, ñI donôt see the OXM happening in June, lets replace it with more MDDò)).

a) Impax worked with federal agencies and outside parties to purchase raw materials for manufacturing

RESPONSE TO FINDING NO. 175:

Respondent has no specific response.

176. In March 2009, Impax requested oxymorphone quota from the DEA to be used for commercial manufacturing in 2010. (CX4027 (Anthony, Dep. at 68-69)). In December 2009, the DEA denied this request because Impaxôs submission did not justify the need for the requested quota. (CX2874 at 005 (Dec. 23, 2009 letter from the DEA); CX4027 (Anthony, Dep. at 95)).

RESPONSE TO FINDING NO. 176:

Respondent has no specific response.

177. After this initial denial, in January 2010 Impax employees were instructed to follow up with DEA ñaggressivelyò to get the quota because the planned launch for oxymorphone ER was only ñfive months away.ò (CX2866 at 001 (Jan. 12, 2010 email chain)).

RESPONSE TO FINDING NO. 177:

Complaint Counselôs Proposed Finding No. 177 is misleading and not supported by the cited evidence. The cited evidence (CX2866) does not contain an instruction to any employee, but rather a comment by Chris Mengler as follows: ñNote that our currently planned launch is only five months away, so we need to follow up aggressively.ò (CX2866 at 001). Complaint Counsel never asked Mr. Mengler about this comment at trial, deposition, or during his investigational hearing. And when Complaint Counsel asked John Anthony, one of the recipients of the email and the individual at Impax who was responsible for DEA quota requests, about Mr. Menglerôs statement, Mr. Anthony indicated Mr. Menglerôs remark carried no particular importance. (CX4027 (Anthony Dep. at 136) (ñQ: Do you know why you needed to follow up aggressively? A: Well, Chris Mengler, everything he did he wanted to be done quickly or aggressively. Heôs talking about the product launch, so just going along with what

amount of product Impax ñhopedò to sell as a way of justifying Impaxôs request for quota. (CX4027 (Anthony, Dep. at 123)).

The forecast Mr. Anthony ultimately submitted as part of Impaxôs quota request was therefore a truthful and accurate estimate of representation of what Impax *hoped* to sell, and the DEA understood it as such. (CX4027 (Anthony, Dep. at 123)). Moreover, Mr. Anthony ð Impaxôs Senior Director of DEA Compliance for eleven years and a former DEA employee (CX4027 (Anthony, Dep. at 8 & 65) ð did not believe the DEA took such supporting estimates ñat face value to be a hundred percent accurate,ò but rather took them ñinto consideration.ò (CX4027 (Anthony, Dep. at 123) (ñQ: Do you know how DEA would use this chart to make a decision about quota to grant? A: They would take it into consideration. Whether or not they take it at face value to be a hundred percent accurate, itôs mostly an estimate of what they hope to be able to sell.ò)). Consistent with this, Mr. Anthony testified that there would be no ramifications for Impax if such estimates were inaccurate. (*See* CX4027 (Anthony, Dep. at 115-17 & 85-88)). That the launch dates and other aspects of the forecast submitted to the DEA reflected only best estimates of what Impax hoped to sell is supported by the fact that, in later forecasts, the launch date for oxymorphone ER remained an ñobviously controversial element.ò (CX0514-001).

179. Impax also supported its quota request with an email from Meg Snowden, Impaxôs head in-house counsefi ﺓ ’ a

characterizes the email from Ms. Snowden that was submitted as an attachment to Impaxôs quota request. (CX3157). First, nowhere in the cited email ð or in any other portion of CX3157 ð is there a reference to an at-risk launch. While the communication acknowledges the ongoing patent litigation, it does not speak to any patent litigation damages risk at all. Instead, it states that Impax does not expect the patent litigation to end in the near future, but that ñwe do not need [a court decision] in order to obtain FDA approval or launch.ò (CX3157-020). It is in this context, and in the letterôs larger context of providing documentation to support Impaxôs ability to sell oxymorphone ER and therefore acquire oxymorphone API quota, that Ms. Snowden notes that FDA approval is the ñonly legal/regulatory hurdle.ò (*See* CX3157-015-16).

180. In March 2010, the DEA partially granted Impaxôs January quota request. (CX2870 at 002 (Mar. 3, 2010 letter from the DEA) (allowing procurement of additional 147 kg of oxymorphone ñto support commercial manufacturing efforts (validation and launch)ò); CX2868 at 001 (Mar. 9, 2010 email chain); JX-001 at 008 (¶ 26)).

RESPONSE TO FINDING NO. 180:

Respondent has no specific response.

Impax needed. The second sentence is also misleading and unsupported by the cited testimony of Joseph Camargo. Mr. Camargo never mentioned a possible launch in 2010. Mr. Camargo testified that Impax was ñshort ofò API as of May 12, 2010, but ñcould have made some of the additional batches if we got the word to do so.ò (CX4028 (Camargo, Dep. at 172)). Specifically, Impax did not have ñthe desired amountò of API and it was ñnot optimalò for a theoretical launch because ñnormally we have an agreed-upon amount of inventory at the time of launch. And that would have required post PV inventory build lots. And . . . we didnôt have enough at this point in time to complete all those batches. So we would have been launching with less than the targeted amount of inventory.ò (CX4028 (Camargo, Dep. at 172-73); *see* Camargo, Tr. 979-80 (API would leave Impax ña bit under our target amount of three months of inventoryò)). Respondent has no specific response to the third sentence of Proposed Finding No. 181.

> 182. To receive additional commercial manufacturing quota for 2010, John Anthony, the Impax employee responsible for seeking quota from the DEA, advised that Impax would need to submit ñLetters of Intentò (ñLOIsò). (CX2868 at 001 (Mar. 9, 2010 email); CX4027 (Anthony, Dep. at 139)). Letters of intent are written statements by pharmaceutical customers that ñprove to the DEA that the Impax customers will order the Oxymorphone [requested by Impax] in quantities that exceed the Procurement Quota already granted.ò (CX2864 at 001 (Apr. 2, 2010 email chain and LOI)).

RESPONSE TO FINDING NO. 182:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 182. The second sentence of Proposed Finding No. 182 is inaccurate and misleading because it ignores the testimony of John Anthony, the author of the quoted language, who explained that letters of intent are only ñan indication that the customer was willing to consider purchasing a finished product from Impax,ò and ñare not legal documents that bind the customer into any specific quantity of purchase.ò (CX4027 (Anthony, Dep. at 59) (expressly rejecting suggestion that letters of intent are ñas accurate as possibleò); *see* Engle, Tr. 1788

(letters of intent do not cont

documents.ò Moreover, Professor Bazerman did not testify that Impax had an ñactual intention to launchò or that any of Impaxôs actions was consistent with such an intent. He stated only that maintaining confidentiality is inconsistent with bluffing. (Bazerman, Tr. 930-31).

184. Despite these earlier concerns about secrecy, in order to receive additional quota that could sustain the launch of oxymorphone ER, Impax also began working with customers to obtain LOIs as justification for an additional quota request. (CX2868 at 001 (Mar. 9, 2010 Impax email) (ñImpax must submit óLetters of Intent to Purchaseô signed by customers . . . to receive additional 2010 Procurement Quota.ò); CX2864 at 001-05 (Apr. 2010 email chain attaching LOIs); CX2882 (Apr. 2010 email chain attaching LOI)). To secure LOIs, Impax had to tell customers that ñImpax is preparing the launchò of oxymorphone ER in 2010. (CX4038 (Engle, Dep at 153-54); CX4027 (Anthony, Dep. at 81)).

RESPONSE TO FINDING NO. 184:

Respondent has no specific response to Complaint Counselôs Proposed Finding No. 184, other than to note that none of the cited evidence supports the proposition that Impax had ñconcerns for secrecy.ò

185. By April 12, 2010, Impax had received LOIs from four customers. (CX2882 at 001 (Apr. 2010 email chain and LOI) (attaching Walgreensô letter of intent; referencing ABCôs, Cardinalôs, and McKessonôs letters of intent)). The customer commitments in these LOIs represented 88% of t

the packages size, and it asks the customer for their good-faith estimate, is if Impax were to have this product, how much of the product would you be likely to buy, based on their own forecast of how much they need or how much they sell, with the -- the idea is that itôs a good-faith estimate to secure additional quota from DEA.ò); CX4027 (Anthony, Dep. at 59) (letters of intent are ñindication[s] that the customer was willing to consider purchasing a finished product from Impaxò and ñare not legal documents that bind the customer into any specific quantity of purchase.ò); CX4027 (Anthony, Dep. at 59) (expressly rejecting the suggestion from Complaint Counsel that letters of intent are ñas accurate as possibleò); *see* Engle, Tr. 1788 (noting that letters of intent do not contain ñpricing or any agreementò)).

186. On April 15, 2010, Impax submitted an additional supplemental request for oxymophone quota to the DEA, which included the LOIs from Impaxôs customers. (CX3157 at 035-37 (Apr. 15, 2010 Impax letter to DEA); CX2881 at 002-03 (June 15,

Results) (head of operations sharing accomplishments, including ñOxymorphone: approved & ready to launch same day but settled (achieved goal)ò); Koch, Tr. 247, 251-52 (describing goals of ñsuccessfully launchingò oxymorphone ER); CX2562 at 002 (2010 Company Key Goals); Camargo, Tr. 1001-02).

RESPONSE TO FINDING NO. 188:

The first sentence of Complaint Counselôs Proposed Finding No. 188 is misleading and not supported by the cited evidence. Mr. Hildenbrand did not testify about Impax taking any steps toward an at-risk launch. He testified generally about the steps necessary to prepare a new product, and the fact that Impax had completed process validation for oxymorphone ER in 2010. (CX4023 (Hildenbrand, Dep. at 41-42, 155)). Process validation need not be repeated once it is successfully completed and, as a result, the process validation Impax conducted in 2010 could (and did) support a launch after 2010. (*See* CX4010 (Mengler, IHT at 71) (ñitôs a one and done, once you have done process validationò)).

The second sentence of Proposed Finding No. 188 is incomplete and m

RESPONSE TO FINDING NO. 189:

Respondent has no specific response.

190. By October 2009, Impax had added oxymorphone ER to its Product Launch Checklist. (CX2915 at 001, 03 (Oct. 2009 Product Launch Checklist)).

RESPONSE TO FINDING NO. 190:

Respondent has no specific response.

191. As of March 2010, Impax had received enough quota and purchased enough API to enable it to complete process validation for generic oxymorphone ER and launch with ñjust under three months of inventory.ò (CX4028 (Camargo, Dep. at 172-73); *see also* Camargo, Tr. 975-76). Impax, however, desired additional oxymorphone quota from the DEA to sustain demand for the product after launching. (CX4028 (Camargo, Dep. at 172-73); CX2898 at 001 (May 12, 2010 email re: Launch Planning) (ñImpax submitted an additional request in April 2010 for quota ñneeded to sustain the product shortly after launch.ò)).

RESPONSE TO FINDING NO. 191:

The first sentence of Proposed Finding No. 191 is incomplete and misleading. As of May 2010, Impax did not have ñthe desired amountò of API and it was ñnot optimalò for a theoretical launch because ñnormally we have an agreed-upon amount of inventory at the time of launch. And that would have required us to complete all of the post PV inventory build lots. And . . . we didnôt have enough at this point in time to complete all those batches. So we would have been launching with less than the targeted amount of inventory.ò (CX4028 (Camargo, Dep. at 172-73); *see* Camargo, Tr. 979-80 (API would leave Impax ña bit under our target amount of three months of inventoryò)).

The second sentence of Proposed Finding No. 191 is not supported by the cited evidence. The cited evidence does not state that Impax ñdesiredò additional quota to sustain demand for an actual launch. The cited documents state only that Impax would need additional quota in order

to be in a position to launch with ñthe targeted amount of inventory.ò (CX4028 (Camargo, Dep. at 172-73); *see* CX2898).

192. To sell commercial drug products, pharmaceutical manufacturers are required by the FDA to complete process validation. Through process validation, manufacturers seek to demonstrate that their manufacturing process can be scaled up to manufacture commercial size batches, that the process is repeatable, and that the product created is of a satisfactory quality. (Camargo, Tr. 967; CX4023 (Hildenbrand, Dep. at 136-37)). The time it takes to complete process validation can vary from a month to an entire year, depending on the product specifications. (CX4023 (Hildenbrand, Dep. at 144)).

RESPONSE TO FINDING NO. 192:

Respondent has no specific response other than to clarify that process validation can be completed any time before launch and, once successfully completed, need not be repeated. (CX4010 (Mengler, IHT at 71) (ñitôs a one and done, once you have done process validationò)).

193. Process validation concludes with the approval of a ñPV summary report,ò which is reviewed and approved by various departments within Impax. (CX4028 (Camargo, Dep. at 171); CX4023 (Hildenbrand, Dep. at 136-37)). Process validation must be complete before a product is launched. (Camargo, Tr. 967).

RESPONSE TO FINDING NO. 193:

Respondent has no specific response.

194. The batches that are manufactured as part of process validation can be sold commercially as part of the launch inventory. (Camargo, Tr. 967; CX4023 (Hildenbrand, Dep. at 137-38)). However, if process validation batches are not sufficient to meet projected demand, Impax will manufacture additional product for a launch. (Camargo, Tr. 967-68).

RESPONSE TO FINDING NO. 194:

Respondent has no specific response.

195. The terms ñinventory buildò and ñlaunch inventory build,ò as used by Impax personnel, include process validation batches among the commercial product needed for the initial launch. (CX4023 (Hildenbrand, Dep. at 137-39); CX2898 (May 12, 2010 Camargo email); Camargo Tr. 967-68; CX4028 (Camargo, Dep. at 51-52)).

RESPONSE TO FINDING NO. 195:

Complaint Counselôs Proposed Finding No. 195 is inaccurate. The evidence is clear that the phrase ñlaunch inventory buildò refers to the product ñmanufactured after the PV summary report is signed off on.ò (Camargo, Tr. 968 (ñQ. The launch inventory build is the additional product manufactured when the process validation batches are not enough to meet your expected needs to launch the product, correct? A. Thatôs correct, and they would be manufactured after.ò); CX4028 (Camargo, Dep. at 51-52) (same); CX2898 (despite process validation complete, ñwe will not commence the launch inventory build until we receive direction to do so from senior mgmt.ò)).

196. As of May 11, 2010, using the API it already had on hand, Impax aimed to complete manufacturing of the launch inventory build by May 28, 2010. (Camargo Tr. 985-86).

RESPONSE TO FINDING NO. 196:

Complaint Counselôs Proposed Finding No. 196 is inaccurate and misleading. The cited testimony says nothing about using the API on hand to do anything, but rather speaks to theoretical goals in one document that Mr. Camargo noted was not necessarily up to date. (Camargo, Tr. 985-86). Looking beyond this snippet of testimony about a single line item in a single Excel spreadsheet, the record ð including several contemporaneous documents ð actually indicates that Impax stopped its launch preparedness efforts in May 2010. (*See, e.g.*, CX2904-001 (May 25, 2010 email chain in which Chuck Hildenbrand tells Joe Camargo and others, ñI donôt see the OXM happening in June, lets replace it with more MDDò)). For example, as early as May 7, 2010, the Supply Chain Group reported that they would not begin a launch inventory build until they were instructed by senior management. (RX-186.0004 (ñWe are then await [sic] management decision to proceed with 8-lot launch inventory build.ò); Camargo, Tr. 1016-17

(ñAt that point, we need management decision and direction to proceed with the launch inventory build.ò)). Again on May 12, 2010, Mr. Camargo indicated that ñwe will not commence the launch inventory build until we receive direction to do so from senior management.ò (CX2898). The plan was to wait for directions from senior management before beginning a launch inventory build. (Camargo, Tr. 1017).

On May 25, 2010, Impaxôs senior director of operations, Chuck Hildenbrand, instructed Mr. Camargo, to shift manufacturing resources to another product, noting that ñI donôt see the OXM happening in June.ò (CX2904-001; Camargo, Tr. 1017-18). Mr. Camargo responded that he had already ñadvised the team that it was unlikely that we would make the Oxymorphone.ò (CX2904-001; *see* Camargo, Tr. 1020 (ñI 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 thatò)). And according to a June 8, 2010, planning document, the date on which Impax anticipated to be ñLaunch Readyò still remained ñTBD.ò (CX2914-003; CX4023 (Hildenbrand, Dep. at 209)).

197. By May 12, 2010, Impax had manufactured

decision and direction to proceed with the launch inventory build.ò)). Again on May 12, 2010, Mr. Camargo indicated that ñwe will not commence the launch inventory build until we receive direction to do so from senior management.ò (CX2898-001). The plan was to wait for directions from senior management before beginning a launch inventory build. (Camargo, Tr. 1017).

On May 25, 2010, Impaxôs Senior Director of Operations, Chuck Hildenbrand, instructed Mr. Camargo to shift manufacturing resources to another product, noting that ñI donôt see the OXM happening in June.ò (CX2904-001; Camargo, Tr. 1017-18). Mr. Camargo responded that he had already ñadvised the team that it was unlikely that we would make the Oxymorphone.ò (CX2904-001; *see* Camargo, Tr. 1020 (ñI had been given no direction at that point in time to actually execute the product launch, and it seemed unlikely to

have enough at this point in time to complete all those batches. So we would have been launching with less than the targeted amount of inventory.ò (CX4028 (Camargo, Dep. at 172-73); *see* Camargo, Tr. 979-80 (API would leave Impax ña bit under our target amount of three months of inventoryò)).

> 199. On May 13, 2010, the day Impax received tentative FDA approval, CEO Larry Hsu instructed the head of Impaxôs Operations department to ñmove on with our next step of preparation for launch.ò (CX2929 at 001 (May 2010 Impax email chain)). At that point, the team needed only about two more weeks to finalize the launch inventory manufacturing. (CX2929 at 001 (May 2010 Impax email chain)). This included making six lots of product in addition to the product that was manufactured as part of process validation once the PV summary report was finalized. (CX2929 at 001 (May 2010 Impax email chain); CX2898 (May 12, 2010 Camargo email) (PV batches were already manufactured)).

RESPONSE TO FINDING NO. 199:

The first and second sentences of Complaint Counselôs Proposed Finding No. 199 are incomplete and misleading. The full statement quoted in the first sentence is, ñLetôs move on with our next step of preparation for launch . . . *the court stuff[] should occur timely enough for us to build inventory*.ò (CX2929-001 (emphasis added; ellipsis in original)). The quoted language attributed to Dr. Hsu, moreover, was actually written by Chris Mengler. With respect to timing, the document actually states that ñ*[i]f we elect to move forward*, it will take about 2 weeks to complete mfg and 1-2 weeks, if we push for QC/QA release.ò (CX2929-001 (emphasis added)). Finally, the document also indicates that Impax ñlikely [] will make launch decision based on court decision on the PI.ò (CX2929-001).

The Proposed Finding selectively quotes and characterizes the document in an effort to avoid the documentsô plain language indicating that Impaxôs launch preparation efforts were on hold, pending additional information regarding the patent litigation. This is supported by extensive evidence that, as of May 2010, Impax had stopped its oxymorphone launch

preparedness efforts ð before e

Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second, third, and fourth sentences of Proposed Finding No. 201 other than to clarify that there is no cited evidence supporting when the brite-stocking occurred. The cited evidence states only that *by* May 20, some batches had been brite-stocked. The record is clear that the Operations team had already stopped their oxymorphone ER preparation efforts. (RX-186.0004 (May 7, 2010, email noting awaiting management instruction before further preparation); CX2898-001 (same on May 12, 2010); CX2904-001 (by May 25, 2010, Operations had shifted resources to another product ñadvised the team that it was unlikely t

do so from senior managementò); Camargo, Tr. 1016-17, 1020 (ñAt that point, we need management decision and direction to proceed with the launch inventory build.ò)).

c) Impax had to discard over $1.3 million of manufactured oxymorphone ER product

203. As the Opana ER settlement discussions progressed, Impaxôs preparations for a June 2010 oxymorphone ER launch were postponed. (CX3062 (May 26, 2010 Mengler email) (instructing Operations to postpone packaging oxymorphone ER); CX0320 at 001 (May 26, 2010 email to Mengler with initial term sheets from Endo)). Eventually, Impaxôs efforts to complete manufacturing of the launch inventory batches were stopped ñin view of [the Endo/Impax] settlement.ò (CX2542 (June 9-10, 2010 email chain on oxymorphone quota); Camargo, Tr. 989, 991; *compare* CX2914 at 003 (June 8, 2010 Product Launch Checklist) (listing oxymorphone ER as ñDROPPEDò because of the settlement) *with* CX3078 at 003 (May 11, 2010 Product Launch Checklist) (listing oxymorphone ER ñLaunch Readyò date as Jun. 14, 2010)).

RESPONSE TO FINDING NO. 203:

The first sentence of Complaint Counselôs Proposed Finding No. 203 is inaccurate, misleading, and not supported by the cited evidence. CX3062 does not contain an instruction to any employee, refer to any settlement discussions, or make any reference to a launch of oxymorphone ER. It simply states, ñNo rush to pack oxym.ò (CX3062). This is consistent with the numerous emails about halting oxymorphone launch preparedness efforts well before Impax and Endo began discussing settlement in 2010. (*See, e.g.*, RX-186.0004 (May 7, 2010, email: ñWe are then await [sic] management decision to proceed with 8-lot launch inventory build.ò); Camargo, Tr. 1016-17 (ñAt that point, we need management decision and direction to proceed with the launch inventory build.ò); CX2898-001 (May 12, 2010, email: ñwe will not commence the launch inventory build until we receive direction to do so from senior management.ò)).

The second sentence of Proposed Finding No. 203 is inaccurate and misleading. It offers a misleadingly selective quotation from CX2542, which reflects Impax withdrawing a pending DEA quota request ð not Impax aborting some ongoing launch preparation or launch build

effort ð to ñcreate good willò with the DEA. The second sentence also selectively quotes one-word answer from Mr. Camargoôs trial testimony, (Camargo, Tr. 989), ignoring the more in depth discussion of this issue in Mr. Camargoôs contemporaneous documents and elsewhere in his trial testimony. (*See, e.g.*, CX2905 (ñlaunch inventory build was ready to start should management give the go-ahead.ò); Camargo, Tr. 1016-17 (ñAt that point [May 12, 2010], we need management decision and direction to proceed with the launch inventory build.ò)). The record further reflects that, as of May 24, 2010, Mr. Camargo has already ñadvised the team that it was unlikely that we would make the Oxymorphone.ò (CX2904-001).

> 204. But for the settlement, Impax would have been ñready to launch [on the] same dayò as ANDA approval in June 2010. (CX2899 at 002 (2010 Operations MBOs); CX4028 (Camargo, Dep. at 205-06)).

RESPONSE TO FINDING NO. 204:

Complaint Counselôs Proposed Finding No. 204 is incomplete, inaccurate, and misleading. The cited document (CX2899) states that the Operations teamôs objective was to, ñAchieve new product launch on the day of ANDA approval *without putting Company into unnecessary financial or legal risks*.ò (CX2899-002; CX3069-002 (emphasis added)). Joseph Camargo, Impaxôs Vice President of Supply Chain, testified that achieving the stated objective meant receiving sign off on a process validation report and being ready to execute a launch inventory build if management so instructed. (Camargo, Tr. 1033-34). The stated objective was also consistent with Impaxôs efforts to have every product in its generic pipeline ñlaunch readyò at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)).

Impax, moreover, would not have actually been ñready to launchò until it manufactured the launch inventory build, which required management authorization. Yet as early as May 7,

2010, the Supply Chain Group had stopped preparedness efforts because it had not received instructions from management. (RX-186.0004 (ñWe are then await [sic] management decision to proceed with 8-lot launch inventory build.ò); Camargo, Tr. 1016-17 (ñAt that point, we need management decision and direction to proceed with the launch inventory build.ò)). Again on May 12, 2010, Mr. Camargo indicated that ñwe will not commence the launch inventory build until we receive direction to do so from senior management.ò (CX2898-001). This meant that the plan was to wait for directions from senior management before beginning a launch inventory build. (Camargo, Tr. 1017).

And by May 25, 2010, the Operations group had shifted its resources to another product, noting that ñI donôt see the OXM happening in June.ò (CX2904-001; Camargo, Tr. 1017-18). Mr. Camargo explained that he had already ñadvised the team that it was unlikely that we would make the Oxymorphone.ò (CX2904-001). Mr. Camargo testified that ñgiven 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.ò (Camargo, Tr. 1020).

> 205. Ultimately, the Executive Committee never asked the Impax Board one way or the other to reach a decision for an at-risk launch of oxymorphone ER. (JX-003 at 011 (¶ 70); Koch, Tr. 332; Snowden, Tr. 470; CX2704 at 018-19 (Impax Objection and Response to Interrogatory No. 10)). Before the Board was asked to make any at-risk launch decision, Impax entered the Impax-Endo Settlement Agreement on June 8, 2010. (JX-001 at 009 (¶ 33); Koch, Tr. 299, 333-35).
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> **RESPONSE TO FINDING NO. 205:**

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 205. The second sentence of Proposed Finding No. 205 is inaccurate and not supported by the cited evidence in its attempt to suggest the Executive Committee was

134) (emphasis added)). Later in the proceeding, Mr. Engle clarified that discarding product because Impax sought to be prepared for all possible outcomes ñfalls under the category of cost of doing business in weighing all your options and all your -- your options, your risks,ò and that no one ñgot in troubleò as a result of discarded oxymorphone ER. (CX4004 (Engle, IHT at 181)). Mr. Engle also testified that write offs of this magnitude were not unusual at Impax, and provided another example of when Impax incurred a $1.5 million loss as a ñcost of doing business.ò (CX4004 (Engle, IHT at 182) (citing caprofen example, and noting other situations in which this likely occurred)).

At trial, Mr. Engle reiterated this point when he testified unambiguously that ñ[t]hrowing away product or discarding product in about a 1.5 million range happens frequently and it ð itôs not unusual.ò (Engle, Tr. 1785-86). Other witness testimony supports the fact that discarding products or materials was ña matter of course pretty much every month.ò (Camargo, Tr. 1020-21, 1033; *see* Koch, Tr. 273 (discarding and writing off product is a routine and ñsmall costò of doing business)). For example, over $1 million in non-oxymorphone ER products was written off in April 2010, and $560,000 worth of non-oxymorphone ER product was written off in June 2010. (CX2905-003; CX2896-002-03; Camargo, Tr. 1023-24)). Impax also discarded and wrote off roughly $25 million in finished product in 2017. (Engle, Tr. 1786).

207. Forecasting and planning by Impax personnel tried to be accurate to minimize the chance that Impax would have to throw away large amounts of manufactured product because the product expired before being sold. (CX4004 (Engle, IHT at 133-34)). Operations was evaluated on the cost of products that had to be discarded. (CX2899 at 003 (2010 Operations Objectives) (discussing COGS and cost of rejected batches); CX4023 (Hildenbrand, Dep. at 198)).

RESPONSE TO

misleading because it ignores the testimony of Mr. Hildenbrand, who explained that the evaluation related only to ñvariable pay[and] Bonus targets,ò not Operationsô overall performance. (CX4023 (Hildenbrand, Dep. at 198)). Even then, whether the discarding of product will impact bonus compensation depends on the reason for discarding the product, and that if such a loss occurs as a result of generally accepted costs of doing business, it generally will not negatively affect compensation. (CX4023 (Hildenbrand, Dep. at 199-200) (ñif a decision is made whether it [is] due to risk or opportunity to not to launch, we donôt get approval, whatever it is, but we were rea

RESPONSE TO FINDING NO. 208:

Complaint Counselôs Proposed Finding No. 208 is inaccurate and misleading. The first sentence is misleading because the referenced product was not discarded ñdue to the Impax-Endo Settlement Agreement.ò The Settlement and License Agreement did not require Impax to discard any materials; these materials were discarded because of expiration dates. (Camargo, Tr. 998). Indeed, Impax was able to use much of the API it had purchased for its 2013 launch. (Camargo, Tr. 1022).

The second sentence of Proposed Finding No. 208 is an inaccurate and misleading characterization of Mr. Engleôs testimony during his investigational hearing. During that proceeding, Mr. Engle spoke about discarding ñproduct because it expired *because [he] over-projected*ò the amount of the product that needed to be manufactured. (CX4004 (Engle, IHT at 134) (emphasis added)). Later in the proceeding, Mr. Engle clarified that discarding product because Impax sought to be prepared for all possible outcomes ñfalls under the category of cost of doing business in weighing all your options and all your -- your options, your risks,ò and that no one ñgot in troubleò as a result of discarded oxymorphone ER. (CX4004 (Engle, IHT at 181)). Mr. Engle also testified that write offs of this magnitude were not unusual at Impax, and provided another example of when Impax incurred a $1.5 million loss as a ñcost of doing business.ò (CX4004 (Engle, IHT at 182) (citing caprofen example, and noting other situations in which this likely occurred)).

At trial, Mr. Engle reiterated this point when he testified unambiguously that ñ[t]hrowing away product or discarding product in about a 1.5 million range happens frequently and it ð itôs not unusual.ò (Engle, Tr. 1785-86). Other witness testimony supports the fact that discarding products or materials was ña matter of course pretty much every month.ò (Camargo, Tr. 1020-

21, 1033; *see*

assessing whether the relevant objective was met. (CX2899-002). That brought the cost of discarded product in 2010 to 2.1 percent of COGS. (CX2899-003). Mr. Hildenbrand explained that it did so because, in essence, Impax expects this type of loss as a cost of preparedness efforts: ñif a decision is made whether it [is] due to risk or opportunity to not to launch, we donôt get approval, whatever it is, but we were ready to have that loss counted against usò before the product was ever made, then it could be deducted from the relevant COGS evaluation. (CX4023 (Hildenbrand, Dep. at 198)). As Impaxôs CEO at the time of settlement explained, ñin order to make sure whatever the discussion or the decision is meaningful, you have to have a supply ready. Then you can talk about [possible launches]. . . . [Y]ou have to have material ready. Then you decide which way you want to go.ò (CX4030 (Hsu, Dep. at 86)). Discarding and writing off products under these circumstances is a routine and ñsmall costò of doing business. (Koch, Tr. 273).

> 211. Impaxôs 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. (CX4023 (Hildenbrand, Dep. at 8, 95-97)).

RESPONSE TO FINDING NO. 211:

Complaint Counselôs Proposed Finding No. 211 is an incomplete, inaccurate, and misleading description of Mr. Hildenbrandôs testimony. Mr. Hildenbrand was asked, ñon how many occasions did operations manufacture product for a launch date the company decided not to launch and the product had to be destroyed?ò (CX4023 (Hildenbrand, Dep. at 95-96)). Mr. Hildenbrand testified that he had ñno ability to kind of give you an exact numberò or an estimate, but that the company had at least done so with respect to a methylphenidate product. (CX4023 (Hildenbrand, Dep. at 96)). Moreover, nothing the evidence cited (or the record generally)

213. The Operations group was only able to meet the 2010 MBO regarding rejected product by excluding the oxymorphone ER product from the normal COGS calculation. (CX2899 at 003 (2010 Operations Objectives)).

RESPONSE TO FINDING NO. 213:

Complaint Counselôs Proposed Finding No. 213 is inaccurate, incomplete, and misleading. Mr. Hildenbrand explained that Impax excluded oxymorphone ER form the calculation because, in essence, Impax expects this type of loss as a cost of preparedness efforts: ñif a decision is made whether it [is] due to risk or opportunity to not to launch, we donôt get approval, whatever it is, but we were ready to have that loss counted against usò before the product was ever made, then it could be deducted from the relevant COGS evaluation. (CX4023

several Impax-Endo settlement communications that occurred before October 14, 2009, when the first communication regarding any ñpotential transactionò or ñpotential areas of mutual business interestò took place. (*See* CX1301-110).

> 215. In order to facilitate the settlement discussions, including the partiesô evaluation of a potential side deal, Impax and Endo executed a confidential disclosure agreement (ñCDAò) on October 13, 2009. (RX-359 at 0006 (Oct. 13, 2009 emails between Doug Macpherson and Meg Snowden); CX1816 at 002-04 (executed CDA); RX-284 at 0001 (Nov. 3, 2009 emails from Cobuzzi and Mengler)). In the CDA, Impax and Endo ñrecognize and agree that any statements made by the parties or their counsel are part of settlement discussionsò and that they cannot use any information exchanged ñfor any purpose whatsoever other than settling the partiesô current disputes.ò (CX1816 at 003-04 (CDA ¶ 9)).

RESPONSE TO FINDING NO. 215:

To the extent that Complaint Counselôs Proposed Finding No. 215 suggests the October 13, 2009, CDA was executed ñin order to facilitate the settlement discussions,ò it is incorrect and not supported by the cited evidence. (Nor does RX-284 contain ñNov. 3, 2009 emails from Cobuzzi to Menglerò described in the parenthetical for that exhibit).

The executed CDA indicates on its face that the parties entered into the agreement ñin view of the . . . stated intentionsò that they ñare interested in entering into discussions which would involve the mutual exchange of information relating to a possible business transaction (the ñTransactionò) and which will include information that is confidential to the respective parties.ò (CX1816-002 (CDA preamble)). Nowhere does the CDA suggest the purpose of the agreement was ñto facilitate settlement discussions.ò The cited portions of the CDA provide only that the discussions about a possible business transaction are ñpart of settlement discussions.ò (CX1816-003 (CDA ¶ 9)).

> 216. Under the CDA and as part of the settlement talks in October and November 2009, Impax and Endo discussed partnering together on a deal concerning Endoôs migraine drug, Frova, as part of a potential settlement of the patent infringement

litigation. (RX-284 at 0001 (Nov. 3, 2009 emails from Cobuzzi and Mengler); CX0310 at 004 (Impax CID Response)).

RESPONSE TO FINDING NO. 216:

Complaint Counselôs Proposed Finding No. 216 is incomplete and misleading. Impax and Endo communicated regarding a

218. Settlement discussions ceased following a final teleconference on December 7, 2009. (CX1301 at 112 (Endo CID Response)). Discussions on any side business deal ended as well. (CX0310 at 003-04 (Impax CID Response); Snowden, Tr. 495 (discussion around Frova never resulted in a deal)).

RESPONSE TO FINDING NO. 218:

Respondent has no specific response.

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B. After Impax received tentative approval, settlement discussions began again

219. Settlement negotiations resumed in May 2010 after Endo learned that the FDA tentatively approved Impaxôs ANDA for generic oxymorphone ER. (CX0310 at 004 (Impax CID Response); CX1301 at 112 (Endo CID Response); CX0513 at 001 (May 13, 2010 Impax internal email from Michelle Wong re tentative approval)).

RESPONSE TO FINDING NO. 219:

Respondent does not dispute that Endo and Impax reinitiated settlement negotiations in May 2010, but the cited evidence does not support the assertion that settlement negotiations were reinitiated after (or because) Endo learned of tentative approval.

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RESPONSE TO FINDING NO. 221:

Respondent has no specific response.

222. By that time, Impax knew that Endo already had agreed to a 2011 entry date for at least one 2011 generic oxymorphone ER. (CX4003 (Snowden, IHT at 56-57)). On February 20, 2009, Endo announced it had reached its first settlement concerning generic Opana ER in its patent infringement suit against Actavis. The following business day, news of the Actavis settlement was made public and circulated among Impaxôs top executives. (CX0309 at 001-02 (internal Impax email attaching analyst report on Endoôs settlement with Actavis)). Impax knew that Endo had granted Actavis a license to the asserted patents beginning on July 15, 2011, which was approximately midway between the 2009 expiration of Endoôs new dosage form exclusivity and the expiration of the asserted patents in August 2013. (CX0309 at 001-02).

RESPONSE TO FINDING NO. 222:

Respondent has no specific response.

223. Thus, at the time Impax obtained tentative approval on May 13, 2010, Impax was thinking about trying to get a settlement with Endo with a generic entry date in January 2011, rather than launching at risk in June 2010. (CX0505 at 001 (May 13-14, 2010 Mengler-Hsu e-mail chain)).

RESPONSE TO FINDING NO. 223:

Complaint Counselôs Proposed Finding No. 223 is not supported by the cited evidence. The cited document (CX0505) says nothing about an at-risk launch, and certainly not an at-risk launch in June 2010. With respect to Impaxôs ñthinking,ò the document states ñI want to consider pros and cons on postponing the launch of Oxymorphone in January 2011.ò (CX0505-001).

224. But Chris Mengler, President of Impaxôs Generics Division, was concerned about postponing Impaxôs generic oxymorphone ER launch. As he informed Larry Hsu, Impaxôs CEO, ñthe cost of Jan ó11 is lost/delayed sales ï you know what they [s]ay about a bird in the hand...ò (CX0505 at 001) (May 14, 2010 Mengler email)). But when Dr. Hsu asked Mr. Mengler ñWhat if we can settle with Endo for January 2011 launch with No AG?ò, Mr. Mengler replied: ñSettlement ---- different story. Iôd love that !!!!ò (CX0505 at 001 (emphasis in original)).

RESPONSE TO FINDING NO. 226:

Respondent has no specific response.

227. From the beginning of the renewed negotiations, Endo offered compensation in exchange for Impaxôs agreement to stay off the market until 2013. (CX0320 (May 26, 2010 Endo term sheets)).

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RESPONSE TO FINDING NO. 228:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 228. Respondent has no specific response to the second sentence of Proposed Finding No. 228 other than to clarify that the cited evidence does not support the proposition that the suggested Parkinsonôs collaboration was a ñside deal.ò The record is clear that the Development and Co-Promotion Agreement, was a ñstand-alone legal document[].ò (CX4017 (Levin, Dep. at 157-58); *see* Koch, Tr. 313-14 (Impax assessed and considered DCA and SLA as standalone agreements ñall the timeò); CX4036 (Fatholahi, Dep. at 138-39)). Accordingly, both Endo and Impax assessed the Development and Co-Promotion Agreement independently from the Settlement and License Agreement. (Koch, Tr. 313 (Impaxôs CEO ñwas very clear that each agreement should be evaluated on their own merits as a standalone agreementò); CX4001 (Koch, IHT at 41) (DCA was ña separate negotiation that came up during settlement negotiationsò); Mengler, Tr. 586; CX4017 (Levin, Dep. at 159); CX4031 (Bradley, Dep. at 196)).

229. Mr. Donatiello sent the term sheets to Mr. Mengler and Ms. Snowden following a discussion of their contents that morning and more than week of discussions and a significant exchange of information pertaining to IPX-066. (CX0320 at 001 (May 26, 2010 Endo term sheets); RX-272 at 0001-03 (May 19-22, 2010 Paterson/Cobuzzi email exchange and attached list of IPX-066 data made available to Endo)).

RESPONSE TO FINDING NO. 229:

Respondent has no specific response to Complaint Counselôs Proposed Finding No. 229 other than to clarify that the cited evidence does not support the proposition that Mr. Donatiello, Mr. Mengler, and Ms. Snowden had more than a week of discussions.

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Mr. Mengler that the confidential disclosure agreement the parties entered as part of settlement negotiations in the fall of 2009 was still effective. (CX1816 at 001).

RESPONSE TO FINDING NO. 232:

Respondent has no specific response.

236. On May 22, 2010, Dr. Paterson provided Dr. Cobuzzi and a number of additional Endo employees with access to a ñdata roomò with ña large amount of IPX 066 related documents.ò (RX-272 at 0001-02 (May 19-22, 2010 Paterson/Cobuzzi email exchange)). The documents covered: (i) intellectual property/legal; (ii) chemistry, manufacturing, and controls (ñCMCò); (iii) commercial; (iv) regulatory; (v) clinical; (vi) clinical pharmacology; and (vii) Impaxôs unredacted confidential presentation on IPX-066. (RX-272 at 0001(May 19-22, 2010 Paterson-Cobuzzi email exchange)).

RESPONSE TO FINDING NO. 236:

Respondent has no specific response.

237. On May 26, 2010, one of the two term sheets Mr. Donatiello sent to Impax proposed an option agreement concerning IPX-066 ñand all improvements, modifications, derivatives, formulations and line extensions thereof.ò (CX0320 at 002 (May 26, 2010 Endo term sheets)). The term sheet gave Endo the option to receive either the right to co-promote the product within the U.S. or to purchase an exclusive license to the product in the U.S. (CX0320 at 003). Endo would pay Impax a $10 million ñOption Feeò upon signing the agreement and a $5 million milestone fee upon the FDAôs acceptance of the NDA for the product. (CX0320 at 003).

RESPONSE TO FINDING NO. 237:

Respondent has no specific response.

238. If Endo elected the co-promotion option, Endoôs right to co-promote IPX-066 would be limited to ñareas outside the practice of neurology.ò (CX0320 at 004 (May 26, 2010 Endo term sheets)). Endo would receive a fee of 50% of net sales prescribed by those outside the practice of neurology. (CX0320 at 004).

RESPONSE TO FINDING NO. 238:

Respondent has no specific response.

239. If Endo elected the license option, Endo would pay Impax a one-time fee equal to five times the average of the productôs projected sales for its first three years post-approval. (CX0320 at 004-05 (May 26, 2010 Endo term sheets)). In return, Impax would x l' p þ .

The fifth sentence of Proposed Finding No. 240 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endoôs Senior Director of Marketing and the individual often responsible for Endo forecasts, including the cited exhibit (CX3445). Mr. Bingol testified that Endo always forecast ña num

and the United States for a new oral formulation of long-acting oxymorphone, which is designed to be crush resistant.ò)).

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Mr. Mengler told Mr. Levin he thought Endo had ña secret plan to damage the market.ò (CX0217 at 001 (June 2, 2010 email from Mengler to Smolenski)). Mr. Levin denied that Endo was planning to reformulate, assuring Mr. Mengler: ñóChris, I promise we have no plans to not continue to pursue our existing formulation.ôò (CX0117 at 002 (Aug. 9, 2010 email from Mengler re Endoôs announcement of application for Reformulated Opana ER)); *see also* CX4010 (Mengler, IHT at 41) (ñSitting this close, looked me right in the eye, and told me, óWe are absolutely not switching this product. I promise you, Chris.ôò)).

RESPONSE TO FINDING NO. 249:

Respondent has no specific response.

250. Despite Endoôs proclamations that it did not plan to move the Opana ER market, Impax sought contractual provisions to address the possibility. Impaxôs fear ñthat Endo had a strategy in place that would have led to the elimination of the Opana ER marketò was a ñvery significant business issue[]ò that would have been a ñdeal-breaker[]ò for Impax. (CX4010 (Mengler, IHT at 20-21)). As Impax ñlearned more about the market, something that didnôt protect us from the downside was becoming a deal-breaker.ò (CX4010 (Mengler, IHT at 44)).

RESPONSE TO FINDING NO. 250:

Respondent has no specific response.

1. Initially, Impax sought a market degradation acceleration trigger

251. Impax first proposed to address its concern with an acceleration trigger for market degradation. After receiving Endoôs May 26th term sheets, Impax responded by proposing a January 1, 2013 license entry date, with the No-AG provision and ñcertain acceleration triggers, including market degradation to any alternate product.ò (CX1305 at 001 (May 27, 2010 email from Mengler to Levin)).

RESPONSE TO FINDING NO. 251:

Respondent has no specific response, except to clarify that Endo had already offered the No-AG provision in Endoôs opening term sheet. (*See* CX0320 (May 26, 2010 email to Mengler with initial term sheets from Endo)).

252. An acceleration provision for market degradation would allow Impax to launch its generic oxymorphone ER product earlier than January 1, 2013 in the event that Opana ER brand sales fell by a certain amount or percentage. (CX4010 (Mengler, IHT at 33-34)). Impax wanted a market acceleration provision as ñprotection in case Endo had any

intentions of moving the market to a next-generation product.ò (CX4032 (Snowden, Dep. at 104)). Impax had included similar provisions in other patent settlements with brand companies. (CX4003 (Snowden, IHT at 121-22)).

RESPONSE TO FINDING NO. 252:

The second sentence of Complaint Counselôs Proposed Finding No. 252 is an incomplete and misleading quotation from Ms. Snowdenôs testimony, which is as follows: ñQ. And do you remember what was the rationale that Impax provided as to why it wanted that acceleration trigger?... A. As a corporate designee, Impax said it wanted that as protection in case Endo had any intentions of moving the market to a next-generation product. ***Impax said it was important***

still coming out and Iôm going to take this market out as quickly as I can and sell as much product as I can, but if youôre not telling me the truth, youôre going to pay me what I would have made anyway.ò (CX4010 (Mengler, IHT at 36)). This was ña carrot and a stick approachò to incentivize Endo to make investments in its original Opana product and ensure Impax had a measure of control over its generic opportunity. (Koch, Tr. 23

insistence is due to a known strategy to reduce the market. This may be a sticking point.ò (CX1308 at 001 (June 2, 2010 email from Mengler to Levin)).

RESPONSE TO FINDING NO. 256:

Respondent has no specific response.

257. Despite Impaxôs reservations, the parties reached an agreement in principle, including a make whole payment, on the afternoon of June 3, 2010. (CX3334 at 001 (Levin reporting that Endo had ñreached a handshake agreement with Impax); CX4012 (Donatiello, IHT at 139) (ñEndo and Impax reached an agreement in principal [*sic*] around midday on June 3rd.ò); CX0114 at 001 (June 3, 2010, email from Mengler reporting that ñ[i]t seems all parties internally are good to goò)). After Endo had agreed to the make whole payment provision, Impax ñstop[ped] pursuing an earlier launch date.ò (CX4018 (Koch Dep. at 71)).

RESPONSE TO FINDING NO. 257:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 257. The second sentence of Proposed Finding No. 257 is inaccurate, misleading, and not supported by the cited evidence. Mr. Koch actually testified that ñWhat we did was

1, 2010, summary of terms with proposed license date of February 1, 2013, and Endo Credit);

of the market at that generic entry date could be different than what they had previously expected or assumed, and so the provision was intended to insulate them from that sort of risk or reduce

Tr. 631, 673; CX4017 (Levin, Dep. at 96-98); Noll, Tr. 1649 (neither Endo nor Impax forecast or planned for a payment under the settlement)).

259. Each party negotiated to make the provision more financially favorable for themselves. (*See* CCF ¶¶ 260-69, below).

RESPONSE TO FINDING NO. 259:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

260. In a teleconference, Mr. Mengler told Mr. Levin that Impax would accept the alternative of the make-whole payment in place of an acceleration trigger, but all assumptions would have to be in Impaxôs favor and Endo would have to agree to ñaggressive numbers.ò (Snowden, Tr. 386).

RESPONSE TO FINDING NO. 260:

Respondent has no specific response other than to clarify that Ms. Snowden did not testify about a ñmake-whole payment,ò only a ñcredit.ò (Snowden, Tr. 386).

261. Roberto Cuca, Endoôs Vice President of Financial Planning & Analysis, was tasked with developing the Endo Credit provision on behalf of Endo. (CX4035 (Cuca, Dep. at 68-69); Cuca, Tr. 612, 614-15). Mr. Cucaôs ñgoal was to make the provision be as beneficial to Endo as possible.ò (CX4035 (Cuca, Dep. at 96)). Mr. Cuca looked for ways to ñimprove the economic effect of this provision to Endo.ò (CX4035 (Cuca, Dep. at 96-97)).

RESPONSE TO FINDING NO. 261:

Respondent has no specific response.

262. Endo drafted the first iteration of the make-whole provision, which it included in the first draft of the SLA it sent on Friday June 4, 2010. (CX0323 at 001, 012 (June 4,

2010 email from Mr. Donatiello sending attached draft SLA; draft SLA § 4.4)). Under Endoôs initial proposal, Endoôs obligation to pay Impax a cash amount would be triggered if the amount of oxymorphone active pharmaceutical ingredient (ñAPIò) shipped in the Opana ER strengths for which Impax was first to file fell below a set threshold from the peak consecutive three-month sales period between the SLAôs effective date and the fourth quarter of 2012. (CX0323 at 006-07, 12 (June 4, 2010 draft SLA § 4.4 and definitions of ñPre-Impax Amount,ò ñThree Month Shipment Amount,ò and ñTrigger Thresholdò)).

RESPONSE TO FINDING NO. 262:

Respondent has no specific response other than to clarify that the draft settlement agreement did not contain the term ñmake-whole provision.ò (CX0323-012).

263. The amount Endo would be obligated to pay, however, depended on Impaxôs sales during its six-month No-AG exclusivity period. The lower Impaxôs net profits during the exclusivity period, the lower the amount Endo was obligated to pay; if Impax did not or could not launch and sell generic oxymorphone ER, then the amount Endo would have to pay Impax would be $0. (CX0323 at 006-07, 12 (June 4, 2010 draft SLA § 4.4 and definitions of ñImpaxôs Net Profit,ò ñImpax Product,ò ñExclusivity Period, ñPre-Impax Amount,ò and ñTrigger Thresholdò) (ñIf the Pre-Impax Amount is less than

> Endo that ñif youôre not telling me the truth [about switching the market], youôre going to pay me what I would have made anyway.ò)).

RESPONSE TO FINDING NO. 264:

Complaint Counselôs Proposed Finding No. 264 is inaccurate and not supported by the cited evidence. Neither Ms. Nguyen nor Mr. Mengler testified about an early formulation of the Endo Credit, or whether such a formulation failed its so-called purpose. Moreover, Proposed Finding No. 264 ignores that the ini

RESPONSE TO FINDING NO. 268:

Respondent has no specific response.

269. Second, though Endo largely agreed to Impaxôs proposed approach for calculating the amount to be paid if the Endo Credit was triggered, Endo wanted the amount to reflect Impaxôs expected profits during the No-AG exclusivity period, rather than Impaxôs expected revenues. (CX2771 at 005-06, 14 (June 6, 2010 draft SLA § 4.4,

273. The Endo Credit in the executed SLA provided that Endo would be obligated to pay Impax a cash amount if Endoôs Original Opana ER dollar sales (as calculated by units multiplied by the WAC price) fell by more than 50% from the ñQuarterly Peakò (the highest sales quarter between Q3ô2010 and Q3ô2012) to the fourth quarter of 2012 (the quarter before Impax would be permitted to launch its generic oxymorphone ER product). (RX-364 at 0003-06, 12 (SLA § 4.4, definitions of ñEndo Credit,ò ñMarket Share Profit Factor,ò ñMarket Share Profit Value,ò ñPre-Impax Amount,ò ñPrescription Sales,ò ñQuarterly Peak,ò and ñTrigger Threshholdò)).

RESPONSE TO FINDING NO. 273:

Respondent has no specific response.

274. If Endoôs obligation to pay the Endo Credit was triggered, the amount would approximate the net profits Impax would have expected to make during its six-month No-AG exclusivity period had Endo not moved the market to a new formulation. The provision achieved this by basing the calculation in part on the expected generic substitution rate (90%), the expected generic price (75% of the brand WAC price), Impaxôs net profit margin (87.5%), and the length of the No-AG exclusivity period (50%, or 180 days expressed as half a year). (RX-364 at 0004 (SLA § 4.4, definitions of ñMarket Share Profit Valueò); *see also* Cuca, Tr. 635-37). By including Impaxôs net profit margin rather than just looking to Impaxôs expected revenues, any amount Endo would be required to pay was reduced by 12.5%. (RX-364 at 0004 (SLA § 4.4, definitions of ñMarket Share Profit Valueò); Cuca, Tr. 640-41).

RESPONSE TO FINDING NO. 274:

The first sentence of Complaint Counselôs Proposed Finding No. 274 is not supported by any record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). The first sentence of the Proposed Finding No. 274 is also wrong. Actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their quarterly peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales

RESPONSE TO

RESPONSE TO FINDING NO. 284:

Complaint Counselôs Proposed Finding No. 283 is misleading and incomplete in its discussion of the SLA sections 4.1(a) (the License) and 4.1(d) (referring to additional good faith negotiations to amend the License) without referencing the broad Covenant Not to Sue set forth in SLA section 4.1(b). (RX-364.0009-11 (SLA §§ 4.1(a), 4.1(b), 4.1(d))). No evidence suggests section 4.1(d) has any effect on section 4.1(b)ôs Covenant Not to Sue, which covered any patents licensed to Endo or Pennwest that ñcover or potentially could coverò the manufacture or sale of Opana ER. (RX-364.0010 (SLA §§ 4.1(b))).

G. Impax switched the side deal subject from IPX-066 to IPX-203 and demanded greater milestone payments

1. Initially, Impax and Endo discussed an IPX-066 side deal

285. As discussed above (¶¶ 232-39), from the outset of the renewed settlement discussions, Impax and Endo began discussing a side deal in which Endo would collaborate with Impax on IPX-066, Impaxôs treatment for Parkinsonôs disease that was in the last stage of clinical development prior to be ready to submit an NDA to the FDA.

RESPONSE TO FINDING NO. 285: C8

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondents

287. Endo began work on an Opportunity Evaluation Worksheet (ñOEWò) to assess a potential collaboration on IPX-066 on May 20, 2010 (CX1006 at 001 (Endo internal email)), but did not complete it prior to sending the term sheet to Impax on May 26, 2010. (CX1704 (May 24, 2010 draft OEW); CX2775 (May 27, 2010 email forwarding the incomplete OEW)).

RESPONSE TO FINDING NO. 287:

Respondent has no specific response.

288. Endo rushed to review IPX-066 and to prepare an offer to Impax.

(RX-072 at 0004 (May 21, 2010 email to Equinox) (*in camera*).

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[redacted] (RX-072 at 0001 (Endo emails with Equinox (*in camera*)). [redacted] (RX-072 at 0001) (*in camera*).

RESPONSE TO FINDING NO. 289:

Complaint Counselôs Proposed Finding No. 289 is incomplete and misleading in its selective description of Equinoxôs market research. Subsequent portions of the cited document indicate that [redacted] (RX-072.0001). And the sentence Complaint Counsel selectively quotes actually states: [redacted] (RX-072.0001 (emphasis added)). The cited document also refers to [redacted] (RX-072.0004).

290. On May 25, 2010, Dr. Cobuzzi continued to press his team to get a review done quickly, warning R&D employees that ñ[w]e have very little time for this evaluation ï ie, we need to have a perspective by EOB [end of business] *this* Thursday.ò (CX1007 at 001 (Cobuzzi email re IPX066) (emphasis in original)). Dr. Cobuzzi asked that they not ñstart sending me a lot of disparaging emails or slandering me personally for the condensed timeline for this review.ò (CX1007 at 001).

RESPONSE TO FINDING NO. 290:

Respondent has no specific response other than to clarify that the document states ñthis should not be a difficult evaluation.ò (CX1007-001; Cobuzzi, Tr. 2548-49 (discussing CX1007 and explaining ñI didnôt think this was going to be difficult to evaluateò because ñ[w]e knew the space, we knew the underlying molecules, the carbidopa and levodopa, and we looked at a number of Parkinsonôs opportunities in the pastò)).

291. As discussed above (¶ 228, 237-39), on May 26, 2010, Endo sent a term sheet for an IPX-066 side deal to Impax, proposing an option agreement for IPX-066 in which Endo would pay Impax $10 million upfront and $5 million upon the FDAôs acceptance of an NDA in exchange for the right to either purchase an exclusive license to the product or to co-promote the product to non-neurologists. (CX0320 at 002-04 (May 26, 2010 Endo term sheets)). Equinox did not send its estimate of the percentage of Parkinsonôs patients diagnosed (37%) and managed (40%) by non-neurologists until after Endo had sent the term sheet to Impax. (CX1009 at 001, 008 (May 26, 2010 email from Equinox to Cobuzzi attaching ñStrategic Insightsò presentation)).

RESPONSE TO FINDING NO. 291:

To the extent the first sentence of Complaint Counselôs Proposed Finding No. 291 attempts to incorporate and summarize other findings, it should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Moreover, the individual findings cited are misleading or incomplete for the reasons set out in Respondentôs replies to those findings. In any event, the first sentence of Proposed Finding No. 291 is misleading and incomplete in (1) its suggestion that Endoôs initial May 26, 2010, term sheet proposed ñan IPX-066 side deal,ò when the term sheet refers to the entire IPX-066 franchise and does not link the potential collaboration to settlement; and (2) its failure to acknowledge that the proposed terms called for Endo to receive 50 percent of all the profits from sales generated by non-neurologist prescriptions. (CX0320).

The second sentence of Proposed Finding No. 291 is incomplete and misleading in its suggestion that Endo did not independently have knowledge about Parkinsonôs disease or the number of prescriptions written by non-neurologists. The record reflects that Endo had extensive experience vetting potential Parkinsonôs disease products, which included performing market research on the Parkinsonôs disease market. (Cobuzzi, Tr. 2548-49).

2. Impax switched the subject of the side deal from IPX-066 (a late-stage product) to "IPX-066a"/IPX-203 (a preclinical product)

292. On May 26 and 27, 2010, after a week

professional respect, he thought it would be doable, and that was good enough for meò; noting Dr. Gupta has ñdone a number of product developments where he has basically taken an existing chemical compound and improved it and then had those products come to market and been very successful commercial productsò); CX4033 (Nestor, Dep. at 82-83) (describing Dr. Gupta as a renowned formulator)). Finally, Mr. Nestor went on to note in his email to Mr. Mengler mM p M

proposal also called for Endo to receive all profits from sales generated by non-neurologists.

(*See* RX-387 (ñor they co-promote to Impax targets, *retaining 100%*ò) (emphasis added)).

297. On June 2, 2010, Mr. Levin clarified that Endoôs offer for ñ066aò was for an upfront payment of $10 million and single additional milestone payment of $5 million upon successful completion of Phase II. (CX1011 (June 2, 2010 Levin email to Mengler)). If Endo elected to exclusively in-license the compound, Endo would pay Impax fives the projected first four years of sales (rather than three years) as well as give Impax a co-promote on 10% of the total promotion effort. (CX1011).

RESPONSE TO FINDING NO. 297:

Respondent has no specific response.

298. As discussed above (¶ 257), on June 3, 2010, Mr. Mengler and Mr. Levin reached an agreement in principle, which covered both the license terms and the side deal. (CX3334 at 001 (Mr. Levin reporting that Endo had ñreached a handshake agreement with Impaxò); CX0412 (Donatiello, IHT at 139) (ñEndo and Impax reached an agreement in principal [*sic*] around midday on June 3rd.ò); CX0114 at 001 (June 3, 2010, email from Mr. Mengler reporting that ñ[i]t seems all parties internally are good to goò); Cobuzzi, Tr. 2632-33 (SLA and DCA comprised a ñpackage of dealsò)).
(CX0114 at 001 (June 3, 2010 Mengler email to Nestor) (partially *in camera*); CX0407 at 001-02 (June 3, 2010 Mengler email to Hsu et al. re Status)). Mr. Mengler felt the ñproposal balances the interests of the business with our FTF [first-to-file] status.ò (CX0407 at 001-02 (June 3, 2010 Mengler email to Hsu et al. re Status)).

RESPONSE TO FINDING NO. 298:

Respondent has no specific response.

299. The parties reached this agreement in principle even though Impax had yet to provide any information on the drug or even provide the productôs actual code name. Mr. Mengler had ñasked about an 066a resourceò (CX1308 (June 2, 2010 Mengler email to Levin)), but had yet to provide the name of a resource or any written materials to Endo. On June 3, 2010, Mr. Mengler asked Mr. Nestor, President of Impaxôs Branded Division, for ña person for Endo to speak with on 066a,ò warning that ñotherwise were [*sic*] done.ò (CX0114 at 002 (June 3, 2010 Mengler email to Nestor)). Mr. Mengler needed someone from Impax to provide Endo ñany info so they can ócheck the box.ôò (CX0114 at 001 (June 3, 2010 Mengler email to Nestor); *see also* CX2948 at 001 (June 3, 2010 Nestor email to Gupta re Endo Contact Person) (ñNeed to give Endo a contact person for 066A (L-dope ester concept) for development aspects of drug.ò)).

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RESPONSE TO FINDING NO. 303:

Respondent has no specific response.

5. Endo completed its review of IPX-203 within days

304. Despite Mr. Mengler notifying Endo of the switch to ñ066aò on May 27 (RX-565 at 0001) and Endo agreeing to the switch on June 1, 2010 (RX-387 at 0001 (June 1, 2010 Mengler internal email recapping the ñcurrent proposalò); CX1011 (June 2, 2010 Levin email to Mengler)), Mr. Levin did not immediately inform Dr. Cobuzzi or his team. On June 1, 2010, Dr. Cobuzzi sent the latest draft of the IPX-066 OEW = ' e aobuzzi

understanding IPX-203, and ñtremendously valuableò to Endo in assessing IPX-203. (Cobuzzi, Tr. 2625-26, 2602).

305. Even after Dr. Cobuzzi was notified of the change (CX1011 (June 2, 2010 Levin email to Mengler)), Dr. Cobuzziôs team continued to evaluate the IPX-066 opportunity. (CX3338 (June 3, 2010 Pong email and attached Project Imperial Due Diligence

309.

(CX2780 at 001

(June 5, 2010 Cobuzzi email to Levin et al.) (*in camera*

RESPONSE TO FINDING NO. 311:

Respondent has no specific response.

312. The Endo team worked on an OEW for IPX-203 on Monday, June 7, 2010, and Dr. Cobuzzi sent a final OEW to the Endo Board of Directors on the evening of June 8, 2010. (CX1209 at 001 (June 8, 2010 Cobuzzi email to Endo BoD attaching final Imperial OEW)).

RESPONSE TO FINDING NO. 312:

Complaint Counselôs Proposed Finding No. 312 is misleading and not supported by the cited evidence to the extent it attempts to imply that the Endo team began preparing an OEW for IPX-203 on Monday June 7, 2010. The cited document (CX1209) does not reflect when the Endo team began work on the document, but rather when it was circulated to the Endo Board of Directors.

H. Endo and Impax entered the Settlement and License Agreement and the Development and Co-Promotion Agreement

1. Impax and Endo finalized the settlement

313. The patent infringement trial began on Thursday June 3, 2010. (CX2759 at 022 (*Endo v. Impax* docket sheet minute entry for bench trial held on June 3, 2010)). Once informed that the parties had reached an agreement in principle, the presiding judge adjourned the trial until the following week, stating that she would resume trial on Tuesday, June 8 unless the parties were able to reach a definitive settlement agreement by

RESPONSE TO FINDING NO. 314:

Respondent has no specific response.

315. Early on the morning of Tuesday, June 8, 2010, Mr. Donatiello notified Ms. Snowden that the Endo signature pages for both agreements were ñin placeò and that he would call his counsel ñin a few hours to release them.ò (CX3186 at 001 (June 8, 2010 Donatiello email)). Endo did not want to release the signature pages until Sandoz, another generic manufacturer seeking to market oxymorphone ER, had signed a separate settlement agreement with Endo. (CX3186 at 001).

RESPONSE TO FINDING NO. 315:

Respondent has no specific response.

316. On the morning of June 8, 2010, outside counsel for Endo sent the Endo signature pages for both the SLA and the DCA to Impaxôs outside counsel, but requested that Impaxôs counsel hold the signature pages in escrow ñpending our instructions to release them.ò (CX3332 at 001 (June 8, 2010 Watkins email and attachments). Endo ultimately

this discount from Penwest as ña way of sharing .... the costs of the settlement with a partner who benefits from the sales of the product.ò (CX4035 (Cuca, Dep. at 109-10)).

RESPONSE TO FINDING NO. 318:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 318. The second sentence of Proposed Finding No. 318 lacks foundation, is speculative, and not supported by the cited evidence. Mr. Cuca testified that he did not recall a reduction of royalties to Penwest in association with the Opana ER settlement. (CX4035 (Cuca, Dep. at 108) (ñQ. Do you have any understand of why you were looking to reduce the royalty with Penwest? . . . THE WITNESS: I donôt.ò); CX4035 (Cuca, Dep. at 109) (stating that a document regarding Penwest royalties ñdoesnôt refreshò his recollection about reductions in Penwest royalties)). He nevertheless was asked ñwhy would Endo be seeking a royalty reduction,ò to which he said it ñ*potentially*ò was a way to share costs. (CX4035 (Cuca, Dep. at 109-10) (emphasis added)).

319. Penwestôs ñcontribution to [Endoôs] settlement agreementò with Impax was to ñforego [*sic*] royalty income from expected future sales of Opana ER in amount capped at $8.75 million.ò (CX3133 at 001 (June 7, 2010 emails from Levin and Good re Penwest Royalties); *see also* CX3043 at 001 (June 7, 2010 Levin email re Penwest) (ñPenwest have agreed to an $8 million royalty credit as part of their contribution to the settlement agreement on Opana ER litigation.ò)). The royalty reduction was ñfrontloaded to capture more than 90% of the benefit before Impax launch their generic in January 2013.ò (CX3043 at 001 (June 7, 2010 Levin email re Penwest)).

RESPONSE TO FINDING NO. 319:

Respondent has no specific response.

3. Endo paid Impax the $10 million upfront payment

320. Though Impax would have to wait until 2013 to receive value from either the No-AG provision or the Endo Credit, the upfront payment guaranteed Impax immediate cash in June 2010. In accordance with Section 3.1 of the DCA, Endo owed Impax $10 million within five business days of the DCAôs effective date. (RX-365 at 0009 (DCA § 3.1 and preamble)). When Endo had failed to pay Impax by June 23, 2010,

RESPONSE TO FINDING NO. 321:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1. The No-AG provision and the Endo Credit worked together to ensure that Impax would receive value from the settlement

322. Under § 4.1(c) of the SLA, Impaxôs license for generic Opana ER was exclusive during Impaxôs 180-day first-filer exclusivity period for five dosage strengths. (RX-364 at 0010 (SLA § 4.1(c)) (Impaxôs license during the Exclusivity Period for five dosages was ñexclusive as to all but (i) the Opana ER® Product and any Opana ER®-branded products that are not sold as generic products and (ii) generic products covered by agreements executed by Endo and/or Penwest and a Third Party [...] prior to the Effective Dateò)).

RESPONSE TO FINDING NO. 322:

Complaint Counselôs Proposed Finding No. 322 is incomplete and misleading. The plain language from Section 4.1(c) indicates the license ñshall be exclusive as to all *but* (i) the Opana ER® Product and any Opana ER® branded products that are not sold as generic products *and* (ii) generic products covered by agreements executed by Endo and or Penwest and a Third Party that holds an ANDA referencing the Opana® ER Product as of or prior to the Effective Date.ò (RX-364.0010 (emphasis added); *see* CX3164-0009-10 (ñnothing in the Opana ER Settlement Agreement prohibited Endo from lowering the price of its Branded Opana ER Product to compete with Impaxôs Generic Oxymorphone ER Productò)).

323. This provision in § 4.1(c) meant that Endo could not sell an authorized generic product of the five relevant dosages until the exclusivity period ended. (CX3164 at 009-10 (Impax Response to Request for Admission No. 15)).

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325. To address this concern, Impax and Endo developed the Endo Credit, an insurance-like provision under which Endo would make Impax whole by paying for the lost profits that Impax would have made during its exclusivity period. (Mengler, Tr. 533 (ñwhere the market was in fact destroyed, I at least wanted to be made whole for the profits that we would have otherwise achieved); Koch, Tr. 265-66 (testifying that Impax ñviewed [the Endo Credit] as insuranceò because Impax had a reasonable outcome almost no matter what Endo did)).

RESPONSE TO FINDING NO. 325:

Complaint Counselôs Proposed Finding No. 325 is incomplete and misleading. Mr. Menglerôs actual answer was ñin the absence of an acceleration trigger . . . we needed an

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RESPONSE TO FINDING NO. 329:

Respondent has no specific response other than to clarify that Endo agreed to an ñupfront paymentò ñin consideration for the rights granted to Endo hereunder [the DCA].ò (RX-365.0009).

330. On June 24, 2010, Impax received a wire transfer from Endo with the upfront payment. (CX0327 at 0001 (email entitled ñRE: Upfront paymentò from R. Cooper dated Jun. 24, 2010, stating that ñpayment has been wired to your account per your instructionsò); Snowden, Tr. 400).

RESPONSE TO FINDING NO. 330:

Respondent has no specific response.

331. The $10 million upfront payment was not refunded when Endo and Impax terminated the DCA. (Snowden, Tr. 408).

RESPONSE TO FINDING NO. 331:

Respondent does not dispute that the $10 million payment was not refunded, but Proposed Finding No. 331 is inaccurate and misleading in its attempt to suggest that the payment should have been refunded. (Snowden, Tr. 409 (ñJUDGE CHAPPELL: Let me go back to one of your previous questions. Is it the governmentôs position th

RESPONSE TO FINDING NO. 332:

333. Complaint Counselôs Proposed Finding No. 332 is inaccurate. Under the SLA, Impax received a license to launch its generic oxymorphone ER product no later than the date certain of January 1, 2013. However, Impaxôs settlement license also permitted it to launch free from patent risk earlier under certain circumstances, specified in the agreement. (See RX-364.0001-02, 09 (SLA §§ 1.1, 4.1(a)) (defining the ñCommencement Dateò for license granted with several alternatives)).In section 3.2 of the SLA, Impax agrees ñnot to, prior to the applicable Commencement Date, directly or indirectly market, offer to sell, sell, import, manufacture or have manufactured in or for the [United States] any Opana® ER Generic Product.ò (RX-364 at 0007 (SLA § 3.2)). For the 5mg, 10mg, 20,mg, 30mg, and 40mg dosage strengths, the Commencement Date is defined as the earliest of (i) January 1, 2013; (ii) 30 days after a final federal court decision that the Opana ER Patents are invalid or unenforceable or not infringed by an ANDA version of Original Opana ER; or (iii) the date Endo and/or Penwest withdraws patent information (RX-364 at 0001-02 (SLA § 1.1)).

RESPONSE TO FINDING NO. 333:

Respondent has no specific response.

334. The parties to the SLA agreed that, if Impax breached the provisions of section 3.2, Endo would ñsuffer immediate and irreparable injury not fully compensable by monetary damages and for which the other Parties may not have an adequate remedy at lawò and Endo could seek injunctive or other equitable relief. (RX-364 at 0019-20) (SLA § 9.7)).

RESPONSE TO FINDING NO. 334:

Respondent has no specific response.

335. Through these provisions of the reverse-payment settlement, Impax and Endo eliminated the possibility of generic oxymorphone ER entry prior to January 1, 2013, including the possibilities that Impax would launch at risk (*see* CCF ¶¶ 336-60, below), that Impax would launch after a successful final court decision (*see* CCF ¶¶ 361-77, below), and that other generics would launch to compete against branded Opana ER (*See* CCF ¶¶ 378-87, below).

RESPONSE TO FINDING NO. 335:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally,

RESPONSE TO FINDING NO. 338:

Complaint Counselôs Proposed Finding No. 338 is unsupported by the cited testimony and inconsistent with the record. In the cited testimony of Mr. Koch, Mr. Koch responded in the affirmative to Complaint Counselôs question whether an at-risk launch was ñunder considerationò at Impax at that time. The quotation attributed to Mr. Koch was actually a question from Complaint Counsel. This testimony, taken in context, reflects that Impax ñconsideredò an at-risk launch only as part of a general decision-making and routine forecasting processes. Specifically, Mr. Koch testified that Impax considered an at-risk launch in the sense that it ñevaluatedò it. (Koch, Tr. 247). Elsewhere in Mr. Kochôs testimony, he confirmed that Impax never intended to launch oxymorphone ER at-risk. (Koch, Tr. 324-25 (ñJUDGE CHAPPELL: Are you a hundred percent certain you would be aware of whether or not Impax planned an at-risk launch of Opana ER? WITNESS: Absolutely. I would have a key role in that. JUDGE CHAPPELL: Do you know in fact whether Impax intended an at-risk launch of Opana ER? . . . THE WITNESS: I do know. JUDGE CHAPPELL: Did they intend to do an at-risk launch of Opana ER? THE WITNESS: No.ò); *see also* Koch, Tr. 310 (Impax would only consider an at-risk launch after a favorable court ruling)).

In the case of oxymorphone ER, Impax attempted to ñlook[] at different various scenariosò and tried ñvery hard to . . . describe the possible outcomes under any number of different assumptions.ò (Koch, Tr. 299-300; *see* Mengler, Tr. 553 (financial projections did not ñimply or mean that any legal decision ha[d] been made to clear the way for a launchò); Mengler, Tr. 584 (forecasting ñalert[s] the board as to the product being out there that might get to the point of an at-risk launch, so that was itò)). This modelling is intended to inform and facilit] m x я ING

regarding launch dates. (Engle, Tr. 1720 (ñdescribing forecasting as a ñtoolò and a ñstarting point, which senior management can use to make their judgments and decisionsò); Engle, Tr. 1771 (Engle not involved in launch decisions); Mengler, Tr. 553 (financial modelling based on assumed launch date does not ñimply or mean that any legal decision ha[d] been made to clear the way for a launch.ò); Koch, Tr. 299-300 (Impax merely tried to ñlook[] at different various scenariosò and attempt ñvery hard to . . . describe the possible outcomes under any number of different assumptions.ò)). Indeed, in the case of oxymorphone ER, Impax modelled a set of assumptions involving a June 2010 launch date even when that date remained an ñobvious[] controversial element.ò (CX0514-001).

Consistent with this, Larry Hsu, Impaxôs founder and former CEO, explained that evaluating an at-risk launch was part of a larger process that looks at all options in making a launch decision, in order to be able to defend any potential course of action to Impaxôs Board of Directors later on. (CX4041 (Hsu, IHT at 129-30) (ñWe could settle, we could launch at risk, we could do many other things, and as the job of CEO, I just have to, you know, lay out everything, get prepared so I don't get accused by the board and say, well, wait a minute, how come you didn't prepare for plan B?ò); CX4041 (Hsu, IHT at 130) (ñQ: So, as of May 13th, 2010, Impax was at least considering the possibility of an at-risk launch for Oxymorphone ER? A. Yes, thatôs one of the options, absolutely.ò)). Moreover, contemporaneous documents make clear that such ñevaluationò of all possible ñoptionsò does not suggest an at-risk launch was likely to occur, or that Impax intended to launch oxymorphone ER at risk. To the contrary, in contemporaneous documents, Dr. Hsu noted that ñitôs unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reasons)ò (CX-297.0002; p ı ı ı tha ä A D

340. The Impax Board of Directors had a meeting on May 24-25, 2010 at which the status of generic Opana ER was discussed. Mr. Mengler, the president of the generics

oxymorphoneô s opportunity had anything to do with an at-risk launch, as Proposed Finding No. 341 attempts to imply.

342. A recommendation from management to launch would have been a significant factor in the Boardôs decision. In fact, the Impax Board of Directors has never rejected a formal at-risk launch recommendation by Impax management. (CX3164 at 019 (Impax Response to Request for Admission No. 43)).

RESPONSE TO FINDING NO. 342:

The first sentence of Complaint Counselôs Proposed Finding No. 342 is not supported by any record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 342 other than to clarify that the cited document states only that the Board of Directors had not rejected a formal launch-at-risk recommendation by Impax Management ñprior to June 8, 2010.ò (CX3164-019).

343. With respect to generic Opana ER, the Impax Board of Directors never reached a decision either to launch, or not to launch, generic Opana ER at risk. (Koch, Tr. 332). The Impax Board was never asked one way or the other. (Koch, Tr. 332).

RESPONSE TO FINDING NO. 343:

Respondent has no specific response.

344. Between 2001 and 2015, there have been at least 48 generic pharmaceuticals launched at risk in the United States. (CX5004 at 092-115 (Exhibit 4) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 344:

Complaint Counselôs Proposed Finding No. 344 is incomplete and misleading. While there have been forty-eight at-risk launches over a fifteen year period, twenty-one of those

launches were conducted by Teva, which Professor Noll explains ñis by far the most likely company to do at-risk launches.ò (Noll, Tr. 1608-09; *see* Hoxie, Tr. 2820 (Teva has ña high willingness to take risks and ña greater appetite for risk than othersò)). Only four at-risk launches over the fifteen-year period were conducted by companies with less than $1 billion in revenue. (Noll, Tr. 1609). And 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).

345. Generic companies launch at risk often enough that branded pharmaceutical companies take at-risk launches very seriously in their plannin

The second sentence of Proposed Finding No. 345 is incomplete and misleading. The record is clear that Impax undertook at-risk launches only under unique circumstances and always with limits on its potential exposure. Impax launched a generic version of oxycodone only after it received a favorable district court decision holding the relevant patents unenforceable. (Snowden, Tr. 425-26; Koch, Tr. 275). Impax launched the product in only one dosage strength, and only after Teva, the first ANDA filer for the relevant dosage, had launched at risk six months earlier. (Snowden, Tr. 425; Noll, Tr. 1609-10). And Impax limited its risk of damages by capping its potential sales at $25 million. (Koch, Tr. 275). Impax launched an azelastine product only after its development partner notified Impax that it intended to conduct the launch and Impax limited its participation to 150,000 units. (Snowden, Tr. 462, 464-65; CX4021 (Ben-Maimon, Dep. at 37-39); CX2689 (Minutes of a Special Meeting of the Board of Directors of Impax Laboratories, Inc.)).

The second sentence of the Proposed Finding also violates this Courtôs Order on Post-Trial Briefs to the extent it cites ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò

346. With respect to Opana ER, Endo recognized the threat that an at-risk launch by Impax posed to Endoôs Opana ER sales and took steps to react with an authorized generic in the event of an at-risk launch. (*See* CCF ¶¶ 347-51, below).

RESPONSE TO FINDING NO. 346:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

347. Contemporaneous with the SLA being negotiated in late May and early June 2010, Endo businesspeople prepared profit and loss scenario models that included multiple scenarios assuming a generic launch in July 2010. (CX3011 at 001, 004-05 (email chain entitled ñOpana ER/IR P&L Scenario Model,ò dated May 21-25, 2010); CX3443 at 001-02 (email with revised and updated models, dated May 26, 2010); CX3009 at 003 (email chain entitled ñOpana ER Combined P&L scenarios ï Jul-10 generics.xlsx,ò dated June 1, 2010)).

RESPONSE TO FINDING NO. 347:

Complaint Counselôs Proposed Finding No. 347 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endoôs Senior Director of Marketing, and Roberto Cuca, Endoôs Vice President of Financial Planning and Analysis. Mr. Bingol testified that the estimates were based on ñmanyò assumptions and Endo was looking at ñany possible scenario.ò (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 (ñWe have to consider all scenariosò)). Indeed, Mr. Bingol explained that Endo forecasts were ñbased on scenarios that we had created, I mean, the accuracy of which are always debatable.ò (Bingol, Tr. 1303). And many of the assumptions were actually total unknowns. (Bingol, Tr. 1307 (ñJUDGE CHAPPELL: Okay. Well, I donôt want you to guess[], so according to this document, whatever those claims were you didnôt know. THE WITNESS: Well, we would be -- thatôs correct.ò); Cuca, Tr. 662-63).

In the case of Opana ER, Endoôs ñbase caseò and ñlatest best estimateò did not assume generic entry. (CX4035 (Cuca, Dep. at 62) (discussing CX3009)). Indeed, in the spring of 2010, Endo knew ñthere had been ANDAs filed for generic versions of Opana ER,ò but believed ñthere was not imminently at that point going to be a generic.ò (Cuca, Tr. 643). But Endo still forecast different scenarios regarding the future of its Opana ER product to ñanalyze the full range of potential outcomes.ò (Cuca, Tr. 663-64).

348. Finally, all of the hypothetical scenarios at issue in these documents discuss a possible authorized generic in response to what would necessarily be an at-risk generic launch in 2010. No documents or testimony address whether, let alone suggest that, Endo would launch an authorized generic under other circumstances, such as in response

to Impax (or another generic) launching pursuant to a settlement license.Each such model that Endo created showed large declines in sales following a generic launch. (CX3011 at 005 (email chain entitled ñOpana ER/IR P&L Scenario Model,ò dated May 21-25, 2010); CX3443 at 001-02 (email with revised and updated models, dated May 26, 2010); CX3009 at 003 (email chain entitled ñOpana ER Combined P&L scenarios ï Jul-10 generics.xlsx,ò dated June 1, 2010)).

RESPONSE TO FINDING NO. 348:

Complaint Counselôs Proposed Finding No. 348 is inaccurate. The cited documents do not ñshowò declines, they merely ñassumedò lost sales. (CX3011-004 (discussing ñkey assumptionsò including different scenarios, including ñsteep erosion of branded businessò); CX3009-003 (same); CX3443 (showing what sales would be under various ñerosionò scenarios)). Indeed, the record is clear that Endo created financial forecasts to look at ñany possible scenario.ò (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 (ñWe have to consider all scenariosò)). Endo did so to ñanalyze the full range of potential outcomes.ò (Cuca, Tr. 663-64).

349. One of these models was to be included in a ñconsolidated viewò to be reviewed by the Board. (CX3009 at 001 (email chain entitled ñOpana ER Combined P&L scenarios ï Jul-10 generics.xlsx,ò dated June 1, 2010)).

RESPONSE TO FINDING NO. 349:

Respondent has no specific response.

350. On June 1, 2010, Endo projected that it would lose $71.2M in branded ER sales if Impax launched its generic version of Opana ER on July 1, 2010. (CX1314 (Levin/Cuca email chain, dated June 1, 2010)). Endo also projected that if it launched an authorized generic version of Opana ER on the same day as Impaxôs launch, it would gain $25 million in authorized generic sales. (CX1314 (Levin/Cuca email chain, dated June 1, 2010)). Endo planned to be ready to launch an authorized generic if Impax launched a generic version of Opana ER. (*See* CCF ¶¶ 84-92, above).

354. Endoôs actions during negotiations further raised concerns at Impax about possible reformulation of Opana ER. For example, Endo rejected Impaxôs proposed acceleration trigger (something that was commonly seen in settlements) and insisted on keeping a 2013 entry date. Impaxôs lead negotiator at that time, Mr. Mengler, interpreted these positions as ñtroubling,ò adding to his concern that Endo was planning on reformulating Opana ER. (Mengler, Tr. 568). A reformulation by Endo presented a significant risk to Impax because sales of Impaxôs generic would be largely driven by Endoôs brand sales, due to automatic substitution at pharmacies

Original Opana ER had been withdrawn because of safety reasons. (Snowden, Tr. 479-80 (a finding that Original Opana ER was withdrawn for safety reasons ñwould have prevented Impaxô launchò); C

2910). And 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). The record, however, is clear that those damages can be in the billions of dollars, (Hoxie, Tr. 2782), and can result in bankruptcy, (Koch, Tr. 287 (generic entry before patent expiration can be a ñbet-the-companyò undertaking and can ñtake the solvency of the company entirelyò); CX4030 (Hsu, Dep. at 43) (ñthe risk can be huge depending on the size of the product and depending on whether weôre the first to fileò)).

The Proposed Finding also is inaccurate and misleading in its suggestion that Impax would ñdelayò launch. The record is clear that Impax never intended an at-risk launch. (Koch, Tr. 324-25 (ñJUDGE CHAPPELL: Are you a hundred percent certain you would be aware of whether or not Impax planned an at-risk launch of Opana ER? WITNESS: Absolutely. I would have a key role in that. JUDGE CHAPPELL: Do you know in fact whether Impax intended an at-risk launch of Opana ER? . . . THE WITNESS: I do know. JUDGE CHAPPELL: Did they intend to do an at-risk launch of Opana ER? THE WITNESS: No.ò)). Impaxôs CEO at the time of settlement, Larry Hsu, made the same point: ñitôs unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reason[s]).ò (RX-297.0002; *see* Hoxie, Tr. 2768, 2770 (opining Impax would not launch without a favorable court decision)).

> 357. Based on these factors, if Impax had received a favorable decision at the district court level, a launch prior to the appellate decision could be a reasonable risk from Impaxôs perspective, taking into account the countervailing risks of delay. (CX5007 at 024 (¶ 44) (Hoxie Rebuttal Report)).

RESPONSE TO FINDING NO. 357:

Complaint Counselôs Proposed Finding No. 357 violates this Courtôs Order on Post-Trial Briefs to the extent it cites ñto expert testimony to support factual propositions that should be

365. For example, whether Endoôs patents were invalid ñwas going to be litigated, and the issues certainly could have come out either way.ò (Figg, Tr. 1904).

RESPONSE TO FINDING NO. 365:

Complaint Counselôs Proposed Finding No. 365 is incomplete and misleading because it selectively quotes Mr. Figgôs testimony. Mr. Figgôs full statement was that invalidity ñwas going to be litigated, and the issues certainly could have come out either way. But having evaluated all of the materials that I evaluated, I think it was likely that Endo was going to prevail on these validity issues.ò (Figg, Tr. 1904). Proposed Finding No. 365 also ignores Mr. Figgôs testimony that Endo was likely to prove infringement of its patents. (Figg, Tr. 1875, 1880-81, 1883-84). And Proposed Finding No. 365 ignores Mr. Figgôs testimony that the likely outcome of the Endo-Impax litigation would have been an injunction preventing Impax from marketing its product until Endoôs patents expired in September 2013. (Figg, Tr. 1904-05).

366. Impax took steps to get a decision] n] iga d̰ʿ و

RESPONSE TO FINDING NO. 368:

Complaint Counselôs Propose

Hoxie offered no opinion on the strength of either partyôs litigation positions before the claim construction issue was decided by the district court. (Hoxie, Tr. 2835).

370. Prior to the SLA, Endo estimated that the Federal Circuit decision would likely happen around June 2011. (CX2576 at 001 (Feb. 2010 internal Endo e-mail chain) (ñIf [Impax] wait[s] for the appeal to play out, it will likely happen around June of next year.ò)).

RESPONSE TO FINDING NO. 370:

Complaint Counselôs Proposed Finding No. 370 is incomplete and misleading. The estimate of a June 2011 Federal Circuit decision was in response to a question asking about ñthe *earliest* dateò a competitor could ñstart shipping the generic.ò (CX2576-001 (emphasis added); CX4025 (Bingol, Dep. at 175-76) (discussing CX2576 and explaining there were ña lot of scenariosò and that Mr. Bingol was ñsimply looking at numbers of scenarios that could play out and the influencing factors in those scenarios . . . But as I point out below, there are many scenarios to play out, and we really donôt know.ò)).

371. According to Impaxôs expert, the Federal Circuit could have ruled on an appeal in the Impax generic Opana ER litigation by November 2011 or possibly earlier. (Figg, Tr. 2033-34, 2044-45).

RESPONSE TO FINDING NO. 371:

Complaint Counselôs Proposed Finding No. 371 is incomplete and misleading. Mr. Figg testified that November 2011 is ña very conservative, optimistic view of the timing.ò (Figg, Tr. 2044-45). Indeed, the median time from docketing to final decision in the Federal Circuit was eleven months in 2010 and 2011, but that figure takes into account settlement and summary affirmances. (Figg, Tr. 1908-09). It consequently is possible that the Federal Circuit would not have issued a decision until long after 2011. (Figg, Tr. 1908-09; Hoxie, Tr. 2865).

372. Impax could have started selling generic Opana ER in 2011 free from risk if the Federal Circuit had affirmed a favorable judgment from the district court, or reversed an unfavorable district court decision and entered judgment for Impax. (Figg, Tr. 1911; (CX5007 at 044 (¶ 81) (Hoxie Rebuttal Report)).

RESPONSE TO FINDING NO. 372:

Complaint Counselôs Proposed Finding No. 372 is not supported by the cited evidence. Mr. Hoxieôs report says nothing about risk-free entry in 2011. (CX5007-044 (Hoxie Rep. ¶ 81)). The cited testimony of Mr. Figg says nothing about what would happen if Impax lost at trial. Mr. Figgôs testimony was limited to the earliest possible time Impax would be free from the risk of having a favorable district court decision reversed. (Figg, Tr. 1911 (ñQ. If Impax had won at the trial level, what is the earliest likely date, in your opinion, that Impax could have entered free from the risk of the Federal Circuit Court of Appeals reversing the trial courtôs opinion? A. Well, it would be upon -- free of that risk would mean when the Federal Circuit issues its mandate affirming the district courtôs decision, so it would have been at some point after November 2011, using the dates that are on this chart, or it would have been after the decision, whenever that decision is issued.ò)). As Mr. Figg, explained, however, November 2011 is ña very conservative, optimistic view of the timing.ò (Figg, Tr. 2044-45). Indeed, the median time from docketing to final decision in the Federal Circuit was eleven months in 2010 and 2011, but that figure takes into account settlement and summary affirmances. (Figg, Tr. 1908-09). It consequently is possible that the Federal Circuit would not have issued a decision until long after 2011. (Figg, Tr. 1908-09; Hoxie, Tr. 2865).

373. The reverse-payment settlement terminated the Impax litigation and prevented a decision on the merits of the patent suit against Impax by either the trial court or the Federal Circuit. (*See* CCF ¶¶ 374-77, below).

3. The reverse-payment settlement eliminated the risk of competition from any other generic company on the most important dosage strengths of Opana ER

378. Impaxôs first-filer exclusivity ï combined with provisions in the SLA precluding Impax from selling generic Opana ER and from aiding or assisting other generic companies ï eliminated the risk of competition to Endoôs Opana ER from generic companies other than Impax on the five most important dosage strengths. (*See* CCF ¶¶ 379-87, below).

RESPONSE TO FINDING NO. 378:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on P

Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 382 other than to clarify that none of the cited evidence supports the suggestion that Actavis had tentative approval for Impaxôs first-filer dosages at the time of settlement.

383. In addition to blocking other generic companies from selling oxymorphone ER, the SLA also prevented Impax from pursuing an alternate route to market, such as partnering with Actavis, which had a licensed entry date in July 2011. (*See* CCF ¶¶ 384-87, below).

RESPONSE TO FINDING NO. 383: M ‘

RESPONSE TO FINDING NO. 385:

Respondent has no specific response.

386. Prior to settling with Endo, an option available to Impax was partnering with Actavis by waiving or relinquishing Impaxôs first-filer exclusivity in favor of Actavis and allowing Actavis to sell generic Opana ER starting in July 2011, in exchange for Impax receives a share of Actavisôs profits. (CX4034 (Rogerson, Dep. at 74) (agreeing that ñif prior to July of 2011 Impax had waived or selectively waived first filer exclusivity in favor of Actavis and Actavis was granted final approval,ò then Actavis would ñhave been able to start selling Generic Opana ER in those five dosage strengths on July 15, 2011ò)).

RESPONSE TO FINDING NO. 386:

Complaint Counselôs Proposed Finding No. 386 should be disregarded because it lacks foundation, is based on a question beyond the scope of Mr. Rogersonôs deposition, and is an improper hypothetical. Mr. Rogerson is a Teva employee. (CX4034 (Rogerson, Dep. at 5)). Mr. Rogerson previously worked at Actavis, but not until Actavis merged with Watson in 2012. (CX4034 (Rogerson, Dep. at 76)). Mr. Rogerson has no personal knowledge of events at Actavis prior to the Endo-Impax settlement agreement. (CX4034 (Rogerson, Dep. at 76)). As such, when Complaint Counsel asked Mr. Rogerson a hypothetical question about the theoretical possibility of a waiver of exclusivity and a partnership, he was simply speculating. (CX4034 (Rogerson, Dep. at 76)). Mr. Rogerson did not speak to anyone employed by Actavis during the relevant time to inform his speculation. (CX4034 (Rogerson, Dep. at 76-77)).

There is, moreover, no record evidence to support the proposition that ñan option available to Impax was partnering with Actavis by waiving first-filer exclusivity,ò or that Impax and Actavis believed such an option existed, considered it, or would have pursued it. The only mention in the entire record of waiving exclusivity and partnering with another company is found in the hypothetical question by Complaint Counsel to an individual who was not employed by either Impax or Actavis at the relevant time. (CX4034 (Rogerson, Dep. at 74)).

387. Any opportunity to partner with Actavis was terminated by the SLA, which prohibited Impax from assisting or

RESPONSE TO FINDING NO. 388:

Complaint Counselôs Proposed Finding No. 388 is improper because it states a legal conclusion, not a fact.

389.

395. The term ñauthorized genericò is a term of art used in the phar

document, moreover, discusses ñwholesale expenditures,ò not actual first-filer revenue.

(CX6052-047).

> 398. The presence of authorized generic competition during the 180-day exclusivity period reduces the first-filer genericôs revenues by 40 to 52%, on average. Moreover, revenues of the first-filer generic manufacturer in the 30 months following exclusivity are between 53% and 62% lower when facing an AG. (CX6052 at 005 (FTC Authorized Generics Report)). A first-filerôs revenue will approximately double absent an authorized generic. (CX6052 at 008 (FTC Authorized Generics Report)).

RESPONSE TO FINDING NO. 398:

Complaint Counselôs Proposed Finding No. 398 is incomplete and misleading. The only document cited regarding purportedly ñuniqueò impacts (CX6052) is a report from the FTC itself, which was drafted in part by members of Complaint Couns

launch ð Endoôs income before taxes, which considers revenues and expenses together ð would only be $2 million at the ñmore aggressive end of the range of cost savingsò and $13.5 million if Endo was ñless aggressive about cost savings.ò (CX4035 (Cuca, Dep. at 67) (discussing CX1314)). Similarly in the second cited document (CX3009), Endo did not ñestimateò reductions, it merely ñassumedò it for purposes of the forecast. (CX3009-003 (describing ñassumptionsò regarding ñerosionò and ñreduction in allocationò)). In fact, Endoôs ñbase caseò and ñlatest best estimateò did not assume generic entry in 2010. (CX4035 (Cuca, Dep. at 62) (discussing CX3009)).

Mr. Cuca explained that Endo forecast different scenarios regarding the future of its Opana ER product to ñanalyze the full range of potential outcomes,ò but did not know if any of the many different assumptions in its forecasts would come true. (Cuca, Tr. 662-64; *see* CX4025 (Bingol, Dep. at 180) (an authorized generic is ñanother scenario that you go through, just like when youôre making an assumption around potential launch datesò); Bingol, Tr. 1292, 1303 (Endo simply forecasted ña number of different potential outcomes over the course of years,ò the accuracy of which were ñalways debatable.ò)).

> 400. Endo intended to launch an authorized generic if Impax entered with generic oxymorphone ER. (CX2576 at 003 (Kelnhofer email to Kehoe) (ñWe will launch on word/action of first generic competitor.ò); CX2581 at 001 (Opana Lifecycle Management Team Meeting Minutes) (ñEndo is prepared to launch an authorized generic if another generic is approved first.ò); CX2573 at 004 (February 2010 Endo internal presentation ñEN3288 Commercial Updateò) (Endo planned a ñLaunch of authorized genericò in the event that Impax launched at risk) CX3007 at 003 (Endo oxymorphone ER pricing proposal) (ñIf Impax launches, Endo will launch its authorized generic . . .ò)).

RESPONSE TO FINDING NO. 400:

Complaint Counselôs Proposed Finding No. 400 is inaccurate, incomplete, and misleading. Brian Lortie, Endoôs Senior Vice President for Pain Solutions, testified that Endo ñnever seriously considered taking any further steps to prepare for or to do [an authorized

generic of Opana ER] because we really didnôt want to.ò (CX4019 (Lortie, Dep. at 118-19)). Demir Bingol, Endoôs Senior Director of Marketing and the person responsible for marketing Endoôs Opana ER products, testified that an authorized generic ñwas never . . . to my knowledge . . . fully realized as a plan or an idea.ò (Bingol, Tr. 1338-39; *see* Bingol, Tr. 1337 (ñI donôt recall specific forecasts about an authorized generic.ò)). And Mark Bradley, Endoôs Senior Director of Corporate Finance at the time of settlement, testified, ñI donôt recall having any conversation with any colleagues regarding the launch of an authorized generic.ò (CX4031 (Bradley, Dep. at 198)).

The cited evidence does not reflect that ñEndoò ñintendedò to do anything. The exhibits include (1) a single statement by an ñaccount executive on our managed markets team,ò (CX4025 (Bingol, Dep. at 174, 179) (discussing CX2576, testifying that he did not ñknow what their conversation meant or why they wrote those thingsò)); (2) a statement about authorized generics in the context of crush-resistant Opana ER, (CX2581 (discussing EN3288); CX4025 (Bingol, Dep. at 183) (discussing CX2581, explaining language meant that ñmentally we have all options on the table to be commercially successful, and this is one of these levers we could pull if we had to, and at this point no steps were taken, and I donôt recall that any ever were.ò)); (3) a draft document, (CX2573-004 (ñDraft Not Approved by Managementò); Bingol, Tr. 1298-99 (discussing identical ñdraftò language: ñJUDGE CHAPPELL: . . . it says itôs a draft. Why would he have presented a draft to anybody?ò)); and (4) a ñproposal,ò (CX3007-003).

401. By late 2009, Endo began preparing for an authorized generic launch in the summer of 2010. (*See* CCF ¶¶ 86-90).

RESPONSE TO FINDING NO. 401:

The proposed summary finding shou

by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

> 402. Endo has launched authorized generics of its branded drugs, including another branded drug called Fortesa. (CX6044 at 034, 057 (FDA listing of authorized generics); CX5001 at 026 (¶ 50) (Bazerman Report)).

RESPONSE TO FINDING NO. 402:

To the extent Complaint Counselôs Proposed Finding No. 402 purports to rely on expert testimony, it violates this Courtôs Order on Post-Trial Briefs by improperly citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò

Proposed Finding No. 402 is also incomplete and misleading. The cited evidence makes clear that (CX6 - ÐÐ t 034, 0 2 u f authorized genep01 ` aes

best possible deal that gets the product on the market as quickly as possible and maximizes the value to Impax shareholders, so early entry and no AG are certainly among the more important things, yes.ò (Mengler, Tr. 526). Mr. Mengler also explained that Impax derives value ñby selling the drug [] with or without anò authorized generic. (Mengler, Tr. 528-29).

407. Mr. Mengler, Impaxôs primary negotiator with Endo, believed that getting a No-AG would be beneficial to Impax. (Mengler, Tr. 526). In May 2010, Impaxôs then-CEO asked Chris Mengler, then-President of Impaxôs generic drug business, ñWhat if we can settle with Endo for January 2011 launch with No AG?ò (CX0505 at 001 (Mengler/Hsu email chain) (emphasis in original)). Mr. Mengler responded: ñIôd love that!!!!ò (CX0505 at 001 (Mengler/Hsu email chain); *see also* CX4010 (Mengler, IHT at 113-14)).

RESPONSE TO FINDING NO. 407:

Respondent has no specific response to the first sentence of Proposed Finding No. 407. The second and third sentences of Proposed Finding No. 407 are incomplete and misleading. Mr. Mengler did not mention a No Authorized Generic provision. His full statement was, ñSettlement --- different story. Iôd love that !!!!ò (CX0505-001).

408. The settlement agreement that Impax and Endo executed in June 2010 included a No-AG provision. (Koch, Tr. 234; Snowden, Tr. 392, 429). At time of the execution of the SLA, Impax did not know whether Endo would launch an authorized generic of the dosages as to which Impax was first-filer during Impaxôs 180-day exclusivity period. (CX3164 at 019-20 (Impax Response to Request for Admission No. 45)).

RESPONSE TO FINDING NO. 408:

Respondent has no specific response.

409. At the time of the execution of the SLA, Impax was concerned that Endo would launch an authorized generic of the dosages as to which Impax was first-filer during Impaxôs 180-day exclusivity period. (CX0514 at 004 (Email from Chris Mengler attaching 5-year forecast 2010) (showing Impax with less than 100% of the generic market share within the 180-day exclusivity period); CX2825 at 008 (Email from Ted Smolenski attaching 5-year forecast 2010) (same); CX2852 at 002 (Email from Todd Engle re: Meeting Minutes from Feb. 2, 2010 Quarterly Launch Planning Meeting) (noting that Endo ñmay have potential to launch AG immediatelyò); CX3154 at 001

(Email from Larry Hsu to Todd Engle, Chris Mengler, and Meg Snowden) (ñArenôt we too optimistic to assume that we will have a 2-4 weeks head start to AG?ò)).

RESPONSE TO FINDING NO. 409:

Complaint Counselôs Proposed Finding No. 409 is misleading and not supported by the cited evidence. None of the cited documents express a concern that Endo would launch an authorized generic. Rather, the documents simply consider possible scenarios. (CX3154 (ñThe [a]ttached file has a summary tab listing Impax Profits given 3 scenarios,ò including an authorized generic); CX2852-002 (ñpotential AGò); CX0514-004 (no mention of an authorized generic); CX2825 (same)). What is more, Todd Engle, Vice President of Sales and Marketing for Impaxôs Generic Division, testified that such financial planning documents simply reflected Mr. Engleôs ñthinking walking into th[e relevant] meetingò and did not reflect Impaxôs thinking. (Engle, Tr. 1777).

c) The No-AG provision was a payment to Impax

410. The ñNo-AG provisionò was worth substantial value to Impax when the SLA was executed because the ñNo-AG provisionò ensured that Impax would face no generic

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higher price for generic Opana ER than compared to a marketplace that had two companies selling generic products. (Reasons, Tr. 1215). That higher price is about 30 to 35% higher than if there were another generic in the marketplace. (Reasons, Tr. 1215).

RESPONSE TO FINDING NO. 411:

Respondent has no specific response to the first, third, and fourth sentences of Complaint Counselôs Proposed Finding No. 411. The third sentence of Proposed Finding No. 411 is incomplete and misleading. The record is replete with evidence indicating that generic oxymorphone ER would still compete with generic and branded versions of many different long-

from formulary coverage in favor of other long-acting opioids. (Noll, Tr. 1546; RX-017.0001; RX-017.0002 at 11).

412. Impax executives estimated that if Original Opana ER were still on the market and Endo launched an AG when Impax entered, Endoôs AG would capture roughly half of sales and cause substantially lower generic prices during the exclusivity period than would be the case if Impax sold the only generic. (CX4037 (Smolenski, Dep. at 53-54); CX4002 (Smolenksi, IHT at 80-81); CX0202 at 001 (Smolenski email) (ñworst caseò is that Impax shared the market with an AG)).

RESPONSE TO FINDING NO. 412:

Respondent has no specific response to the second sentence of Proposed Finding No. 415.

The third sentence of Proposed Finding No. 415 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll,

Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

2. The Endo Credit was valuable to Impax

a) Impax executives wanted to protect the value of their first-filer status in the event that Endo introduced a reformulated Opana ER product

418. Impax executives were concerned that during the period between signing the

RESPONSE TO FINDING NO. 419:

Respondent has no specific response.

420. If Endo were to move to a next-generation product, then the market opportunity for Impaxôs generic product would be significantly reduced or even zero. (Snowden, Tr. 434). Impaxôs primary negotiator, Mr. Mengler, became concerned during settlement negotiations with Endo that Endo was planning to launch a reformulated version of Opana ER. (Mengler, Tr. 527). Mr. Mengler was concerned that reformulation was an effort to subvert the value of the deal he was trying to put together to get Impaxôs product on the market and that reformulation was potentially damaging to Impaxôs business. (Mengler, Tr. 526-27).

RESPONSE TO FINDING NO. 420:

Respondent has no specific response to the first and second sentences of Complaint Counselôs Proposed Finding No. 420. The third sentence of Proposed Finding No. 420 is incomplete and misleading. Mr. Mengler testified in full that reformulation ñwas more an effort to subvert the value of the deal that I was trying to put together to get my product on the market to -- because the only way Iôm in business is selling generic drugs, and so call it whatever you want. I thought it was subversion.ò (Mengler, Tr. 526-27). Mr. Mengler also explained that the ñsubversion of the benefitsò was ñthe benefits to the American consumer for getting a generic version of what would have been an important drug and also I benefit, too, in the way I make money is by selling generic drugs, so.ò (Mengler, Tr. 527).

421. Mr. Menglerôs concern was that Endo would try to shift sales away from Original Opana ER to Reformulated Opana ER such that Opana ER in its original form disappears or becomes insignificant. (Mengler, Tr. 527). Impaxôs generic would not be AB-rated to the Reformulated Opana ER product. (Mengler, Tr. 528). This was a concern because ñthe way generic drugs are sold is by having a substitute, and if thereôs no substitute, I get nothing.ò (Mengler, Tr. 527). This would reduce the value of Impaxôs generic product including the value of Impaxôs 180-day exclusivity, and increase costs to consumers. (Mengler, Tr. 528).

RESPONSE TO FINDING NO. 421:

Respondent has no specific response.

422. During negotiations with Endo, Impaxôs primary negotiator (Mr. Mengler) told Endo that he believed that Endo was planning to launch a reformulated version of Opana ER before Impax could launch its generic. (Mengler, Tr. 531). Endo denied this. (Mengler, Tr. 531-32). Mr. Mengler did not believe Endo. (Mengler, Tr. 532).

RESPONSE TO FINDING NO. 422:

Respondent has no specific response.

423. In response, Impax negotiated for protections in case Endo moved the market away from the original formulation of Opana ER. (Snowden, Tr. 385; Mengler, Tr. 532; Snowden, Tr. 431-32; RX-318 at 0001 (Mengler email summarizing negotiations); CX0321 at 001 (Mengler email summarizing negotiations)). Protecting the market for Impaxôs entry date was a priority for Impax. (Snowden, Tr. 490).

RESPONSE TO FINDING NO. 423:

Respondent has no specific response.

424. Initially, Impax proposed an acceleration trigger. (Snowden, Tr. 385). Under Impaxôs proposed acceleration triggers, the launch date for Impaxôs generic version of Opana ER could become earlier than January 1, 2013, if the market for Opana ER degraded or declined to a certain level. (Mengler, Tr. 532; Snowden, Tr. 385, 432; RX-318 at 001 (Mengler email summarizing negotiations)). An acceleration trigger would have protected Impax from a decline in sales of Original Opana ER while providing consumers the benefit of generic competition at an earlier date. (CX4032 (Snowden, Dep. at 103ï04) (Rule 3.33(c)(1) testimony); CX4026 (Nguyen, Dep. at 163)).

RESPONSE TO FINDING NO. 424:

Respondent has no specific response other than to note that neither Ms. Snowden nor Ms. Nguyen testified about benefits to consumers or generic competition, as Complaint Counsel attempts to suggest. Their testimony was limited to the operation of a possible acceleration trigger. (CX4032 (Snowden, Dep. at 103-04); CX4026 (Nguyen, Dep. at 163)).

425. Endo rejected the idea of an acceleration trigger. (Snowden, Tr. 385, 432; Koch, Tr. 237-39). The discussions regarding an acceleration trigger turned instead to a term called the Endo Credit. (Mengler, Tr. 532; Snowden, Tr. 385, 432).

RESPONSE TO FINDING NO. 425:

Respondent has no specific response.

b) Impax and Endo agreed to the Endo Credit provision as a means of making Impax whole if Endo launched a reformulated Opana ER product and reduced the value of the No-AG provision

426. Endo moved away from the concept of an accelerated launch date in favor of something that Impax understood as a ñmake-whole provision.ò (Koch, Tr. 238). Endo insisted on a firm entry date in 2013 but agreed to compensate Impax if the demand for Original Opana ER fell substantially before the agreed entry date. (CX4032 (Snowden, Dep. at 103-04, 113-15) (Rule 3.33(c)(1) testimony); CX4026 (Nguyen, Dep. at 163)).

RESPONSE TO FINDING NO. 426:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 426 other than to note that the cited evidence does not support the proposition that ñEndo movedò away from or to anything. (Koch, Tr. 238 (ñQ. But at some point *the negotiations with Endo* moved away from an accelerated launch date in favor of something that you understood as the make-whole provision; correct? A. Yes.ò) (emphasis added)). And while Respondent does not dispute that Endo refused to offer a license date earlier than 2013, the remainder of the second sentence of Proposed Finding No. 426 is not supported by the cited evidence.

427. Getting downside protection for Impax in the event Endo reformulated Opana ER was ñsuper, super importantò to Impaxôs primary negotiator of the Endo-Impax settlement. (Mengler, Tr. 535-36). According to Impaxôs primary negotiator, ñsomething that didnôt protect us from the downside was . . . a deal-breaker.ò (CX4010 (Mengler, IHT at 44)).

RESPONSE TO FINDING NO. 427:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 427. The second sentence of Proposed Finding No. 427 is incomplete,

429. The term ñmake-whole provisionò is another phrase for what became the Endo Credit. (Mengler, Tr. 545). The Endo Credit was ñintended to make [Impax] whole for what [Impax] would have otherwise achieved.ò (Mengler, Tr. 582). ñSo, [Impaxôs primary negotiator] didnôt really care what the size of the market wasò going to be. (Mengler, Tr. 582). The concept of ñdownside protection,ò or a ñmake-goodò payment is what became the Endo Credit. (Koch, Tr. 241; Snowden, Tr. 434; Mengler, Tr. 543, 582).

RESPONSE TO FINDING NO. 429:

Respondent has no specific response to the first, second, and fourth sentences of Complaint Counselôs Proposed Finding No. 429. The third sentence of Proposed Finding No. 429 is inaccurate and misleading because it selectively quotes Mr. Mengler out of context. The relevant exchange was as follows: ñQ. With respect to the Endo credit formula, did you do any analyses or forecasting as to what Impax might be paid under the Endo credit formula? A. No. Q. Why not? A. Well, because the Endo credit, make good, was not an attempt to, you know, generate income. It was intended to make us whole for what we would have otherwise achieved, so I didnôt really care what the size of the market was. It was going to get in there no matter what.ò (Mengler, Tr. 582). The record, moreover, is clear that Mr. Mengler and Impax wanted a robust generic opportunity. (Mengler, Tr. 528-30 (Impax derives value from being able to sell its product); Snowden, Tr. 432-33 (Mr. Mengler told Endo that Impax was ñhappy to payò a royalty if the generic opportunity increased); Reasons, Tr. 1226 (Impax wanted a ñrobust, 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 investorsò); Koch, Tr. 239 (royalty provision meant to incentivize Endo to support original Opana ER)).

430. The ñEndo Creditò provision was designed to insulate Impax against a substantial decrease in sales of Opana ER. (Cuca, Tr. 617). At the time the parties were negotiating the terms of the ñEndo Creditò provision, Endo was developing a reformulated version of Opana ER, the introduction of which could lead to such a decrease in the sales of Original Opana ER. (Cuca, Tr. 618-19; *see also* CCF ¶ 72-83, 240-48, 418-23, above)

RESPONSE TO FINDING NO. 430:

Respondent has no specific response.

431. Impax and Endo each understood that the Endo Credit might be triggered and require a significant payment. Thus, each party extensively negotiated changes to the formula that would benefit it. I

435.

would be entitled to a ómake goodô payment such that our potential profits would equal to 50%.ò)).

RESPONSE TO FINDING NO. 436:

Complaint Counselôs Proposed Finding No. 436 is inaccurate. Actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their quarterly peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales divided by 100, and (2) the number of percentage points under 50)). There is no evidence to suggest that such potential liabilities under the Endo Credit represented ñguaranteesò of Impaxôs profits over six months.

437. On the other hand, if Endo did not reformulate and in fact grew the market for Original Opana ER, then Impax would launch its generic and would get value from its 180-day exclusivity period and the No-AG provision. If sales of Original Opana ER reached a sufficiently high level, Impax would have paid a royalty to Endo. (Mengler, Tr. 533). Impax still would be benefited ð even if it were paying a royalty to Endo ð by making sales during the 180-day exclusivity period without competition from an authorized generic. (Mengler, Tr. 534; *see also* CCF ¶ 468, below).

RESPONSE TO FINDING NO. 437:

The first sentence of Complaint Counselôs Proposed Finding No. 437 is not supported by any record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second or third sentences of Proposed Finding No. 437 other than to note that to the extent the Proposed Finding purports to summarize and

incorporate other findings, those findings do not support the Proposed Finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

> 438. Impax understood that the No-AG provision backed-up by the Endo Credit ensured that Impax would receive value from its agreement with Endo. During a November 2011 earnings call, Impaxôs then-CFO discounted the impact of Endo switching Opana ER to a new formulation because of Impaxôs agreement with Endo: ñFortunately, though, we do have [downside] protection built into the agreement so we should have a reasonable outcome almost no matter what happens.ò (Koch, Tr. 264-65; CX2703 at 012-13 (Transcript of Q3 2011 Impax Earnings Call)). If Endo did a ñswitchoutò to Opana tamper-resistant, Impax would be able to realize a payment from Endo. (Koch, Tr. 265). Thus, Impax had protection that ensured that Impax had a reasonable outcome almost no matter what Endo did, and Impax executives viewed that protection as a form of insurance. (Koch, Tr. 265-66; Reasons, Tr. 1218-19; CX4020 (Reasons, Dep. at 55-56) (agreeing that ñif 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 creditò)).

RESPONSE TO FINDING NO. 438:

The first sentence of Complaint Counselôs Proposed Finding No. 438 is not supported by any record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

The remainder of Proposed Finding No. 438 is incomplete and misleading. The record indicates that the Endo Credit was part of ña carrot and a stickò approach to incentivize Endo to make investments in its original Opana product, and to ensure Impax had a measure of control over its generic opportunity. (Koch, Tr. 236-37, 240-41, 265; Snowden, Tr. 386). It was intended to act as ña deterrent to prevent [Endo] form switching the market.ò (CX4021 (Ben-Maimon, Dep. at 118, 122); *see* CX4037 (Smolenski, Dep. at 244-45) (ñintended to disincentivize Endo fromò introducing a reformulated product); CX4026 (Nguyen, Dep. at 163-64) (Endo Credit was used to ñput [Endo] to [its] wordò with respect to reformulation)).

RESPONSE TO FINDING NO. 441:

Respondent has no specific response other than to note that to the extent Complaint Counselôs Proposed Finding No. 441 suggests that a substantial decrease in original Opana ER sales was planned or anticipated, it is inaccurate and misleading. Indeed, the first time that Endo knew its sales would be zero in the last quarter of 2012 was after the Novartis plant shutdown and resulting supply interruption in 2012. (Cuca, Tr. 615, 617, 677 (ñI donôt know that anyone was anticipating a change in the marketplaceò); RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)). Until that point, Endo expected to sell Opana ER through the fourth quarter of 2012. (CX4017 (Levin, Dep. at 131); RX-094.0006 (ñPrior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012ò); RX-108.0002 at 10).

442. On January 18, 2013, Margaret Snowden, Impaxôs Vice President for intellectual property litigation and licensing, provided Endo with written documentation supporting its demand for payment of the Endo Credit in the amount of $102,049,199.64, pursuant to Section 4.4 of the SLA. (JX-001 at 011 (¶ 45); Snowden, Tr. 386-87, 389; CX0332 at 007-08 (Letter from Snowden to Endo notifying Endo that Endo Credit payment was due)). Ms. Snowdenôs letter included the backup information showing how she had calculated the value of the Endo Credit payment. (CX0332 at 010-13 (Letter from Snowden to Endo notifying Endo that Endo Credit payment was due)).

RESPONSE TO FINDING NO. [illegible]

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RESPONSE TO FINDING NO. 447:

Respondent has no specific response.

448. On June 24, 2010, Endo wired payment of $10 million to Impax in accordance with Section 3.1 of the DCA. (JX-001 at 011 (¶ 44); *see also*

WITNESS: I havenôt looked at the per-hour charges, but Iôve looked at them all -- outside --

charge per hour in trial? THE WITNESS: I havenôt looked at the per-hour charges, but Iôve looked at them all -- outside -- JUDGE CHAPPELL: Those hours matter. THE WITNESS: Huh? JUDGE CHAPPELL: Those hours matter.ò)).

> 455. At the time of the settlement, which occurred during trial, most of the litigation costs had been incurred. Endo had spent between $6 million and $7 million and Impax had spent about $4.7 million on litigating the infringement case. (CX2696 at 013-14 (Impax response to FTC CID); CX3212 at 009-10 (Endo response to FTC CID); CX5000 at 108 (¶ 247) (Noll Report)).

RESPONSE TO FINDING NO. 455:

The first sentence of Complaint Counselôs Proposed Finding No. 455 is not supported by any record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 455.

> 456. The top end of the range that Impax uses to estimate costs for a generic patent litigation is about $3 million to $4 million per litigation. (Reasons, Tr. 1222). The $3 million to $4 million represents expenses from the start of litigation to the finish. (Reasons, Tr. 1222). As part of its budgeting process, Impaxôs CFO makes the best estimate he can for litigation expenses in advance. (Reasons, Tr. 1222). Impaxôs patent litigation expenses are largely comprised of expenses from outside counsel, such as hourly fees for attorneys. (Reasons, Tr. 1221). Impax might allocate some expenses for its internal legal departmentôs work on patent litigation, but those allocations are minor. (Reasons, Tr. 1221).

RESPONSE TO FINDING NO. 456:

Respondent has no specific response other than to clarify that Proposed Finding No. 456 is incomplete because it ignores Mr. Reasonsô testimony that the ñamount that Impax spends on a specific patent litigation can vary based on a variety of factors.ò (Reasons, Tr. 1221 (quoting

457. For example, during a public earnings conference call in November 2011, Impaxôs then-CFO stated that Impax had ñlowered [its] patent litigation expense guidance for the full year for 2011 from $13 million to $10 million primarily due to recent settlements.ò (Koch, Tr. 262; CX2703 at 004 (Transcript of Q3 2011 Impax Earnings Call)). Impaxôs then-CFO told the investment community that Impax was going to save $3 million in litigation expenses because of settlements, including the Endo settlement. (Koch, Tr. 263).

RESPONSE TO FINDING NO. 457:

Respondent has no specific response.

458. Impaxôs total budgeted patent litigation spending for 2013 was $16.5 million. (Reasons, Tr. 1222-23). Impaxôs $16.5 million budget for all patent litigation expenses in 2013 is far less than the $102 million Endo Credit payment that Endo paid to Impax and is far less than the $65 million net income value of the Endo Credit payment. (Reasons, Tr. 1224-25).

RESPONSE TO FINDING NO. 458:

Respondent has no specific response.

2. Endo's actual payments to Impax exceeded the possible saved litigation costs

459. The payments that were actually made from Endo to Impax pursuant to the SLA and DCA far exceeded the possible saved litigation costs. (Noll, Tr. 1463; CX5000 at 168-69 (¶¶ 375-76) (Noll Report)). Endo paid $10 million immediately under the DCA, and, 2.5 years later, another $102 million for the Endo Credit. (*See* CCF ¶¶ 320, 328-31, above). At the time of the settlement, the discounted present value of this payment, using a 15% discount rate, would have been over $65 million. (CX5000 at 169 (¶ 376) (Noll Report)).

RESPONSE TO FINDING NO. 459:

Complaint Counselôs Proposed Finding No. 459 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). And applying a discount rate to the actual payments made in 2013 says nothing about the expected value, if any, conveyed to Impax in June 2010,

since it excludes any scenario in which Impax would receive zero ñpaymentò under the settlement agreement. (Court, Tr. 71, 75 (ñJUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? Youôre going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldnôt have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.ò); Noll, Tr. 1654 (ñQ. And that example where you get zero of both, you didnôt include that on your demonstrative of scenarios, did you? A. No, I didnôt.ò)).

The record, however, is clear that if Endo launched reformulated Opana ER late in 2012 but continued to sell original Opana ER into the fourth quarter of that year, Endo ñcould 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.ò (Reasons, Tr. 1228; *see* CX4032 (Snowden, Dep. at 205-06)). If that occurred, Impax would have a much reduced opportunity for its generic version of the original Opana ER. (Mengler, Tr. 583; CX4037 (Smolenski, Dep. at 251-52)). Impax considered it ñentirely plausi

3. Under any reasonable scenario, the ex ante value of the No-AG/Endo Credit payment was large, even if the exact value was uncertain at the time of settlement

461. The No-AG provision of the settlement had value to Impax even if there was uncertainty about whether Endo would have launched an authorized generic. The No-AG provision provided Impax with a guarantee that there would not be an authorized generic during its 180-day exclusivity period, and that guarantee had value to Impax. (Mengler, Tr. 526; Reasons, Tr. 1210; Koch, Tr. 234; Noll, Tr. 1453-54; *see also* CX0505 at 001 (Mengler email stating of No-AG provision, ñIôd love that!!!!ò)).

RESPONSE TO FINDING NO. 461:

The first sentence of Complaint Counselôs Proposed Finding No. 461 is not supported by record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 461 is incomplete and misleading. Mr. Mengler explained that Impax derives value ñby selling the drug [] with or without anò authorized generic. (Mengler, Tr. 528-29). Dr. Hsu, Impaxôs CEO at the time of settlement, similarly explained that getting on the market as early as possible is what matters. Impax did not value the absence of an authorized generic if it meant delaying its own product. (CX4030 (Hsu, Dep. at 76-77)). The cited evidence, moreover, does not support the proposition advanced. (Mengler, Tr. 526 (ñQ. You believe that getting a no-AG would be beneficial to Impax; right? A. Yes.ò); Koch, Tr. 234 (generally, absence of an authorized generic would mean more control,

exclusive. If one provision is valueless, the other has substantial value, and the sum of the expected values of the two provisions is always not only positive, but ñlargeò in comparison with the cost of litigating the patent infringement case to conclusion, given that at the time of the settlement the case was in trial. (CX5000 at 173 (¶ 384) (Noll Report); *see also* CX4020 (Reasons, Dep. at 55-56) (agreeing that ñif 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 creditò)).

RESPONSE TO FINDING NO. 462:

The first sentence of Complaint Counselôs Proposed Finding No. 462 is not supported by record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 462 is inaccurate, lacks foundation, and is not supported by record evidence. Mr. Reasons explained that he was testifying only about his personal understanding. (CX4020 (Reasons, Dep. at 55-56)). Mr. Reasons, however, joined Impax in 2012 and had no role in the development or negotiation

463. The precise magnitude of the ñEndo Creditò was not known in Jun

sales of Opana in the last quarter immediately before Impaxô[s] launch. When the Novartis supply disruption took place, we know that sales in that quarter were likely to be close to zero.ò (Cuca, Tr. 671). No one at Endo expected or discussed the possibility of a supply disruption at the time of settlement. (Cuca, Tr. 671). Similarly, 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). Impax did not even attempt to calculate the size of any payment until the third quarter of 2012. (Engle, Tr. 1765-66).

> 464. The eventual magnitude of the ñEndo Creditò was determined by the rapid growth of Opana ER sales in 2010 and 2011, and then the rapid descent to zero in 2012 when Original Opana ER was withdrawn from the market. This outcome was consistent with the expectations of both Endo and Impax. (CX5000 at 170 (¶ 379) (Noll Report)).

RESPONSE TO FINDING NO. 464:

Complaint Counselôs Proposed Finding No. 464 violates this Courtôs Order on Post-Trial Briefs to the extent it cites ñto expert testimony to support f

zero.ò); Noll, Tr. 1654 (ñQ. And that example where you get zero of both, you didnôt include that on your demonstrative of scenarios, did you? A. No, I didnôt.ò); Addanki, Tr. 2355 (a rational actor like Endo ñwould manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make.ò)). Indeed, Mr. Cuca of Endo testified that Endo sought to reduce the payment under the Endo Credit during negotiations. (Cuca, Tr. 639-40).

> 467. If sales of Original Opana ER continued to increase after June 2010, then the value of the No-AG provision to Impax also would grow. If Endo did not withdraw Original Opana ER from the market, and the revenues from Original Opana ER continued to grow after the settlement was signed in June 2010 such that at the time of Impaxôs launch Original Opana ER sales equaled their peak sales achieved in the real world, then the value of the No-AG provision would end up being at least $53 million to Impax in 2013 (or $35 million in present value in 2010). (CX5000 at 172, 240 (¶ 382, App. F) (Noll Report); Noll, Tr. 1476-77).

RESPONSE TO FINDING NO. 467:

Complaint Counselôs Proposed Finding No. 467 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). All Professor Noll did was come up with ñexamplesò of the potential value to Impax of the Endo Credit and No-AG provisions in January 2013, ñunder various circumstances,ò but he ñdidnôt attach probabilities to those.ò (Noll, Tr. 1613).

Neither Impax nor Endo expected or forecast the theoretical scenario Professor Noll created. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88); CX4017 (Levin, Dep. at 99-100) (ñat the time the transaction was inked I did not expect that Endo would have to make a payment under this provisionò); Cuca, Tr. 664-65 (Endo did not book a r

469. If sales of Opana ER did not grow at all and stayed flat from until the date of Impaxôs entry, then the ñNo AG Provisionò was worth at least $33 million to Impax in 2013 (with a present value of $22 million in 2010). (CX5000 at 155, 240 (¶ 350, App. F) (Noll Report) (using Impax models to estimate value of No-AG provision); Noll, Tr. 1475-76).

RESPONSE TO FINDING NO. 469:

Complaint Counselôs Proposed Finding No. 469 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). All Professor Noll did was come up with ñexamplesò of the potential value to Impax of the Endo Credit and No-AG provisions in January 2013, ñunder various circumstances,ò but he ñdidnôt attach probabilities to those.ò (Noll, Tr. 1613).

Neither Impax nor Endo expected or forecast the theoretical scenario Professor Noll created. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88); CX4017 (Levin, Dep. at 99-100) (ñat the time the transaction was inked I did not expect that Endo would have to make a payment under this provisionò); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was ñprobable and estimableò at settlement); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

And both Complaint Counsel and Professor Noll admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 (ñJUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? Youôre going to stand there wa ﺓ ʻ я ʻ

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88); CX4017 (Levin, Dep. at 99-100) (ñat the time the transaction was inked I did not expect that Endo would have to make a payment under this provisionò); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was ñprobable and estimableò at settlement); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

471. If Original Opana ER sales declined after the settlement, but the Endo Credit provision was not triggered, Impax would still receive substantial value from the No-AG provision. Putting aside any Endo Credit payment, even if one assumes that the value of the No-AG provision could end up being only half of the value calculated if Original Opana ER sales stayed flat from 2010 to January 2013, the No-AG provision would still

2355 (a rational actor like Endo ñwould manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it

RESPONSE TO FINDING NO. 474:

Complaint Counselôs Proposed Finding No. 474 is inaccurate and not supported by actual record evidence. Impax considered it ñentirely plausibleò that Endo could employ a late switch in products such that there was a reduced generic opportunity for Impax ð and thus no benefit from a No-AG provision ð while Endo still made no Endo Credit payment. (Mengler, Tr. 589-90; CX4002 (Smolenski, IHT at 50-51, 129, 187-88)).

Endo not only believed it was possible, but planned to implement such a late-switch strategy. Brian Lortie, Endoôs Senior Vice President for Pain Solutions at the time of settlement, explained, Endo ñintended to replace one product with the other, and that would be the only product that we had on the market,ò (CX4019 (Lortie, Dep. at 117-18)), but Endo still ñdid not expect to make a payment to Impax,ò (CX4017 (Levin, Dep. at 126)). Indeed, Endo intended to transition to a reformulated version of Opana ER at the very end of 2012. (CX4017 (Levin, Dep. at 99-100, 131) (ñit was not [Endoôs] expectation that a payment would have to be madeò); RX-094). Endoôs original budget for 2012 projected original Opana ER sales into the fourth quarter of 2012. (RX-108.0002 at 10; RX-094.0006 (ñPrior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012.ò)). Professor Noll admitted that such a strategy would have permitted Endo to carry out the ñlate switchò (and zero-payment) plan. (*See* CX4039 (Noll, Dep. at 124) (testifying that zero-payment outcome ñwould have required entry along about the 1st of September of 2012ò)).

Finally, the proposition that any Endo Credit liability under the 50 percent threshold would result in a ñlargeò payment is not supported by record evidence. Actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their

quarterly peak, this would mean the resulting liability would be roughly $2 million. If sales

more accurate than assigning no percent, except to know that that possibility exists.ò (CX4037 (Smolenski, Dep. at 255-56)).

476. Impaxôs hired economics expert, Dr. Addanki, also did not assess the likelihood of this hypothetical scenario coming to pass and did not offer any opinions as to the likelihood that the combination of the No-AG provision and Endo Credit was not ñlargeò when the SLA was executed. Dr. Addanki did not assess the likelihood that both the No-AG provision and Endo Credit provisions would have provided zero value to Impax. (Addanki, Tr. 2437). Dr. Addanki simply asserts that his hypothetical scenario is ñpossible.ò (RX-547 at 067 (¶ 126) (Addanki Report) (ñ[I]t is possible that the óNo AGô and Endo Credit provisions would have provided zero value to Impax.ò)).

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477. Dr. Addanki concedes that he did not study whether Endo would maximize its profits by launching Reformulated Opana ER earlier and paying the Endo Credit or launching later in an attempt to avoid the Endo Credit. (Addanki, Tr. 2463-64; *see also* Addanki, Tr. 2463 (ñ[I]f [Endo] could make profit elsewhere by incurring the Endo [C]redit, they would.ò)).

RESPONSE TO FINDING NO. 477:

Complaint Counselôs Proposed Finding No. 477 is incomplete and misleading. Dr. Addanki testified that ñitôs

482. Endoôs actual plans are not consistent with the notion of Endo introducing Reformulated Opana ER late in 2012 so that it could reduce the value of the Endo Credit to zero. Endoôs long-standing strategy was to introduce Reformulated Opana ER quickly before any generic oxymorphone ER product launched, because Endo knew that it would be harder to transition patients to Reformulated Opana ER if generic oxymorphone ER were already on the market. (CX2578 at 008-09; CX2732 at 002, CX4025 (Bingol, Dep. at 32, 63-64); CX1108 at 004 (Endo presentation showing planned launch of Reformulated Opana ER (called ñRevopanò) in February 2011); CX4019 (Lortie, Dep. at 11-12)).

RESPONSE TO FINDING NO. 482:

The first sentence of Proposed Finding No. 482 is not supported by any record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 482 is incomplete and not supported by the cited evidence. None of the cited evidence states that Impax would introduce reformulated Opana ER ñquickly.ò Endo ñplan[ned] for different eventualitiesò and analyzed ñdifferent scenariosò and different ñassumption[s]ò about launch. (CX4025 (Bingol, Dep. at 31-32); CX2578 (a ñdraftò document from 2007, just after original Opana ER launched); CX2732-001-02 (ñstrictly in draftò; ñDraft - Not for Distributionò); CX4019 (Lortie, Dep. at 11-12) (discussing CX1108 and noting that dates were ñassumptions at that point,ò but that ñ[t]here was some subsequent work that needed to be doneò)).

483. Endoôs brand manager for Opana ER testified that Endoôs strategy depended on introducing Reformulated Opana ER ña reasonable amount of timeò before generic oxymorphone ER launched. (CX4025 (Bingol, Dep. at 63-64). Endoôs internal forecasts showed that if Endo launched Reformulated Opana ER before any generic oxymorphone ER product launched, then Endoôs sales of Reformulated Opana ER would grow. (CX2724 at 006; CX2578 at 008-09; CX2732 at 002; CX4025 (Bingol, Dep. at 95-96)). But if Endo waited to launch reformulated until after generic oxymorphone ER came to market, then Endoôs sales of Reformulated Opana ER would be dramatically lower. (CX2724 at 006; CX2578 at 008-09; CX2732 at 002; CX4025 (Bingol, Dep. at 95-96); CX1106 at 004 (2010 Opana Brand Strategic Plan) (ñSignificant erosion of oxymorphone

franchise to generics is likely if EN3288 [reformulated Opana ER] is not filed and approved in a timely manner.ò)).

RESPONSE TO FINDING NO. 483:

Respondent has no specific response other than to clarify that Mr. Bingol testified ñfor this asset it was important to try to have your follow-on formulations, products, improvements, whatever would separate this product from potential generics *or* with a reasonable amount of time to make the conversion.ò (CX4025 (Bingol, Dep. at 64) (emphasis added)).

484. Endoôs internal documents and testimony of its executives shows

486. Brian Lortie, who was involved in efforts to launch Endoôs Reformulated Opana ER product, testified that Endo wanted to get the reformulated product out as soon as possible and ñsmoothly transition from old product to new product.ò (CX4019 (Lortie, Dep. at 8, 32-33)). According to Mr. Lortie, Endoôs goal was to make the transition ñ[a]s soon as we could, but also in a way that recognized that we wanted as smooth a[s] possible transition for patients that were on the old product and transitioning to the new one.ò (CX4019 (Lortie, Dep. at 33)).

RESPONSE TO FINDING NO. 486:

Complaint Counselôs Proposed Finding No. 486 is incomplete and misleading because it ignores Mr. Lortieôs testimony, in which he explained that Endo several times changed its plans with respect to reformulated Opana ER, particularly after it failed to acquire FDA approval. (CX4019 (Lortie, Dep. at 161); *see also* CX4019 (Lortie, Dep. at 11-12) (dates were ñassumptions at that point,ò but that ñ[t]here was some subsequent work that needed to be doneò)).

487. Endoôs desire for a smooth transition was driven in part by an understanding that patients cannot be switched immediately from one long-acting opioid to another because physicians are ñvery careful as they adjust dosagesò for patients. (CX4019 (Lortie, Dep. at 8, 39)). Endoôs plan was ñfor an orderly and phased transition from one product to the other so we made sure we werenôt leaving any current patients in a difficult situation.ò (CX4019 (Lortie, Dep. at 156-57)). This process could last several months. (CX4019 (Lortie, Dep. at 41-42); Mengler, Tr. 530-31 (a timeline of ñsix to nine monthsò for a branded company to shift the market from an original branded product to a reformulated product might be considered ña little fast but not unreasonableò); Addanki, Tr. 2459-60 (conceding that it takes months for a brand to switch prescriptions from an original product to a reformulated product)).

RESPONSE TO FINDING NO. 487:

Respondent has no specific response.

488. For the hypothetical scenario to have rendered the reverse payments in the SLA not ñlarge,ò the expected value of the ñEndo Creditò plus the ñNo AGò provision at the time the SLA was executed would have to been less than a few million dollars. (CX5004 at 072-73 (¶¶ 152-53) (Noll Rebuttal Report)). For that to be true, there would need to have been a 92% chance as of June 2010 that the combination of the Endo Credit and No-AG provisions would be worth $0. (CX5004 at 073 (¶ 153) (Noll Rebuttal Report); Noll, Tr. 1478-80). Dr. Addanki offers no evidence that this strategy was possible, let

> alone almost certain to occur. And the discovery record indicates that whether Endo could have achieved this outcome was highly uncertain. Yet Dr. Addankiôs conclusions hinge on this outcome being by far the most likely consequence of the settlement. (CX5004 at 073-74 (¶ 154) (Noll Rebuttal Report); *see also* CCF ¶¶ 75-83, 482-87, above).

RESPONSE TO FINDING NO. 488:

Complaint Counselôs Proposed Finding No. 488 is inaccurate, is not supported by evidence, and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). Rather, Professor Noll simply assumed that the Endo Credit had a ñpresent value of $65 million at the time of the settlement.ò (CX5004-073 (Noll Rebuttal Rep. ¶ 153)). He arrived at that value by applying a 15 percent annual discount rate to the $102 million that was actually paid in 2013. (CX5004-073 (Noll Rebuttal Rep. ¶ 153); *see* CX5000-073 (Noll Rep. ¶ 376)). From this premise, Professor Noll opined that in order to bring the ñexpected valueò of the actual Endo Credit payment below $5 million ð his estimate for saved litigation costs ð the zero-payment scenario would have to be roughly 92 percent likely to occur. (CX5004-073 (Noll Rebuttal Rep. ¶ 153)).

The analysis makes no sense given that the fact and amount of any Endo Credit payment hinged on future events that neither party could entirely foresee or control. The first time that Endo knew its sales would be zero in the last quarter of 2012 was after the Novartis plant shutdown and resulting supply interruption in 2012. (Cuca, Tr. 677; RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)). It also ignores the fact that Endo ñintended to replace one product with the other, and that would be the only product that we had on the market,ò (CX4019 (Lortie, Dep. at 117-18)), but Endo still ñdid not expect to make a payment to Impax,ò (CX4017 (Levin, Dep. at 126)).

489. There is no reference in either Impax or Endoôs financial planning documents to a hypothetical scenario in which both the No-AG provision and the Endo Credit provision end up being worth nothing to Impax. (Noll, Tr. 1480). Dr. Addanki merely asserts that he ñwould certainly expect that to be Endoôs plan.ò (Addanki, Tr. 2447). Dr. Addanki acknowledged, however, that he did not consider several of Endoôs planning documents in forming his opinions. (Addanki, Tr. 2448-56).

RESPONSE TO FINDING NO. 489:

The first sentence of Proposed Finding No. 489 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò

The second sentence of Proposed Finding No. 489 is inaccurate and not supported by the cited evidence. Dr. Addanki repeatedly testified that ñI do know that there were at least some documents that I reviewed which were contemplating a launch later in 2012 than Endo actually ended up having to do.ò (Addanki, Tr. 2447-48; *see* Addanki, Tr. 2439 (ñit would make economic sense for Endo to have done that [late-switch], and indeed, it seems like thatôs what Endo had in mindò)).

Respondent has no specific response to the third sentence of Proposed Finding No. 489.

490. Endo anticipated the magnitude of the Endo Credit payment to Impax by recording a $110 million charge to its income statement in the first quarter of 2012. (RX-494 at 0007 (May 1, 2012 Endo press release reporting that Endo first quarter results
m ñinclude[] the impact of a pre-tax charge in the aq f M M

time of settlement. When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) (ñat the time the transaction was inked I did not expect that Endo would have to make a payment under this provisionò)). For that reason, Endo did not book a reserve because no Endo Credit payment was ñprobable and estimable.ò (Cuca, Tr. 664-65; *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

Indeed, the first time that Endo knew its sales would be zero was in the last quarter of 2012 after the Novartis plant shutdown and resulting supply interruption in 2012. (Cuca, Tr. 677; RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)). Until that point, Endo expected to sell Opana ER through the fourth quarter of 2012. (CX4017 (Levin, Dep. at 131); RX-094.0006 (ñPrior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012ò); RX-108.0002 at 10).

491. In the real world, Endo did not implement the hypothetical scenario for rendering both the No-AG provision and Endo Credit valueless. In the real world, Endo paid Impax a m ك ɔ ᴀ א e = m pom l aaM D l p ᴀ M

not expect to make a payment to Impax,ò (CX4017 (Levin Dep. at 126)). Indeed, Endo intended to transition to a reformulated version of Opana ER at the very end of 2012. (CX4017 (Levin, Dep. at 99-100, 131) (ñit was not [Endoôs] expectation that a payment would have to be madeò); RX-094). Endoôs original budget for 2012 projected original Opana ER sales into the fourth quarter of 2012. (RX-108.0002 at 10; RX-094.0006 (ñPrior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012.ò)).

Endo did not undertake a late-switch strategy only because the Novartis plant at which it manufactured original Opana ER shut down and Endo was forced to rush the launch reformulated Opana ER, after which the FDA ordered it to stop selling original Opana ER. (CX4017 (Levin, Dep. at 136-39, 155) (ñsupply chain crisisò altered Endoôs plans); RX-094.0003-04; RX-100.0001 (ñSeveral of [Endoôs] strategies envisioned [Endo] selling both [original and reformulated Opana ER] products at the same time. It was only upon [Endoôs] discussions with the FDA in February [2012] that they told [Endo] not to do this in order to avoid patient confusion.ò)). Professor Bazerman, one of Complaint Counselôs own experts, admits that the FDAôs actions shutting down Novartisô plant ñtook matters out of [Endoôs] hands.ò (Bazerman, Tr. 923-24).

Respondent has no specific response to the second sentence of Proposed Finding No. 491.

5. The size of the payments was sufficient to induce Impax to abandon its patent challenge of the Opana ER patents

492. The size of the payments from Endo to Impax were sufficient to induce Impax to abandon its patent claim. (CX5001 at 014-19 (¶¶ 29, 32-37) (Bazerman Report); Bazerman, Tr. 845-46, 873-74, 877).

RESPONSE TO

494. Impax estimated the value of its expected net sales of oxymorphone ER during its six months of exclusivity as equal to approximately $27 million

increased Impaxôs 2013 net income by about $65 million, which is the amount of the $102 million payment minus taxes. (Reasons, Tr. 1205). Impaxôs net income for 2013, the year that the Endo Credit was paid to Impax, was approximately $101.3 million. (Reasons, Tr. 1207; CX0425 at 069 (Impax 2013 10-K securities filing)). The Endo Credit payment represented almost two-thirds of Impaxôs net inc

from rapidly expanding its sales from its introduction in 2006 until Reformulated Opana ER was introduced in 2012. (CX5000 at 082-83 (¶ 183) (Noll Report)).

RESPONSE TO FINDING NO. 500:

Complaint Counselôs Proposed Finding No. 500 is inaccurate and contrary to the weight of the record evidence. It is ñvery clear that the evidence . . . points to the relevant market being no smaller than the market for long-acting opioids in the United States.ò (Addanki, Tr. 2328). That market includes, at a minimum, extended-release oxycodone, morphine, hydromorphone, tapentadol, hydrocodone, oxymorphone, and fentanyl. (RX-547.0047 (Addanki, Rep. ¶ 85)). Indeed, the evidence at trial demonstrated that all long-acting opioids are interchangeable for the vast majority of patients, and that long-acting opioids compete vigorously on price. (*See, e.g.*, Michna, Tr. 2107; Bingol, Tr. 1324-25; Addanki, Tr. 2291 (*in camera*)).

This includes evidence of actual substitution among long-acting opioids. (RX-449.0007 ([redacted]); CX2732-003 (ñWithdrawal of Embeda by Pfizer/King had led to another unexpected inflexion point in Opana ER TRx demand as clinicians seek alternative therapies for their Embeda patients. . . . Of all branded LAOs, Opana ER and Kadian have benefited the most from the removal of Embeda.ò); RX-073.0002 at 13, 16 (Endo document tracking switching among various long-acting opioids and noting Endo ñmust accelerate the gain of switches from Oxycontinò); RX-060.0002 at 25 (thousands of patients switched between Opana ER and other long-acting opioids every month)).

501. Thus, oxymorphone ER is the relevant product market for purposes of assessing the conduct at issue in this case. Generic oxymorphone ER is a close economic substitute for Original Opana ER. Moreover, generic oxymorphone ER, despite not being therapeutically equivalent, has taken half of the prescriptions from Reformulated Opana

ER at substantially lower prices, and is the only substantial competitive restraint on sales of Reformulated Opana ER. (CX5000 at 083 (¶ 183) (Noll Report)).

RESPONSE TO FINDING NO. 501:

Complaint Counselôs Proposed Finding No. 501 is inaccurate and contrary to the weight of the record evidence. It is ñvery clear that the evidence . . . points to the relevant market being no smaller than the market for long-acting opioids in the United States.ò (Addanki, Tr. 2328). That market includes, at a minimum, extended-release oxycodone, morphine, hydromorphone, tapentadol, hydrocodone, oxymorphone, and fentanyl. (RX-547.0047 (Addanki, Rep. ¶ 85)). Indeed, the evidence at trial demonstrated that all long-acting opioids are interchangeable for the vast majority of patients, and that long-acting opioids compete vigorously on price. (*See, e.g.*, Michna, Tr. 2107; Bingol, Tr. 1324-25; Addanki, Tr. 2291 (*in camera*)).

A. Oxymorphone ER and other long-acting opioids differ in important ways

502. Opioids are among the oldest medicinal substances known, and they remain the most potent analgesic (pain-relieving) medications available. (CX5002 at 009 (¶ 18) (Savage Report)).

RESPONSE TO FINDING NO. 502:

Respondent has no specific response.

503. Opioids are generally indicated when other interventions are not effective in treating pain or when opioids present less risk than other interventions. (Savage, Tr. 697; RX-549 at 0020 (¶ 49 n.28) (

meet the individualized needs and responses of difference patients. (CX5002 at 010 (¶ 21) (Savage Report)).

RESPONSE TO FINDING NO. 504:

Respondent has no specific response.

505. Opioid medications exert their effects when the opioid molecules bind to opioid receptors on nerve cells. (CX5002 at 020 (¶ 53) (Savage Report)).

RESPONSE TO FINDING NO. 505:

Respondent has no specific response.

506. Most commonly-used opioid pain medications, including oxymorphone, act primarily on mu opioid receptors, though some, such as oxycodone, have kappa receptor effects as well. (CX5002 at 021 (¶ 55) (Savage Report)).

RESPONSE TO FINDING NO. 506:

Respondent has no specific response.

507. It has long been observed that different people respond somewhat differently to different opioid medications in term of analgesic response and side effects. At least two mechanisms are likely responsible for the variable responses to different opioids: variability in individual expression of opioid receptors, and metabolic differences between individuals. (CX5002 at 22 (¶ 58) (Savage Report); Michna, Tr. 2186, 2191-92).

RESPONSE TO FINDING NO. 507:

Respondent has no specific response.

508. There is significant variability in the molecular expression of mu opioid receptors from person to person with multiple variants (called polymorphisms). It is believed that observed clinically different responses to different opioid drugs are, at least in part, a result of how a particular mu opioid drug matches the mu opioidgs are, ʻ Mw ₰

509. As a result, opioid treatment often requires tr

would effectively complete, thereby causing prices to be lower. (CX5000 at 016 (¶ 36)

517. A product is a close economic substitute for a reference product if a ñsmall but significant non-transitory increase in priceò (SSNIP) of the reference product would cause a sufficient amount of sales to shift to the other product to make the price increase unprofitable. (CX5000 at 017 (¶ 38) (Noll Report); Noll, Tr. 1374 (ñThat is, if we think about our SSNIP test, we ask the question, if one productôs price goes up relative to the other, does that cause a large enough switch from one category to another that it wasnôt profit-enhancing to increase the price.ò)).

RESPONSE TO FINDING NO. 517: ă es otha ² я ᵠ γ m O

Respondent has no specific response. ≤

521. *Demand substitution* refers to actions by consumers to switch purchases among a given group of products. *Supply substitution* refers to the entry of new products from new sellers in the relevant market, either by shifting sales efforts from another geographic area to the relevant geographic

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. (CX5000 at 018 (¶ 40) (Noll Report); Noll, Tr. 1369 (ñThe key issue in this case is the degree to which there is price competition . . . that is to say, for the prices charged by producers of long-acting opioids to be competitive.ò)).

RESPONSE TO FINDING NO. 525:

Respondent has no specific response.

526. The core underlying fact that economists seek to uncover in defining a relevant market is the cross-elasticity of demand between a reference product and each product that is a plausible close substitute. The cross-elasticity of demand is the percentage change in sales of one product arising from a one percent change in the price of another product. (CX5000 at 018 (¶ 41, 41 n.12) (Noll Report)).

RESPONSE TO FINDING NO. 526:

Respondent has no specific response.

527. If the cross-elasticity of demand between two products is high, an attempt by the producer of one product to increase price will cause a large loss of sales to the other product, assuming that the prices of the other products remain unchanged. (CX5000 at 018 (¶ 41) (Noll Report)).

RESPONSE TO FINDING NOths

RESPONSE TO FINDING NO. 528:

brand-name drug, is clinical researchers. This group writes scholarly articles reporting the results of clinical trials, review articles summarizing many clinical trials, clinical practice guidelines to assist physicians, and the labels that drug companies must include with a prescription drug and that must be approved by the FDA. (CX5000 at 020 (¶ 45) (Noll Report)).

RESPONSE TO FINDING NO. 532:

Respondent has no specific response.

533. Additional evidence about market definition is the actual extent to which buyers switch among sellers. Two products are close economic competitors only if buyers regard them as sufficiently close substitutes that, in response to small changes in relative prices or other market conditions, they switch the product that they purchase. (CX5000 at 020 (¶ 46) (Noll Report)).

RESPONSE TO FINDING NO. 533:

Complaint Counselôs Proposed Finding No. 533 is improper because it states a legal conclusion, not a fact.

534. If products are sold in the same location and have identical attributes, buyers are likely to make their purchase decisions on the basis of price. If products differ in their attributes and where they are sold, buyers may have strong preferences among them and so give little weight to price in making purchase decisions. (CX5000 at 020 (¶ 46) (Noll Report)).

RESPONSE TO FINDING NO. 534:

Respondent has no specific response other than to note that the cited expert report (CX5000) contains no evidence or analysis to support the contention about what buyers are ñlikelyò to do.

535. In economics, ñhorizontal differentiation,ò refers to qualitative attributes for which buyers have different preferences. For example, consumers differ in the amount of salt that they prefer in their soup or sugar in their tea. (CX5000 at 020-21 (¶ 47) (Noll Report)).

RESPONSE TO FINDING NO. 535:

Respondent has no specific response.

RESPONSE TO FINDING NO. 539:

Complaint Counselôs Proposed Finding No. 539 is improper becaus

fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

543. Empirical examination of product choice within a group of drugs

547. The FDA categorizes generic drugs according to whether they are a ñtherapeutic equivalentò to the associated brand-name drug. The term ñtherapeutic equivalentò is potentially confusing because it is a much narrower concept than a ñtherapeutic classò of drugs, which refers to all drugs that are used to treat the same broad medical condition, or a ñpharmacologic class,ò which includes drugs that treat the same condition in a similar way. (CX5000 at 025 (¶ 56) (Noll Report)).

RESPONSE TO FINDING NO. 547:

Complaint Counselôs Proposed Finding No. 547 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

548. To be classified as therapeutically equivalent requires that the generic and brand-name drugs have essentially the same formulation and uses, and so are essentially perfect functional substitutes. Thus, the only source of product differentiation between a brand-name drug and a therapeutically equivalent generic is brand loyalty arising from the reputation and familiarity with the brand name. (CX5000 at 025-26 (¶ 57) (Noll Report)).

RESPONSE TO FINDING NO. 548:

Complaint Counselôs Proposed Finding No. 548 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

549. A generic drug can be bioequivalent to a brand-name drug without being classified as a therapeutic equivalent if it delivers the same API in the same dose at the same rate to the patient, but its formulation differs in other ways that the FDA regards as potentially important to some patient but that do not significantly affect the direct effect of the drug. (CX5000 at 026 (¶ 57) (Noll Report)).

RESPONSE TO FINDING NO. 549:

Complaint Counselôs Proposed Finding No. 549 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by

fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

550. The closest functional substitute for a brand-name drug is a generic that is designated as therapeutically equivalent. (Noll, Tr. 1370-71; CX5000 at 026 (¶ 59) (Noll Report)).

RESPONSE TO FINDING NO. 550:

Complaint Counselôs Proposed Finding No. 550 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

551. Other drugs may be sufficiently similar that they are reasonably close functional substitutes and, therefore, candidates to be economic substitutes and so part of the same relevant market. (CX5000 at 024 (¶ 54) (Noll Report)).

RESPONSE TO FINDING NO. 551:

Respondent has no specific response.

552. The next closest functional substitute for a brand-name drug is a bioequivalent drug that is not categorized as therapeutically equivalent, which includes bioequivalent generic drugs that are not therapeutically equivalent. (Noll, Tr. 1371; CX5000 at 027 (¶ 59) (Noll Report)).

RESPONSE TO FINDING NO. 552:

Complaint Counselôs Proposed Finding No. 552 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

553. While drugs that are therapeutically equivalent constitute the narrowest category of drugs that plausibly are in the relevant market for a drug that is a reference product, the

broadest possible market includes all drugs that are in the same therapeutic class. The broad therapeutic class that contains oxymorphone is analgesics (pain killers). (CX5000 at 027 (¶ 60) (Noll Report)).

RESPONSE TO FINDING NO. 553:

Complaint Counselôs Proposed Finding No. 553 is improper because it states a legal conclusion, not a fact.

554. Within a therapeutic class, drugs are further divided into pharmacologic classes, which are drugs that treat a given medical condition in a similar way. The pharmacologic class that includes oxymorphone is called opioid analgesics. (CX5000 at 028 (¶ 61) (Noll Report)).

RESPONSE TO FINDING NO. 554:

Complaint Counselôs Propose

556. Often different drugs in a pharmacologic class are not close economic substitutes because they are prescribed for different conditions (e.g., mild versus severe pain) and/or different types of patients (e.g., children versus adults, women versus men, opioid experienced versus opioid inexperienced). (CX5000 at 028 (¶ 62) (Noll Report)).

RESPONSE TO FINDING NO. 556:

Complaint Counselôs Proposed Finding No. 556 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

557. In addition, drugs in the same pharmacologic class may not be close therapeutic substitutes because they have different adverse side effects and/or interactions with other drugs. (CX5000 at 028 (¶ 62) (Noll Report)).

RESPONSE TO FINDING NO. 557:

Complaint Counselôs Proposed Finding No. 557 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

558. Thus, in defining a relevant drug market, the appropriate starting place is drugs containing the same API. The next step is to consider other drugs in the same pharmacologic class that are used to treat the same symptoms and have the same or similar therapeutic benefits and risks. (CX5000 at 028-29 (¶ 62) (Noll Report)).

RESPONSE TO FINDING NO. 558:

Complaint Counselôs Proposed Finding No. 558 is improper because it states a legal conclusion, not a fact.

559. Drugs can be functional substitutes but not necessarily close economic substitutes because functionality is not the only thing that matters. In most markets, products are differentiated, and consumers will differ in the values they place upon those attributes.

Moreover, the act of switching from one product to another may be costly. (Noll, Tr. 1373).

RESPONSE TO FINDING NO. 559:

To the extent Complaint Counselôs Proposed Finding No. 559 rela

RESPONSE TO FINDING NO. 562:

Complaint Counselôs Proposed Finding No. 562 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

563. The primary concern of a physician in writing a prescription is to select a drug that will deliver the greatest therapeutic benefit, taking into account the patientôs overall condition, including use of other drugs and reliability in following the prescription. (CX5000 at 029 (¶ 64) (Noll Report); *see also* Savage, Tr. 771; Michna, Tr. 2177)).

RESPONSE TO FINDING NO. 563:

Complaint Counselôs Proposed Finding No. 563 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

The cited testimony of Dr. Savage and Dr. Michna speaks for itself. (Savage, Tr. 771 (ñQ. Now, why wouldnôt minor changes in prices change your prescribing habits? A. First, because Iôm generally not aware of the minor changes in price. Second, because . . . my concerns here are for the clinical well-being of the patient, and those would take priority over more abstract financial concerns.ò); Michna, Tr. 2177 (ñQ. Okay. But you prescribe the product that you feel is the best for your patient in his or her clinical situation? A. Yes. Q. And your priority is the safety and health of your patient? A. Ultimately, yes.ò)).

Finally, the Proposed Finding is misleading to the extent it ignores that, in some instances ð including the treatment of chronic pain with long-acting opioids ð there are multiple prescription drug options that deliver the same therapeutic benefit. (*See* Michna, Tr. 2107; Noll, Tr. 1504-05; *see also* Savage, Tr. 782-83 (ñ[M]ost [opioids] are interchangeable if attention is

paid to relative potencies and onset and duration of action.ò)). Under such circumstances, physician prescribing behavior may be driven by other factors, such as relative cost to the patient, including insurance coverage, and physician habit. (RX-549.0006-07, 20-23 (Michna Rep. ¶¶ 21, 49-51); Michna, Tr. 2148; CX4046 (Michna, Dep. at 115-16); CX4044 (Addanki, Dep. at 148)). In fact, Complaint Counselôs economic expert, Professor Noll, admitted that doctors make prescribing decisions based on price and formulary tiering, among other issues. (Noll, Tr. 1505-06). Dr. Savage, Complaint Counselôs medical expert, similarly admitted that ñthe copay is one variable that may be consideredò when making prescription choices ð ñclinical determinations are usually the first consideration and then copays.ò (CX4041 (Savage, Dep. at 138); *see* Savage, Tr. 772 (availability of insurance coverage for a medication would affect Dr. Savageôs clinical decision-making)).

> 564. Physicians do not have a strong incentive to take into account the relative prices of drugs in selecting among them, especially if a substantial fraction of a patientôs drug expenditures are covered by insurance or a government health program. (CX5000 at 029 (¶ 64) (Noll Report)).

RESPONSE TO FINDING NO. 564:

Complaint Counselôs Proposed Finding No. 564 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

Proposed Finding No. 564 is also inaccurate. Doctors seek to avoid high out-of-pocket costs for patients, and they regularly do so by making prescribing decisions based on price and where a medication is located on an insurance companyôs formulary. (CX4046 (Michna, Dep. at 115-16); CX4044 (Addanki, Dep. at 148)). In fact, Complaint Counselôs economic expert, Professor Noll, admitted that doctors make prescribing decisions based on price and formulary

tiering, among other issues. (Noll, Tr. 1505-06). Dr. Savage, Complaint Counselôs medical expert, similarly admitted that ñthe copay is one variable that may be consideredò when making prescription choices ð ñclinical determinations are usually the first consideration and then copays.ò (CX4041 (Savage, Dep. at 138); *see* CX5002-063 (Savage Rep. ¶ 177) (noting that clinicians will ñconsciously consider costsò when they are ñaware that the patient will need to pay out of pocketò)). Indeed, where there are multiple equally safe and effective treatment options ð for example, when treating severe pain with long-acting opioids ð cost to the patient (which is a function of insurance coverage and formulary placement for insured patients) is a ñmain driverò of prescribing decisions. (RX-549.0007 (Michna R

¶ 177) (noting that clinicians will ñconsciously consider costsò when they are ñaware that the patient will need to pay out of pocketò)).

Indeed, doctors are aware of drug prices when prescribing medications. When they enter a ñdrug order in the system, as

RESPONSE TO FINDING NO. 566:

Respondent has no specific response.

567. Average drug prices are strongly affected by state ñgeneric substitutionò law. All states have laws that allow or even require, under some circumstances, pharmacists to substitute a generic drug for a brand-name drug as long as the generic and the brand-name drug use the same active ingredient in the same dosage, form and method of delivery. (CX5000 at 030 (¶ 66) (Noll Report)).

RESPONSE TO FINDING NO. 567:

The first sentence of Complaint Counselôs Proposed Finding No. 567 violates this

Courtôs Order on Post-Trial Brie

source of price competition in the pharmaceutical industry. (CX5000 at 035 (¶ 76) (Noll Report)).

RESPONSE TO FINDING NO. 572:

Complaint Counselôs Proposed Finding No. 572 is improper and inadmissible. The Proposed Finding purports to summarize academic literature that is not in evidence and, if it were, that literature would be the best evidence of its contents.

573. Drugs within the same therapeutic class usually exhibit sufficiently extensive product differentiation that a brand-name drug usually faces, at best, weak price competition from other drugs in the same therapeutic class. (CX5000 at 035 (¶ 77) (Noll Report)).

RESPONSE TO FINDING NO. 573:

Complaint Counselôs Proposed Finding No. 573 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

574. Prior to the entry of a bioequivalent generic, the price of a drug typically is far above the competitive level. (CX5000 at 035 (¶ 77) (Noll Report)).

RESPONSE TO FINDING NO. 574:

RESPONSE TO FINDING NO. 575:

Complaint Counselôs Proposed Finding No. 575 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

576. Within a few months after entry, generics take away most sales from the brand-name drug. The price of the first generic entrant typically is substantially below the price of the brand-name equivalent, and as more generic drugs enter, generic prices continue to fall. (CX5000 at 035-36 (¶ 78) (Noll Report)).

RESPONSE TO FINDING NO. 576:

Complaint Counselôs Proposed Finding No. 576 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

577. Thus generic entry can be used as a reasonable indicator or proxy of substantially lowered price for the product. (CX5000 at 072 (¶ 158 n.214) (Noll Report)).

RESPONSE TO FINDING NO. 577:

Complaint Counselôs Proposed Finding No. 577 is improper becaus

578. The smallest price difference between generic and brand-name drugs arise during the 180-day exclusivity period when a single generic firm is in the market as a first-filer. If a single independently-sold generic drug is available during the exclusivity period, its price averages about thirty percent less than the brand-name price. When generic entry occurs with no exclusivity period, generic prices are about fifty percent below the brand-name price during the first six months after generic entry. (CX5000 at 036 (¶ 78) (Noll Report)).

RESPONSE TO FINDING NO. 578:

Complaint Counselôs Proposed Finding No. 578 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

D. Generic versions of oxymorphone ER are uniquely close substitutes for Opana ER

579. Reformulated Opana ER is bioequivalent to Original Opana ER. Impaxôs oxymorphone ER is bioequivalent and therapeutically equivalent to Original Opana ER, but only bioequivalent to the reformulated version. (CX5000 at 038 (¶ 86) (Noll Report); Engle, Tr. 1703 (agreeing that Impaxôs generic was not AB-rated to the reformulated version of Opana ER)).

RESPONSE TO FINDING NO. 579:

While Respondent does not dispute that Impaxôs oxymorphone ER product was not AB-rated to the reformulated version of Opana ER, the remainder of Complaint Counselôs Proposed Finding No. 579 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

580. The most plausible candidates to be close economic substitutes for a brand-name drug are other drugs that contain the same API and are bioequivalent. (CX5000 at 038 (¶ 86) (Noll Report)).

RESPONSE TO FINDING NO. 580:

Complaint Counselôs Proposed Finding No. 580 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

581. When analyzing pharmaceutical product markets, one technique to determine whether drugs are close substitutes is to observe what happens to the price and sales volume of one drug when a generic version of another, functionally substitutable, drug is introduced. (Noll, Tr. 1374-1375).

RESPONSE TO FINDING NO. 581:

Complaint Counselôs Proposed Finding No. 581 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

582. Generic entry significantly erodes the market share of a therapeutically equivalent branded pharmaceutical product within a very rapid period of time. (CX4025 (Bingol, Dep. at 43)).

RESPONSE TO FINDING NO. 582:

Complaint Counselôs Proposed Finding No. 582 is not supported by the cited evidence. Mr. Bingol did not say anything about ñtherapeutically equivalentò products. He spoke only of generic products generally, and explained ñ[w]e monitored all matter. Competitive intelligence and generics are one component that you have to monitor as a course of normal due diligence in your business.ò (CX4025 (Bingol, Dep. at 43)).

583. Numerous documents show that both Endo and Impax anticipated that entry of Impaxôs generic oxymorphone ER would reduce the sale of Opana ER, and that this loss

would be far greater if generics were rated as therapeutically equivalent. (CX5000 at 043 (¶ 94) (Noll Report); *see also* CCF ¶¶ 590-98, 603-27, below).

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RESPONSE TO FINDING NO. 591:

Complaint Counselôs Proposed Finding No. 591 is incomplete and misleading. Mr. Engle testified that his forecasts ñassumedò things like launch dates and the amount of sales Impax could capture for purposes of modelling possible outcomes based on those assumptions. (Engle, Tr. 1710-11, 1719 (five-year plans are ñdraft[s] with many, many assumptionsò)). With respect to the cited document

understand possible outcomes, and that the forecast would not contain all relevant information. (Engle, Tr. 1720, 1766-67).

593. In the February 2010 Five Year Plan, Impaxôs ñBaseò case indicated that Impax expected generic oxymorphone ER would have a net price that was 35% of the brand WAC price. (CX0004 at 015 (Updated Five Year Plan); Engle, Tr. 1727-28).

RESPONSE TO FINDING NO. 593:

Complaint Counselôs Proposed Finding No. 593 is incomplete and misleading. Mr. Engle testified that his forecasts ñassumedò things like launch date and the amount of sales Impax could capture for purposes of forecasting possible results. (Engle, Tr. 1710-11, 1719 (five-year plans are ñdraft[s] with many, many assumptionsò)).

as a result of the forecast, but rather that assumptions were used to understand possible outcomes, and that the forecast would not contain all relevant information. (Engle, Tr. 1720, 1766-67).

595. In May 2010, the head of Impaxôs generics subsidiary, Chris Mengler, circulated a five-year plan that included Impaxôs expected net sales, market shares and substitution rates for generic oxymorphone ER. (CX0514 at 001, 004 (Impax Five Year Plan)).

RESPONSE TO FINDING NO. 595:

Respondent has no specific response other than to clarify that the cited evidence does not indicate that Impax expected each of the results. Five year plans instead utilize ñmany, many assumptionsò to understand possible outcomes based on those assumptions. (Engle, Tr. 1710, 1719-20 (they ñgive a good range of possibilitiesò)). Among those assumptions are substitution rates and market shares. (Engle, Tr. 1711, 1713-14). Moreover, these forecast would not contain all relevant information. (Engle, Tr. 1766-67).

596. In the May 2010 Five Year Plan ñUpsideò case, generic substitution was estimated to be 50% in June 2010, and 90% by October 2010. (CX0514 at 004 (Impax Five Year Plan)).

RESPONSE TO FINDING NO. 596:

Complaint Counselôs Proposed Finding No. 596 is incomplete and misleading because it omits the plain language of the document, which notes that the launch-date assumption in the forecast was an ñobvious[] controversial element.ò (CX0514-001; *see* Engle, Tr. 1710-11, 1719 (five year plans are ñdraft[s] with many, many assumptionsò)).

597. In the May 2010 Five Year Plan ñBaseò case, which assumed that generic launch occurred in July 2011 and others followed immediately, generic penetration was 50% of prescriptions initially and 80% by October 2011. (CX0514 at 004 (Impax Five Year Plan)).

show that potential impact. Whether or not it comes to pass is another question. . . . [F]orecasts, especially these types of assumptions, arenôt always probability based. You canôt really know.ò (CX4025 (Bingol, Dep. at 74-76)).

600. Endo ordinary business documents support the conclusion that Opana ER and generic oxymorphone ER are close economic substitutes and, therefore, in the same relevant market. (CX5000 at 043 (¶ 95) (Noll Report); *see also* CCF ¶¶ 603-27, below)).

RESPONSE TO FINDING NO. 600:

Complaint Counselôs Proposed Finding No. 600 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Moreover, to the extent Proposed Finding No. 600 purports to summarize and incorporate other findings, the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

601. Endo regularly produced and obtained forecasts of future sales volume and net sales, and Endo relied on these forecasts for business planning purposes and to inform investors. As such, Endo took great pains in establishing the most reliable methodology possible for its forecasts. (CX2607 at 013 (¶ 30) (Lortie Decl.)).

RESPONSE TO FINDING NO s, the x l > † ‘ M ŏM ‘ ǯ ‘ ‘ v

604. In its 2007 ñOPANA Brand LCM Update,ò Endo estimated that if it beat generics to market with Reformulated, but was unable to force generics off the market with a citizen petition, generics would capture about 50% of the market. (CX2578 at 009 (Opana Brand LCM Update)). [redacted] (CX5000 at 177-83 (Exhibits 2A1 through 2A7) (*in camera*)).

RESPONSE TO FINDING NO. 604:

The first sentence of Complaint Counselôs Proposed Finding No. 604 is incomplete and misleading in its suggestion that ñEndoò ñestimatedò anything. The cited document is a draft from 2007, just after original Opana ER launched. (CX2578-009 (ñdraftò); *see* Bingol, Tr. 1298-99 (discussing ñdraftò language: ñJUDGE CHAPPELL: . . . it says itôs a draft. Why would he have presented a draft to anybody?ò)).

The second sentence of Proposed Finding No. 604 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò

605. In January 2010, Endo forecasted a substantial decline in Opana ER sales if it was unable to launch its reformulated product ahead of generic entry. (CX2724 at 006 (Endo Commercial Strategy Scenarios); Bingol, Tr. 1309-10 (stating that the blue/green line is ña scenario in which we have Opana ER only, the current formulation, with generics.ò); CX4025 (Bingol, Dep. at 59-60) (agreeing that the dashed blue line showed a substantial decrease in value following entry of generic Opana ER)).

RESPONSE TO FINDING NO. 605:

Complaint Counselôs Proposed Finding No. 605 is incomplete and misleading because it ignores the testimony of Mr. Bingol, the author of the cited document (CX2724). Mr. Bingol explained that the forecast was based on ñmanyò assumptions and Endo was looking at ñany possible scenario.ò (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 (ñWe have to consider all scenariosò)). It was ñbased on scenarios that we had created, I mean, the accuracy of which are always debatable.ò (Bingol, Tr. 1303). And many of the assumptions were actually total

RESPONSE TO FINDING NO. 610:

Respondent has no specific response other than to note that Mr. Bingol did not state that generic entry would be ñunique and disastrous,ò or that a launch was imminent: ñEndo has been planning that the launch of a generic substitute for Opana ER in these higher tablet strengths will not occur until at least September 2013.ò (CX3273-007-08).

611. In January 2011, Endo was estimating that Reformulated Opana ER would suffer 85% erosion in611.

there was a risk of generic entry before the settlement. (CX2732 at 002 (Opana ER Demand Justification); CX4025 (Bingol, Dep. at 95)).

RESPONSE TO FINDING NO. 612:

Complaint Counselôs Proposed Finding No. 612 is incomplete, misleading, and not supported by the cited evidence. The cited evidence does not discuss ñeliminating the risk of generic entry.ò Moreover, the document states it is ñ[s]trictly in draftò and ñDraft- Not for Distribution.ò (CX2732-001-02). Finally, Endo ñplan[ned] for different eventualitiesò and analyzed ñdifferent scenariosò and different ñassumption[s]ò about launch. (CX4025 (Bingol, Dep. at 31-32, 95-96) (ñI donôt know that Iôm qualified to answer what the level of risk was for other products, but certainly there was a settlement here.ò)).

613. In December 2011, Endoôs 10 Year Outlook compared a ñBaseò case and more conservative ñDownsideò case. The ñBaseò case assumed Reformulated Opana ER launch in 2012, and generic entry in 2017. (CX2579 at 009 (Endo 10 Year Revenue Outlook)). The ñDownsideò case assumed Reformulated Opana ER launch in 2012, and AB rated generic entry in 2013. (CX2579 at 011 (Endo 10 Year Revenue Outlook)). In the ñBaseò projection, Reformulated Opana ER revenues grew from $262.5 million in 2012 to $744.2 million in 2016, followed by a decline to $455.4 million in 2017. (CX2579 at 003 (Endo 10 Year Revenue Outlook)). In the ñDownsideò case, revenues of Reformulated Opana ER would peak at $233.4 million in 2012, then fall to $142.1 million in 2013. (CX2579 at 007 (Endo 10 Year Revenue Outlook)).

RESPONSE TO FINDING NO. 613:

While Respondent does not dispute that the cited figures appear in the cited document, Complaint Counselôs Proposed Finding No. 613 is incomplete and misleading. The cited document contained additional scenarios, and other forecasting assumptions, including sales erosion. (CX2579-009-11). Indeed, it was Endoôs practice to forecast different scenarios regarding the future of its Opana ER product to ñanalyze the full range of potential outcomes.ò (Cuca, Tr. 663-64). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted ña number of different

potential outcomes over the course of years,ò the accuracy of which were ñalways debatable.ò

(Bingol, Tr. 1292, 1303).

614. In August 2012, Endo submitted a ñCitizen Petitionò requesting that the FDA determine that Original Opana ER was withdrawn from the market for safety reasons. (CX3203 at 030 (Endoôs Citizen Petition)).

RESPONSE TO FINDING NO. 614:

Respondent has no specific response.

615. In November 2012, Endo sued the FDA to obtain a court order to require that the FDA rule on its citizen petition, which would have the effect of prohibiting ANDA filers from selling generic oxymorphone ER. (CX1223 at 002 (Endo Complaint Against FDA)).

RESPONSE TO FINDING NO. 615:

Respondent has no specific response.

616. In its 2012 lawsuit against the FDA, Endo submitted a sworn declaration from Chief Operating Officer Julie H. McHugh asserting that, if the FDA waited until May 10, 2013 to make its withdrawn-for-safety

significant share of Endoôs Reformulated Opana ER market share if it entered the market with its generic oxymorphone ER in January 1, 2013. (CX3204 at 038 (Endoôs opposition to motions to dismiss filed by the FDA and Impax)).

RESPONSE TO FINDING NO. 617:

While Respondent does not dispute that the cited language appears in the cited document, Complaint Counselôs Proposed Finding No. 617 is incomplete and misleading. Endo subsequently admitted that Impaxôs actual ñgeneric sales have had a relatively small effect on Opana ER.ò (CX2607-010-11 (ñEndo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mildò)).

618.

RESPONSE TO FINDING NO. 619:

621. In May 2013, after Impax had entered, another Endo document set forth further estimates of the consequences of limiting generic competition. Three market conditions were examined: (1) the FDA removal of generics from the market, (2) no new generic launches, and (3) at least three generics on the market by the end of 2013. Estimated 2014 revenues for Reformulated Opana ER under these three scenarios are $315 million, $226 million, and $35 million, respectively. (CX3202 (Opana ER Scenario Request)).

RESPONSE TO FINDING NO

RESPONSE TO FINDING NO. 626:

While Respondent does not dispute that the language appears in the cited document, Complaint Counselôs Proposed Finding No. 626 is incomplete and misleading. Mr. Lortieôs declaration has nothing to do with Impax and admits that Impaxôs actual ñgeneric sales have had a relatively small effect on Opana ER.ò (CX2607-010-11 (ñEndo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mildò)).

627. In September 2013, as part of its appeal of a District Court ruling denying an injunction against Actavis, Endo argued that further generic entry by Actavis in the oxymorphone ER market would irreparably harm Endo by causing the prices and sales of Opana ER to fall. (CX2608 at 013 (Endoôs reply in support of motion for an injunction pending appeal)).

RESPONSE TO FINDING NO. 627:

Respondent has no specific response other than to clarify that the cited document has nothing to do with Impax or the Endo-Impax settlement.

3. Data available since the entry of generic oxymorphone ER confirms the unique impact of such generic entry on Opana ER sales and prices

628. The proposition that generic oxymorphone ER is a close economic substitute for Opana ER can be tested by examining the effect of generic entry on the sales and prices of Opana ER and the total sales and average prices of all forms of oxymorphone ER. These data are shown in Exhibits 2A and 2B of the Noll Report. (CX5000 at 053-54 (¶ 116) (Noll Report)).

RESPONSE TO FINDING NO. 628:

Complaint Counselôs Proposed Finding No. 628 is both unsupported and wrong. Professor Nollôs analysis is based on his scanning for any ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Professor Noll recognizes that a SSNIP test is the

RESPONSE TO FINDING NO. 631:

Complaint Counselôs Proposed Finding No. 631 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself.

632. [redacted] (CX5000 at 054-55 (¶ 118) (Noll Report); CX5000 at 178, 180 (Exhibits 2A2, 2A4) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 632:

Complaint Counselôs Proposed Finding No. 632 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself.

633. Exhibits 2B1 through 2B7 of the Noll Report show the average net realized price per tablet of prescriptions for each of the seven doses of Opana ER, generic oxymorphone ER, and all formulations of oxymorphone ER. These data are actual average realized prices as derived from the financial records of Endo, Actavis and Impax. Data have not been produced by Endo and Actavis for the entire period that each was selling oxymorphone ER. (CX5000 at 055 (¶ 120, ¶ 120 n.139) (Noll Report); CX5000 at 184-190 (Exhibits 2B1-7) (Noll Report)).

RESPONSE TO FINDING NO. 633:

Respondent has no specific response other than to note that the data speaks for itself, but is incomplete and does not consider other long-acting opioid products.

634. [redacted] (CX5000 at 055 (¶ 120) (Noll Report); CX5000 at 184 (Exhibits 2B1) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 634:

Complaint Counselôs Proposed Finding No. 634 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself, but is incomplete and does not consider other long-acting opioid products. Finally, Respondent objects

Engle testified that Impax would ñperiodicallyò lower prices. (CX4038 (Engle, Dep. at 119)). Dr. Ben-Maimon said that she did not recall whether Impaxôs prices were ever lowered. (CX4021 (Ben-Maimon, Dep. at 132)).

640. Impaxôs February 2014 generics division board presentation noted ñActavis launched in Sept 2013 ï Defended vigorously except for a few small accounts.ò (CX2537 at 013 (Impax Board Meeting Presentation)). Similarly, the December 2014 generics division board presentation noted ñOxymorphone ER sales continued to experience pricing pressure from Actavis with Global defending all price challenges.ò (CX3140 at 015 (Impax Board Meeting Presentation)).

RESPONSE TO FINDING NO. 640:

Respondent has no specific response.

641. The sales and price data for oxymorphone ER reveal that generic entry caused Opana ER to lose market share and the average price of oxymorphone ER to fall, although these outcomes were more protracted than would have been expected had the generics been rated therapeutically equivalent substitutes for Opana ER. (CX5000 at 056 (¶ 122) (Noll Report)).

RESPONSE TO FINDING NO. 641:

Complaint Counselôs Proposed Finding No. 641 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself, but is incomplete and does not consider other long-acting opioid products.

642. The evidence shows that nearly half of the sales of branded Opana ER diverted to sales of generic oxymorphone. At the time generics entered, the market for Opana ER could not have been competitive, or else the price would not have fallen as dramatically as it did and the shift to generics would not have been as great. (Noll, Tr. 1380-81).

RESPONSE TO FINDING NO. 642:

Complaint Counselôs Proposed Finding No. 642 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by

RESPONSE TO FINDING NO. 646:

Respondent has no specific response, except to clarify that this approach must be understood in the larger context that generic companies like Impax achieve generic sales primarily through substitution of generic products for the corresponding brand-name product. (Mengler, Tr. 522; Engle, Tr. 1703).

647. The best way to estimate the size of a generic market opportunity is to look at the size of the brand plus the existing generic products. (Reasons, Tr. 1219-20; CX4020 (Reasons, Dep. at 74) (ñIn the generic industry, generally . . . the size of the brand and existing generics is used to estimate the potential opportunity of your own generics.ò); CX4037 (Smolenski, Dep. at 48) (ñ[G]enerally speaking, doing generic forecasting, you would focus specifically on the reference listed product.ò)).

RESPONSE TO FINDING NO. 647:

Respondent has no specific response, except to clarify that this approach must be understood in the larger context that generic companies like Impax achieve generic sales primarily through substitution of generic products for the corresponding brand-name product. (Mengler, Tr. 522; Engle, Tr. 1703).

648. In a December 2012 Board of Directors presentation, Impax indicated that the market value of the oxymorphone ER dosage strengths on which Impax was first to file was $450 million. Consistent with Impaxôs general practice, this market value included only Opana ER, and did not include any other products. (CX3119 at 020 (December 4, 2012 Board of Directors Presentation); CX4020 (Reasons, Dep. at 75-76)).

RESPONSE TO FINDING NO. 648:

Respondent has no specific response to the first sentence of Proposed Finding No. 648. The second sentence of Proposed Finding No. 648 is not supported by the cited evidence and lacks foundation. The cited evidence says nothing about Impaxôs general practice. Mr. Reasons also testified that he was not sure what was included in the market value. (CX4020 (Reasons, Dep. at 73-74) (ñQ. Is anything else included in that market value? A. I donôt know.ò)).

649. In other contemporaneous business documents, Impax considered only other oxymorphone ER products as competitors to its generic oxymorphone ER. It did not consider any other long-acting opioids as competitors. (CX3102 at 017 (October Rating Agency Presentation) (identifying Endoôs branded Opana as the only competitor); CX3107 at 007 (November 2014 Executive Committee Review) (identifying ñno competitorsò for oxymorphone)).

RESPONSE TO FINDING NO. 649:

Complaint Counselôs Proposed Finding No. 649 is incomplete and misleading. The first cited document (CX3102) lists Endo as a competitor but says nothing about whether other long-acting opioids are competitors. The second cited document (CX3107) does not conclude there are ñno competitorsò for oxymorphone ER, it simply assumed it for purposes of the specific forecast. (CX3107-007). Proposed Finding No. 649 also ignores the testimony of Todd Engle, Impaxôs Vice President of Sales and Marketing for the Generics Division, who explained that Impax specifically targeted OxyContin/oxycodone prescribers with its promotional efforts after it launched its oxymorphone ER product. (CX4004 (Engle, IHT at 210-11); RX-394.0001). Mr. Engleôs testimony is consistent with contemporaneous Impax documents as well. (*See* RX-394; RX-304).

5. Impax considered only the price of other oxymorphone ER products in setting the price of its generic oxymorphone ER product

650. In forecasting generic prices, Impax assumes a discount off the reference brandôs list price and not the prices of other branded products. (Engle, Tr. 1715).

RESPONSE TO FINDING NO. 650:

Complaint Counselôs Proposed Finding No. 650 is not supported by the cited evidence and is misleading. Mr. Engle did not testify about forecasting generic prices. He was asked about ñforecasting sales of a generic product.ò (Engle, Tr. 1715). In order to do that, Mr. Engle makes an ñassumptionò about ñthe average net selling price,ò for which he will use a discount off the brandôs list price. (Engle, Tr. 1715). Such general testimony should be viewed in the larger

context that generic companies like Impax achieve generic sales primarily through substitution of generic products for the co

E. Other long-acting opioids did not sufficiently constrain Opana ER sales and prices

654. Complaint Counselôs economic expert, Roger Noll, was able to infer the lack of demand cross elasticity between different long-acting opioids based on facts about market events. (Noll, Tr. 1509-10; CX4039 (Noll, Dep. at 188) (ñAnd if we observe that thereôs little interaction between events in ï that occur in the sales of one opioid on the sales of another opioid, then thatôs indirect evidence that the cross-elasticities of demand are relatively low, and so thereôs relatively little competition.ò)).

RESPONSE TO FINDING NO. 654:

Complaint Counselôs Proposed Finding No. 654 is not supported by the record. Professor Noll ñdid not attempt to estimate the elasticity of the demand curve for any drug.ò (Noll, Tr. 1509-10). In fact, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Professor Noll merely scanned for any ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384).

The record is clear, however, that market events regularly lead to switching between Opana ER and other long-acting opioid products. [redacted] (RX-449.0007). [redacted] (Addanki, Tr. 2266-67). Formulary changes and changes in price also led to switches. When UPMC instituted formulary changes that preferenced Opana ER and several generic long-acting opioids over OxyContin ð thereby lowering the prices that patients paid for those drugs ð roughly 70 percent of OxyContin patients switched to alternative long-acting opioids, including Opana ER, generic Morphine Sulfate ER (MS ER), and generic Fentanyl patches. (RX-087).

Endo regularly was impacted by such market events. (RX-087 (significant increase in usage for Opana ER following formulary change in which it was preferenced over OxyContin); CX2732-003 (ñWithdrawal of Embeda by Pfizer/King had led to another unexpected inflexion point in Opana ER TRx demand as clinicians seek alternative therapies for their Embeda patients. . . . Of all branded LAOs, Opana ER and Kadian have benefited the most from the removal of Embeda.ò); RX-26.0005-08 (

); RX-073.0002 at 13, 16 (Endo document tracking switching among various long-acting opioids and noting Endo ñmust accelerate the gain of switches from Oxycontinò); RX-060.0002 at 25 (thousands of patients switched between Opana ER and other long-acting opioids every month)).

655. The use of indirect evidence regarding the lack of cross-elasticity of demand between Opana ER and other long-acting opioids is required because both economists agree that it was not possible to reliably calculate cross-elasticity based on the available data. (Noll, Tr. 1517; Addanki, Tr. 2476 (ñI think your economist and I agree that

[redacted]

[redacted]

[redacted]

CX5000 at 194-195 (Exhibit 4) (Noll Report); CX5002 at 106 (Appendix C) (Savage Report)).

RESPONSE TO FINDING NO. 656:

Respondent has no specific response.

657. Many LAOs (although not oxymorphone) are available as compound products, combining an LAO with another drug, but single-API LAOs are the natural starting place to try to find economic substitutes for oxymorphone ER since a drug that combines an LAO with some other drug is unlikely to be a close competitive substitute for oxymorphone ER if the single-API version of the same drug is not a close competitive substitute. (CX5000 at 060-61 (¶ 130) (Noll Report)).

RESPONSE TO FINDING NO. 657:

Complaint Counselôs Proposed Finding No. 657 is based on unreliable expert testimony and should be disregarded. Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

Respondent also objects to Proposed Finding No. 657 because the term ñnatural starting placeò is vague and ambiguous. Further, if there is any ñnatural starting placeò to try to find economic substitutes for oxymorphone ER, it is by evaluating price competition among long-acting opioids at three levels: the payor, prescriber, and patient levels. (

RESPONSE TO FINDING NO. 658:

Complaint Counselôs Proposed Finding No. 658 is incomplete, inaccurate, and misstates the facts in the record. Whether two long-acting opioids that use different APIs are economic substitutes depends on actual substitution in the face of price changes. Product differentiation is only one part of that calculus. As Professor Noll notes, ñtwo products are close economic substitutes if a buyer will switch from one to the other in response to a small change in relative prices.ò (CX5000-061-62 (Noll Rep. ¶ 133)). And the record is replete with evidence that long-acting opioid prescriptions switched between products as a result of changes in price. (RX-087 (UPMC formulary change led 70 percent of patients on OxyContin to switch to a different, lower-priced long-acting opioid, including Opana ER, generic Morphine Sulfate ER (MS ER), and generic Fentanyl patches); RX-021.0005, 07 ([redacted]); RX-022.0004 (same); RX-448.0020 ([redacted]); Addanki, Tr. 2500 (describing formulary price competition and noting that rebates are on the order of magnitude of a small but significant non-transitory increase in price, indicating that ñeven small price changes were competitively potentially significantò)).

Further, the record shows that all long-acting opioids are equally safe and effective in relieving pain in the vast majority of patients. (Michna, Tr. 2107; Noll, Tr. 1504-05). ñ[M]ost [opioids] are interchangeable if attention is paid to relative potencies and onset and duration of action.ò (Savage, Tr. 782-83). Accordingly, no one long-acting opioid is superior to any other long-acting opioid across broad populations of patients. (Savage, Tr. 790-91). The only differences in long-acting opioid treatments occur among ñ*individual* patients with *specific* types

also RX-073.0002 at 13, 16 (Endo document tracking switching among various long-acting opioids and noting Endo ñmust accelerate the gain of switches from Oxycontinò); RX-060.0002 at 25 (thousands of patients switched between Opana ER and other long-acting opioids every month)).

660. In the case of LAOs, patients cannot easily switch in response to a change in relative prices for two reasons. First, even if two opioids are equally safe and effective for a given patient, switching between them is risky. Second, opioids differ in medically important ways so that they are not all equally safe and effective for all patients, regardless of the patientôs physiology and health status. (CX5000 at 061 (¶ 133) (Noll Report); CX5002 at 041-42, 061-062 (¶¶ 115-116, 172) (Savage Report); Savage, Tr. 770 (ñIf theyôre tolerating [Opana ER] well and itôs meeting their needs, Iôd prefer to keep them on the drug that theyôre using.ò); Michna, Tr. 2126 (ñ[A]s humans weôre 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 would be some

For these reasons, rotating from one long-acting opioid to another does not involve significant risks when conducted by a doctor who knows the medications, and it occurs frequently. (Michna, Tr. 2124, 2126 (switching is ñprobably done thousands of times each dayò); Savage, Tr. 693-94, 762, 782-83; RX-073.0002 at 45 (ñOpioid rotation/switching is common in this therapeutic category.ò)). Indeed, patients are almost always switched between opioids when they leave the hospital, even if they are tolerating a specific opioid. (Savage, Tr. 798-801; Noll, Tr. 1530 (ñphysicians very often switch which molecule is used when the patient leaves the hospitalò)). The most commonly used opioids in emergency rooms and other inpatient settings are hydromorphone, fentanyl, and morphine. (Savage, Tr. 787). The most commonly prescribed opioids in outpatient settings are oxycodone, hydrocodone, and morphine. (Savage, Tr. 786). More generally, thousands of patients are switched from Opana ER to other long-acting opioids ð and from other long-acting opioids to Opana ER ð every month. (RX-073.0002 at 16).

Finally, the Proposed Findingôs use of Dr. Michnaôs testimony is misleading because it selectively quotes his answer, in which he explained that the ñfear of the unknownò does not change the fact that long-acting opioids are therapeutically equivalent, and that switching is not a complex process. (Michna, Tr. 2126-27).

661. In markets with high switching costs firms are likely to possess sufficient market power to set price above the competitive level even if products are perfect functional substitutes and the market contains many sellers. (CX5000 at 061-62 (¶ 134) (Noll Report)).

RESPONSE TO FINDING NO. 661:

Complaint Counselôs Proposed Finding No. 661 is improper because it states a legal conclusion. Proposed Finding No. 661 is also irrelevant and misleading because the evidence indicates that the market for long-acting opioids is not characterized by high switching costs.

(*See* Michna, Tr. 2127-29). Instead, switching costs are insignificant and characterized only by follow-up visits with the doctor to assess whether the patient is getting adequate pain relief. (Michna, Tr. 2127). These visits can be completed over the phone in some instances. (Michna, Tr. 2127). Because switching between long-acting opioids is often driven by insurance companies and their formulary changes, insurance companies calculate the savings achieved by their formulary changes and believe that ñsavings they have on the medication front more than make[] up for the additional cost of the follow-up visit.ò (Michna, Tr. 2127-29). Patients, for their part, generally do not mind extra doctor visits in order to treat their pain effectively. (Michna, Tr. 2128). In fact, there are some indications that the more often patients suffering from pain see doctors, the less pain they experience overall. (Michna, Tr. 2128-29).

662. Switching costs go beyond any price difference between drugs, to other costs one might experience because of the switch. Here, the price differences in the drugs are small compared to the costs of switching from one drug to another. (Noll, Tr. 1388).

RESPONSE TO FINDING NO. 662:

Complaint Counselôs Proposed Finding No. 662 is inaccurate, lacks foundation, and is not supported by record evidence. Professor Noll has not done any empirical analysis of the switching costs in the long-acting opioid market and cannot quantify whether the cost of switching between long-acting opioids is high. (Noll, Tr. 1552-53). Still, Dr. Addanki identified three reasons why the unsubstantiated claim of high switching costs is wrong: *first*, the expert clinicians testified that ñswitching can and does occurò and that it ñdoes occur in response to economic forces, such as formulariesò; *second*, there is no switching cost at all for new patients starting an opioid therapy; and *third*, the UPMC study showed a natural experiment in which a large number of switches were made because of a change in price. (Addanki, Tr. 2330-31; RX-

087 (UPMC formulary change led to 70 percent of patients on one long-acting opioid switching to a different long-acting opioids, both branded and generic, with no adverse increase in cost)).

As Dr. Addanki explained, if switching costs actually were high, ñyou wouldnôt see the efforts by managed care and by manufactures responding to managed care to be getting the best terms possible for the most favorable position on the formulary because . . . when you see that happening, that underscores that economic substitution is in fact taking place, so whatever the switching costs were, they were not an impediment to economic substitution.ò (Addanki, Tr. 2330-31).

663. When a patient initiates treatment on a new opioid when switching from one to another, treatment begins with a low dose that is then gradually increased until pain relief is achieved. This dosage titration process must be monitored by a medical professional to ensure that patients are not overdosed before achieving pain relief. (CX5000 at 061-62 (¶ 134) (Noll Report); CX5002 at 061-062 (¶¶ 172-173) (Savage Report); Noll, Tr. 1389-90 (ñThe first part of the switching cost is that you canôt just go from the final dose of the first drug to the final dose of the second drug instantaneously. . . . And then the second part is that the whole process of tapering off and tapering in has to be supervised by a physician . . .ò); Michna, Tr. 2127 (testifying that switching a patient from one ER opioid to another involves monitoring by the physicians)).

RESPONSE TO FINDING NO. 663:

Complaint Counselôs Proposed Finding No. 663 is incomplete. While switches between opioids are monitored by a medical professional, this monitoring is a relatively straight-forward and non-burdensome process. (Michna, Tr. 2127). In fact, the record indicates that insurance companies calculate the savings achieved by their formulary changes and believe that ñsavings they have on the medication front more than make[] up for the additional cost of the follow-up visit.ò (Michna, Tr. 2129). Patients, for their part, generally do not mind extra doctor visits in order to treat their pain effectively. (Michna, Tr. 2128).

664. Thus, while patients can be switched from one opioid to another, the process is risky, time-consuming, and expensive because of the need for medical supervision. For

this reason, it is implausible that patients who are taking one LAO would switch to another just because the former experienced a ñsmall but significant, non-transitory increase in price.ò (CX5000 at 063 (¶ 136) (Noll Report); Noll, Tr. 1390 (ñAnd so those are the switching costs. Itôs that you have to invest a significant fraction of your own time and you have to have the supervision of a physician in order to switch from one to the other.ò)).

RESPONSE TO FINDING NO. 664:

The first sentence of Complaint Counselôs Proposed Finding No. 664 is not supported by any evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Complaint Counsel cites *no* evidence to support the claim that the process of switching from one opioid to another is ñrisky, time-consuming, and expensive.ò

Moreover, Proposed Finding No. 664 is inaccurate. As Professor Noll admitted under cross-examination, he made no attempt to quantify or estimate the alleged ñswitchingò costs; he merely ñidentifiedò the supposed costs. (Noll, Tr. 1553-54). Nor did he analyze how frequently patients are switched from one long-acting opioid to another. (Noll, Tr. 1525). Dr. Savage, Complaint Counselôs own medical expert, confirmed that switching between long-acting opioids is not prohibitively risky, expensive, or time-consuming. For example, she testified that switching a patient between long-acting opioids can be ñsimple.ò (Savage, Tr. 762). If ñyouôre taking two Percocet a day and you want to switch to a couple of hydrocodone, thatôs not going to be a complicated switch.ò (Savage, Tr. 765-66, 768-69). Even for patients on high doses of multiple opioids, it is only ña bit more complicatedò to switch. (Savage, Tr. 762). In fact, Dr. Savage has *never* been unable to switch a patient between long-acting opioids. (Savage, Tr. 793-94; Michna, Tr. 2126 (never heard of any instance when a switch was not accomplished safely and effectively)). For these reasons, rotating from one long-acting opioid to another does not

involve significant risks when conducted by a doctor who knows the medications, and, in fact, it occurs frequently. (Michna, Tr. 2124, 2126 (switching is ñprobably done thousands of times

Finally, Proposed Finding No. 664 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert regarding medical risks. (Noll, Tr. 1358).

> 665. This is consistent with the testimony of Dr. Savage, who stated that minor changes in price would not change her prescribing habits because she is generally not aware of them and because her concerns are for the clinical well-being of the patient. (Savage, Tr. 771).

RESPONSE TO FINDING NO. 665:

Complaint Counselôs Proposed Finding No. 665 is inaccurate, incomplete, and misleading. Dr. Savage personally is not aware of drug prices because formulary tiering and what patients pay in copays ñtruly is outside [her] experienceò since she is ña consultant in [her] practice areaò and ñthe staff physicians who do the direct management of the patients deal with insurance companies.ò (CX4041 (Savage, Dep. at 117)). Even still, Dr. Savage noted that she does take economic considerations into account in her ñclinical decision-makingò when the patient raises the issue with her, especially if the patient does not have insurance. (Savage, Tr. 772-73; CX4041 (Savage, Dep. at 138) (ñthe copay is one variable that may be consideredò when making prescription choices ð ñclinical determinations are usually the first consideration and then copaysò)). Dr. Savage also testified that she would rotate a patient between long-acting opioids based on a minor increase in price ñdepend[ing] upon the patient and what the increase in price meant to them.ò (Savage, Tr. 770; *see* CX5002-063 (Savage Rep. ¶ 177) (noting that clinicians will ñconsciously consider costsò when they are ñaware that the patient will need to pay out of pocketò)). Dr. Michna reiterated this point, noting that the patientôs insurance coverage ñplays a major roleò in the choice of a long-acting opioid. (Michna, Tr. 2129).

666. Impaxôs expert, Dr. Michna likewis

specific brand of product? A. From day to day, no. I mean, I ï itôs the dramatic events that I mentioned to you.ò)).

RESPONSE TO FINDING NO. 667:

Complaint Counselôs Proposed Finding No. 667 is incomplete and misleading. While Dr. Michna does not keep track of prices ñon a daily basis,ò doctors have access to electronic systems through which they ñget an immediate feedback as to whether thatôs a covered medication for that insurance company, [and] also what level of additional pay that the patient has to pay at the pharmacy.ò (Michna, Tr. 2122). Dr. Michna also testified that patients will often raise cost concerns during visits, and pharmacists will call to inform the physician of cost concerns. (Michna, Tr. 2123; *see* CX4046 (Michna, Dep. at 148-49) (ñI donôt trawl the daily cost of all the pharmaceutical products, but I have a general idea.ò)). He further testified that drug manufacturers inform him regarding changes in cost and insurance coverage as well. (Michna, Tr. 2123). Dr. Michna further explained, he is aware of formulary changes, and has switched hundreds of patients among LAOs in recent years due to such changes. (CX4046 (Michna, Dep. at 149); RX-549.0007 (Michna Rep. ¶ 23)).

668. The fact that consumers cannot easily switch LAOs in response to a change in relative prices does not preclude the possibility that, at the time that treatment is initiated, some LAOs may be close economic substitutes for a first prescription. Whether competitionsg " r ɔ ⅂ t ҏ ᵀ s] ʻ χ mM l p я h ŭ ʻ ʻ

the ñlikelyò views of patients and physicians. (Noll, Tr. 1358). The cited portion of Professor Nollôs expert report, moreover, does not include any citations to evidence or analysis in support of his assertions. The first two sentences of Proposed Finding No. 668 should also be disregarded because they violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

Proposed Finding No. 668 is also inaccurate and not supported by the record. First, patients and doctors can and do choose among long-acting opioids on the basis of price. (CX5002-063 (Savage Rep. ¶ 177) (noting that clinicians will ñconsciously consider costsò when they are ñaware that the patient will need to pay out of pocketò); Michna, Tr. 2148; RX-087 (UPMC formulary change led 70 percent of patients on one long-acting opioid to switch to different long-acting opioids, both branded and generic); RX-448.0020 (

)).

Second, patients and their physicians do regard different long-acting opioids as close substitutes. Complaint Counselôs own expert physician conceded that ñmostò people can get equally effective and safe pain relief from numerous long-acting opioids, and that individual responses to any particular opioid cannot be identified in advance of treatment. (CX4041 (Savage, Dep. at 60, 66-67)). Accordingly, no one long-acting opioid is superior to any other long-acting opioid across populations of patients. (Savage, Tr. 790-91; Michna, Tr. 2149).

Third, first-time opioid prescriptions are ñthe biggest opportunity in the market.ò (RX-060.0002 at 29).

[redacted]); RX-022.0004 (same); Addanki, Tr. 2500 (describing formulary price competition and noting that rebates are on the order of magnitude of a small but significant non-transitory increase in price, indicating that ñeven small price changes were competitively potentially significantò)).

Manufacturers also compete on price at the consumer level in order to secure additional sales. (*See, e.g.*, RX-448.0020 [redacted]); Addanki, Tr. 2236-37 (ñJUDGE CHAPPELL: Let me ask another way. Have you ever seen a rebate being used like this when thereôs only one brand on the market with no competition? THE WITNESS: No. No. It is the hallmark of when thereôs actually competition.ò)).

1. Data confirms that the introduction of new long-acting opioids or generic versions of existing LAOs had no discernible impact on Opana ER sales

670. The conclusion that other long-acting opioids are not close economic substitutes that lead to price competition for Opana ER can be tested by examining whether changes in the market environment for other LAOs affected output and prices for oxymorphone ER. (CX5000 at 072 (¶ 158) (Noll Report)).

RESPONSE TO FINDING NO. 670:

Complaint Counselôs Proposed Finding No. 670 is based on unreliable expert testimony and wrong. Professor Nollôs analysis is based on his scanning for any ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Professor Noll recognizes that a SSNIP test is the normal method used to determine close economic substitutes. (CX5000-017 (Noll Rep. ¶ 38)). But Professor Noll admits he did not conduct a SSNIP test. (Noll, Tr. 1514).

Further, the test described by Professor Noll deliberately ignores the multitude of evidence of economic substitution between long-acting opioids, including switching after

changes on insurance formularies. (*See* Addanki, Tr. 2232). Indeed, Professor Noll dismisses as irrelevant evidence that demand for oxymorphone ER increased after Impaxôs generic entry, with patients switching from other long-acting opioids to oxymorphone ER. (Noll, Tr. 1525). Professor Noll similarly dismisses evidence that Opana ER experienced its highest loss rates in 2012 when physicians switched their patients to other long-acting opioids. Professor Noll claims instead that patients leaving Opana ER switched to heroin or other illegal drugs instead. (Noll, Tr. 1525-26).

> 671. Generic entry is a price phenomenon as well as a product phenomenon. In other words, one can look at generic entry in one drug market ï for example ER morphine ï and see what happens to brand name ER morphine and what happens to another other long-acting opioid. If those effects are different, the other l l l] ' ‘ m D f M m Į M x

the proposition. Professor Nollôs analysis is based on his scanning for any ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Professor Noll recognizes that a SSNIP test is the normal method used to determine close economic substitutes. (CX5000-017 (Noll Rep. ¶ 38)). But Professor Noll admits he did not conduct a SSNIP test. (Noll, Tr. 1514).

Further, the test described by Professor Noll deliberately ignores the multitude of evidence of economic substitution between long-acting opioids, including switching after changes on insurance formularies. (*See* Addanki, Tr. 2232). Indeed, Professor Noll dismisses as irrelevant evidence that demand for oxymorphone ER increased after Impaxôs generic entry, with patients switching from other long-acting opioids to oxymorphone ER. (Noll, Tr. 1525). Professor Noll similarly dismisses evidence that Opana ER experienced its highest loss rates in 2012 when physicians switched their patients to other long-acting opioids. Professor Noll claims instead that patients leaving Opana ER switched to heroin or other illegal drugs instead. (Noll, Tr. 1525-26).

> 673. No pattern of substitution is exhibited between oxymorphone ER sales and the introduction or exit of other brand-name LAOs or the entry or exit of generics against these other brand-name LAOs. (CX5000 at 073 (¶ 158) (Noll Report); Noll, Tr. 1394 (ñ[T]here is no spillover effect from state of competition for one long-acting opioid into prices and sales of another long-acting opioid.ò)).

RESPONSE TO FINDING NO. 673:

Complaint Counselôs Proposed Finding No. 673 is inaccurate and is not supported by the record. Professor Noll did not calculate cross-elasticity of demand between Opana ER and any other long-acting opioid, nor did he conduct a SSNIP test. (NopqNols analcam

the opioids in the long-acting opioid market. Therefore, even if there was a lack of a ñstrong negative correlationò of sales between OxyContin and oxymorphone ER, it would not be indicng

(CX5000 at 074-75 (¶ 162) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 676:

Complaint Counselôs Proposed Finding No. 676 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself.

677. Sales of OxyContin then began a long decline that continued into 2017, but most of this decline occurred after the sales of oxymorphone peaked. [redacted] (CX5000 at 074-75 (¶ 162) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 677:

Complaint Counselôs Proposed Finding No. 677 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself.

678. Thus, except for 2010-11, sales of OxyContin and Opana ER rose and fell in parallel, with no substitution between them apparent in the data. (CX5000 at 074-75 (¶ 162) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 678:

Complaint Counselôs Proposed Finding No. 678 is not supported by the record and is misleading. Professor Noll did not actually conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Professor Noll merely scanned for any ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Respondent, moreover, objects to the term ñparallelò as vague and ambiguous. Whether or not Professor Noll believes substitution between OxyContin and Opana ER is ñapparent in the dataò

he used to create the exhibits in his report, its irrelevant in the face of significant real-world evidence of substitution and switching. (*See, e.g.,* Addanki, Tr. 2266-67, 2309; Savage, Tr. 762; RX-073.0002 at 13, 16; RX-449.0007 (*in camera*); RX-26.0005-08 (partially *in camera*); RX-087).

679. Between the third quarter of 2010 and the third quarter of 2011, sales of OxyContin fell while sales of Opana ER increased, but the magnitudes were very different. (CX5000 at 075 (¶ 163) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 679:

Respondent objects to the phrase ñvery differentò in this Proposed Finding as vague and

RESPONSE TO FINDING NO. 681:

Complaint Counselôs Proposed Finding No. 681 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself.

> 682. These data show that both drugs experienced a significant loss of sales when reformulated versions were introduced, but neither drug benefitted appreciably from the lost sales of the other. (CX5000 at 075 (¶ 163) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 682:

Complaint Counselôs Proposed Finding of Fact No. 682 is incomplete and misleading. The statement that ñneither drug benefitted appreciably from the lost sales of the otherò does not follow from the fact that ñboth drugs experienced a significant loss of sales when reformulated versions were introduced.ò The cited paragraphs of Professor Nollôs report do not include any

Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 684 should be disregarded.

685. Thus, these data support the conclusion that oxymorphone ER and oxycodone ER are not close economic substitutes and so are not sold in the same relevant product market for purposes of assessing the conduct at issue in this case. (CX5000 at 076 (¶ 164) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING

686. Exhibits 5B1, 5B2 and 5B3 of the Noll Report compare prescriptions, MME sales quantities, and total sales revenues between oxymorphone ER and morphine ER. (CX5000 at 076 (¶ 166) (Noll Report); CX5000 at 199-201 (Exhibi

> and that generic entry occurred several years earlier . . . the generic entry in morphine would have had the same effect as the generic entry in oxymorphone, and it didnôt. . . . [T]he price [of Opana ER] didnôt actually fall and the sales decline until generic oxymorphone entered.ò)).

RESPONSE TO FINDING NO. 689:

Complaint Counselôs Proposed Finding No. 689 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether morphine ER is a ñclose economic substitute for Opana ERò for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Nollôs analysis ignores significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Nollôs analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 689 should be disregarded.

> 690. The output measures for morphine ER diverge from the patterns for oxymorphone ER. The MME measure shows a gradual decline in output for morphine ER since the end of 2011, while the number of prescriptions has continued to rise. Revenues for generic morphine ER also rose dramatically, especially after mid-2013. (CX5000 at 077 (¶ 167) (Noll Report); CX5000 at 199-201 (Exhibits 5B1-5B3) (Noll Report)).

RESPONSE TO FINDING NO. 690:

Complaint Counselôs Proposed Finding No. 690 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself.

> 691. These data imply substantial increases in realized prices for morphine ER that did not result in a decline in prescriptions, much less a shift in sales to oxymorphone, which in turn implies that oxymorphone ER and morphine ER are not close economic substitutes. (CX5000 at 077 (¶ 167) (Noll Report); CX5000 at 199-201 (Exhibits 5B1-5B3) (Noll Report)).

RESPONSE TO FINDING NO. 691:

Complaint Counselôs Proposed Finding No. 691 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and morphine ER are ñclose economic substitutesò for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or stati

monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 684 should be disregarded.

692. Exhibits 5C1, 5C2 and 5C3 of the Noll Report show the sales of hydromorphone ER (Exalgo) and oxymorphone ER as measured by prescriptions, MME and sales revenue. (CX5000 at 077-078 (¶¶ 168-69) (Noll Report); CX5000 at 202-204 (Exhibits 5C1-5C3) (Noll Report)).

RESPONSE TO FINDING NO. 692:

Respondent has no specific response. The data and associated charts speak for themselves.

693. The introduction of Exalgo in 2010 occurred during the period of rapid growth in M go)!

694. Moreover, the introduction of generic oxymorphone ER, while taking substantial sales away from Opana ER, had no apparent effect on the growth in sales of Exalgo. (CX5000 at 078 (¶ 169) (Noll Report); CX5000 at 202-204 (Exhibits 5C1-5C3) (Noll Report)).

RESPONSE TO FINDING NO. 694:

Respondent objects to the phrases ñsubstantial salesò and ñapparent affectò in Complaint Counselôs Proposed Finding No. 694 as vague and ambiguous. The Proposed Finding also violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself. But the use of the term ñapparentò in Proposed Finding No. 694 demonstrates that Professor Noll failed to conduct any empirical or econometric analysis to determine any actual effects, and that the Proposed Finding is based on unreliable expert testimony. (Noll, Tr. 1384 (noting he scanned for ñvisible effect[s]ò); Addanki, Tr. 2331 (noting Profess Noll conducted no econometric or statistical analysis)). Finally, the cited portion of Professor Nollôs report (CX5000-077-78 (Noll Rep. ¶ 169)) contains no external citations for the proposition that generic oxymorphone ER had no apparent effect on the growth in sales of Exalgo.

695. The entry of generic hydromorphone ER occurred only near the end of the data period, in 2014, but for the limited period in the exhibits the only apparent effect of generic entry is on sales of Exalgo. There was no apparent effect on total sales of oxymorphone ER, which rose slightly after generic hydromorphone ER was introduced. (CX5000 at 078 (¶ 169) (Noll Report); CX5000 at 202-204 (Exhibits 5C1-5C3) (Noll Report)).

RESPONSE TO FINDING NO. 695:

Respondent objects to the phrase ñapparent affectò in Complaint Counselôs Proposed Finding No. 695 as vague and ambiguous. Proposed Finding No. 695 also violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself. Moreover,

the use of the term ñapparentò in Proposed Finding No. 695 demonstrates that Professor Noll failed to conduct any empirical or econometric analysis to determine any actual effects, and that the Proposed Finding is based on unreliable expert testimony. (Noll, Tr. 1384 (noting he scanned for ñvisible effect[s]ò); Addanki, Tr. 2331 (noting Professor Noll conducted no econometric or statistical analysis)).

696. These data support the conclusion that hydromorphone ER is not a close economic substitute for oxymorphone ER. (CX5000 at 078 (¶ 169) (Noll Report); CX5000 at 202204 (Exhibits 5C1-5C3) (Noll Report)).

RESPONSE TO FINDING NO. 696:

Complaint Counselôs Proposed Finding No. 696 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and hydromorphone ER are ñclose economic substitutesò for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Nollôs analysis ignores significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Nollôs analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished

monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 696 should be disregarded.

697. Butrans (buprenorphine patch) was introduced in 2010 during the period when Opana ER sales were growing rapidly. (CX5000 at 078-79 (¶¶ 170-72) (Noll Report); CX5000 at 205-207 (Exhibits 5D1-5D3) (Noll Report)).

RESPONSE TO FINDING NO. 697:

Complaint Counselôs Proposed Finding No. 697 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò

698.

(CX5000 at 078-79 (¶¶ 170, 172) (Noll Report); CX5000 at 205207 (Exhibits 5D1-5D3) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 698:

Briefs bp citing "to expert tstimony to support factual propos

Complaint Counselôs Proposed Finding No. 698 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Any data speaks for itself. Further, Respondent objects to the phrase in Complaint Counselôs Proposed Finding No. 698 as vague and ambiguous.

699. The rapid decline in Opana ER sales in 2012, when Reformulated Opana ER replaced the old Opana ER, did not cause a change in sales growth for Butrans. (CX5000 at 079 (¶ 172) (Noll Report); C

RESPONSE TO FINDING NO. 706:

Respondent objects to the phrase ñsubstantial effectò in Complaint Counselôs Proposed Finding No. 706 as vague and ambiguous. Proposed Finding No. 706 also violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò The cited portion of Professor Nollôs report (CX5000-080 (Noll Rep. ¶ 175)) cites no sources for the proposition that oxymorphone ER did not have a substantial effect on sales of fentanyl ER. Professor Noll merely surmises this by looking for a ñvisible effect.ò (Noll, Tr. 1384). But Exhibit 5E3

(CX5000-210 (Noll Rep., Ex. 5E3)).

707. Thus, the patterns of sales of fentanyl ER and oxymorphone ER are not consistent with the hypothesis that these drugs are close economic substitutes. (CX5000 at 081 (¶ 175) (Noll Report); CX5000 at 208-210 (Exhibits 5E1-5E3) (Noll Report)).

RESPONSE TO FINDING NO. 707:

Complaint Counselôs Proposed Finding No. 707 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and fentanyl ER are ñclose economic substitutesò for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Nollôs analysis ignores

significant price competition at the payor, prescriber, and patient levels. (*See*

that the sales of Zohydro did not substitute for sales of oxymorphone ER. The Proposed Finding fails to acknowledge that Zohydroôs sales may have come at the expense of additional oxymorphone ER sales. The cited portion of Professor Nollôs report (CX5000-081 (Noll Rep. ¶ 177)) contains no external citations for the proposition that Zohydro did not substitute for sales of oxymorphone ER. Finally, no conclusions related to Zohydro can be reliably drawn from Professor Nollôs analysis since it only looks at three quartersô of sales of Zohydro across a ten-year period.

710. Zohydroôs sales also were achieved despite the presence of a generic form of oxymorphone ER. (CX5000 at 081 (¶ 177) (Noll Report); CX5000 at 211-213 (Exhibits 5F1-5F3) (Noll Report)).

RESPONSE TO FINDING NO. 710:

The data and associated charts cited in Complaint Counselôs Proposed Finding No. 710 speak for themselves. Nonetheless, the fact Zohydro had sales while there were simultaneous sales of generic oxymorphone ER does not mean that potential sales of oxymorphone ER were not lost to Zohydro, or vice versa. Finally, no conclusions related to Zohydro can be reliably

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Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding braq vvvvvvvvv th ^ c or

RESPONSE TO FINDING NO. 715:

Complaint Counselôs Proposed Finding No. 715 is not supported b

549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Nollôs analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 716 should be disregarded.

2. Endo's internal documents confirm that other long-acting opioids did not meaningfully constrain Opana ER

717. The information in the Endo discovery record supports the conclusion that other LAOs, while of [illegible] Moision i ʒ arnt Ṫ opana ER in

719. Opana ER had continued to grow in 2009 despite generic versions of OxyContin coming back on the market. (CX2731 at 001 (Endo email to sales leadership)).

RESPONSE TO FINDING NO. 719:

Complaint Counselôs Proposed Finding No. 719 is incomplete and misleading. The cited document (CX2731) states that ñOpana ER has continued to grow in 2009 even though generic OxyContin *has been back in the market on a limited basis*.ò (CX2731-001 (emphasis added) (noting further that there ñwill no doubt [be an] increase [in] the amount of generic OxyContin in the marketò)).

720. In Mr. Bingolôs May 2010 declaration from the patent litigation against Impax, he stated that ñdespite the presence of new entrants in the market who are actively promoting their new products (

RESPONSE TO FINDING NO. 721:

Complaint Counselôs Proposed Finding No. 721 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Further, the cited portion of Professor Nollôs report actually references a document in which Endo compared the prices of OxyContin and Opana ER for high dose patients. (*See* CX3158). In any event, Endo tracked its competitorsô ñ[a]ggressive couponingò when formulating its own patient copay program. (RX-028.0011; *see* Addanki, Tr. 2280-82). [redacted] (RX-445.0015). Professor Noll also discusses an email in which Endo noted that Purdue had offered Group Purchasing Organizations (ñGPOsò) discounts on OxyContin ranging from 15 percent to 20 percent. (CX5000-068 (Noll Rep. ¶ 149) (citing CX3206)). In order to ñachieve pricing parity to Oxycontin,ò Endo proposed ñan additional 11% discount on Opana ERò in response. (CX3206-002). Finally, Respondent objects to the word ñrarelyò in the Proposed Finding as vague and ambiguous.

> 722. Rather, the importance of differentiation between Opana ER and other opioids was discussed in Endoôs internal business documents. For example, the Opana ER strategic plan for 2010 notes the importance of sales efforts to high-prescribing physicians that emphasize differentiating factors of Opana ER, stating: ñFailure to adequately differentiate Opana ER will limit the brandôs growth . . . .ò (CX1106 at 004 (2010 Opana Brand Strategic Plan)).

RESPONSE TO FINDING NO. 722:

Complaint Counselôs Proposed Finding No. 722 is inaccurate and misleading in its suggestion that marketing efforts focused on product differentiation require a narrow market definition. Professor Noll fails to appreciate that long-acting opioid manufacturers attempt to differentiate their products precisely *because* they are close substitutes and competing vigorously. Demir Bingol, Endoôs Senior Director of Marketing, testified that the differences between Opana ER and other long-acting opioids were used as a marketing tactic because they

represented Endoôs ñbest opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market.ò (Bingol, Tr. 1314); *see* CX4025 (Bingol, Dep. at 104) (Opana ER is ñthe same as everything else. Differentiation is always your mission in marketing.ò)). And Mr. Bingol explained that Opana ER competed with all other branded and generic long-acting opioids, including on price. (Bingol, Tr. 1326-27). Finally, the quoted language in the Proposed Finding is incomplete and misleading. The statement in CX1106 is ñFailure to adequately differentiate Opana ER will limit the brandôs growth in 2010 *vs. existing competitors*.ò (CX1106-004 (emphasis added)).

> 723. It was important for Endo to differentiate Opana ER from other long-acting opioids because otherwise there was no basis for creating value or having a prescriber want to prescribe it for a patient. (CX4025 (Bingol, Dep. at 104) (ñDifferentiation is always your mission in marketing.ò)).

RESPONSE TO FINDING NO. 723:

Complaint Counselôs Proposed Finding No. 723 is misleading and not supported by the cited evidence. Mr. Bingol testified that Opana ER is ñ*the same as everything else*. Differentiation is always your mission in marketing.ò (CX4025 (Bingol, Dep. at 104) (emphasis added)). Mr. Bingol testified at trial that any differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endoôs ñbest opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market.ò (Bingol, Tr. 1314).

> 724. A promotional strategy that focuses on product differentiation reduces the intensity of price competition, it doesnôt increase it. (Noll, Tr. 1402-03).

RESPONSE TO FINDING NO. 724:

Complaint Counselôs Proposed Finding No. 724 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by

fact witnesses or documents.ò Professor Noll fails to appreciate that long-acting opioid manufacturers attempt to differentiate their products precisely *because* they are close substitutes and competing vigorously. Demir Bingol, Endoôs Senior Director of Marketing, testified that the differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endoôs ñbest opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market.ò (Bingol, Tr. 1314); *see* CX4025 (Bingol, Dep. at 104) (Opana ER is ñthe same as everyth

because they represented Endoôs ñbest opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market.ò (Bingol, Tr. 1314).

726. Oxymorphone as a molecule has intrinsic qualities that might have meaningful importance to clinicians or patients. (Bingol, Tr. 1270; CX4025 (Bingol, Dep. at 99-100); CX2529 at 050 (Opana ER ñis the only long-acting opioid that contains oxymorphone, a molecule with distinct pharmacologic properties compared with most other opioids...ò) (Opana ER Strategic Platform presentation).

RESPONSE TO FINDING NO. 726:

While Respondent does not dispute that oxymorphone may be preferred by individual patients in particular contexts, the record does not support the proposition that oxymorphone has any inherent qualities that make it superior to any other long-acting opioid across any population of patients. (Savage, Tr. 790-91; Michna, Tr. 2149). Complaint Counselôs own medical expert, Dr. Savage, admits that ñmostò people can get equally effective and safe pain relief from numerous long-acting opioids. (CX4041 (Savage, Dep. at 60, 66-67)). Doctors Savage and Michna agree that no medical conditions produce pain for which oxymorphone ER or any other opioid medication is the only long-acting opioid option. (Savage, Tr. 791; Michna, Tr. 2149). ñ[M]ost [opioids] are interchangeable if attention is paid to relative potencies and onset and duration of action.ò (Savage, Tr. 782-83). Indeed, doctors use every long-acting opioid to treat the same medical conditions, including post-operation pain, lumbago, and chronic pain syndrome. (RX-547.0105 (Addanki Rep., Ex. 4); Addanki, Tr. 2245-47).

727. As early as 2007, in an attempt to highlight one such intrinsic quality, Endo sent letters to health care professi

RESPONSE TO FINDING NO. 727:

Complaint Counselôs Proposed Finding No. 727 is incomplete and misleading. Opana ER was not (and is not) the only long-acting opioid that did not raise CYP 450 issues, as the Proposed Finding attempts to suggest. Neither morphine nor hydromorphone utilize the CYP 450 pathway. (Savage, Tr. 795-96). Endo nevertheless used metabolic differences between Opana ER and some other long-acting opioids as a marketing tactic because it represented Endoôs ñbest opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market.ò (Bingol, Tr. 1314). Still, such metabolic differences are ñnot clinically relevant.ò (Michna, Tr. 2154-55; *see also* RX-549.0018-19 (Michna Rep. ¶ 46) (ñI have never seen a case in which CYP 450 metabolism had any real clinical relevance in my decision to prescribe an opioid.ò)).

728. Likewise, Demir Bingol, who was responsible for marketing Opana ER, testified that Endo marketed Opana ER by ñcreat[ing] different strategies or promotional tactics in order to be able to effectively communicate why your product is different and why it would be needed by certain patient types.ò (Bingol, Tr. 1265).

RESPONSE TO FINDING NO. 728:

Respondent has no specific response other than to note that fact that Endo used ñpromotional tacticsò to compete against other long-acting opioids is consistent with a long-acting opioids market. (CX4025 (Bingol, Dep. at 104) (Opana ER is ñthe same as everything else. Differentiation is always your mission in marketing.ò); Bingol, Tr. 1314 (marketing tactics highlighting any differences represented Endoôs ñbest opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market.ò)).

729. Another Endo document summarizes a strategy for convincing physicians to prescribe Opana ER rather than OxyContin, but the document emphasizes qualitative

> attributes of Opana ER, such as ñ12 hour pain relieverò and ñNo CYP450 PK drug-drug interactionsò that make it a better choice for patients. (CX3198 at 044 (Branded Pharmaceuticals Business Review)).

RESPONSE TO FINDING NO. 729:

Complaint Counselôs Proposed Finding No. 729 is incomplete and misleading. Opana ER was not (and is not) the only long-acting opioid that did not raise CYP 450 issues, as the Proposed Finding attempts to suggest. Neither morphine nor hydromorphone utilize the CYP 450 pathway. (Savage, Tr. 795-96). Endo nevertheless used differences between Opana ER and other long-acting opioids as a marketing tactic because it repr

2149). Complaint Counselôs own medical expert, Dr. Savage, admits that ñmostò people can get equally effective and safe pain relief from numerous long-acting opioids. (CX4041 (Savage, Dep. at 60, 66-67)). Doctors Savage and Michna agree that no medical conditions produce pain for which oxymorphone ER or any other opioid medication is the only long-acting opioid option. (Savage, Tr. 791; Michna, Tr. 2149). ñ[M]ost [opioids] are interchangeable if attention is paid to relative potencies and onset and duration of action.ò (Savage, Tr. 782-83). Indeed, doctors use every long-acting opioid to treat the same medical conditions, including post-operation pain, lumbago, and chronic pain syndrome. (RX-547.0105 (Addanki Rep., Ex. 4); Addanki, Tr. 2245-47).

731. Again in Endoôs Q4 2011 investor call, Ms. McHugh noted that ñOpana ER is a product that has inherent characteristics that make it a product that physicians and patients both want to use.ò (CX3221 at 019 (Endoôs Q4 2011 Earnings Call Transcript) (citing cytochrome P450 drug-drug interactions and true BID dosing regimen)).

RESPONSE TO FINDING NO. 731:

Complaint Counselôs Proposed Finding No. 731 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endoôs Senior Director of Marketing, who explained that Opana ER is ñthe same as everything else. Differentiation is always your mission in marketing.ò (CX4025 (Bingol, Dep. at 104); *see* Bingol, Tr. 1314). That an Endo executive ð charged with touting Endoôs future success for investors ð cited ñinherent characteristicsò of the Opana ER for its ñrapid growthò is hardly probative of market definition. The record, moreover, does not support the proposition that oxymorphone has any inherent qualities that make it superior to any other long-acting opioid across any population of patients. (Savage, Tr. 790-91; Michna, Tr. 2149). Complaint Counselôs own medical expert, Dr. Savage, admits that ñmostò people can get equally effective and safe pain relief from numerous long-acting opioids. (CX4041 (Savage, Dep. at 60, 66-67)). Doctors Savage and Michna agree that no medical conditions produce pain

for which oxymorphone ER or any other opioid medication is the only long-acting opioid option. (Savage, Tr. 791; Michna, Tr. 2149). ñ[M]ost [opioids] are interchangeable if attention is paid to relative potencies and onset and duration of action.ò (Savage, Tr. 782-83). Indeed, doctors use every long-acting opioid to treat the same medical conditions, including post-operation pain, lumbago, and chronic pain syndr

every long-acting opioid to treat the same medical conditions, including post-operation pain, lumbago, and chronic pain syndrome. (RX-547.0105 (Addanki Rep., Ex. 4); Addanki, Tr. 2245-47).

733. One document entitled ñValue Strategy Reviewò does contain a comparison of the prices of OxyContin and Opana ER, but the document primarily examines the cost advantages from differentiating therapeutic features of Opana ER compared to OxyContin, such as lower daily consumption and lack of CYP 450

734.

equivalents for Opana ER. Dr. Savage admits that ñmostò people can get equally effective and safe pain relief from numerous long-acting opioids, and that any individuals who react better to a particular opioid cannot be identified in advance of treatment. (CX4041 (Savage, Dep. at 60, 66-67)). Accordingly, no one long-acting opioid is superior to any other long-acting opioid. (Savage, Tr. 790-91; Michna, Tr. 2149). In fact, there is no medical condition for which oxymorphone ER or any other long-acting opioid is the only safe and effective option to treat pain. (Michna, Tr. 2149; RX-547.0105 (Addanki Rep., Ex. 4); Addanki, Tr. 2248 (ñthereôs no indication for which oxymorphone had any significant use for which there isnôt at least one other long-acting opioid available that was also used for the same indicationò)). All told, thousands of patients switch from Opana ER to other long-acting opioids ð and from other long-acting opioids to Opana ER ð every month. (RX-073.0002 at 16, 45 (ñOpioid rotation/switching is common in this therapeutic categoryò); Michna, Tr. 2124, 2126 (switching is ñprobably done thousands of timesò); Savage, Tr. 693-94, 762, 782-83).

737. Most Endo documents that deal with Opana ER pricing do not refer to any other drugs, and make no mention of the prices of any competing product. (CX5000 at 69-70 (¶ 152) (Noll Report); *see also* CX2678 at 019-022 (January 2009 Opana ER Price Proposal) (recommending a 4.5% price increase); CX2665 (February 2011 Oxymorphone Franchise Pricing Proposal);y ® A Bg g ' p ı

[redacted] (Noll, Tr. 1684-85). [redacted] (Noll, Tr. 1681).

Third, the evidence indicates that Endo tracked relative prices of competing long-acting opioids. For example, [redacted] (CX3206-002). Endo also compared the prices of OxyContin and Opana ER for high dose patients. (CX3158). And Endo tracked its competitorsô ñ[a]ggressive competitive couponingò when formulating its own patient copay program. (RX-028.0011; *see* Addanki, Tr. 2280-82). Endo also tracked switching between various long-acting opioids. (RX-083.0003 at 35; *see* RX-073.0002 at 13, 16; RX-060.0002 at 25).

Finally, there is significant evidence that Endo compared formulary placement, and actively worked to exclude competing long-acting opioids from formularies by offering price discounts to insurance companies. (*See* Addanki, Tr. 2293). For example, [redacted] (RX-021.0005; Addanki, Tr. 2296). [redacted] (RX-021.0005).

738. By contrast, a proposed 4.5% price increase for another Endo product, Frova, compares the price of Frova to the prices of six other brand-name drugs and recommends ña óvalueô pricing strategy for the brand within the triptan market.ò (CX2678 at 003 (January 2009 Frova Price Proposal)).

RESPONSE TO FINDING NO. 738:

Respondent has no specific response.

739. This comparison indicates that the extent of price competition varies among pharmacologic classes and that Opana ER, unlike Frova, is in a pharmacologic class for which the prices of competitors are not sufficiently important to include them in making a business justification for a price increase. (CX5000 at 70 (¶ 152) (Noll Report)).

RESPONSE TO FINDING NO. 739:

Complaint Counselôs Proposed Finding No. 739 is inaccurate and not supported by the record. The purported comparison ð based on a single document ð between Frova and Opana ER is not sufficient to conclude competitor prices are ñnot sufficiently importantò to justify a broad long-acting opioid market. This comparison ignores the record, which shows price-based competition at the payor level (*i.e.*, competing for superior formulary placement); prescriber

access for the product *and could require higher discounts than currently offered on OPANA ER*.ò (CX2664-004 (emphasis added)). The document also notes that ñsignificant increases in the price of OPANA and/or OPANA ER may negatively impact overall profitability of Revopan.ò (CX2664-005). The document even leaves a placeholder for the ñimpact on net salesò from a potential price increase. (CX2664-005).

RESPONSE TO FINDING NO. 744:

Respondent has no specific response.

745. Dr. Savage offered testimony about the important differences be

What is more, Demir Bingol, Endoôs Senior Director of Marketing, testified that the differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endoôs ñbest opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought t

aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16).

748. Opana ER contains a different opioid molecule (oxymorphone) than other long-acting opioids, therefore individuals may experience different levels of analgesia, different side effect profiles, and different tolerances. (Savage, Tr. 709; Michna, Tr. 2167 (ñWe never know how a patient is going to respond. . . . they may have adverse events.ò)).

RESPONSE TO FINDING NO. 748:

Respondent has no specific response.

749. The practical significance of two drugs having different active ingredients is that different patients may respond differently to the medications. (Savage, Tr. 729; Michna, Tr. 2167 (ñQ. And there is variability from person to person in terms of the way they respond to drugs? A. We never know how a patient is going to respond. As I think I testified earlier, they may have adverse events. Itôs un ï you know, itôs impossible to predict that, yes.ò); CX4025 (Bingol, Dep. at 99-100) (ñAnd patient variability is such that patients respond differently to different opioids . . . So this becomes another option where other pain medicines might not be effective.ò)).

RESPONSE TO FINDING NO. 749:

Respondent has no specific response.

750. It is useful to have a variety of opioids available for the treatment of pain because people respond very differently to different opioids. (Savage, Tr. 712-13).

RESPONSE TO FINDING NO. 750:

Respondent has no specific response.

751. Indeed, approximately fifty percent of patients donôt tolerate the first opioid they try. (Michna, Tr. 2169).

RESPONSE TO FINDING NO. 751:

Respondent has no specific response.

752. Opioid rotation is the substitution of one opioid medication for another. It may be done due to inadequate analgesia, the development of tolerance to analgesic effects, or persistent side effects. (CX5002 at 060 (¶ 170) (Savage Report)).

RESPONSE TO FINDING NO. 752:

Respondent has no specific response other than to clarify that substitution among opioids is not limited to the listed reasons. It can and often does occur because of changes in price or availability as well. (*See, e.g.*, RX-087 (UPMC formulary change led to 70 percent of patients on OxyContin switching to different long-acting opioids, including Opana ER, generic Morphine Sulfate ER (MS ER), and generic Fentanyl patches); Michna, Tr. 2125, 2148; Noll, Tr. 1561; Addanki, Tr. 2305). For these various reasons, switches are frequent. (Savage, Tr. 693-94; Michna, Tr. 2124 (switching is ñprobably done thousands of times each dayò); RX-073.0002 at 45 (ñOpioid rotation/switching is common in this therapeutic category.ò)). Substitution among opioids may also occur as a result of hospitalization or surgery, when an intravenous opioid must be administered. (RX-549.0019 (Michna Rep. ¶ 47) (ñWhat I have seen countless times ð what is indeed very common ð is that a patient switched from one IV opioid to a totally different oral medication without incident. It is telling that the most common oral opioid in a post-operative setting is oxycodone, which does not have an injectable form.ò)).

753. Because of individual variability in responses to opioids, it is impossible to reliably predict an individual patientôs response 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. (CX5002 at 061-62 (¶ 172) (Savage Report); RX-549 at 0025 (¶ 57) (Michna Report) (ñ[P]atients 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.ò)).

RESPONSE TO FINDING NO. 753:

Complaint Counselôs Proposed Finding No. 753 is incomplete and misleading because it ignores the testimony of Dr. Savage, who explained that switching a patient between long-acting

opioids can be ñsimple.ò (Savage, Tr. 762). If ñyouôre taking two Percocet today and you want to switch to a couple of hydrocodone, thatôs not going to be a complicated switch.ò (Savage, Tr. 765-66, 768-69). Even for patients on high doses of multiple opioids, it is only ña bit more complicatedò to switch. (Savage, Tr. 762). In fact, Dr. Savage has never been unable to switch a patient between long-acting opioids. (Savage, Tr. 793-94). For these reasons, rotating from one long-acting opioid to another does not involve significant risks when conducted by a doctor who knows the medications, and it occurs frequently. (Michna, Tr. 2124, 2126 (switching is ñprobably done thousands of times each dayò); Savage, Tr. 693-94, 762, 782-83; RX-073.0002 at 45 (ñOpioid rotation/switching is common in this therapeutic category.ò)).

754. The complexity and risks inherent in opioid rotation means 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. (CX5002 at 063 (¶ 176) (Savage Report); Savage, Tr. 770).

RESPONSE TO FINDING NO. 754:

Complaint Counselôs Proposed Finding No. 754 is inaccurate. Dr. Savage explained that switching a patient between long-acting opioids can be ñsimple.ò (Savage, Tr. 762). If ñyouôre taking two Percocet today and you want to switch to a couple of hydrocodone, thatôs not going to be a complicated switch.ò (Savage, Tr. 765-66, 768-69). Even for patients on high doses of multiple opioids, it is only ña bit more complicatedò to switch. (Savage, Tr. 762). In fact, Dr. Savage has never been unable to switch a patient between long-acting opioids. (Savage, Tr. 793-94). For these reasons, rotating from one long-acting opioid to another does not involve significant risks when conducted by a doctor who knows the medications, and it occurs frequently. (Michna, Tr. 2124, 2126 (switching is ñprobably done thousands of times each dayò); Savage, Tr. 693-94, 762, 782-83; RX-073.0002 at 45 (ñOpioid rotation/switching is common in this therapeutic category.ò)).

757. The numerous differences between Opana ER and other long-acting opioids are identified in Appendix C to Dr. Savageôs expert report. (CX5002 at 106 (Appendix C) (Savage Report)).

RESPONSE TO F

of patients for which oxymorphone ER or any other long-acting opioid is the only treatment option. (Michna, Tr. 2148-49; Noll, Tr. 1508-09; CX4041 (Savage, Dep. at 60)).

761. In contemporaneous documents and promotional materials, Endo highlighted certain intrinsic qualities of oxymorphone that might have meaningful importance to clinicians or patients, including ñNo CYP450 PK DDIs,ò ñTrue 12-hour dosing,ò and ñLow euphoria.ò (CX2610 at 014 (Revopan [reformulated Opana ER] Playbook); Bingol, Tr. 1270;

Finding No. 762 attempts to suggest. Neither morphine nor hydromorphone utilize the CYP 450 system. (Savage, Tr. 795-96).

763. There can be considerable variability between different individuals in the CYP 450 system that can affect opioid metabolism in clinically important ways. (CX5002 at 026 (¶ 74) (Savage Report)).

RESPONSE TO FINDING NO. 763:

Respondent has no specific response.

764. In addition, the use of some drugs can alter activity of certain CYP 450 enzymes. Many drugs commonly used by pain patients, such as antidepressants, anti-seizure medications, and antibiotics, can inhibit or induce CYP 450 enzymes. (CX5002 at 027 (¶ 75) (Savage Report); CX2558 at 030 (Opana ER Presentation); Savage, Tr. 716 (ñYes. Many drugs use those metabolic pathways.ò); Michna, Tr. 2151 (ñ[S]ince a lot of the medications we prescribe, you know, concurrent meds for depression and other diseases, are metabolized through that system, there can be effects on the other drugs when theyôre coprescribed.ò)).

RESPONSE TO FINDING NO. 764:

Respondent has no specific response.

765. Variations in metabolic activity, particularly in the CYP 450 system can have meaningful clinical consequences. Higher enzyme activity may result in rapid metabolism of an active drug, rendering usual doses ineffective. On the other hand, lower enzyme activity can result in higher blood levels of a drug, potentially leading to side effects or toxicity. (CX5002 at 027 (¶ 78) (Savage Report); CX2558 at 030 (Opana ER Presentation); Bingol, Tr. 1273-74 (ñ[T]he patients may be fast metabolizers or slow metabolizers through this pathway, and if youôre avoiding it, then youôre potentially able to avoid certain types of interactions, potentially making a safer choice for a patient.ò)).

RESPONSE TO FINDING NO. 765:

While Respondent does not dispute that there are variations in metabolic activity among individuals and that those variations can lead to differences in metabolism of a medication, the record does not support the proposition that CYP 450 metabolism is a clinically relevant factor when physicians are prescribing long-acting opioids. (Michna, Tr. 2151-52). When doctors

prescribe a long-acting opioid, they start at low doses and then build up to assess reaction and side effects. (Michna, Tr. 2151-52). Accordingly, even if a patient has trouble metabolizing via the CYP 450 pathway, it would simply mean that the patient would achieve pain relief ñat a much earlier pointò in the buildup of dosing than if the patient had more rapid metabolism. (Michna, Tr. 2152). Even Dr. Savage concedes that individual patients who do not respond well to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796). And while there is a test to assess how a patient will metabolize drugs though the CYP 450 pathway, Dr. Savage did not testify that she has ever used it and Dr. Michna has never seen any other doctor use it when prescribing long-acting opioids. (Michna, Tr. 2152). The CYP 450 pathway, finally, is utilized by the majority of all medications prescribed generally. (Michna, Tr. 2151).

766. As such, physicians must take care when prescribing opioids that are metabolized via the CYP 450 system to consider possible drug interactions or biogenetic variations. (CX5002 at 028 (¶ 79) (Savage Report); Savage, Tr. 716-17 (testifying that drug interactions may cause higher blood levels, and thus more side effects, or lower blood levels, thus a reoccurrence of pain)).

RESPONSE TO FINDING NO. 766:

While Respondent does not dispute that doctors must take care when prescribing any medication, the record does not support the proposition that CYP 450 is a clinically relevant factor when physicians are prescribing long-acting opioids. (Michna, Tr. 2151-52). When doctors prescribe a long-acting opioid, they start at low doses and then build up to assess reaction and side effects. (Michna, Tr. 2151-52). Accordingly, even if a patient has trouble metabolizing via the CYP 450 pathway, it would simply mean that the patient would achieve pain relief ñat a much earlier pointò in the buildup of dosing than if the patient had more rapid metabolism. (Michna, Tr. 2152). Even Dr. Savage concedes that individual patients who do not respond well

to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796). And while there is a test to assess how a patient will metabolize drugs though the CYP 450 pathway, Dr. Savage did not testify that she has ever used it and Dr. Michna has never seen any other doctor use it when prescribing long-acting opioids. (Michna, Tr. 2152). The CYP 450 pathway, finally, is utilized by the majority of all medications prescribed generally. (Michna, Tr. 2151).

767. Oxymorphone is metabolized through glucuronidation and does not significantly engage the CYP 450 system. (CX5002 at 039 (¶ 107) (Savage Report); CX2558 at 030 (Opana ER Presentation); Savage, Tr. 715-16; Michna, Tr. 2151).

RESPONSE TO FINDING NO. 767:

Respondent has no specific response.

768. Drug interactions and genetic variability involving the CYP 450 system do not appear to affect drugs, such as oxymorphone, that are exclusively metabolized through glucuronidation and do not rely on the CYP 450 system. Thus, oxymorphone is not subject to increased or decreased effects due to drug interactions or genetic variability in CYP 450 metabolic pathways. As a result, patients at risk for CYP 450 drug interactions or genetic variability may be better candidates for an opioid like oxymorphone. (CX5002 at 028 (¶ 80) (Savage Report); Bingol, Tr. 1273 (ñOxymorphone is metabolized through the liver through glucuronidation, not through the CYP450 enzymatic pathway, thereby potentially being safer]M k ẅ ESPONSE TO FINDING > 7

would simply mean that the patient would achieve pain relief ñat a much earlier pointò in the buildup of dosing than if the patient had more rapid metabolism. (Michna, Tr. 2152). Even Dr. Savage concedes that individual patients who do not respond well to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796). And while there is a test to assess how a patient will metabolize drugs though the CYP 450 pathway, Dr. Savage did not testify that she has ever used it and Dr. Michna has never seen any other doctor use it when prescribing long-acting opioids. (Michna, Tr. 2152). The CYP 450 pathway, finally, is utilized by the majority of all medications prescribed generally. (Michna, Tr. 2151).

769. Endoôs documents show that it touted the lack of CYP 450 drug-drug interactions, among other characteristics, in its marketing materials and internal documents related to Opana ER. (CX2717 at 008 (Opana ER Advisory Board Executive Summary) (identifying lack of CYP450 interactions as a key benefit of Opana ER); CX2610 at 014 (Revopan [reformulated Opana ER] Playbook) (identifying ñNo CYP450 PK DDIsò as part of the heritage of oxymorphone); CX2716 at 022 (Opana Marketing Presentation) (listing ñNo known CYP450 PK drug-drug interactionsò as a key message); CX3220 at 023 (Endo Q2 2012 Earnings Call Transcript) (ñOxymorphone is not metabolized by the cytochrome P450 system, unlike other opioids . . .ò)).

RESPONSE TO FINDING NO. 769:

Complaint Counselôs Proposed Finding No. 769 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endoôs Senior Director of Marketing, who explained that the metabolic differences between Ocu1

has ever used it and Dr. Michna has never seen any other doctor use it when prescribing long-acting opioids. (Michna, Tr. 2152).

Finally, to the extent Proposed Finding No. 770 attempts to summarize academic literature, the Proposed Finding is improper and inadmissible. The relevant literature is not in evidence and, if it were, that literature would be the best evidence of its contents.

> 771. For example, a patient in Dr. Savageôs practice who had been stable on methadone treatment suddenly became sedated when prescribed an antidepressant, likely because of a CYP450 drug interaction. (Savage, Tr. at 718-19).

RESPONSE TO FINDING NO. 771:

Complaint Counselôs Proposed Finding No. 771 is improper and inadmissible. The Proposed Finding consists entirely of speculation, even though there is a test to assess how a patient metabolizes drugs though the CYP 450 pathway. (Michna, Tr. 2152).

> 772. Likewise, there are examples of CYP450 interactions from the medical literature, for example where a patient on oxycodone was prescribed an antifungal agent and subsequently experienced sedation due to inhibition of the breakdown of oxycodone. (Savage, Tr. at 719).

RESPONSE TO FINDING NO. 772:

Complaint Counselôs Proposed Finding No. 772 is improper and inadmissible. The Proposed Finding purports to summarize academic literature that is not in evidence and, if it were, that literature would be the best evidence of its contents.

> 773. The risk of CYP 450 drug-drug interactions carries economic consequences in terms of significantly higher medical and pharmacy costs. (CX2549 at 005 (EN3288

RESPONSE TO FINDING NO. 773:

Complaint Counselôs Proposed Finding No. 773 is inaccurate and misleading. The cited document (CX2549) explicitly states that the language quoted by Complaint Counsel ñonly focused on observed economic events. *There are no claims of therapeutic superiority among the products whose utilization patterns were observed*.ò (CX2549-005 (emphasis added) (discussing only oxycodone and oxymorphone and the possibility that patients who do not respond well to CYP 450 may have ñhigher medical and pharmacy costs (~$100-200/month)ò)). Such claims were advanced by Endo in hopes of crafting a ñvalue platform message.ò (CX2549-004).

Demir Bingol, Endoôs Senior Director of Marketing, explained that any metabolic differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endoôs ñbest opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market.ò (Bingol, Tr. 1314). When Endo attempted to market such differences, clinicians ñuniversally . . . said no because itôs really not clinically relevant.ò (Michna, Tr. 2154-55). Indeed, the CYP 450 pathway is utilized by the majority of all medications prescribed generally. (Michna, Tr. 2151).

Even Dr. Savage concedes that individual patients who do not respond well to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796). And while there is a test to assess how a patient will metabolize drugs ‘ Ď- ‘

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RESPONSE TO FINDING NO. 774:

Complaint Counselôs Proposed Finding No. 774 is inaccurate and not supported by the record. The CYP 450 pathway is utilized by the majority of all medications prescribed

aspirin, which are used for the same treatments and compete for the same customers despite their differences. (Savage, Tr. 812-16).

2. True 12-hour dosing

775. The concept of drug half-life is important to understanding the duration of effects of different drugs. Half-life is defined as the amount of time it takes the plasma concentration of a drug to decline by one half. (CX5002 at 029 (¶ 82) (Savage Report)).

RESPONSE TO FINDING NO. 775:

Respondent has no specific response.

776. Different drugs have different typical half-lives or ranges of half-lives based on inherent pharmacologic factors. A longer plasma half-life of a drug is usually associated with a longer duration of action ï in the case of opioids, longer duration of pain relief. (CX5002 at 029 (¶ 83) (Savage Report)).

RESPONSE TO FINDING NO. 776:

Respondent has no specific response.

777. When considering the half-life of extended release opioids, one must also consider the duration of release of the medication, since uptake of the full dose is delayed. (CX5002 at 029 (¶ 84) (Savage Report)).

RESPONSE TO FINDING NO. 777:

Respondent has no specific response.

778. The half-life of oxymorphone is ~7-9 hours. Opana ER is formulated to provide sustained release of oxymorphone over a 12-hour period and is to be taken every 12 hours. The half-life of Opana ER is ~9-11 hours. (CX5002 at 038 (¶ 106) (Savage Report)).

RESPONSE TO FINDING NO. 778:

Respondent has no specific response.

779. The relatively long half-life of oxymorphone, per se, combined with its sustained release formulation, results in sustained effects over 12 hours. (CX5002 at 038 (¶ 106) (Savage Report); Savage, Tr. 720 (ñQ. What is the practical significance of the relatively

long half-life of oxymorphone compared to other opioids? A. We would expect it to have a longer duration of action.ò)).

RESPONSE TO FINDING NO. 779:

Respondent has no specific response.

780. This long half-life may result in more sustained analgesia at end of dose when given at 12-hour intervals than some other controlled release opioids. For example, OxyContin is also approved for 12 hour dosing, but patients sometimes experience decreased analgesia towards the end of the dosing period, resulting in breakthrough pain. As a result OxyContin is often prescribed for use at 8-hour intervals. (CX5002 at 038-39 (¶ 106) (Savage Report)).

RESPONSE TO FINDING NO. 780:

Respondent has no specific response.

781. The longer half-life of oxymorphone was promoted by Endo and treated as significant in its internal documents. (CX2717 at 008 (Opana ER Advisory Board Executive Summary) (identifying no end of dose failure as a key benefit of Opana ER); CX2610 at 014 (Revopan [reformulated Opana ER] Playbook) (identifying ñTrue 12-hour dosingò as part of the heritage of oxymorphone); CX2716 at 022 (Opana Marketing Presentation) (listing ñStable, steady-state plasma levels for true 12-hour dosing that lastsò as a key message); CX3220 at 023 (Endo Q2 2012 Earnings Call Transcript) (stating that Opana ER is ña compound that given its PK profile lends itself to twice daily dosing whereas with a lot of other product [sic] including oxycodone doses tend to get migrated to 3 sometimes even greater frequency of dosages per day.ò)).

RESPONSE TO FINDING NO. 781:

Complaint Counselôs Proposed Finding No. 781 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endoôs Senior Director of Marketing, who explained that frequency of dosage differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endoôs ñbest opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market.ò (Bingol, Tr. 1314). But as Dr. Savage admitted, the differences among long-acting opioids are no different than those found in over-the-counter pain relievers like Advil, Tylenol, Aleve, and

aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16). D

nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16). Dr. Savage also explained that frequency of dosing is mostly about patient preferences. She explained that some patients may want to take a certain long-acting opioid that requires more pills more frequently so that they have a sense of control over their treatment; other patients do not. (Savage, Tr. 742).

> 783. The relatively long half-life of Opana ER carried economic and clinical significance. (Bingol, Tr. 1272 (ñ[F]rom a payer perspective, it was reassuring perhaps to know that [Opana ER] wouldnôt be used more frequently than as prescribed, from a cost perspective.ò); Bingol, Tr. 1272 (ñFrom a clinician or a patient perspective, it had more of a clinical message to know that their pain could be controlled with a reliable dosing scheme of . . . every twelve hours rather than having to maybe rely on breakthrough medications . . .ò)).

RESPONSE TO FINDING NO. 783:

Complaint Counselôs Proposed Finding No. 783 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endoôs Senior Director of Marketing, who explained that frequency of dosage differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endoôs ñbest opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market.ò (Bingol, Tr. 1314). As Dr. Savage admitted, the differences among long-acting opioids are no different than those found in over-the-counter pain relievers like Advil, Tylenol, Aleve, and aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16). Dr. Savage also explained that frequency of dosing is mostly about patient preferences. She explained that some patients may want to take a certain long-acting opioid that requires more pills more frequently so that they have a sense of control over their treatment; other patients do not. (Savage, Tr. 742).

3. Flexible dosing

784. Oxymorphone, unlike some other long-acting opioids used for oral analgesia, is available in an injectable or IV formulation. This is significant because a patient using Opana ER that requires IV opioids can continue to use oxymorphone without the need to transition to a new opioid with the inherent uncertainty in terms of analgesic response and potential side effects. (CX5002 at 039-40 (¶ 108) (Savage Report)).

RESPONSE TO FINDING NO. 784:

While Respondent does not dispute that oxymorphone is available in both injectable and tablet formulations, there is no support in the record for the proposition that the availability of both formulations is ñsignificantò for purposes of pain treatment or market definition. Dr. Savage admitted the point is only a ñtheoretical consideration,ò and keeping patients on a tablet version of an injectable opioid is ñnot often done.ò (Savage, Tr. 802). In fact, the most commonly used opioids in emergency rooms and other inpatient settings are hydromorphone, fentanyl, and morphine. (Savage, Tr. 787). The most commonly prescribed opioids in outpatient settings are oxycodone, hydrocodone, and morphine. (Savage, Tr. 786; Michna, Tr. 2150). When patients are released from the hospital they are almost always switched from one opioid to an entirely different opioid for outpatient purposes. (Savage,

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keeping patients on a tablet version of an injectable opioid is ñnot often done.ò (Savage, Tr. 802). In fact, the most commonly used opioids in emergency rooms and other inpatient settings are hydromorphone, fentanyl, and morphine. (Savage, Tr. 787). The most commonly prescribed opioids in outpatient settings are oxycodone, hydrocodone, and morphine. (Savage, Tr. 786; Michna, Tr. 2150). 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; Noll, Tr. 1530 (physicians ñvery often switch which molecule is used when the patient leaves the hospitalò)). For this reason, the availability of oxymorphone in both injectable and tablet form is not a clinically relevant factor. (Michna, Tr. 2149-50).

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786. In addition to the ER and IV formulations, oxymorphone is also available in an immediate release (IR) formulation, meaning that the molecule can be dosed in a variety of ways as needed for an individual patient. (CX2529 at 059 (Opana ER Strategic Platform) (ñOpana has an advantage over other opioids in that it is available in both parenteral [injectable] and oral (IR and ER) formulations, which leads to easy titration and conversion when patients need to transition from IV to oral dosage forms.ò)).

RESPONSE TO FINDING NO. 786:

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relievers like Advil, Tylenol, Aleve, and aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16).

4. Less euphoria/cognitive impairment

787. Endoôs clinical data indicated that Opana ER was less euphorige

provide 1 top key benefit of Opana ER.ò (CX2717-003-04, 08). Among the ñ[c]ommon themesò was that Opana ER was ñwell tolerated/lack of side effects.ò (CX2717-008). The cited document says nothing about Opana ER side effects in relation to any other long-acting opioid.

790. Endo identified an incidence of adverse events (AEs) similar to that of a placebo in its internal documents. (CX2610 at 024 (Revopan [reformulated Opana ER] Playbook) (identifying ñAEs similar to placebo post titrationò as a key advantage of Revopan); CX2528 at 023 (Revopan [reformulated Opana ER] Launch Readiness Review) (same)).

RESPONSE TO FINDING NO. 790:

Respondent has no specific respons

RESPONSE TO FINDING NO. 792:

Respondent has no specific response other than to clarify that Dr. Savage testified that to the extent patients develop side effects, those side effects can be treated with additional medications and that there is no way to tell which opioid will work best or result in minimal side effects in advance of tre

pharmaceutical industry. (Noll, Tr. 1358). Proposed Finding No. 794 also is improper because it states a legal conclusion.

795. ER opioids have advantages over IR opioids. First, ER drugs reduce pill burden (the number and frequency of doses), which is beneficial to the extent that a lower pill burden improves adherence to the prescription and reduces the likelihood of misuse, such as accidental overdose. Second, an ER formulation allows the drug to be put into the system continuously ñaround the clock,ò even when the patient is sleeping. (CX5000 at 057 (¶ 125) (Noll Report); Savage, Tr. 705 (ñExtended-release opioids are indicated for people who have sustained pain usually that goes on longer than 12 to 24 hours or of a chronic nature that requires relief 24 hours a day.ò)).

RESPONSE TO FINDING NO. 795:

Proposed Finding No. 795 violates this Courtôs Order on Post-Tr

possible to overlap doses of short-acting medications in a way that provides a steady state.ò (Savage, Tr. 707). Indeed, there is no difference in the efficacy of immediate-release and long-acting opioids. (Michna, Tr. 2117).

797. ER Opioids also have disadvantages compared with IR opioids that make them unlikely to be close substitutes. For example, IR opioids are more amenable to use ñas neededò (based on the presence of pain), which can lead to a lower daily dosage. (CX5000 at 0558 (¶ 126) (Noll Report); Savage, Tr. 705 (ñIf somebody has short-lived, quick onset pain that goes away fairly quickly, a shorter-acting opioid would be indicated.ò)).

RESPONSE TO FINDING NO. 797:

Proposed Finding No. 797 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358). The quoted portion of Dr. Savageôs testimony speaks for itself and does not support the propositions advanced in the Proposed Finding.

798. Thus, short acting opioids are not routinely or reliably interchangeable with a long-acting opioid with like Opana ER. (Savage, Tr. 708).

RESPONSE TO FINDING NO. 798:

Complaint Counselôs Proposed Finding No. 798 is not supported by the record. Dr. Michna explained that even for ñchronic conditions, [patients] might be very doing very well on the short-acting opioid and we would continue them on it.ò (Michna, Tr. 2113). Dr. Savage testified that ñit is possible to overlap doses of short-acting

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oxymorphone IR affected sales of Opana ER. Exhibit 3A counts total prescriptions, Exhibit 3B shows total mg for each formulation of oxymorphone, and Exhibit 3C shows gross revenues from sales of the two products. (CX5000 at 058-59 (¶ 127) (Noll Report)).

RESPONSE TO FINDING NO. 799:

While Respondent does not dispute that the cited exhibits in Professor Nollôs expert report purport to test the asserted propositions, Professor Nollôs analysis is based on his scanning for any ñvisible effectò on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Professor Noll recognizes that a SSNIP test is the normal method used to determine close economic substitutes. (CX5000 at 017 (Noll Rep. ¶ 38)). But Professor Noll admits he did not conduct a SSNIP test. (Noll, Tr. 1514).

800. Generic entry for a product is a r

H. Other pain relief products did not meaningfully constrain Opana ER sales and prices

804. Individuals have highly variable responses to many classes of medications that are used to treat pain, including nonsteroidal anti-inflammatory drugs, anticonvulsant drugs, certain antidepressants that are used for pain, and to opioids. (Savage, Tr. 689-90).

RESPONSE TO FINDING NO. 804:

Respondent has no specific response.

805. Nonsteroidal anti-inflammatory drugs are generally indicated for mild to moderate pain, whereas opioids are indicated for greater pain severity. Anti-inflamatory drugs also have a different mechanism of action from opioids. (Savage, Tr. 699; CX5002 at 015 (¶¶ 3336) (Savage Report)).

RESPONSE TO FINDING NO. 805:

Respondent has no specific response.

806. Acetaminophen is also indicated for only mild to moderate pain, and also has a different mechanism of action than opioids. (Savage, Tr. 699; CX5002 at 016 (¶¶ 37-40) (Savage Report)).

RESPONSE TO FINDING NO. 806:

Respondent has no specific response.

807. Anticonvulsants are not as potent as opioids in relieving pain, and their efficacy appears to be greater for nerve-related pain, unlike opioids. (Savage, Tr. 700-701).

RESPONSE TO FINDING NO. 807:

Respondent has no specific response.

808. Similarly, anti-depressants than can be used to treat pain are less potent than opioids. (Savage, Tr. 701; CX5002 at 017-18 (¶¶ 45-47) (Savage Report)).

RESPONSE TO FINDING NO. 808:

Respondent has no specific response.

809. From a clinical perspective, the various non-opioid options for the treatment of pain are not reliably interchangeable with Opana ER because they have different indications, different side e

814. A rule of reason analysis includes a determination of market power. (Noll, Tr. 1343; CX5000 at 083 (¶ 184) (Noll Report)).

RESPONSE TO FINDING NO. 814:

Complaint Counselôs Proposed Finding No. 814 improperly states a proposed legal conclusion, not a fact, and should be disregarded.

815. Assessing market power helps to determine whether the conduct at issue in a rule-of-reason analysis preserved or enhanced the market power of a company. (CX5000 at 006, 012 (¶¶ 9, 27) (Noll Report); Noll, Tr. 1365). In so doing, the market power analysis aids a rule-of-reason assessment in determining the anticompetitive effects for conduct at-issue in a particular relevant market. (CX5000 at 006 (¶ 9) (Noll Report)).

RESPONSE TO FINDING NO. 815:

Complaint Counselôs Proposed Finding No. 815 improperly states a proposed legal conclusion, not a fact. In addition, the proposed legal conclusion is incomplete and misleading. A market participant cannot harm competition unless that participant possessed monopoly power in the relevant market at the time. As Dr. Addanki explained: ñBecause the economic harm engendered by an allegedly anticompetitive settlement results directly from its ability to create enhance or maintain monopoly power, if Endo did not possess monopoly power in the relevant market no further inquiry on the competitive effects of the settlement is necessary the settlement cannot be anticompetitive.ò (RX-547.008 (Addanki Rep. ¶ 11(a))). Professor Noll agrees with Dr. Addanki on this point; as Dr. Noll admitted at trial, the SLA could not have been anticompetitive unless Endo had ñ[s]ubstantial market power.ò (Noll, Tr. 1574).

816. Economists can ascertain market power in two ways, indirectly and directly. (CX5000 at 083 (¶ 184) (Noll Report); Noll, Tr. 1404-05).

RESPONSE TO FINDING NO. 816:

Respondent has no specific response.

817. Complaint Counselôs economic expert and Professor Emeritus of Stanford University, Roger G. Noll, applied real-world data to both the indirect and direct methods of assessing market power. (Noll, Tr. 1366, 1693-96; CX5000 at 083-100 (¶¶ 184-227) (Noll Report)).

RESPONSE TO FINDING NO. 817:

Complaint Counselôs Proposed Finding No. 817 is incomplete and misleading. Whether or not Professor Noll ñapplied real-world dataò when assessing market power is not probative of market power without understanding whether that data is relevant to the market power inquiry, especially whether it is reflective of power to constrain output, and whether that data was properly and empirically analyzed. As described in Respondentôs responses to Complaint Counselôs Proposed Findings Nos. 818 through 965, Professor Noll and Complaint Counselôs use of supposed ñreal-world dataò is improper to assess market power for the reasons explained in the responses to those proposed findings.

818. Real-world data applied to the indirect and direct methods supports the conclusion that Endo had substantial market power/monopoly power in the market for Opana ER. (Noll, Tr. 1404-05; CX5000 at 087-88, 095, 100 (¶¶ 197, 214, 227) (Noll Report)). This was true at the time of the settlement and remained true for many years following the settlement. (Noll, Tr. 1405; CX5000 at 100 (¶ 227) (Noll Report)).

RESPONSE TO FINDING NO. 818:

Complaint Counselôs Proposed Finding No. 818 is an inaccurate assessment of market power in the relevant antitrust market and is unsupported by the record. First, the ñmarket for Opana ERò is not the relevant market. The proper antitrust market is the market for long-acting opioids. (*See also* RX-547.0047 (Addanki Rep. ¶ 85)). ñBecause the relevant market is broader than the narrow market definition that Dr. Noll contends, his market concentration analysis does not shed any light on whether Opana ER has had monopoly power.ò (RX-547.0052 (Addanki Rep. ¶ 98)). Indeed, from January 2009 through December 2012, Opana ERôs share of the long-acting opioid market never reached 10 percent. (Addanki, Tr. 2333; RX-547.0050-51, RX-

547.0132 (Addanki Rep. ¶ 94, Ex. 10)). By Endoôs own estimate, its market share was just 3.4 percent near the time of the settlement. (CX3273-003). It is ñinconceivableò that Endo could command monopoly power with such a small share of the relevant market. (Addanki, Tr. 2333). As Complaint Counselôs own economic expert acknowledged, the SLA could not have been anticompetitive unless Endo had ñ[s]ubstantial market power.ò (Noll, Tr. 1574).

Further, Professor Noll identified only three supposed ñindicatorsò of monopoly power under the ñdirect methodò: ñ1) the ability to exclude firms from the market, 2) the attention given by a firmôs executives to the prices and likely competitive response of other firms to a contemplated price change a companyôs internal estimates of the effects of a price change on sales volume and profitability, and 3) the Lerner Index.ò (RX-547.0052 (Addanki Rep. ¶ 99); *see* Noll, Tr. 1412ï14). ñBut [w]e have known for a very long time now that patents do not confer monopoly powerò (Addanki, Tr. 2343), that Endo very much viewed itself as competing with other long-acting opioids (CX2610 at 24; Bingol, Tr. 1311-15; RX-547.0043-47 (Addanki Rep. ¶¶ 80-84)), and Professor Noll himself admitted that a high Lerner Index ñdoesnôt necessarily meanò that a firm has monopoly power, (Noll, Tr. 1415).

B. Indirect method of establishing market power

819. The indirect method of establishi

economies of scale, and can be reinforced by product differentiation and loyalty. (CX5000 at 086 (¶ 193) (Noll Report); Noll, Tr. 1406-09).

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the rule of reason analysis (Noll, Tr. 1365) ð not the ñindirect method of establishing market powerò itself, as Proposed Finding No. 827 wrongly asserts.

As Dr. Addanki explains, the market power inquiry and the rule of reason inquiry are separate analyses, though the latter is unnecessary unless the former is satisfied. Once ñthe brandôs monopoly power has been established,ò then ñthe *next step* is to determine whether in fact consumers are worse off under the actual settlement agreement than they would have been in its absence (*i.e.*, in the but-for world). (RX-547.0020 (Addanki Rep. ¶ 20) (emphasis added); *see also* RX-547.00022-23 (Addanki Rep. ¶ 41) (describing monopoly power screen)).

1. At all relevant times, Endo had substantial market power in the relevant market

828. The relevant market is the s

RESPONSE TO FINDING NO. 829:

acting opioids in the United Statesò); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). Endo never had more than a 10 percent share of the long-acting opioid market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94)). By Endoôs own estimate, its market share was only 3.4 percent near the time of the settlement. (CX3273-003 (Bingol Decl.) (referring to a long-acting opioid market)).

831. The number of firms in the relevant oxymorphone ER market has always been small. The only branded oxymorphone ER products sold prior to and subsequent to the Impax-Endo Settlement Agreement are Endoôs Opana ER products, Original Opana ER and Reformulated Opana ER. (JX-001 at 006 (¶ 8); Bingol, Tr. 1262; CX6050 at 006-13 (FDA Regulatory History of Opana ER); CX5000 at 084-85 (¶¶ 187-88) (Noll Expert Report)).

RESPONSE TO FINDING NO. 831:

Complaint Counselôs Proposed Finding No. 831 is misleading and inconsistent with the record, to the extent it refers to a ñmarket for oxymorphone ER.ò The record evidence indicates that oxymorphone ER and Opana ER completed in a market for all long-acting opioids. (*See* Addanki, Tr. 2328 (testifying that ñthe relevant market is no smaller than the market for long-acting opioids in the United Statesò); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The market for long-acting opioids includes a significant number of firms, including the sellers of OxyContin (Purdue Pharma LP), Dragesic/fentanyl patches (Janssen Pharmaceuticals, Inc.), MS Contin/Morphine Sulfate (Purdue Pharma LP), Opana ER/oxymorphone ER, Avinza (King Pharmaceuticals LLC), Kadian (Allergan Sales LLC), Embeda (Alpharma Pharmaceuticals LLC), Exalgo (Mallinckrodt, Inc.), among others. (*See* CX3273-003 (Bingol Decl. ¶ 6); RX-547.0051, RX-547.0133 (Addanki Rep. ¶¶ 95-96, Ex. 11)).

832. Original Opana ER was the only product in the relevant market from 2006 until July 2011. July 2011 was when Endo had licensed Actavis, another generic company, to enter with first-to-file exclusivity for the 7.5 and 15 mg doses of generic Opana ER. CX2607 at 009 (¶ 25) (Lortie Decl.); CX0309 at 002; CX5000 at 008 (¶ 14) (Noll

Report)). These dosages were the least profitable dosages of Opana ER and comprised only 5% of Endoôs Opana ER revenues. (JX-001 at 007 (¶ 13); CX2607 at 010 (¶ 26) (Lortie Decl.) (ñActavisôs sale of the 7.5 and 15 mg dosage strengths did not have a major impact on Endoôs brand sales, because together these dosages account for less than 4% of OPANA ER CRF sales.ò)).

RESPONSE TO FINDING NO. 832:

Complaint Counselôs Proposed Finding No. 832 is inaccurate and inconsistent with the record. The record evidence shows that oxymorphone ER and Opana ER competed in a market for long-acting opioids. (*See* Addanki, Tr. 2328 (testifying that ñthe relevant market is no smaller than the market for long-acting opioids in the United Statesò); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The market for long-acting opioids includes a significant number of firms, including the sellers of OxyContin (Purdue Pharma LP), Dragesic/fentanyl patches (Janssen Pharmaceuticals, Inc.), MS Contin/Morphine Sulfate (Purdue Pharma LP), Opana ER/oxymorphone ER, Avinza (King Pharmaceuticals LLC), Kadian (Allergan Sales LLC), Embeda (Alpharma Pharmaceuticals LLC), Exalgo (Mallinckrodt, Inc.), among others. (*See* CX3273-003 (Bingol Decl. ¶ 6); RX-547.0047-48, RX-547.0133 (Addanki Rep. ¶¶ 85, 95-96, Ex. 11)).

833. The Actavis generic oxymorphone ER dosages were therapeutically equivalent substitutes for the version of Opana ER that were on the market at the time of generic entry. (CX5000 at 084-85 (¶ 187) (Noll Report); Noll, Tr. 1380). Therapeutic equivalence makes it more likely that a generic will be substituted for the brand drug. (JX-001 at 003 (¶ 18); Noll, Tr. 1309; Reasons, Tr. 1219).

RESPONSE TO FINDING NO. 833:

Respondent has no specific response.

834. Rather than compete with Actavis on these low-profit dosages, Endo simply abandoned the sale of Original Opana ER for these doses, until Endo introduced Reformulated Opana ER. (CX4007 (Lortie, IHT at 124-26); JX-001 at 012 (¶ 49) (Endo introduced Reformulated Opana ER in 2012); CX5000 at 084-85 (¶ 187) (Noll Report)).

competition between the generic and brand drugs. (CX5000 at 141-42, 150 (¶¶ 322-23, 340) (Noll Report)).

RESPONSE TO FINDING NO. 837:

Complaint Counselôs Proposed Finding No. 837 is misleading to the extent that it implies that Reformulated Opana ER and Original Opana ER do not have the same active ingredient or were not used for the same purposes. Opana ER and reformulated Opana ER are bioequivalent and are used interchangeably by consumers for the same purpose. (RX-547.0011, 0028-29. 0105-09 (Addanki Rep. ¶¶ 14, 61-64; Ex. 4); CX5000-038 (Noll Rep. ¶ 86)).

838. Nonetheless, since Impax began selling all seven dosage strengths of oxymorphone ER in January 2013 at prices substantially below Endoôs prices, Endoôs market share has declined. (CX5000 at 008 (¶ 14) (Noll Report); Noll, Tr. 1381-82).

RESPONSE TO FINDING NO. 838:

Complaint Counselôs Proposed Finding No. 838 is vague as to which ñmarketò is being discussed, unsupported by the cited

than the minimum threshold of 2500. (CX5000 at 008, 085 (¶¶ 14, 189) (Noll Report); Noll, Tr. 1404-05).

RESPONSE TO FINDING NO. 839:

Complaint Counselôs Proposed Finding No. 839 is misleading, unsupported, and inconsistent with the record. The record indicates that oxymorphone ER competes in the long-acting opioids market. (*See* Addanki, Tr. 2328 (testifying that there is no evidence indicating ñthe relevant market being no smaller than the market for long-acting opioids in the United Statesò); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The record further reflects that, in the appropriately-defined relevant market for long-acting opioids, Endo never had more than a 10 percent share. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). Therefore, any proper HHI calculation would be far lower than indicated in Proposed Finding No. 839. (RX-547.0052 (Addanki Rep. ¶ 98) (noting ñ[b]ecause the relevant market is broader than the narrow market definition that Dr. Noll contends, his market concentration analysis does not shed any light on whether Opana ER has had monopoly powerò)).

840. For much of the period after Endo introduced Opana ER, Endo had a monopoly in the relevant market: the HHI equaled 10000, indicating that Endo had a 100% share of the market. (CX5000 at 008, 085 (¶¶ 14, 189) (Noll Report); Noll, Tr. 1404-05).

RESPONSE TO FINDING NO. 840:

Complaint Counselôs Proposed Finding No. 840 is vague as to which ñmarketò is being discussed. The record shows that oxymorphone ER competes in the long-acting opioids market. (*See* Addanki, Tr. 2328 (testifying that there is no evidence indicating ñthe relevant market being no smaller than the market for long-acting opioids in the United Statesò); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The sources cited in Proposed Finding No. 840 do not speak to the HHI in the long-acting opioids market. Rather, Proposed

long-acting opioids, but rather to an improper, oxymorphone ER-

any proper HHI calculation would be far lower than indicated in the proposed finding. (RX-547.0052 (Addanki Rep. ¶ 98) (noting ñ[b]ecause the relevant market is broader than the narrow market definition that Dr. Noll contends, his market concentration analysis does not shed any light on whether Opana ER has had monopoly powerò)). The market for long-acting opioids has never been highly concentrated. (RX-547.0052 (Addanki Rep. ¶ 98) (ñOpana ERôs market share in the relevant market was and has been too low for Endo to exercise monopoly power.ò)).

2. There are significant barriers to entry into the relevant market

843. The market for oxymorphone ER also has significant barriers to entry. (*See* CCF ¶¶ 844-52, below).

RESPONSE TO FINDING NO. 843:

Complaint Counselôs Proposed Finding No. 843 finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are inconsistent with the record, unsupported by the evidence cited, and/or unreliable for the reasons set out in Respondentôs replies to those findings. Further, the proposed summary finding is inconsistent with the record to the extent it refers to an oxymorphone ER-only market. The record reflects that oxymorphone ER competes in the market for long-acting opioids. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). Professor Nollôs report demonstrates that entry is common in the long-acting opioid market. (CX5000-194-95 (Noll Rep., Ex. 4)). Indeed, Exhibit 4 to Professor Nollôs report lists over 20 long-acting opioid products that have entered the market since 2010. (CX5000-194-95 (Noll Rep., Ex. 4)).

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547.0052 (Addanki Rep. ¶ 98) (ñ[M]ost pharmacists cannot substitute Impaxôs product . . . for prescriptions written for reformulated Opana ER.ò)). Moreover, the record belies the assertion that formularies cannot readily facilitate switching between a branded long-acting opioid and a non-AB-rated generic version of a different long-acting opioid. When UPMC instituted formulary changes to preference Opana ER and various generic long-acting opioids over the branded long-acting opioid OxyContin, nearly 70 percent of OxyContin patients switched to a different long-acting opioid. (RX-087). UPMC reported a significant increase in usage of Opana ER and generic Morphine Sulfate ER (MS ER), and to a lesser extent, generic Fentanyl patches. (RX-087 (Figures 3, 5)).

> 852. The sources of Endoôs market power include the patents on Opana ER, entry barriers that are created by the licensing process for pharmaceuticals by the FDA, regulation of all opioids by the Drug Enforcement Agency (DEA), and brand loyalty created by Endoôs marketing campaigns and product-differentiation promotions. (CX5000 at 008-09 (¶ 15) (Noll Report); Noll, Tr. 1402-03). Collectively these factors explain why Endo was a monopolist or near-monopolist in the relevant oxymorphone ER market. (CX5000 at 00809, 087-88 (¶¶ 15, 197) (Noll Report)).

RESPONSE TO FINDING NO. 852:

Complaint Counselôs Proposed Finding No. 852 is inaccurate, misleading, inconsistent with the record, and based on unreliable expert testimony. Endoôs patents, licensing procedures, regulations, and brand loyalty have not prevented the entry of over 20 long-acting opioid products since 2010. (CX5000-194-95 (Noll Rep., Ex. 4). Complaint Counselôs Proposed Finding No. 852 also mischaracterizes the relevant market as one for oxymorphone ER, though the record reflects that oxymorphone ER competes in the market for long-acting opioids, and that there is no cognizable oxymorphone ER-only market. (*See* Addanki, Tr. 2328 (testifying that there is no evidence indicating ñthe relevant market being no smaller than the market for long-acting opioids in the United Statesò); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003

(Bingol Decl. ¶ 6)). Endo never had more than a 10 percent share of the long-acting opioid market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). Therefore, the proposed finding is also incorrect in that Endo was a ñmonopolist or near-monopolistò in the properly defined market. Further, Complaint Counsel seems to concede that Endo may have not truly been a monopolist, only a ñnear monopolist.ò

Finally, the proposed finding is wrong to suggest that patents are a source of market power (*see* Addanki, Tr. 2343 (ñWe have known for a very long time now that patents do not confer monopoly power.ò)), or that the Hatch-Waxman Act presents a barrier to entry (*see* CX5007-045-46 (Hoxie Rep. ¶¶ 84-85) (noting the Hatch-Waxman Act ñstreamlines the process by which a company may attempt to market a generic version of an FDA-approved drugò and that the share of generic prescriptions in the United States rose from 19 percent to 86 percent since the Hatch-Waxman Act was enacted)). Nor has brand loyalty prevented Impax from successfully marketing its generic drug despite the presence of a number of brand-name long-acting opioids despite having no reference-listed drug to trigger automatic substitution. (CX5000-196 (Noll Rep., Ex. 5A1) ([redacted]); RX-547.0052 (Addanki Rep. ¶ 98) (ñ[M]ost pharmacists cannot substitute Impaxôs product . . . for prescriptions written for reformulated Opana ER.ò)). Therefore, Proposed Finding No. 852 should be disregarded.

C. Direct evidence of market power

853. Market power can also be established through an analysis of the direct effects from the conduct at issue. (Noll, Tr., 1365-66). The direct effects method simply observes the conduct at issue and assesses how it impacted and harmed the market. (Noll, Tr. 1366; CX5000 at 013-14 (¶¶ 30-31) (Noll Report)).

RESPONSE TO FINDING NO. 853:

Complaint Counselôs Proposed Finding No. 853 improperly states a proposed legal conclusion, not a fact, and should be disregarded. Further, as described by Dr. Addanki, any purportedly ñdirectò showing of market power must include proof that the firm has reduced output. (RX-547.0008 (Addanki Rep. ¶ 11 n.8) (monopoly power consists of ñthe ability to *restrict output* and sustain supracompetitive profitsò) (emphasis added); RX-547.0051 (Addanki Rep. ¶ 96) (ñ[H]ad Endo in fact exercised monopoly power and restricted the output of Opana ER we would have expected an increase in output after Impax launched its generic versions of original Opana ER.ò)).

854.

1. Endo excluded competitors from the oxymorphone ER market by entering agreements with first-to-file generic oxymorphone ER ANDA applicants

859. Under regulatory schemes governing the pharmaceutical industry, brand-named drug manufactures may be entitled by law to try to delay competitive entry by generic manufacturers when the brandôs drug is protected by patents. (CX5000 at 088-89 (¶ 199) (Noll Report)).

RESPONSE TO FINDING NO. 859:

Complaint Counselôs Proposed Finding No. 859 improperly states a proposed legal conclusion, not a fact, and should be disregarded. It is also misleading. The Hatch-Waxman Act provides for a 30-month stay in the face of an infringement suit in response to a Paragraph IV filing. (JX-001-004 (¶ 23)). The Hatch-Waxman Act also provides for 180 days of generic exclusivity for the first to file a Paragraph IV filing. (JX-001-005 (¶ 27)). These provisions are intended to enhance competition by ñstreamlin[ing] the process by which a company may attempt to market a generic version of an FDA-approved drug,ò and has increased competition from generic drug manufacturers. (*See* CX5007-045-46 (Hoxie Rep. ¶¶ 84-85)).

860. In particular, if the brand-name drug files an infringement suit against the generic firm that filed a Paragraph IV ANDA, the FDAôs regulatory procedures protect the brand-name drug against entry by the generic first filer until the end of the 30-month stay, among other things. The regulatory scheme also protects against entry by other generic firms for another 180 days after the first-filerôs entry. (JX-001 at 004 (¶ 23); CX5000 at 088-89 (¶ 199) (Noll Report)).

RESPONSE TO FINDING NO. 860:

Complaint Counselôs Proposed Finding No. 860 improperly states a proposed legal conclusion, not a fact, and should be disregarded.

litigation over the validity and infringement of Endoôs patents was settled by the Impax-Endo Settlement Agreement. (JX-001 at 007-08 (¶¶ 15, 19)).

RESPONSE TO FINDING NE

Second, the Settlement and License Agreement did not ñextend[] the market powerò of the brand-named company ñregardless of how the relevant market is defined.ò In the properly-defined long-acting opioid market, Endo did not have market power at all ð meaning that there was no market power to ñextend[].ò Indeed, the market share of Opana ER was always less than 10 percent and never had market power. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)).

863.

(CX5000 at 088-89 (¶ 199) (Noll Report); CX2607 at 009-10 (¶ 26) (Lortie Decl.) (partially *in camera*)). This ability of Endo to exclude firms from the market indicates that Endo possesses market power in sales of oxymorphone ER. (CX5000 at 088-89 (¶ 199) (Noll Report)).

RESPONSE TO FINDING NO. 863:

Complaint Counselôs Proposed Finding No. 863 is misleading and inconsistent with the record to the extent it refers to a market for oxymorphone ER. The record reflects that oxymorphone ER competes in the market for long-acting opioids, and that there is no cognizable oxymorphone ER-only market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). The record further reflects that Endoôs patents are not a proper source of market power. (*See* Addanki, Tr. 2343 (ñWe have known for a very long time now that patents do not confer monopoly power.ò)). Endo was unable to ñexclude firmsò from the long-acting opioid market as indicated by Professor Nollôs report, which shows over 20 long-acting opioid products have entered the long-acting opioid market since 2010. (CX5000-194-95 (Noll Rep., Ex. 4)).

2.

867. Endoôs practice for implementing price changes involved executives responsible for a product line submitting price proposals to the Executive Pricing Committee. (CX5000 at 090-95, 219-26 (¶¶ 203-14 & Exs. 7A-7B7) (Noll Report); CX2673 at 003-06 (Mar. 2008 Pricing Proposal); CX2678 at 002-06 (Dec. 2008 Pricing Proposal); CX2670 at 001-08 (Jan. 2010 Pricing Proposal); CX1217 at 001-05 (May 2010 Pricing Proposals)).

RESPONSE TO FINDING NO. 867:

Complaint Counselôs Proposed Finding No. 867 is misleading and inaccurate to the extent it does not distinguish between WAC prices and net prices. As Professor Noll admits in his report, the pricing proposals that Complaint Counsel cites expressly pertain to changes in WAC (list) prices. (*See* CX5000-090 (Noll Rep. ¶ 203) (ñThese proposals contain a

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868. These proposals recommend changes to the list price, which is also called wholesale average cost (WAC). In the drug industry, list price is not the price that is paid by drug wholesalers, large health care providers and pharmacy chains that buy directly from pharmaceutical companies. (CX5000 at 090-91 (¶ 203) (Noll Report)).

RESPONSE TO FINDING NO. 868:

Respondent has no specific response.

869. The price actually paid by many drug purchasers is called the net realized price. Net realized prices reflect discounts, rebates, and other concessions ð some of which are determined by formulas that apply to all buyers within a class, others of which are negotiated with a buyer. (CX5000 at 090-91 (¶ 203) (Noll Report)).

RESPONSE TO FINDING NO. 869:

Respondent has no specific response.

870. Usually, the price proposals do not discuss discounts and net floor prices. Nonetheless, discounts and rebates are sufficiently formulaic that the documents that show only list prices inherently incorporate the impact of discounts and net price floors on revenues. (CX5000 at 090-92, 219-26 (¶¶ 203-07 & Exs. 7A-7B7) (Noll Report)).

RESPONSE TO FINDING NO. 870:

Complaint Counselôs Proposed Finding No. 870 is incomplete, misleading, and based on unreliable expert testimony. First, Proposed Finding No. 870 is vague and ambiguous as to what ñsufficiently formulaicò is intended to convey. Proposed Finding No. 870 is also inconsistent with record evidence, including Professor Nollôs testimony.

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547.0053-54 (Addanki Rep. ¶ 101(b)): CX5000-219 (Noll Rep., Ex. 7A);lA) l’ʻ

Addanki, Tr. 2290 (

)).

(Addanki, Tr. 2290). Thus, Professor Noll was forced to concede that the discounts and rebates were not ñsufficiently formulaicò for him to accurately calculate, for example, what Endo charges to specific customers. (Noll, Tr. 1512 (ñQ. Sir, is that a way of saying you couldnôt tell the actual prices Endo was charging its customers from Endoôs documents? A. You could not tell the specific price to a specific customer . . .ò)).

> 871. In March 2008, anticipating the launch of three new doses (7.5mg, 15mg, 30mg) of Opana ER, Endo executives proposed a price increase of 4% for all current doses of Opana ER and initial prices for the new doses. (CX2673 at 004 (Mar. 2008 Price Change Proposal); CX5000 at 092 (¶ 208) (Noll Report)). Endo executives projected a revenue increase of $2 million, or 2.4%, for Opana ER from the price increase. (CX2673 at 005 (Mar. 2008 Pricing Proposal); CX5000 at 092 (¶ 208) (Noll Report)).

RESPONSE TO FINDING NO. 871:

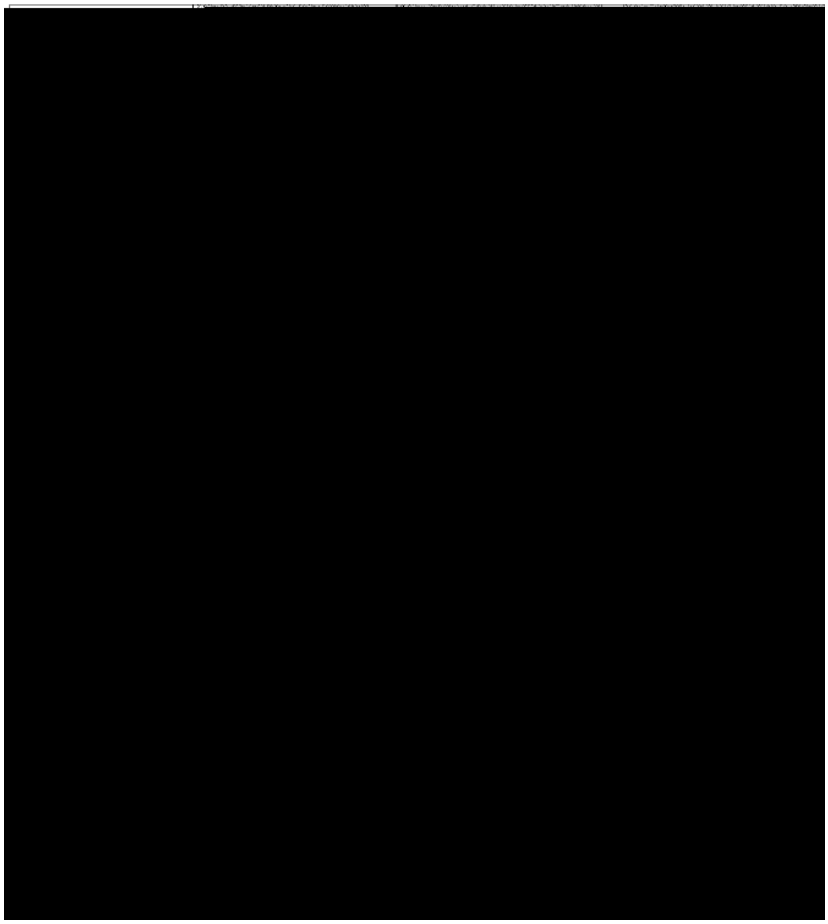
Complaint Counselôs Proposed Finding No. 871 is incomplete and misleading. The cited document is ambiguous as to whether it reflects a projected $2 million revenue increase, because the cited chart is not labeled. (CX2673). = â rojelliot i | iabereven | nt = א plaint Counsse fabe

872. These calculations imply that price competition against Opana ER was not sufficient to prevent a profitable non-transitory price increase. (CX2673 at 005 (Mar. 2008 Pricing Proposal); CX5000 at 092 (¶ 208) (Noll Report)).

RESPONSE TO FINDING NO. 872:

Complaint Counselôs Proposed Finding No. 872 is an inaccurate and misleading selective characterization of CX2673, and is inconsistent with record evidence. In portions of CX2673 that Complaint Counsel conspicuously omits from its proposed finding, the document analyzes ñMarket Pricing For Direct Competitors,ò listing prices of competing long-acting opioids like Avinza, Kadian, and OxyContin. (CX2673-008 (pictured below)).

Attachment A UPDATE
Market Pricing for Direct Competitors



This analysis is directly probative of price competition among long-acting opioids and shows that several of Endoôs long-acting opioid ñdirect competitorsò had announced that they

As Professor Noll admitted at trial,

(Noll, Tr. 1681). Moreover, the cited document (CX2678) is merely a forecast. There is no record evidence that Endoôs *net* prices actually increased, or that Endo

874. This pricing proposal shows that Endo anticipated no loss in sales volume arising from a price increase. (CX2678 at 018-22 (Dec. 2008 Pricing Proposal); CX5000 at 092-93 (¶ 209) (Noll Report)).

RESPONSE TO FINDING NO. 874:

Complaint Counselôs Proposed Finding No. 874 is unsupported by the evidence cited and is based on unreliable expert testimony. The cited document (CX2678) does not reference sales volumes in any way. The cited portion of Professor Nollôs report, which claims that ñEndo anticipated no loss in sales volume,ò is a factual assertion not supported by any citation of any kind. (*See* CX5000-092-93 (Noll Rep. ¶ 209)). Moreover, there is no record evidence that Endoôs *net* prices actually increased, or that Endo actually increased its revenue as a result of the proposed change in its WAC price. In fact, the evidence shows just the opposite. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873)). Professor Noll [redacted] (Noll, Tr. 1681-82).

875. In January 2010, Endoôs Executive Pricing Committee approved a 9.9% increase in the list price for all Opana ER dosages, effective February 1, 2010. (CX2670 at 001-02 (Jan. 2010 Pricing Proposal); CX5000 at 093 (¶ 210) (Noll Report)). This pricing proposal originally requested a 5.2% price increase, and noted that the medical care consumer price index had increased by 3.2% in 2009. (CX2670 at 002 (Jan. 2010 Pricing Proposal); CX5000 at 093 (¶ 210) (Noll Report)). The price increase was changed to 9.9% during the process of reviewing the proposal. CX2670 at 002, 005 (Jan. 2010 Pricing Proposal); CX5000 at 093 (¶ 210) (Noll Report)). The document does not include a revenue forecast for the 9.9% price increase, but does forecast that the original 5.2% increase would raise revenues by $9 million, or 4.6%, implying only a slight reduction in sales quantity as a result of the price increase. (CX2670 at 003 (Jan. 2010 Pricing Proposal); CX5000 at 093 (¶ 210) (Noll Report)).

RESPONSE TO FINDING NO. 875:

Complaint Counselôs Proposed Finding No. 875 is an incomplete and misleading characterization of the cited document (CX2670), which refers to an increase in WAC prices. [redacted] (Noll, Tr. 1680 [redacted] Moreover, the cited document (CX2670) is merely a forecast. There is no record evidence that Endoôs *net* prices actually increased, or that Endo actually increased its revenue as a result of the proposed change in its WAC price. In fact, the evidence shows just the opposite. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873)). Professor Noll

(Noll, Tr. 1681-82).

876. This proposed price increase substantially exceeded the projected increase in unit costs, which implies that it increased price above the competitive level that is dictated by marginal cost. (CX5000 at 093 (¶ 211) (Noll Report)).

RESPONSE TO FINDING NO. 876:

Complaint Counselôs Proposed Finding No. 876 is incomplete, misleading, and based on unreliable expert testimony. The price increase proposed in the cited document (CX2670) is an increase in WAC prices.

(Noll, Tr. 1680

Moreover, the cited document

(CX2670) is merely a forecast. There is no record evidence that Endoôs

RESPONSE TO FINDING NO. 878:

Complaint Counselôs Proposed Finding No. 878 is inaccurate, misleading, and based on unreliable expert testimony. In the paragraph of Professor Nollôs report that Complaint Counsel

Proposed Finding Nos. 870-78, these documents reflect [redacted] (Noll, Tr. 1680 [redacted] Moreover, the cited documents are merely projections, plans, or forecasts. There is no record evidence that Endoôs *net* prices actually increased, or that Endo actually increased its revenue as a result of the proposed change in its WAC price. In fact, the evidence shows just the opposite. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873)). Accordingly, there is no basis for the proposed finding that Endo ñhad sufficient market power to adopt profit-enhancing price increases.ò

880. [redacted] (CX5000 at 090-92, 219-26 (¶¶ 203-07 & Exs. 7A-7B7) (Noll Report) (partially *in camera*)). [redacted] (CX5000 at 090-92, 219-26 (¶¶ 203-07 & Exs. 7A-7B7) (Noll Report) (partially *in camera*)).

RESPONSE TO FINDING NO. 880:

Complaint Counselôs Proposed Finding No. 880 is misleading, inaccurate, and inconsistent with record evidence. Complaint Counselôs statement that ñ[t]he average net realized price for Opana ER has continued to rise slowly, even after generic entry,ò is simply false. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873)). [redacted]

[redacted] (CX5000-219 (Noll Rep., Ex. 7A)).

Respondent has no specific response to the second sentence in Proposed Finding No. 880.

881. [redacted] (CX5000 at 092, 219-26 (¶ 207 & Exs. 7A-7B7) (Noll Report) (partially *in camera*).

RESPONSE TO FINDING NO. 881:

Complaint Counselôs Proposed Finding No. 881 is inaccurate and based on unreliable expert testimony. The Proposed Finding [redacted] The record evidence indicates that oxymorphone ER and Opana ER competed in a market for all long-acting opioids. (*See* Addanki, Tr. 2328 (testifying that ñthe relevant market is no smaller than the market for long-acting opioids in the United Statesò); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). Endo never had more than a 10 percent share of the long-acting opioid market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94)). By Endoôs own estimate, its market share was only 3.4 percent near the time of the settlement. (CX3273-003 (Bingol Decl.) (referring to a long-acting opioid market)).

Moreover, the record is inconsistent with the proposed finding that Opana ER has been ñprotectedò against intense competition from brand-name and generic long-acting opioids. In 2017, Opana ER competed directly with at least generic oxymorphone ER, oxycodone products, fentanyl products, morphine sulfate products, hydromorphone products, and tapentadol products. (*See* RX-547.0047, 0105-09 (Addanki Rep. ¶ 85, Ex. 4)). This competition occurred at the payor

pharmaceutical industry, a high markup of price over marginal cost is a ñnormal market outcome.ò (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 (ñyou can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.ò)).

884. In an intensely competitive industry with constant long-run marginal and average cost (i.e., no fixed costs), price equals marginal cost, so the Lerner Index is zero. (CX5000 at 095-96 (¶ 215) (Noll Report)).

RESPONSE TO FINDING NO. 884:

Complaint Counselôs Proposed Finding No. 884 is inaccurate and misleading. As Dr. Addanki explained at trial, the assumption ñthat the competitive benchmark price is represented by marginal cost . . . may be useful as a textbook case or a pedagogical example in the classroom, but itôs no use at all in analyzing real-world industries where there are substantial fixed costs that need to be covered. And again, antitrust economists and scholars have noted this for a long time.ò (Addanki, Tr. 2342).

At trial, Professor Noll admitted that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a ñnormal market outcome.ò (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 (ñyou can have a price above marginal cost and have absolutely no monopoly power, because you have no

887. One possible cause of more elastic firm-specific demand is an increase in competition. In a highly competitive economic environment the Lerner Index is at or near zero. If the Lerner Index is above zero, competition must be less intense, implying that firms possess some degree of market power. (CX5000 at 096 (¶ 217) (Noll Report)).

RESPONSE TO FINDING NO. 887:

Complaint Counselôs Proposed Finding No. 887 is inaccurate and based on unreliable expert testimony. The Lerner Index may not be ñat or near zeroò in ñhighly competitive economic environment[s]ò that include fixed costs. (*See* Addanki, Tr. 2342 (ñThe basic problem with the use of the Lerner Index . . . is that it implicitly assumes that the competitive benchmark price is represented by marginal cost. And that just simply cannot be right in the real world in most industries.ò)). Industries with high fixed costs will have Lerner Indexes above zero ð and sometimes significantly so ð despite being highly competitive. (*See* Addanki, Tr. 2341). Indeed, Professor Noll admitted at trial that a high Lerner Index ñdoesnôt necessarily meanò that a firm has market power. (Noll, Tr. 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a ñnormal market outcome.ò (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 (ñyou can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.ò)).

888. An increase in the Lerner Index for a specific product is a reliable indicator that the profitability of a product has risen. As a result, firms often use the Lerner Index or a similar indicator in long-term financial plans. (CX5000 at 097-98 (¶ 220) (Noll Report)).

RESPONSE TO FINDING NO. 888:

The first sentence of Complaint Counselôs Proposed Finding No. 888 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll

proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). It is also inaccurate. Because the Lerner Index only accounts for *marginal* costs, but not fixed costs or sunk costs, an increase in the Lerner Index for a specific product does not necessarily mean that ñthe profitability of [the] product has risen,ò as Complaint Counsel asserts. (*See* RX-547.0055-57 (Addanki Rep. ¶¶ 104-07)). A product with a positive Lerner Index may still be unprofitable ð even after an increase in the Lerner Index ð when fixed costs and sunk costs are accounted for. (*See* RX-547.0055-57 (Addanki Rep. ¶¶ 104-07)).

Respondent objects to the second sentence of Proposed Finding No. 888 because the terms ñreliableò and ñoftenò are vague and ambiguous.

889. The estimated Lerner Index for Opana ER can be derived from estimates of average net realized price and marginal cost for 2008 through 2014. (CX5000 at 100 (¶ 226) (Noll Report)).

RESPONSE TO FINDING NO. 889:

Respondent has no specific response.

890. [redacted] (Noll, Tr. 1681-82 (*in camera*)).

RESPONSE TO FINDING NO. 890:

Respondent has no specific response.

891. The only feasible measure of net realized price is the average net price, which can be calculated by dividing net revenues by output. (CX5000 at 099 (¶ 223) (Noll Report)). Endo used this procedure to calculate forecasts of product-specific profit. (CX5000 at 099 (¶ 223) (Noll Report); *see, e.g.*, CX3017 at 001, 017 (Hogan/Cuca email & attachment) (May 2010 Opana profit and loss model)).

RESPONSE TO FINDING NO. 891:

Respondent has no specific response.

892. Marginal cost is the additional cost of producing one more unit of output. Because marginal cost is difficult to measure, economists normally use average incremental costs ð a companyôs operating costs divided by the amount of output. (CX5000 at 089 (¶ 200 n.244) (Noll Report)).

RESPONSE TO FINDING NO. 892:

Respondent has no specific response.

893. Endo has produced two cost variables for Opana ER, cost of goods sold (COGS) and total operating expenditures (OPEX). (CX5000 at 099 (¶ 225) (Noll Report)). COGS consists almost exclusively of costs that are genuinely marginal. OPEX contains some operating expenditures that plausibly are marginal, but others, such as conferences and epidemiological research on patients who are taking the drug, that are not marginal. (CX5000 at 099 (¶ 225) (Noll Report)).

RESPONSE TO FINDING NO. 893:

Respondent has no specific response.

894. Marginal costs are estimated by dividing COGS and OPEX data by total output. True marginal costs are likely to be somewhere between these measures. (CX5000 at 099 (¶ 225) (Noll Report)).

RESPONSE TO FINDING NO. 894:

Respondent has no specific response.

895. [redacted] (CX5000 at 100, 227 (¶ 226 & Ex. 8) (Noll Report) (partially *in camera*)). [redacted] (CX5000 at 100, 227 (¶ 226 & Ex. 8) (Noll Report) (partially *in camera*)).

RESPONSE TO FINDING NO. 895:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 895. Complaint Counselôs assertion that [redacted] should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support

factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). The second sentence of the proposed finding is also inconsistent with record evidence. Roberto Cuca, who was involved in financial forecasting at Endo, testified that

supporting portions of Professor Nollôs testimony and reports do not use that term. (*See* Noll, Tr. 1374-75; CX5000-017-18 (Noll Rep. ¶¶ 38, 41); CX5004-013 (Noll Rebuttal Rep. ¶ 23)). Rather, as Professor Noll seemingly acknowledges, it is simply not true that a ñsmall reductionò will invariably produce a ñsignificant reduction in salesò in a market that is comprised of multiple competing products. (*See, e.g.*, CX5000-014 (Noll Rep. ¶ 38) (stating that two products compete in the same market where a ñsmall *but significant increase* in priceò for one product ñwould cause a sufficient amount of sales to shift to the other product to make the price increase unprofitableò) (emphasis added)).

Because the second sentence of Proposed Finding No. 897 is inaccurate, it is not true that the ñconceptò expressed therein applies to ñproducts that are differentiated or paid for by third parties,ò as asserted in the third sentence of Proposed Finding No. 897.

899. When analyzing pharmaceutical product markets, one technique to determine whether drugs are close substitutes is to observe what happens to the price and sales volume of one drug when a lower-priced generic version of another, functionally substitutable, drug is introduced. (Noll, Tr. 1374-1375). This technique is related to the SSNIP test ï by observing a productôs reaction to changes in the price of another product, we can draw conclusions about the degree of cross-elasticity between two drugs and whether they are close substitutes. (Noll, Tr. 1374; CX5000 at 018 (¶ 41) (Noll Report) (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. (Noll, Tr. 1374-1375). Dr. Addanki does not use this method for defining a relevant product market. (CX5004 at 006-07 (¶ 9) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 899:

Complaint Counselôs Proposed Finding No. 899 is incomplete and misleading. While the first sentence of Proposed Finding No. 899 is true that this is ñone technique,ò this technique is insufficient in itself as it does not account for the unique structure of the pharmaceutical market. As Dr. Addanki explained, for example, insurers use formularies to drive volume to particular drugs over others. (Addanki, Tr. 2219-20, 2225-27, 2231-33). Frequently, when a generic version of a particular drug becomes available, insurers will place that generic drug in a preferred tier and de-preference the corresponding brand-name drug. (Addanki, Tr. 2313-15). Further, automatic substitution laws ensure that ñwhen a prescription is presented to a pharmacy for the branded drug, the pharmacy either is required by law to fill it with the [AB-rated] generic product or has strong financial incentives to do so (or both).ò (RX-547.0026-27 (Addanki Rep. ¶ 50)). While these features ð formularies and automatic substitution laws ð may help to explain the rate of substitution that one typically sees between a generic drug and the corresponding brand-name drug, they do not preclude price-based competition (or cross-elasticity of demand) across a wider universe of therapeutically interchangeable products. (*See* RX-547.0022-31 (Addanki Rep. ¶¶ 41-59)).

RESPONSE TO FINDING NO. 900:

Complaint Counselôs Proposed Finding No. 900 is incomplete and misleading. That ñOpana ER and generic oxymorphone ER are economic substitutes to one another, and thus in the same relevant marketò is irrelevant. Dr. Addanki has shown that the relevant market is for all long-acting opioids, including *both* generic oxymorphone ER and branded Opana ER, among a number of other long-acting opioids. (*See* Addanki, Tr. 2328 (ñthe relevant market is no smaller than the market for long-acting opioids in the United Statesò)). Proposed Finding No. 900 is misleading to the extent that it suggests that branded Opana ER and generic oxymorphone ER are the only long-acting opioids in the relevant market. This is wrong. The trend observed by Dr. Noll described in Proposed Finding No. 900 does not indicate otherwise because, as Dr. Addanki explained, insurers use formularies to drive volume to particular drugs over others. (Addanki, Tr. 2219-20, 2225-27, 2231-33). And frequently, when a generic version of a particular drug becomes available, insurers will place that generic drug in a preferred tier and de-preference the corresponding brand-name drug. (Addanki, Tr. 2313-15). This may help to explain the rate of substitution that one typically sees between a generic drug and the corresponding brand-name drug, but does not preclude price-based competition (or cross-elasticity of demand) across a wider universe of therapeutically interchangeable products. (*See* RX-547.0022-31 (Addanki Rep. ¶¶ 41-59)). Further, Dr. Addanki has shown vigorous price competition among generic oxymorphone ER, branded Opana ER, and numerous other long-acting opioids at the payor, prescriber, and patient levels that demonstrate the relevant market is broader than just generic and branded oxymorphone ER. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Finally, Dr. Nollôs conclusion is not based ñany analysis, econometric or statistical analysis.ò (Addanki, Tr. 2331-32).

901. In contrast to the competitive interplay between generic oxymorphone ER and Opana ER, the data also show that there was far less competitive interaction between oxymorphone ER and other LAOs. (CX5000 at 196-216 (Exhibits 5A1-5G3) (Noll Report); CX5004 at 015 (¶ 27) (Noll Rebuttal Report)). Dr. Addanki ignores this evidence. (CX5004 at 015 (¶ 27) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 901:

Complaint Counselôs Proposed Finding No. 901 is incomplete, misleading, and based on unreliable expert testimony. The allegedly greater ñcompetitive interactionò between generic and branded oxymorphone ER is merely a function of certain industry features, namely the use of formularies and (in the case of Actavisô generic oxymorphone ER product) state automatic substitution laws. As Dr. Addanki explained, insurers use formularies to drive volume to particular drugs over others. (Addanki, Tr. 2219-20, 2225-27, 2231-33). Frequently, when a generic version of a particular drug becomes available, insurers will place that generic drug in a preferred tier and de-preference the corresponding brand-name drug. (Addanki, Tr. 2313-15). Further, automatic substitution laws ensure that ñwhen a prescription is presented to a pharmacy for the branded drug, the pharmacy either is required by law to fill it with the [AB-rated] generic product or has strong financial incentives to do so (or both).ò (RX-547.0026-27 (Addanki Rep. ¶ 50)). While these features ð formularies and automatic substitution laws ð may help to explain the rate of substitution that Professor Noll observed between Opana ER and generic oxymorphone ER, they do not preclude price-based competition (or cross-elasticity of demand) across a wider universe of long-acting opioids. (*See* RX-547.0022-47 (Addanki Rep. ¶¶ 41-84)).

Far from ñignor[ing]ò Professor Nollôs purported evidence, as Proposed Finding No. 901 asserts, Dr. Addanki identified and evaluated evidence of significant competition and economic substitution among long-acting opioids at various levels in the prescription drug industry: the payor, prescriber, and patient levels. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). This included direct evidence of cross-elasticity of demand between long-acting opioids. For instance, when

UPMC instituted formulary changes to preference Opana ER and various generic long-acting opioids over the branded long-acting opioid OxyContin ð which represented a change in relative price for consumers, whereby the prices of Opana ER and the favored long-acting opioids decreased relative to the price of OxyContin ð nearly 70 percent of OxyContin patients switched to a different long-acting opioid. (RX-087; *see* Addanki, Tr. 2304-09; RX-547.0042 (Addanki Rep. ¶ 78)). UPMC reported a significant increase in usage of Opana ER and generic Morphine Sulfate ER (MS ER), and to a lesser extent, generic Fentanyl patches. (RX-087 (Figures 3, 5)). Professor Noll simply ignores the operation of formularies in the marketplace. (*See* RX-547 (Addanki Rep. ¶ 88)).

Finally, Complaint Counselôs assertion in Proposed Finding No. 901 that ñthe data . . . show that there was far less competitive interaction between oxymorphone ER and other LAOsò is misleading and based on unreliable expert testimony. At no point did Professor Noll conduct any quantitative or statistical analysis of long-acting opioid sales. (Addanki, Tr. 2331). As Professor Noll admitted at trial, he did not try to calculate the cross-elasticity of demand between Opana ER and any other long-acting opioid product, nor did he conduct a SSNIP test. (Noll, Tr. 1514, 1517). He testified that he merely scanned Opana ER sales trends for any ñvisible effect,ò a metric that he never bothered to define. (Noll, Tr. 1384).

> 902. Thus, Dr. Noll used the techniques described in CCF ¶¶ 898-99 above to analyze whether other LAOs were economic substitutes for oxymorphone ER. (Noll, Tr. 1375). Dr. Addanki did not undertake any such analysis. (Noll, Tr. 1395; CX5004 at 006-07 (¶ 9) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 902:

Complaint Counselôs Proposed Finding No. 902 is incomplete, misleading, and inconsistent with the record to the extent it implies Professor Noll conducted a serious analysis of the effects of generic entry described in Proposed Finding Nos. 898-899. The record supports

that, instead of such an empirical analysis, Professor Noll merely scanned sales trends for a ñvisible effectò on Opana ER sales, a metric he did not define. (Noll, Tr. 1384; *see also* Addanki, Tr. 2331-32) (Professor Noll did not conduct ñany analysis, econometric or statistical analysis . . . to support his conclusionò)).

To the extent Complaint Counsel asserts in Proposed Finding No. 902 that Dr. Addanki did not ñanalyze whether other LAOs were economic substitutes for oxymorphone ER,ò it is wrong. Dr. Addanki identified and evaluated evidence of significant competition and economic substitution among long-acting opioids at various levels in the prescription drug industry: the payor, prescriber, and patient levels. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). This included direct evidence of cross-elasticity of demand between long-acting opioids. For instance, when UPMC instituted formulary changes to preference Opana ER and various generic long-acting opioids over the branded long-acting opioid OxyContin ð which represented a change in relative price for consumers, whereby the prices of Opana ER and the favored long-acting opioids decreased relative to the price of OxyContin ð nearly 70 percent of OxyContin patients switched to a different long-acting opioid. (RX-087; *see* Addanki, Tr. 2304-09; RX-547.0042 (Addanki Rep. ¶ 78)). UPMC reported a significant increase in usage of Opana ER and generic Morphine Sulfate ER (MS ER), and to a lesser extent, generic Fentanyl patches. (RX-087 (Figures 3, 5)). Neither the proposed finding, nor anything in the record, addresses or refutes Dr. Addankiôs analysis.

> 903. Dr. Nollôs analysis confirms that sales for LAOs other than Opana ER were not materially affected by the introduction of generic oxymorphone ER, and sales of Opana ER were not materially affected by the introduction of generic versions of other LAOs. (Noll, Tr. 1393-94; CX5000 at 196-216 (Exhibits 5A1-5G3) (Noll Report); CX5004 at 015 (¶ 27) (Noll Rebuttal Report); *see also* CCF ¶¶ 654-740 above). These patterns support a conclusion that oxymorphone ER is a distinct market. As explained above, if a small reduction in the price of a product does not cause a reduction in the sales of another, then the products are not close substitutes. (*See* CCF ¶¶ 898-99; Noll, Tr. 1374-

relative to the price of OxyContin ð nearly 70 percent of OxyContin patients switched to a different long-acting opioid. (RX-087; *see* Addanki, Tr. 2304-09; RX-547.0042 (Addanki Rep. ¶ 78)). UPMC reported a significant increase in usage of Opana ER and generic Morphine Sulfate ER (MS ER), and to a lesser extent, generic Fentanyl patches. (RX-087 (Figures 3, 5)). Professor Noll simply ignores the operation of formularies in the marketplace. (*See* RX-547 (Addanki Rep. ¶ 88)).

Moreover, the particular compe

pricing than pric

power.ò)). The remainder of Complaint Counselôs Proposed Finding No. 905 should be

brand-name drug with the same active ingredient is far more intense than competition between brand-name drugs. (CX5000 at 035-36 (¶¶ 77-78) (Noll Report)). Dr. Addanki does not address this literature in his report. (CX5004 at 006-07 (¶ 9) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 907:

Complaint Counselôs Proposed Finding No. 907 is incomplete and misleading. While generic oxymorphone ER undoubtedly competed with brand-named Opana ER, so do numerous other long-acting opioids. Indeed, the record shows that Opana ER competed directly with at least generic oxymorphone ER, oxycodone products, fentanyl products, morphine sulfate products, hydromorphone products, and tapentadol products. (*See* RX-547.0050-51 (Addanki Rep., Ex. 4)). This competition occurred at the payor level for formulary placement, the prescriber level with detailing activities, and at the patent level with direct rebates to consumers. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Internal Endo documents indicate that Endo consistently portrayed Opana ER in direct competition with other long-acting opioids. (*See* RX-073, RX-078; RX-085; RX-114; RX-115).

In addition, statements in the proposed findings regarding the content of economic literature are misleading and unsupported by record evidence. This literature is not in the record. Professor Nollôs representations regarding the content of those articles are hearsay.

908. Nearly half of the sales of branded Opana ER diverted to sales of generic oxymorphone ER. (Noll, Tr. 1380-81; CX5000 at 056, 177-83 (¶ 122, Exhibits 2A1 through 2A7) (Noll Report); CX5004 at 014 (¶ 25) (Noll Rebuttal Report)). The fact that generic oxymorphone ER took nearly half of all Opana ER sales indicates that generic oxymorphone ER competitively constrains Opana ER. (Noll, Tr. 1380-81; CX5000 at 056 (¶ 122) (Noll Report) CX5004 at 014 (¶ 25) (Noll Rebuttal Report)). Generic oxymorphone ER could not have had such a dramatic effect on the sales of Opana ER if all the other LAOs that Dr. Addanki contends are in the relevant market were close substitutes. (Noll, Tr. 1381-82; CX5000 at 082 (¶ 182) (Noll Report)).

RESPONSE TO FINDING NO. 908:

Complaint Counselôs Proposed Finding No. 908 is incomplete, misleading, inaccurate, and inconsistent with record evidence when considered together with Professor Nollôs complete trial testimony describing the limits of his analysis. Professor Noll explained that it ñtook several yearsò for sales of branded Opana ER to fall by nearly half after Impax began marketing its generic oxymorphone ER product. (Noll, Tr. 1380). This change in price ð separated from the introduction of Impaxôs generic launch by ñseveral yearsò ð does not reflect price cross-elasticity that might support Professor Nollôs conclusion ñthat generic oxymorphone ER competitively constrains Opana ER.ò Further, Professor Noll does not indicate that Endo was forced to reduce the price of Branded Opana ER in response to Impaxôs marketing of generic oxymorphone ER. In fact, Professor Nollôs report and testimony [redacted] (Noll, Tr. 1682; (CX5000-219 (Noll Rep., Ex. 7A)). Finally, the ñfact that generic oxymorphone ER took nearly half of all Opana ER salesò ð after four years ð is unsurprising, since formularies create pricing incentives to prioritize drugs, and frequently place a generic drug in a preferred position over the corresponding branded drug. (Addanki, Tr. 2313-15). But that fact does not preclude price-based competition (or cross-elasticity of demand) across a wider universe of long-acting opioids. (*See* RX-547.0022-47 (Addanki Rep. ¶¶ 41-84)).

> 909. Similarly, the entry of generic oxymorphone ER drove down the average price of oxymorphone ER, but this could not have happened if other LAOs were close substitutes for Opana ER. (Noll, Tr. 1380-81). Dr. Addanki does not explain how the entry of generic oxymorphone ER could have had such significant effects on Opana ERôs share and price if other LAOs that were on the market before the release of generic oxymorphone ER were close economic substitutes. (CX5004 at 006-07 (¶ 9) (Noll Rebuttal Report)). Nor does Dr. Addanki explain how other LAOs can be close economic substitutes when they had so little effect on Opana ER sales compared to the effect of generic oxymorphone ER. (CX5004 at 006-07 (¶ 9) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 909:

Complaint Counselôs Proposed Finding No. 909 is incomplete, misleading, and contradicted by record evidence.

(*See* (CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873)).

(CX5000 at 219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873); Addanki, Tr. 2290; Noll, Tr. 1679-82; RX-547 (Addanki Rep. ¶ 101(b), Ex. 13); *see also* RX-547 (Addanki Rep. ʻ ʻ dd] lʼ nkشمƆ ѕ Ůж lʼ lm p d]

drugs, thereby driving consumers to purchase the generics. (Addanki, Tr. 2313-14; *see also* CX3273-008 (Bingol Decl. ¶ 18) (ñIt is likely that Impaxôs product will be immediately positioned on Tier 2 or Tier 1 status.ò)). Complaint Counsel also fails to appreciate that Impax *specifically marketed* its generic oxymorphone ER product to prescribers of Opana ER in an effort to drive substitution between the products. (RX-547.0037 (Addanki Rep. ¶ 69)). But these facts do not preclude price-based competition (or cross-elasticity of demand) across a wider universe of long-acting opioids. (*See* RX-547.0022-47 (Addanki Rep. ¶¶ 41-84)).

> 910. Dr. Addanki dismisses the substantial effect generic entry had on the market for oxymorphone ER on the basis that generics are ñpredictablyò placed at a favorable formulary tier on health insurance plans. (Addanki, Tr. 2313-14). According to Dr. Addanki, there is no point in looking at the effect of genericsô placement on formularies

bars thereò; it would not change the story about the degree to which Opana ER competed against other long-acting opioids for which a generic was not available during the time period studied, such as OxyContin, Avinza, MS Contin, and Exalgo. (Addanki, Tr. 2214).

In other words, Proposed Finding No. 910 both ignores crucial context (i.e., that Dr. Addanki was discussing just one part of his multi-faceted relevant market study) and misses the point of the particular analysis in question (i.e., that the MMIT analysis deliberately focused on competition between Opana ER and other long-acting opioids for which an AB-rated generic was not available during the relevant period). To the extent the proposed finding suggests that Dr. Addanki did not study competition between Opana ER and generic long-acting opioids, it is simply wrong. By way of example, in the UPMC study described in Dr. Addankiôs report and at trial, UPMC changed its for

> Addanki even posits that consumers could be harmed by switching to a lower-priced generic version of a drug. (CX4044 (Addanki, Dep. at 86-87) (ñSo, in the context of paragraph 32, [entry of a lower-priced generic competitor] creates the potential actually to be of consumer harm.ò)). Dr. Addanki presents no evidence that consumers who switch from Opana ER to a lower-priced therapeutically-equivalent generic version of Opana ER are harmed by the switch. Dr. Addanki does not cite to a single academic or factual source for his assertion that lowering the price of a product, or the entry of a lower-priced competitor, harms consumers. (Addanki, Tr. 2429; RX-547 at 0019 (¶¶ 31-32) (Addanki Report)).

RESPONSE TO FINDING NO. 912:

Complaint Counselôs Proposed Finding No. 912 is an incomplete misleading characterization of Dr. Addankiôs testimony. With respect to the first sentence of Proposed Finding No. 912, Dr. Addanki testified that entry of a lower-priced generic competitor ñdoes not reveal anything useful about whether

a price reduction *coupled with a decrease in output* would harm competition, one cannot determine whether a consumer benefits from a price reduction without considering corresponding effects on output. (CX4044 (Addanki, Dep. at 92) (ñAnd I think until you get to the bottom of [output changes], youôre really not in a position of answering the question of whether this is good for consumers or not.ò); CX4044 (Addanki, Dep. at 89)) (ñif I see output expand as I do see in many pharmaceutical contexts . . . when thereôs generic entry, I think I can make the reasonable inference that there was an enhancement of consumer welfare.ò)). Finally, Dr. Addanki explained that if the generic is an inferior product and/or prevents the brand from continuing its educational efforts surrounding the drug, the entry of a lower-priced drug can harm consumers, especially ñwhere thereôs institutionally mandated substitution.ò (CX4044 (Addanki, Dep. at 86-87)).

The fourth sentence of Proposed Finding No. 912 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). It is also highly misleading, since it implies that Dr. Addanki opined on the effect of generic entry on *individual consumers*. He did not. (Addanki, Tr. 2429). Rather, consistent with standard antitrust economics, he offered opinions about potential *aggregate* welfare effects. (RX-547.0018-20 (Addanki Rep. ¶¶ 30-33); *see* CX4044 (Addanki, Dep. at 90-91 (even if ñappeared that certain customers were paying less,ò that does not ñgive you a sense of what the overall welfare effect isò)).

In addition, the fifth sentence of Proposed Finding No. 912 is misleading both in its characterization of Dr. Addankiôs opinions and in its implication that Dr. Addankiôs views lack support. To begin with, nowhere did Dr. Addanki state that ñlowering the price of a productò or

ñthe entry of a lower-priced competitorò invariably ñharms consumers.ò Rather, he made the point that ñthe adverse economic effect that is of concern is the antitrust economic analysis of agreements like the one at issue is the reduction in output (and attendant loss of consumer welfare it engenders) that results from an exercise of monopoly power,ò and that if the entry of a lower priced competitor is not accompanied by an expansion of output, then there is no basis for assuming that the entry increased consumer welfare in the aggregate, ñor that the patentee/brand had exercised monopoly power before generic entry.ò (RX-547.0018-20 (Addanki Rep. ¶¶ 30-33)). Hence the need for a ñmonopoly power screen.ò (RX-547.0018-20 (Addanki Rep. ¶¶ 30-33)). Moreover, the suggestion in Proposed Finding No. 912 that Dr. Addankiôs opinion lacks support ignores Dr. Addankiôs decades of experience as an antitrust economist with expertise in the pharmaceutical industry. (RX-547.0005-06, 0089-92 (Addanki Rep. ¶¶ 1-5, Ex. 1)).

913. The idea that customers do not benefit from lower prices for a product is inconsistent with prevailing economic theory. (CX5004 at 041 (¶ 85) (Noll Report) (citing Steven C. Salop, ñQuestion: What is the Real and Proper Antitrust Welfare Standard? Answer: The *True* Consumer Welfare Standard,ò *Loyola Consumer Law Review* Vol. 22, No. 3 (2010), pp. 336-53, and John B. Kirkwood, ñThe Essence of Antitrust: Protecting Consumers and Small Suppliers from Anticompetitive Conduct,ò *Fordham Law Review* Bol. 81, No. 5 (April 2013), pp. 2425-70)). Economists recognize that increased prices resulting from anticompetitive conduct harm consumers. (Noll, Tr. 1364-5). The *Merger Guidelines* plainly state that price in ı ъ ך Ă (NĄ

no basis to presume that the lower price resulted in increased consumer welfare or that the [incumbent] had exercised monopoly power before [new] entry.ò (RX-547.0019-20 (Addanki Rep. ¶ 33); *see* RX-547.0018 (Addanki Rep. ¶ 30) (ñthe adverse economic effect that is of concern in the antitrust economic analysis of agreements like the one at issue is the reduction in output and attendant loss of consumer welfare it engenders that results from an exercise of monopoly powerò)). But as Dr. Addanki made clear in his report and at trial, the entry of a lower-priced competitor *can* have ñthe welfare-improving effect of expanding output.ò (RX-547.0015 (Addanki Rep. ¶ 30); *see* Addanki, Tr. 2432 (ñConsumer benefit may go up or down depending upon the value of those activities and the price that you see in the marketplace. And as Iôve said before, output iser

Tr. 1574; *see* Compl. Counselôs Post-Trial Br. at 47, Dkt. 9373 (F.T.C. Dec. 20, 2017) (ñA firm without market power will not be able to harm competition successfully.ò)). The evidence here establishes that Endo did *not* possess market power in the relevant market, which was comprised of numerous long-acting opioids. (*See* Addanki, Tr. 2328 (ñthe relevant market is no smaller than the market for long-acting opioids in the United Statesò); RX-547.0047-48, 0050-51 (Addanki Rep. ¶¶ 85-86, 94)); CX3273-003 (Bingol Decl. ¶ 6)).

Moreover, the hypotheticals constructed in Proposed Finding No. 914 ð which assume, among other things, that output is ñconstantò ð are mere tautologies. But as Dr. Addanki testified, in the real world, ñwe know what monopolists do. When a firm has monopoly power, it *restricts output* [and] charges monopoly prices, all of which harm consumers.ò (Addanki, Tr.

RESPONSE TO FINDING NO. 916:

pharmaceuticalsò (emphasis added)); RX-547.0029-30 (¶ 57) (ñ[T]he willingness of a drug benefit plan to vary the relative positioning of products in a given category underscores that the plan regards the products as *economic substitutes*ò (emphasis added)).

Indeed, at trial, Dr. Addanki testified explicitly and at length to *economic substitution* among long-acting opioids. (*See, e.g.*, Addanki, Tr. 2225ï26 (ñThe second thing you can infer [from competition for formulary placement] is that *economic substitutability* is actually happening.ò (emphasis added)); Addanki, Tr. 2232ï33 (ñSo what youôve got going on is youôve got *substitution going on in response to price competition*, which is, of course, exactly the kind of competition weôre talking about when weôre analyzing antitrust cases, when weôre analyzing relevant markets.ò (emphasis added)); Addanki, Tr. 2309 (ñcompetition for formulary coverage was in fact *economic substitution*ò (emphasis added)). Dr. Addanki emphasized that ñeconomic evidenceò showing that ñthese products actually compete with one another in the market, in the market placeò is ñthe most important evidence.ò (Addanki, Tr. 2253). And he expressly distinguished therapeutic substitution from economic substitution. (*E.g.*, Addanki, Tr. 2225-26 (discussing therapeutic substitutability and economic substitutability separately)).

Proposed Finding No. 917 is completely unmoored from record evidence and voluminous trial testimony, and should be disregarded.

documents do not reflect intense price bidding wars between Opana ER and other drugs to gain business, but rather emphasize product differentiation over price competition. (CX5004 at 037-38 (¶ 78) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 919:

Complaint Counselôs Proposed Finding No. 919 is an incomplete and misleading mischaracterization of the documents identified. With respect to the second sentence of the proposed finding, the documents regarding these product differentiation efforts discuss a ñcompetitive set,ò and thus ñ[p]rovide [u]seful [i]nsights into the [n]ature of [c]ompetition and [r]elevant [m]arkets.ò (RX-547.0026 (Addanki Rep. ¶¶ 49-50 and header)). Moreover, the proposed finding neglects to mention that the need to engage in promotion was driven by Endoôs recognition that long-acting opioids ñare not very differentiated.ò (RX-023.0002).

The third sentence of the proposed finding ignores abundant evidence of significant price competition among long-acting opioid makers at the insurer level. (*See* RX-547.0028-31, 0038-42 (Addanki Rep. ¶¶ 53-58; 72-78)). For example, in 2011 Endo sought to get Opana ER on the formulary [redacted] (Addanki, Tr. 2294; RX-547.0041-42 (Addanki Rep. ¶ 78)). Similarly, in 2011, [redacted] (RX-547.0041-42 (Addanki Rep. ¶ 78); Addanki, Tr. 2294-98). The following year, [redacted] (RX-547.0041-42 (Addanki Rep. ¶ 78); Addanki, Tr. 2294-98). In a 2012 document that Professor Noll cites in his own report, Endo noted that Purdue was offering payors discounts on OxyContin that ranged from 15% to 20%. (CX3206-002). Endo proposed ñan additional 11% discount on Opana ERò to ñachieve pricing parity to OxyContin,ò on the expectation that many payors would ñsee the price differential as

sufficient incentive to utilize Opana ER and make the prescribing formulary change.ò (CX3206-002)

The third sentence of the proposed finding also overlooks the fact that long-acting opioid makers competed aggressively at the patient level by directly subsidizing consumersô out-of-pocket prices, effectively lowering the prices they paid for the respective drug makersô products. (*See, e.g.*, RX-028.0011 (Endo document describing ñ[a]ggressive couponing from all direct competitors,ò including by the makers of OxyContin, Avinza, and Kadian; describing Endoôs competitive response); RX-445.0015

; RX-448.0020

. As Dr. Addanki testified at trial, we simply *do not* see price competition at the patient level with respect to products that lack economic competition. (Addanki, Tr. 2236-37).

920. Dr. Addanki concludes that LAOs are in the same market based on the fact that different LAOs have been prescribed to treat the same condition(א ɔ я M

Dr. Addankiôs opinions regarding relevant market and competition among long-acting opioids rely exclusively on the therapeutic patterns. Interchangeability as a treatment option is just one of *many* factors on which Dr. Addanki relied for his conclusions on the relevant market definition. Dr. Addankiôs relevant market definition is based not on therapeutic substitution by itself, but on evidence that therapeutically interchangeable long-acting opioids were *economic substitutes* that competed *on price* at all levels of the pharmaceutical industry. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79); *see* Addanki, Tr. 2253 (ñWell, to me as an economist, the clinical evidence is important, *but the most important evidence is economic evidence*.ò (emphasis added)). Indeed, Proposed Finding No. 920 concedes that ñ[t]he choice of drug to treat a particular condition may be based on price, in which case it could provide insight into whether two drugs are in the same market.ò This is *exactly* what Dr. Addankiôs analysis shows. (RX-547.0038-42 (Addanki Rep. ¶¶ 72-78); Addanki, Tr. 2253-2300).

The final sentence of Proposed Finding No. 920 is incomplete and misleading because it limits analysis of prescriber decisions to ñknowing why a doctor chose to treat a given condition with a given drug.ò This ignores significant record evidence that formulary changes can do routinely do affect prescribing decisions. (*See* Addanki, Tr. 2217-2237; RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125); *see also* CX4039 (Noll, Dep. at 186-87 (ñQ. Would you agree a patientôs insurance coverage is an important driver of the initial selection of a long-acting opioid by a physician? A. Well, thatôs another statement about formularies. Yes.ò)). For example, Professor Noll ignores the testimony of Dr. Michna ð presumably the very type of doctor referenced in Proposed Finding No. 920 ð that insurance coverage ñplays a major roleò in the choice of long-acting opioid. (Michna, Tr. 2129).

921. Second, Dr. Addankiôs conclusion that there is a similar frequency with which various LAOs are used to treat various conditions is incorrect. (RX-547 at 0033 (¶ 64)

(Addanki Report); CX5004 at 022 (¶ 42) (Noll Rebuttal Report). Dr. Addanki does not offer any objective benchmark to evaluate whether the frequency of use of two opioids is similar. (CX5004 at 022 (¶ 43) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 921:

Complaint Counselôs Proposed Finding No. 921 is an incorrect and misleading characterization of Dr. Addankiôs analysis. Dr. Addanki provides a robust statistical analysis, tabulated in Exhibit 4 of his report, showing that each long-acting opioid is used to treat a very similar (and broad) range of medical conditions. (RX-547.0033, 105 (Addanki Rep. ¶ 64, Ex. 4); *see* Addanki, Tr. 2245-48). And as he explained at trial, it *does not matter* that long-acting opioids were not all prescribed with the same frequency. (Addanki, Tr. 2248-50 (ñNow, there may be specific idiosyncrasies suggesting that physicians who prescribe for a particular indication here may, because of habit, tend to prescribe a certain molecule more often, whereas physicians in another specialty where another indication is more commonplace may, for idiosyncratic reasons, have some preference that drive them in

the values are *not* ñnear zero.ò For Lumbago, the first diagnosis code listed, the values range from 6.58 percent (Tapentadol HCl) to 9.90 percent (Fentanyl). (RX-547.105 (Addanki Rep., Ex. 4)). Further, Complaint Counselôs implication that Dr. Addanki achieved artificial similarity between the various diagnoses by using a sample size so large it would drive all values close to zero is simply not supported by the record. The 100 diagnoses included in Dr. Addankiôs analysis account for *nearly 90 of all prescriptions* for the opioids shown. (*See* RX-547.108 (Addanki Rep., Ex. 4) (ñAll Other Diagnosesò represent only 10.38 percent of cumulative prescriptions for the molecules shown)). These 100 diagnoses account for nearly *93 percent* of Oxymorphone HCl prescriptions. (*See* RX-547.108 (Addanki Rep., Ex. 4) (ñAll Other Diagnosesò represent only 7.22 percent of Oxymorphone HCl prescriptions)).

Because the 414 diagnoses not included in Dr. Addankiôs exhibit account for only a small fraction of opioid usage, the values would not be significantly different if Dr. Addanki ñspread[] the overall frequency of LAO use overò all 514 diagnoses.

> 923. But the fact that any particular diagnosis (among 514) accounts for a small fraction of total uses of two LAOs is not economic evidence that the LAOs are in the same relevant market. (CX5004 at 020-21 (¶ 40) (Noll Rebuttal Report)). Arguing as Dr. Addanki does that two products are close substitutes because both are used rarely for a purpose is like arguing that because lactose-intolerant customers account for almost no sales of milk and ice cream, milk and ice cream makers must compete intensively with each other. (CX5004 at 020-21 (¶ 40) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 923:

Complaint Counselôs Proposed Finding No. 923 mischaracterizes Dr. Addankiôs analysis and opinions. Exhibit 4 of Dr. Addankiôs report is valuable both for what it says about specific diagnoses (e.g., that all of the listed molecules treat Lumbago) *and* for what it says about opioid usage in the aggregate: namely, that for the 100 most common diagnoses taken as a whole, *all* of the opioids listed are used with a similar frequency of use. These 100 diagnoses account for

nearly 90 percent if all use for the opioids listed; for specific opioids, the 100 diagnoses account for usages ranging from 84.70 percent (Hydromorphone HCl) to 93.87 percent (Tapentadol). (*See* RX-547.108 (Addanki Rep., Ex. 4) (figured derives from ñAll Other Diagnosesò row); Addanki, Tr. 2247 (ñ[T]he striking thing is that all of these products are used to a greater or lesser extent for all of these indications.ò)).

RESPONSE TO FINDING NO. 924:

Complaint Counselôs Proposed Finding No. 924 is false and misleading characterization of Dr. Addankiôs analysis. The first sentence to Proposed Finding No. 924 is blatantly and demonstrably false: There is not a single diagnosis listed in

of oxymorphone ER varies by more than 50% from the average use of LAOs. (CX5004 at 022-23, 083-85 (¶ 43, Exhibit 1A) (Noll Rebuttal Report)). Even if determining that the pattern of use of different drugs is ñgenerally very similarò told us anything about whether the drugs were in the same relevant market, which is not the case, Dr. Addankiôs analysis would not support the conclusion because the data show that the patterns of use are not in fact ñgenerally very similar.ò (CX5004 at 022-24 (¶¶ 42-46) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 926:

Complaint Counselôs Proposed Finding No. 926 is misleading, inaccurate and based on unreliable expert testimony. Whether or not competing products are used with similar frequency is a red herring. Dr. Addanki does not claim that long-acting opioids were used with the same frequency for each diagnosis, nor is this relevant to Dr. Addankiôs analysis. As Dr. Addanki testified at trial, it *does not matter* that the long-acting opioids studied in his Exhibit 4 are not prescribed with the same degree of frequency for each diagnosis; what matters is ñthey are all or virtually all prescribed for virtually all of these diagnosis codes.ò (Addanki, Tr. 2248-50).

And so the criticisms posed in Proposed Finding No. 926 simply miss the point of Dr. Addankiôs analysis. The analysis shows that (1) long-acting opioids are used interchangeably to treat dozens upon dozens of the most common pain diagnoses, (*see* Addanki, Tr. 2247 (ñthese products are used for really a staggering number of different diagnosis codes.ò)); (2) there is no type of pain for which any long-acting opioid is the only or the superior option, (Addanki, Tr. 2247; Michna, Tr. 2149; Savage, Tr. 791); and (3) there is no medical condition for which Opana ER is the only or the most superior option, (RX-547.033 (Addanki Rep. ¶ 64); Savage, Tr. 743; Michna, Tr. 2149). All of this supports the existence of a long-acting opioid market.

E. Dr. Addanki erred in basing his definition of the relevant market primarily on a marketing, rather than economic, meaning of that term

927. Dr. Addanki errs by basing his definition of the relevant market primarily on a marketing, rather than economic, meaning of the term. (*See* CCF ¶¶ 928-40, below).

RESPONSE TO FINDING NO. 927:

Complaint Counselôs Proposed Finding No. 927 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1. Dr. Addanki improperly relies on marketing documents rather than economic analysis

928. Dr. Addankiôs conclusion that Opana ER is in the same market as other LAOs is based on the fact that Endoôs business documents indicate they viewed other LAOs as competitors to Opana ER, and that Purdue viewed Opana ER as a competitor to OxyContin. (RX-547 at 0035-38, 0041-47 (¶¶ 67-71, 78-84) (Addanki Report)). Yet this is consistent with what would be observed if oxymorphone ER was a distinct market ð even monopolists face some competition from products outside the monopoly. (CX5004 at 037 (¶ 76) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 928:

Complaint Counselôs Proposed Finding No. 928 is an inaccurate and misleading characterization of the documents cited and Dr. Addankiôs opinions regarding those documents. Contrary to Complaint Counselôs suggestion, Dr. Addankiôs evaluation of ordinary course business documents reflecting Endoôs and other long-acting opioid makersô perceptions of competition is just *one* part of his relevant market analysis, which shows that Opana ER competed in a long-acting opioid market. (*See* RX-547.0031-50 (Addanki Rep. ¶¶ 60-92)). Drug makersô recognition that long-acting opioids competed in the same relevant market is borne out by evidence showing that long-acting opioids are reasonably interchangeable for the treatment of chronic pain; that long-acting opioids competed on the basis of price at the payor, patient, and prescriber levels; that long-acting opioids are economic substitutes; and that changes in relative price (particularly as reflected in formulary changes) induce switching among long-

acting opioids. (RX-547.0031-50 (Addanki Rep. ¶¶ 60-92); RX-087; RX-549.0007 (Michna Rep. ¶ 23)). Proposed Finding No. 928 ignores this body of evi

shifted purchases in the past in response to relative changes in price or other terms and conditionsò is probative of market definition. U.S. Depôt of Justice & Fed. Trade Commôn, *Horizontal Merger Guidelines* § 4.1.3 (2010).

931. The ñcellophane fallacyò describes an error of interpretation in which one concludes that competitive interactions at current prices indicate that a product is sold in a competitive market. (Noll, Tr. 1401-02; CX5004 at 034 (¶ 68) (Noll Rebuttal Report)). A monopolist will raise its price to the point at which further price increases are unprofitable because too many customers would switch away from the monopolized product to another functional substitute. (CX5004 at 034 (¶ 68) (Noll Rebuttal Report)). The managers of the monopoly will perceive the other products as imposing a constraint. (CX5004 at 034 (¶ 68) (Noll Rebuttal Report)). But the fact that managers of a product view another product as competing with their own does not mean the other products are in the same relevant product market. (CX5004 at 034 (¶ 68) (Noll Rebuttal Report)). If the price of a particular product is already elevated due to the presence of market power, then products which are outside a properly-defined relevant product market will become economic substitutes. (CX5004 at 036 (¶ 74) (Noll Rebuttal Report)).

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While Professor Noll attacks Dr. Addankiôs ñstrongly wordedò explanation for why the cellophane fallacy does not apply here, he notably offers *no affirmative evidence* supporting his claim that the significant competitive interactions identified by Dr. Addanki are an instance of the fallacy. (*See* CX5004-034-37 (Noll Rebuttal Rep. ¶¶ 68-76)). The cellophane fallacy may be a convenient response for dismissing real-world evidence of economic substitution, such as the UPMC study, (Addanki, Tr. 2302-09; *see* CX4039 (Noll, Dep. at 187-88)), but neither the proposed finding of fact, nor the opinions of Professor Noll on which it relies, offers any record evidence to support the naked asse

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While Professor Noll attacks Dr. Addankiôs ñstrongly wordedò explanation for why the cellophane fallacy does not apply here, he notably offers *no affirmative evidence* supporting his claim that the significant competitive interactions identified by Dr. Addanki are an instance of the fallacy. (*See* CX5004-034-37 (Noll Rebuttal Rep. ¶¶ 68-76)). The cellophane fallacy may be a convenient response for dismissing real-world evidence of economic substitution, such as the UPMC study, (Addanki, Tr. 2302-09; *see* CX4039 (Noll, Dep. at 187-88)), but neither the proposed finding of fa]ᔆ

do not support the proposed summary finding, are unreliable, misleading, and inconsistent with record evidence for the reasons set out in Respondentôs replies to those findings.

Complaint Counselôs Proposed Finding No. 934 also mischaracterizes Dr. Addankiôs analysis. Dr. Addanki addressed competition between oxymorphone ER and Opana ER. (*See, e.g.,* Addanki, Tr. 2313-14 (addressing pricing of Opana ER after Impaxôs entry)). Indeed, Dr. Addanki concluded that both branded and generic Opana ER belonged in the relevant market ð along with other long-acting opioids. (RX-547.0047, 0133 (Addanki Rep. ¶ 85; Ex. 11); Addanki, Tr. 2328). Moreover, the assertion that Dr. Addanki ñfocused exclusively on documents which he purports show competition between Opana ER and other LAOsò is utterly false. In addition to evaluating reams of ordinary course business documents ð which are, in fact, highly probative of the relevant market ð Dr. Addanki (1) analyzed clinical guidelines from the FDA and World Health Organization; (2) evaluated FDA and DEA regulations governing the distribution of long-acting opioids; (3) empirically analyzed the extent to which long-acting opioids are used interchangeably for treatment of the 100 most common pain diagnoses; (4) demonstrated the existence of robust economic competition among long-acting opioids at the payor, patient, and prescriber levels; (5) empirically evaluated long-acting opioidsô placement on commercial and Medicare formularies, both as of June 2010 and over time; (6) demonstrated that output did not expand when Impax launched generic oxymorphone ER, negating the assertion that Endo was exercising monopoly power; and (7) rebutted Professor Nollôs opinions about the relevant market and monopoly power. (*See* RX-547.0018-57 (Addanki Rep. ¶¶ 29-107)). The proposed finding simply ignores this.

935. The fact that Endo competed with other LAOs for sales of Opana ER is not, by itself, evidence they are economic substitutes. (CX5004 at 034, 036-37 (¶¶ 68, 74, 76) (Noll Rebuttal Report); *see also* Addanki, Tr. 2468). The key question is whether generic oxymorphone ER presented an e ȳ l ɤ pelaitionɐc ɖ p ᴰ p ᵐ l ҫ M ɣ ᴀ ᵠ M ᴀ p e Eed andna ER a

other LAOs. The evidence discussed in Section X.B above shows that Opana ER faced stronger competition from generic oxymorphone ER than it did other LAOs. Once released, generic oxymorphone ER took approximately half of Opana ERôs share. (Noll,

ER, even if they were not the closest substitutes imaginable.

(CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873); *see* RX-547.0053-54 (Addanki Rep. ¶ 101(b)

competition (or cross-elasticity of demand) across a wider univ

936. Moreover, the very same documents containing Endoôs references to competition from other LAOs illustrate the fact that Endo used those terms in a general business sense, rather than in an economic sense. (*See* CCF ¶¶ 937-939, below).

RESPONSE TO FINDING NO. 936:

Complaint Counselôs Proposed Finding No. 936 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable, misleading, and inconsistent with record evidence for the reasons set out in Respondentôs replies to those findings.

937. For instance, the Lortie declaration, discussed above, describes Endo as selling Opana ER in the LAO ñmarket segment,ò which he characterizes as.Σ ‘‘ A a : p T ŝ T M

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of OPANA ER Original Formulation, the LAO segment was well-established, highly competitive, and consisted of many products that had been on the market for years, such as OxyContin.ò (CX2607-004 (Lortie Decl. ¶ 10)).

Mr. Lortieôs prediction that the entrance of multiple generics of oxymorphone ER would diminish Opana ERôs market share must be understood in context: insurance companies generally elevate generic drugs over their corresponding brand alternatives on their formularies, pushing customers to the generic product and amplifying the effects of generic entry as compared to entry of a competing branded product. (Addanki, Tr. 2313-14; *see also* (CX3273-008 (Bingol Decl. ¶ 18) (ñIt is likely that Impaxôs product will be immediately positioned on Tier 2 or Tier 1 status.ò)).

Finally, the third sentences of Proposed Finding No. 937 cites a forward looking forecast that has not proven accurate; as Professor Noll explained, it ñtook several yearsò for sales of branded Opana ER to fall by nearly half after Impax began marketing its generic oxymorphone ER product (Noll, Tr. 1380), and this occurred only after Impax embarked on a sustained marketing campaign targeting Opana ER prescribers. (RX-294).

> 938. Mr. Lortieôs declaration also notes that Opana ER grew rapidly, from $5 million in sales in 2006 to $384 million in sales in 2011, and was a ñcommercial success for Endo.ò (CX2607 at 004-05 (¶ 13) (Lortie Decl.)). If it were true that other LAOs, branded and generic, were close economic substitutes to Opana ER, then that very rapid growth over so many years would not have been possible. (*See, e.g.*, CX5000 at 076-78 (¶¶ 166, 169) (Noll Report) (the fact that Opana ER was able to grow despite the presence of other LAOs is evidence the other LAOs are not close substitutes)).

RESPONSE TO FINDING NO. 938:

Complaint Counselôs Proposed Finding No. 938 is inaccurate and misleading. The record does not support that the growth in Opana ER sales referenced in Proposed Finding No. 938 signals that other long-acting opioids were not economic substitutes for Opana ER. Indeed,

internal Endo documents indicate that Endo grew its market share in the LAO market because it was successful in *competing against other long-acting opioids*. (*See* RX-547.0041 (Addanki Rep. ¶ 78)). For example, in 2011, Endo offered a

(RX-547.0041 (Addanki Rep. ¶ 78); Addanki, Tr. 2294-98). As Professor Nollôs own report shows,

(CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873); Addanki, Tr. 2290; Noll, Tr. 1679-82; RX-547.053 (Addanki Rep. ¶

939. In a similar vein, Mr. Demir Bingol of Endo filed a declaration in Endoôs infringement suit against Impax, also discussed above. (CX3273 at 001 (¶ 1) (Bingol Decl.)). Mr. Bingol also described Opana ER as being sold in the LAO ñmarket segment.ò (CX3273 at 003 (¶ 6) (Bingol Decl.)). But in the same declaration, Mr. Bingol described that Endo grew Opana ER sales despite the launch of other heavily-promoted LAOs, Embeda and Exalgo. (CX3273 at 004 (¶ 8) (Bingol Decl.)). The fact that the launch of other, heavily-promoted, LAOs did not prevent Opana ERôs growth (while Opana ERôs promotions were being cut back) shows they are not as close substitutes as generic oxymorphone ER. (*See, e.g.*, CX5000 at 076-78 (¶¶ 166, 169) (Noll Report) (the fact that Opana ER was able to grow despite the presence of other LAOs is evidence the other LAOs are not close substitutes)). On the other hand, Mr. Bingol stated that if Impax launched AB-rated generic oxymorphone ER, it would drive down price by about 15 to 20% and take 80% of Endoôs market share. (CX3273 at 008 (¶ 18) (Bingol Decl.)).

RESPONSE TO FINDING NO. 939:

Complaint Counselôs Proposed Finding No. 939 is incomplete and inaccurate.

Respondent has no specific response to the first three sentences of Proposed Finding No. 939, except to state that Mr. Bingolôs declaration speaks for itself.

But the conclusions reached in the fourth and fifth sentences of Proposed Finding No. 939 are incorrect. Internal Endo documents indicate that Endo grew its market share in the long-acting opioid market because it was *successful in competing against other long-acting opioids*. (*See* RX-547.0041 (Addanki Rep. ¶ 78)). For example, in 2011 Endo [redacted] (RX-547.0041 (Addanki Rep. ¶ 78); Addanki, Tr. 2294-98). As Professor Nollôs own report shows, [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873); Addanki, Tr. 2290; Noll, Tr. 1679-82;

RX-547.053 (Addanki Rep. ¶ 101(b), Ex. 13); *see also* RX-547.133 (Addanki Rep., Ex. 11) (noting that generic MS Contin, generic Duragesic, and generic Kadian were available during

RESPONSE TO FINDING NO. 941:

Complaint Counselôs Proposed Finding No. 941 is incomplete and misleading. Complaint Counsel fails to appreciate that Endoôs perceived need to differentiate Opana ER was driven by the reality that long-acting opioids ñ*are not very differentiated*.ò (RX-023.0002) (Endo internal business document) (emphasis added)). Unlike Professor Noll, Dr. Addanki recognized this in his analysis: ñPharmaceutical firms often engage in efforts to differentiate their branded product from therapeutic alternatives. *Those efforts are often particularly pronounced where the firm's product is therapeutically very similar to the available alternatives*.ò (RX-547.0026 (Addanki Rep. ¶ 49) (emphasis added)). Documents describing these efforts nonetheless ñprovide useful insights into the set of alternatives viewed by the pharmaceutical firm as being the ócompetitive set,ôò which can be a ñgood starting point for a candidate relevant market.ò (RX-547.0026 (Addanki Rep. ¶ 49)). Dr. Addanki then confirmed that the ñcompetitive setò of long-acting opioids identified in Endoôs and other long-acting opioid makersô documents in fact competed on price and constituted a relevant market. (RX-547.0031-50 (Addanki Rep. ¶¶ 60-92)).

More generally, Complaint Counselôs assertion that attempts to encourage switching from a competing product to Opana ER indicates a lack of competition fails the sniff test. Complaint Counsel offers no reason for why Endo would expend significant amounts of money to differentiate Opana ER from other long-acting opioids if patients would not or could not switch from one long-acting opioid to another or from Opana ER to a competing long-acting opioid.

942. Dr. Addanki cites as evidence of interdrug competition some incomplete references to discounts offered by to consumers to cover their co-payments for , respectively. (Addanki, Tr. 2237-38, 2281-82) (*in camera*). However, Dr. Addanki provides no information about the size of

these programs or whether or to what extent these programs affected either average net prices or sales of [redacted]. (CX5004 at 033 (¶ 66) (Noll Rebuttal Report)) (*in camera*). The extent to which these programs actually represented any price competition between [redacted] would depend on how widespread the programs were and what actual effect they had on average net prices. (CX5004 at 033 (¶ 66) (Noll Rebuttal Report)) (*in camera*). Without such information, it is impossible to conclude that these programs demonstrate significant price competition between [redacted]. (CX5004 at 033 (¶ 66) (Noll Rebuttal Report)) (*in camera*).

RESPONSE TO FINDING NO. 942:

Complaint Counselôs Proposed Finding No. 942 is inaccurate, incomplete, and misleading. Contrary to Complaint Counselôs assertions, Dr. Addanki provided extensive information regarding the scope and significance of the programs in question. For example, Dr. Addanki noted that [redacted] (RX-547.0043 (Addanki Rep. ¶ 79) (emphasis added)). Indeed, Mr. Bingol of Endo confirmed that offering coupons directly to consumers is a competitive strategy in the long-acting opioid market. (Bingol, Tr. 1325-26). In 2008, Endo observed ñ[a]ggressive couponing from all direct competitorsò; in response, Endo instituted an ñInstant Savings Cardò that subsidized patientsô copayments by $25 per redemption. (RX-028.0011). Between 2009 and mid-2010, Endo offset a portion of nearly *90,000 prescriptions* for Opana ER through its couponing program. (RX-066.0003). In 2011, [redacted] (RX-123.0006; Addanki, Tr. 2285).

Complaint Counsel suggests that these programs do not constitute evidence of ñprice competitionò among long-acting opioids unless we know the precise ñeffect they had on average net prices.ò But as a logical and mathematical necessity, reducing the price of *tens of thousands*

of Opana ER prescriptions inherently reduces the ñaverage net priceò of Opana ER. And as Professor Nollôs own report acknowledges, [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873); *see* RX-547.0053-54 (Addanki Rep. ¶ 101(b))).

Moreover, Proposed Finding No. 942 fails to account for the fact that, as Dr. Addanki testified at trial, we simply *do not* see this kind of competition at the patient level with respect to products that lack economic competition. (Addanki, Tr. 2236-37).

G. Dr. Addanki incorrectly concluded that evidence relating to formulary placement indicates that LAOs are in the same market

943. Exhibits 7, 8, and 9 of the Addanki Report indicate that LAOs are rarely placed on the same formulary tier and that the placements of the various LAOs on formularies vary across insurance plans. (RX-547 at 0039-40 (¶¶ 74-76) (Addanki Report)). Based on this, Dr. Addanki concludes that differences in formulary placement ñwere more likely to have been based on economic factors rather than on clinical ones.ò (RX-547 at 0039 (¶ 74) (Addanki Report)). However, Dr. Addanki provides no evidence whatsoever that differences in relative placements on formularies actually reflect price competition. (Noll, Tr. 1397; CX5004 at 030-31 (¶¶ 59-61) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 943:

The conclusion to Complaint Counselôs Proposed Finding No. 943 is inaccurate and misleading. Respondent does not have a specific response to the first two sentences of Proposed Finding No. 943, except to note that, as Dr. Addanki explained at trial, these findings are consistent with the existence of extensive price competition at the payor level. (RX-547.0038-40 (Addanki Rep. ¶¶ 72-76); Addanki, Tr. 2309-2328). As for the third sentence in Proposed Finding No. 943, it is simply not true that ñDr. Addanki provides no evidence whatsoever that

RESPONSE TO FINDING NO.

medical preference; itôs a ques

didnôt know they could actually drive volume.ò (Addanki, Tr. 2226). That formulary changes can and *do* drive switching among long-acting opioids is borne out by the record. (*E.g.*, RX-087.)

The second sentence of Proposed Finding No. 945 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). The individual paragraphs cited in the second sentence do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

Finally, the third sentence of Proposed Finding No. 945 has no

by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Moreover, the individual findings of the paragraphs cited in the first sentence do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings. Further, Dr. Addankiôs deposition testimony cited in the first sentence says nothing at all about a ñskewed conclusion.ò (CX4044 (Addanki, Dep. at 165-66)).

The second and third sentences of Proposed Finding No. 946 are incomplete and misleading. In the cited portion of the transcript, Dr. Addanki was *specifically* discussing his analysis of formulary data obtained from MMIT, which was but *one part* of his relevant market analysis. (Addanki, Tr. 2310-28; *see* RX-547.0038-40 (Addanki Rep. ¶¶ 74-76)). As Dr. Addanki explained at trial, the purpose of this particular analysis was to assess the degree of competition among long-acting opioids for which an AB-rated generic was *not* available ð i.e., LAOs on an ñequal footing.ò (Addanki, Tr. 2213-15). Including long-acting opioids with AB-rated generics would not tell him (or the Court) anything new about competition among long-acting opioids, because it is undisputed that generic drugs usually end up on favorable formulary tiers. (Addanki, Tr. 2213-15). Of course, if Dr. Addanki were to add generic long-acting opioids to his MMIT analysis, ñall weôd be doing is adding another layer or another bar here or another few bars thereò; it would not change the story about the degree to which Opana ER competed against other long-acting opioids for which a generic was not available during the time period studied, such as OxyContin, Avinza, MS Contin, and Exalgo. (Addanki, Tr. 2214).

In other words, Proposed Finding No. 946 both ignores crucial c

competition between Opana ER and other long-acting opioids for which an AB-rated generic was not available during the relevant period). To the extent the proposed finding suggests that Dr. Addanki did not study competition between Opana ER and generic long-acting opioids, it is simply wrong. By way of example, in the UPMC study described in Dr. Addankiôs report and at trial, UPMC changed its formularies to favor Opana ER *and various long-acting opioids* over branded OxyContin. (RX-087; *see* RX-547.0042, 0048 (Addanki Rep. ¶¶ 78, 88); Addanki, Tr. 2305). As a result of UPMCôs formulary changes, generic Morphine Sulfate ER and generic Fentanyl patch each saw an uptick in prescriptions. (RX-087 (Figures 3, 5)).

> 948. Third, Dr. Addanki chose to include in the analysis three drugs with the same active ingredient, which also leads to a skewed conclusion. In particular, three of the six drugs in the set he looked at contain morphine. (Noll, Tr. 1399-400; CX5004 at 030 (¶ 60) (Noll Rebuttal Report)). Because they share a molecule and the characteristics of that molecule, different versions of morphine are more likely to be good substitutes for each other than they are to Opana ER. (Noll, Tr. 1399-400; CX5004 at 030 (¶ 60) (Noll Rebuttal Report)). Even if the patterns of formulary placement say anything useful about the state of competition, which they do not, the results would be skewed by the fact that three of the six drugs included in the analysis are more likely to be closer competitors to one another than to the drug at issue, Opana ER. (Noll, Tr. 1399-400; CX5004 at 030 (¶ 60) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 948:

Complaint Counselôs Proposed Finding No. 948 is inaccurate. Th

them as one monolithic product youôre still going to see the formulary variation and the churn.ò (Addanki, Tr. 2325-26). Indeed, ñwhen one looks at a product that isnôt based on morphine sulfate, one can make reasonable inferences about the relative formulary statusò and that inference is ñthat there is churn, there are differences in the way these formulary competitions play out in terms of the formulary positioning . . . which is entirely consistent with there being . . . competition at the formulary stage.ò (Addanki, Tr. 2327-28).

> 949. Fourth, the pattern observed in the formulary placement could just as well be observed in a noncompetitive market, so the analysis sheds no light on how competitive the market is. For example, a pattern of variation among formulary placements could very well be a function of a bid rigging cartel by which producers agree to alternate successful bids. (CX5004 at 030-31 (¶¶ 61-62) (Noll Rebuttal Report)). In such a situation, we would see the same variation in formulary placement that Dr. Addanki concludes indicates a level of price competition. (CX4039 (Noll, Dep. at 183-84)). The fact that Dr. Addankiôs test does not allow him to distinguish between competitive outcomes and non-competitive outc

Thus, the third sentence to Proposed Finding No. 949 should similarly be disregarded because it is based on an utterly unsubstantiated claim that there is ñbid riggingò occurring in the market.

The fourth sentence of Proposed Finding No. 949 is inaccurate. The ñdiversity of outcomesò and ñvariation and churnò that Dr. Addanki identified in long-acting opioidsô formulary placement ð both as of June 2010 and as measured over time ð are consistent with manufacturers competing on price to secure favorable placement, with competitive bidding producing different ñwinners.ò (RX-547.0038-40 (Addanki Rep. ¶¶ 72-76); Addanki, Tr. 2309-2328). The fact that ñdifferent plans accorded preferential treatment to different [long-acting opioid] productsò indicates that the differences in formulary placement were likely not due to therapeutic factors. (RX-547.0039 (Addanki Rep. ¶ 74)). Indeed, the very idea of a formulary is founded on the idea that pricing drives *economic substitution*. As Dr. Addanki testified at trial, ñif the insurers didnôt think they could actually drive volume by adjusting their formularies, drive volume to a favored product versus a nonfavored product ð and again Iôm talking about the favoring being just the tiers of the formulary. Itôs not a question of medical preference; itôs a question of economic tiering ð the insurers wouldnôt bother if they didnôt know they could actually drive volume.ò (Addanki, Tr. 2226).

This inference ð that the ñdiversity of outcomesò and ñchurnò in long-acting opioidsô formulary placement likely resulted from economic competition rather than some other factor ð is borne out by documentary and testimonial evidence. (*See* RX-547.0038-41 (Addanki Rep. ¶¶ 72-78); Addanki, Tr. 2294-98; Bingol, Tr. 1324-25).

> 950. Fifth, Dr. Addankiôs selection of drugs presents a misleading picture about their pattern of use. As noted above, Dr. Addanki systematically excluded drugs for which there was a generic on the market. (CCF ¶¶ 946-47; CX4044 (Addanki, Dep. at 165-66)). This leaves a number of LAOs, such as methadone, out of the data set. Therefore, any use

> of such LAOs is not captured at all in the data. If, for example, opioid-addicted newborns are treated with methadone, then we would not see that in this data, because Dr. Addanki left methadone (and certain other LAOs) out of the data set. If a drug Dr. Addanki ignored is heavily used to treat a particular condition, we would not see this at all in his analysis. Therefore, the data on the pattern of use he used is misleading.

RESPONSE TO FINDING NO. 950:

Complaint Counselôs Proposed Finding No. 950 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings. Proposed Finding No. 950 should be disregarded because it represents a new criticism of Dr. Addanki that was not revealed at trial or in Professor Nollôs rebuttal report. Indeed, neither methadone nor ñopioid-addicted newbornsò was mentioned by Professor Noll at trial.

In any event, this newly invented criticism is baseless. Dr. Addankiôs discussion of MMIT data was but *one part* of his relevant market analysis. (Addanki, Tr. 2310-28; *see* RX-547.0038-40 (Addanki Rep. ¶¶ 74-76)). As Dr. Addanki explained at trial, the purpose of this particular analysis was to assess the degree of competition among long-acting opioids for which an AB-rated generic was *not* available ð i.e., LAOs on an ñequal footing.ò (Addanki, Tr. 2213-15). Including long-acting opioids with AB-rated generics would not tell him (or the Court) anything new about competition among long-acting opioids, because it is undisputed that generic drugs usually end up on favorable formulary tiers. (Addanki, Tr. 2213-15). Of course, if Dr. Addanki were to add generic long-acting opioids to his MMIT analysis, ñall weôd be doing is adding another layer or another bar here or another few bars thereò; it would not change the story about the degree to which Opana ER competed against other long-acting opioids for which a

generic was not available during the time period studied, such as OxyContin, Avinza, MS Contin, and Exalgo. (Addanki, Tr. 2214).

In other words, Proposed Finding No. 950 both ignores crucial context (*i.e.*, that Dr. Addanki was discussing just one part of his multi-faceted relevant market study) and misses the point of the particular analysis in question (i.e., that the MMIT analysis deliberately focused on competition between Opana ER and other long-acting opioids for which an AB-rated generic was not available during the relevant period). To the extent the proposed finding suggests that Dr. Addanki did not study competition between Opana ER and generic long-acting opioids, it is simply wrong. By way of example, in the UPMC study described in Dr. Addankiôs report and at trial, UPMC changed its formularies to favor Opana ER *and various long-acting opioids* over branded OxyContin. (RX-087; *see* RX-547.0042, 0048 (Addanki Rep. ¶¶ 78, 88); Addanki, Tr. 2305). As a result of UPMCôs formulary changes, generic Morphine Sulfate ER and generic Fentanyl patch each saw an uptick in prescriptions. (RX-087 (Figures 3, 5)).

Finally, Proposed Finding No. 950 overlooks the fact that, *even if* the relevant market were strictly limited to the branded LAOs that Dr. Addanki *did* include in the MMIT analysis, Opana ERôs market share of the market would still be miniscule. For example, Endo estimated that from February 2012 to February 2013, branded OxyContinôs share of the long-acting opioid market was about 28% on average, while branded Opana ERôs share hovered between 3.9% and 5.8%. (RX-73.0002 at 4). This is consistent with Dr. Addankiôs market share analysis. (*See* RX-547.0132 (Addanki Rep., Ex. 10); *see also* RX-547.0133 (Addanki Rep., Ex. 11 n.12) (noting that from January 2008 onward, almost no generic OxyContin has been available)). If the relevant market were strictly limited to OxyContin and Opana ER, Endoôs share would be no higher than approximately 20%. Including Avinza, Exalgo, and/or MS Contin ð the other

branded long-acting opioids included in the MMIT analysis ð would only further dilute Endoôs share.

H. Dr. Addanki incorrectly concludes that Endo lacked market power because Opana ER accounted for a small portion of LAO sales

951. Market power is the ability to sustain prices above the competitive level and/or to

in output.ò (Addanki, Tr. 2372; *see also* Addanki, Tr. 2339 (ñwhat [economists] care about is the power of a firm to harm consumers by restricting output or doing something else to prevent consumer benefit from obtaining in a market placeò)). Dr. Addanki has shown that Endo did not possess monopoly power. (RX-547.0050-57 (Addanki Rep. ¶¶ 93-07)).

I. Dr. Addanki ignores key portions of the IP Guidelines in his contention that intellectual property does not create market power

952. Dr. Addanki asserts that intellectual property (ñIPò) does not confer market power, based on language from the 1995 *IP Guidelines* which states ñ. . . the Agencies do not presume that intellectual property creates market power in the antitrust context.ò (RX-547 at 005253 (¶ 100) (Addanki Report) (quoting the 1995 *IP Guidelines* at 2)). However, Dr. Addanki is selectively quoting the *IP Guidelines*. The 2017 *IP Guidelines* have an entire section titled ñIntellectual Property and Market Power.ò (CX5004 at 043 (¶ 89) (Noll Rebuttal Report) (citing the 2017 *IP Guidelines* at 4-5)). In this section the *IP Guidelines* state: ñAlthough 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 produ

RESPONSE TO FINDING NO. 956:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 956.

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Finally, Respondent has no specific response to the quote in the third sentence of Proposed Finding No. 956, except to note that ð as explained in the preceding paragraph ð Professor Noll testified at trial that he *agrees* with Dr. Addanki.

957. Dr. Addanki inappropriately conflated two separate concepts ï market power and anticompetitive conduct. (CX5004 at 054-55 (¶¶ 115-16) (Noll Rebuttal Report)). Dr. Addanki used the term ñmarket powerò to mean the ability to set price above marginal cost *as a result of anticompetitive conduct*. (CX5004 at 055 (¶ 116) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 957:

consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.ò)).

In other words, Professor Nollôs testimony at trial only *confirms* Dr. Addankiôs statement that pricing above marginal cost does not show monopoly power, and hence cannot satisfy the monopoly power requirement in an antitrust rule of reason case.

> 958. A high Lerner Index implies the existence of market power, but it does not imply that such market power is the result of anticompetitive conduct. (CX5004 at 055-56 (¶ 117) (Noll Rebuttal Report)). A high Lerner Index indicates a firm is charging a price well above marginal cost; therefore, the firm enjoys market power. (CX5004 at 055-56 (¶ 117) (Noll Rebuttal Report)). M

Respondent has no specific response to the final sentence of Complaint Counselôs Proposed Finding No. 958.

things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.ò)).

The second sentence of Proposed Finding No. 959 misrepresents Dr. Addankiôs report. Complaint Counsel provides no citation to Dr. Addankiôs report, nor do the cited paragraphs of Professor Nollôs rebuttal report.

The third sentence of Proposed Finding No. 959 is misleading to the extent it suggests that ñenforcing valid patentsò was a ñsource of Endoôs market p

attempt to measure the output e

decline had stabilized by mid-2012 ð months *before* Impaxôs entry. (RX-547.0051, 0135 (Addanki Rep. ¶ 96; Ex. 12)).

2. Prior to generic entry, the demand for Opana ER and all LAOs was declining; Impax's entry stopped that decline

965. Even if Impaxôs entry did not increase oxymorphone ER output, Dr. Addankiôs conclusion also is flawed because he fails to take into account the fact that, prior to Impaxôs entry, the entire market for Opana ER was declining. (CX5004 at 042 (¶ 87) (Noll Rebuttal Report); CX4039 (Noll, Dep. at 206-08)). Since the overall trend had been one of decline prior to Impaxôs entry, a shift to a constant level of output *is* an increase in output compared to the trend. (CX4039 (Noll, Dep. at 207-08)) Even assuming that Impaxôs entry did not expand output, Impaxôs entry stopped an overall decline in output. (CX5004 at 042 (¶ 87) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 965:

Complaint Counselôs Proposed Finding No. 965 is inaccurate and misleading. To begin with, the proposed finding relies on Professor Nollôs rebuttal report, which incorrectly uses quarterly wholesale sales data to measure ñoutput.ò (CX5004-042, 91 (Noll Rebuttal Rep. ¶ 87; Ex. 3). This is not an appropriate measure of output, since it does not reflect what was actually consumed in the marketplace and skews the results. (CX4044 (Addanki, Dep. at 161-63)).

The assertion that Impaxôs generic launch ñstopped an overall decline in outputò is incorrect. Dr. Addankiôs analysis shows that, in fact, the 2012 decline had stabilized by mid-2012 ð months *before* Impaxôs entry. (RX-547.0051, 0135 (Addanki Rep. ¶ 96; Ex. 12)). Using a correct measure of output, it becomes clear that output of oxymorphone ER remained essentially flat from mid-2012 onward. (RX-547.0051, 0135 (Addanki Rep. ¶ 96; Ex. 12); CX4044 (Addanki, Dep. at 161-63)).

with an earlier entry date was actually feasible, or (b) there is a high probability that, if the parties had continued litigating, the generic firm would have prevailed in the underlying patent litigation and entered earlier than the settlement entry date. (RX-547.0019-20, 0070-71 (Addanki Rep. ¶¶ 30, 36, 128-30) (ñUnless there is compelling evidence of a fully-specified alternative agreement that the parties contemplated . . . the operating assumption must be that the but-for world is one in which the parties litigated the patent suit to its conclusion.ò)).

> 971. By eliminating the possibility of generic competition for a period of time (thereby extending the brand-name firmôs monopoly), reverse-payment settlements interfere with the competitive process. Reverse payments therefore harm consumers by depriving them of the possible benefits of increased competition for the period of time specified in the settlement. (Noll, Tr. 1422-23; CX5000 at 119 (¶ 269) (Noll Report)).

RESPONSE TO FINDING NO. 971:

Complaint Counselôs Proposed Finding No. 971 is an improper legal conclusion, not a fact. Moreover, the first second sentence of Proposed Finding No. 953 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

In any event, Proposed Finding No. 971 is inaccurate in its claim that so-called reverse-payment settlements always ñharm consumers.ò As Dr. Addanki explained at trial, ñwhether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it.ò (Addanki, Tr. 2205). The analysis is ñreally not any different from what we would do in any kind of rule of reason case.ò (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and

(2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See*

RESPONSE TO FINDING NO. 974:

Proposed Finding No. 974 is inaccurate and misleading. To begin with, a settlement can have no effect on ñmonopoly profitsò unless the brand company was in fact earning ñmonopoly profitsò ð that is, unless the brand company possessed market power. (RX-547.0018-20 (Addanki Rep. ¶¶ 29-34); *see* Noll, Tr. 1574 (conceding that an alleged reverse-payment settlement cannot be ñanticompetitiveò unless the firm in question possessed ñsubstantial market power.ò)). Assuming monopoly power can be shown, a reverse-payment settlement is not anticompetitive unless it left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). As Dr. Addanki explained at trial, ñwhether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it.ò (Addanki, Tr. 2205). Without performing this analysis, ñ[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive.ò (Addanki, Tr. 2205).

1. Reverse-payment settlements are unusual because money flows in the wrong direction

975. In a typical infringement case, the producer of allegedly infringing products pays royalties to use a patent or damages if the patent is infringed and no license is obtained. (Noll, Tr. 1423; CX5000 at 103-04 (¶ 238) (Noll Report)). In a reverse-payment settlement, the party allegedly damaged by the infringement (the brand-name firm) pays or otherwise provides value to the party that allegedly committed the infringement (the generic firm). Where a brand-name firm pays the generic firm, the normal stream of payments is reversed and such arrangements are therefore called ñreverse-paymentò settlements. (Noll, Tr. 1422-23; CX5000 at 103-04 (¶¶ 237-38) (Noll Report)).

RESPONSE TO FINDING NO. 978:

small compared to the monopoly profits the brand enjoys by extending the monopoly. (Noll, Tr. 1431-32). In other words, the minimum price the generic is willing to accept to stay off the market is likely to be lower than the maximum amount the brand-name firm is willing to pay. (Noll, Tr. 1432-33).

RESPONSE TO FINDING NO. 979:

Complaint Counselôs Proposed Finding No. 979 is not supported by the record or the cited evidence. The cited portions of Professor Nollôs report merely discuss an econometric equation of his own creation, not the pharmaceutical industry generally. Professor Noll, moreover, is not qualified as an expert regarding issues related to patent litigation or settlements of the same. (Noll, Tr. 1358). Neither is Professor Bazerman. (Bazerman, Tr. 844).

Because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 979 were present with Impax or Endo, Proposed Finding No. 979 should be disregarded. Under this Courtôs Order on Post-trial Briefs, Complaint Counsel may not rely on ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). In particular, the proposed finding cites no evidence for the proposition that any particular ñgeneric firmò ð to say nothing of Impax ð was ñwilling to postpone its launch until a later date.ò Contrary to Complaint Counselôs suggestion, Impaxôs January 1, 2013 licensed entry date did not ñdelayò the date on which Impax likely would have been able to market its generic oxymorphone ER product. (Figg, Tr. 1928; RX-547.0073 (Addanki Rep. ¶ 135)).

Finally, Proposed Finding No. 979 is misleading because its rests on the unproven assumption that there are ñmonopoly profits,ò which exist only if the branded-firm has market power in a relevant market. (Addanki, Tr. 2371 (testifying that the first step in an analysis is the

Counselôs implication that ñthe marketò is limited to the branded drug and any generic versions of it is not invariably true. In this case, the relevant market consists of long-acting opioids generally. (RX-547.022-47 (Addanki Rep. ¶¶ 41-85)).

> 980. A positive reverse payment is in the interest of both firms when the brand-name firmôs expected profit from guaranteeing generic entry at a given date exceeds the expected profit of the generic firm if it does not settle. (CX5000 at 129-30 (¶ 294) (Noll Report)). So both firms have an incentive to agree to a reverse-payment settlement when the amount of the payment is larger than the amount the generic expects to make if it does not settle but smaller than the amount of lost profits the brand-name firm saves by paying the generic firm. (CX5000 at 129-30 (¶ 294) (Noll Report)).

RESPONSE TO FINDING NO. 980:

Complaint Counselôs Proposed Finding No. 980 is not supported by the record or the cited evidence. The cited portions of Professor Nollôs report merely discuss an econometric equation of his own creation, not the pharmaceutical industry generally. Professor Noll, moreover, is not qualified as an expert regarding issues related to patent litigation or settlements of the same. (Noll, Tr. 1358).

Further, because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 980 were present with Impax or Endo, Proposed Finding No. 980 should be disregarded. Under this Courtôs Order on Post-trial Briefs, Complaint Counsel may not rely on ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)).

> 981. The Hatch-Waxman regulatory framework creates additional incentives for pharmaceutical companies to enter into reverse payments. Under Hatch-Waxman, the first firm to file a generic application with a Paragraph IV certification is rewarded with the 180-day exclusivity period. (CX5000 at 104 (¶ 239) (Noll Report) *see also* CCF ¶¶ 14-15, above). 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

consumer harm resulting from the reverse-payment agreement. (Noll, Tr. 1460-61; CX4039 (Noll, Dep. 39, 88)).

RESPONSE TO FINDING NO. 982:

Complaint Counselôs Proposed Finding No. 982 is an improper legal conclusion, not a

unjustified payment to the generic firm if the generic firm is likely to lose the infringement case. (CX5000 at 103-05, 120 (¶¶ 238, 242, 271) (Noll Report)). At the same time, even if the brand-name firm is likely (but not certain) to prevail in the patent infringement suit, it still has the incentive to pay a portion of its monopoly profits to guarantee that generic entry will not occur. Thus, the mere fact that the brand-name firm agreed to make a large payment to the generic firm rules out the possibility the settlement was procompetitive. (CX5000 at 120, 133 (¶¶ 271, 302) (Noll Report)).

RESPONSE TO FINDING NO. 984:

Complaint Counselôs Proposed Finding No. 984 is inaccurate, unsupported, and misleading. Because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 984 were present with Impax or Endo, Proposed Finding No. 984 should be disregarded. Under this Courtôs Order or ‘ ‘ p Ó

Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 985 were present with Impax or Endo, the proposed finding should be disregarded. Under this Courtôs Order on Post-trial Briefs, Complaint Counsel may not rely on ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)).

In any event, Proposed Finding No. 985 is wrong as a matter of economics, since it treats all ñreverse-payment settlementsò with ñlargeò payments as *per se* anticompetitive. As Dr. Addanki explained at trial, ñwhether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it.ò (Addanki, Tr. 2205). The analysis is ñreally not any different from what we would do in any kind of rule of reason case.ò (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, ñ[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive.ò (Addanki, Tr. 2205).

Complaint Counsel is also wrong in asserting that the probable result of the settling partiesô patent litigation is irrelevant to the economic inquiry. To establish that consumers fared worse under the settlement than they otherwise would have, the evidence must show that (1) an alternative settlement with an earlier entry date was actually feasible; or (2) there is a high probability that, if the parties had continued litigating, the generic firm would have prevailed in

the underlying patent litigation and entered earlier than the settlement entry date. (RX-547.0020, 0070-71 (Addanki Rep. ¶¶ 36, 128-30) (ñUnless there is compelling evidence of a fully-specified alternative agreement that the parties contemplated . . . the operating assumption must be that the but-for world is one in which the parties litigated the patent suit to its conclusion.ò)). If the brand company was likely to prevail in the patent case, an entry date prior to the expiration of the patents-in-suit would benefit consumers. (*See* Figg, Tr. 1927-28, 1971).

> 986. It also is not necessary to determine the specific date on which a generic would have entered (either by litigating the matter to conclusion or agreeing to an alternative settlement) in order to conclude that the reverse-payment agreement is anticompetitive. (CX5004 at 076-77 (¶ 160) (Noll Rebuttal Report); CX4039 (Noll, Dep. at 58-59)). The fact that a brand-name firm is willing to make a large, unjustified payment confirms that the brand-name firm recognized the possibility that the generic could enter before the agreed-upon entry date; otherwise the brand-name firm would have no reason to make a large and unjustified payment. (CX5000 at 103-05 (¶¶ 238, 242) (Noll Report)).

RESPONSE TO FINDING NO. 986:

Complaint Counselôs Proposed Finding No. 986 is inaccurate, unsupported, and misleading. Because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 986 were present with Impax or Endo, Proposed Finding No. 986 should be disregarded. Under this Courtôs Order on Post-trial Briefs, Complaint Counsel may not rely on ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)).

In any event, Proposed Finding No. 986 is wrong as a matter of economics, since it treats all ñreverse-payment settlementsò with ñlargeò payments as *per se* anticompetitive. As Dr. Addanki explained at trial, ñwhether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse

off with the settlement than they would have been without it.ò (Addanki, Tr. 2205). The analysis is ñreally not any different from what we would do in any kind of rule of reason case.ò (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, ñ[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive.ò (Addanki, Tr. 2205).

Complaint Counsel is also wrong in asserting that the probable result of the settling partiesô patent litigation is irrelevant to the economic inquiry. To establish that consumers fared worse under the settlement than they otherwise would have, the evidence must show that (1) an alternative settlement with an earlier entry date was actually feasible; or (2) there is a high probability that, if the parties had continued litigating, the generic firm would have prevailed in the underlying patent litigation a

RESPONSE TO FINDING NO.

Complaint Counsel is also wrong in asserting that the probable result of the settling partiesô patent litigation and the feasibility of an alternative settlement are irrelevant to the economic inquiry. To establish that consumers fared worse under the settlement than they otherwise would have, the evidence must show that (1) an alternative settlement with an earlier entry date was actually feasible; or (2) there is a high probability that, if the parties had continued litigating, the generic firm would have prevailed in the underlying patent litigation and entered earlier than the settlement entry date. (RX-547.0020, 0070-71 (Addanki Rep. ¶¶ 36, 128-30) (ñUnless there is compelling evidence of a fully-specified alternative agreement that the parties contemplated . . . the operating assumption must be that the but-for world is one in which the parties litigated the patent suit to its conclusion.ò)). If the brand company was likely to prevail in the patent case, an entry date prior to the expiration of the patents-in-suit would benefit consumers. (*See* Figg, Tr. 1927-28, 1971).

Further, Proposed Finding No. 987 is internally contradictory and does not comport with common sense. Complaint Counsel proposes a finding that ñthe existence of the large, unjustified payment indicates that the brand-name firm is extending the monopoly power *beyond*

> monopoly profits for a longer time period under the settlement than it would if it did not settle and pay Impax. (CX5004 at 076 (¶ 159) (Noll Rebuttal Report); *see also* CX5001 at 031 (¶ 57) (Bazerman Report) (ñConsidering all of these factors together, I fail to see any explanation for the No-AG agreement and the back-up Endo Credit other than to compensate Impax to accept an entry date in January 2013.ò)).

RESPONSE TO FINDING NO. 988:

Complaint Counselôs Proposed Finding No. 988 is inaccurate, unsupported, and misleading. Proposed Finding No. 988 is premised on the assertion that Endo agreed upfront to ñpay Impax more than $100 million,ò but that is just not true. When it was signed, the SLA did not require Endo to actually pay *anything* to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) (ñat the time the transaction was inked I did not expect that Endo would have to make a payment under this provisionò)). Indeed, as Professor Noll admits, Endo could not even estimate whether it would make a payment of any size until after an unexpected supply disruption in 2012. (Cuca, Tr. 665-71, 677; *see* CX5004-070-71 (Noll Rebuttal Rep. ¶ 149)).

Proposed Finding No. 998 ignores the fact that Impax could have derived no ñpaymentò from either the Endo Credit *or* the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 (ñQ. And that example where you get zero of both, you didnôt include that on your demonstrative of scenarios, did you? A. No, I didnôt.ò); Addanki, Tr. 2355 (a rational actor like Endo ñwould manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make.ò); *see also* Court, Tr. 71, 75 (ñJUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? Youôre going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor

There was a theoretical possibility of zero.ò)). Indeed, Professor Noll agrees that the payment pursuant to the SLA could have been zero. (Noll, Tr. 1479-81).

Moreover, Dr. Addanki *did* address Complaint Counselôs contrived ñquestion.ò As reflected in the cited portion of his deposition transcript, Dr. Addanki refused to speculate about Endoôs subjective motivations. (*See* CX4044 (Addanki, Dep. at 56) (ñQ. . . . [W]hy did Endo settle at all? A. You have to ask Endo that.ò); CX4044 (Addanki, Dep. at 57) (ñI donôt know what Endo regarded as the uncertainties facing it.ò)). But as Complaint Counsel neglects to mention, he went on to explain that ñ*the provisions involving*

RESPONSE TO FINDING NO. 990:

1.

Impaxôs generic version of Opana ER beyond what would have been expected without those paymentsò is pure speculation, unmoored from any record evidenc

Proposed Finding No. 995 also ignores the fact that Impax could have derived no ñpaymentò from either the Endo Credit *or* the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 (ñQ. And that example where you get zero of both, you didnôt include that on your demonstrative of scenarios, did you?

No, I didnôt.ò); Addanki, Tr. 2355 (a rational actor like Endo ñwould manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make.ò); *see also* Court, Tr. 71, 75 (ñJUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not goin

the future of its Opana ER product to ñanalyze the full range of potential outcomes,ò but did not know if any of the many different assumptions in its forecasts would come true. (Cuca, Tr. 662-64).

Indeed, Endo never intended to l

CX4031 (Bradley, Dep. at 198) (ñI donôt recall having any conversation with any colleagues regarding the launch of an authorized generic.ò)). Thus, the No-AG provision did not ñcostò Endo anything.

And there was no connection between the Authorized-Generic provision and any entry date. In fact, after Endo proposed the No-Authorized Generic term, Impaxôs 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); *see* CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)). And Impax did not accept a later license date in exchange for the No-Authorized Generic provision. (Mengler, Tr. 567).

Finally, Proposed Finding No. 999 incorrectly assumes that Endo had a ñmonopoly.ò In fact, Endo did not have monopoly power. (RX-547.0050-57 (Addanki Rep. ¶¶ 93-107)).

> 1000. In addition to the No-AG provision, Endo also agreed to provide Impax with consideration in the form of the Endo Credit. Impax feared that the January 1, 2013 entry date was designed to give Endo time to reformulate Opana ER, and thereby destroy the market before Impax could launch its generic oxymorphone ER. (CX1308 (Levin/Mengler email)). To address Impaxôs concern, Endo and Impax developed a term called the Endo Credit, which guaranteed Impax a cash payment if sales of the original formulation of Opana ER declined by a particular amount before Impax launched. (Cuca, Tr. 613 (ñThe Endo credit established terms based on expectations of Endo product sales and Impax product sales under which there could be a payment from Endo to Impax if those expectations werenôt met.ò)).

RESPONSE TO FINDING NO. 1000:

The first sentence of Complaint Counselôs Proposed Finding No. 1000 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). The second sentence of Proposed Finding No. 1000 is not supported by the cited document. It states only ñWere [sic] still not comfortable with the 50%

trigger and wonder if your insistence is due to a known strategy to reduce the market.ò (CX1308). The third sentence of Proposed Finding No. 1000 is similarly unsupported by cited testimony. Mr. Cuca testified that ñthere *could* be a payment from Endo to Impax if those [sales] expectations werenôt met.ò (Cuca, Tr. 613). Proposed Finding No. 1000 also ignores the fact that Endo did not expect to make any payment. (CX4017 (Levin,

was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) (ñat the time the transaction was inked I did not expect that Endo would have to make a payment under this provisionò)). And Professor Bazerman did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, and therefore has no basis to claim Impax received anything of value at the time of settlement. (Bazerman, Tr. 923). Nor did Professor Noll attempt to calculate the expected value of the Endo Credit or No-AG provisions, either separately or in tandem. (Noll, 1590-92, 1613; CX4039 (Noll, Dep. at 116)).

Proposed Finding No. 1002 also ignores the fact that Impax could have derived no ñpaymentò from either the Endo Credit or the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 (ñQ. And that example where you get zero of both, you didnôt include that on your demonstrative of scenarios, did you? A. No, I didnôt.ò); Addanki, Tr. 2355 (a rational actor like Endo ñwould manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make.ò); *see also* Court, Tr. 71, 75 (ñJUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? Youôre going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldnôt have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.ò)).

Finally, the Endo Credit was designed to encourage Endo to invest in original Opana ER. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122) (the Endo Credit

was designed to act as ña deterrent to prevent [Endo] from switching the market.ò); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit ñintended to disincentivize Endo fromò introducing a reformulated product)). Complaint Counsel acknowledged as much at trial. (*See* Snowden, Tr.

[to reformulated Opana ER] to mi

1007. If Endo expected the outcome of the litigation would keep Impax off the market later than January 1, 2013, there is no reason for it to agree to that date and also agree to make a payment under either the No-AG provision or the Endo Credit. (CX5000 at 105 (¶ 242) (Noll Report) (ña reverse payment settlement in excess of the saved cost of litigation to the brand-name firm can only occur if it extends the period of patent monopoly beyond the brand-name firmôs expected remaining life of the patentò); *see also* CX5001 at 031 (¶ 57) (Bazerman Report) (ñConsidering all of thes factors together, I fail to see any explanation for the No-AG agreement and the back-up Endo Credit other than to compensate Impax to accept an entry date in January 2013ò). The fact that Endo paid Impax a reverse payment demonstrates that this secured a later entry date than Endo expected would have occurred if the litigation had taken its course. (CX5000 at 103-05 (¶¶ 238, 242) (Noll Report)).

RESPONSE TO FINDING NO. 1007:

Complaint Counselôs Proposed Finding No. 1007 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Proposed Finding No. 1007 also is without support in the record. When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) (ñat the time the transaction was inked I did not expect that Endo would have to make a payment under this provisionò)). And neither Professor Noll nor Professor Bazerman calculated the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, and therefore have no basis to claim there was any so-called ñpayment.ò (Noll, Tr. 1613, 1651-52; Bazerman, Tr. 923; CX4039 (Noll, ˢ

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where you get zero of both, you didnôt include that on your demonstrative of scenarios, did you? A. No, I didnôt.ò); Addanki, Tr. 2355 (a rational actor like Endo ñwould manage that transition [to reformulated Opana ER] to miz "

RESPONSE TO FINDING NO. 1010:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1011. In this case, there were seven ANDA filers apart from Impax for the five dosages for which Impax was the first filer. (CX2607 at 008-09 (¶ 24) (Lortie Decl.)) Those five dosages comprised the vast majority (over 95%) of Opana ER sales. (JX-001 at 007 (¶13)). By agreeing not to enter before January 1, 2013, Impax effectively created a barrier to entry against all other generics (including Actavis, which had received tentative approval) entering with those five dosages until after Impax had used its first-filer exclusivity in 2013. (*See* CCF ¶¶ 378-82, above).

RESPONSE TO FINDING NO. 1011:

Respondent has no specific response to thirst and second sentences of Complaint Counselôs Proposed Finding No. 1011. The third sentence of Proposed Finding No. 1011 is an improper summary finding that should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

D. Dr. Addanki's competitive effects opinions rely on an incorrect methodology and unsupportable assumptions

1012. Dr. Addanki asserts that the test for anticompetitive conduct used by Dr. Noll is ñinappropriateò because it ñrelies on the assumption that an alternative ópureô term-split settlement was feasible.ò (RX-547 at 0009-10 (¶ 11(g)) (Addanki Report)). A pure term-split settlement is one that contains no provisions other than an entry date for the generic. (CX5004 at 057 (¶ 120 n. 81) (Noll Rebuttal Report)). In fact, Dr. Nollôs test does not

depend in any way on the feasibility of a pure term-split or no-payment settlement. (CX5004 at 057 (¶ 120) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1012:

Respondent has no specific response to the first and second sentences of Complaint Counselôs Proposed Finding No. 1012. The third sentence of Proposed Finding No. 1012 is incomplete because it fails to note that Professor Nollôs test hinges entirely on the fact of an alleged ñlargeò payment. (*See* CX5004-065 (Noll Rebuttal Rep. ¶ 138) (ñlarge, unexplained reverse payments are *inherently* anticompetitiveò (emphasis added)); CX5004-058 (Noll Rebuttal Rep. ¶ 122) (ñthe *reverse payment itself* is a reliable index of t

a generic firm unless the agreement increases the brand-name firmôs expected monopoly profits. (CX5000 at 105 (¶ 242) (Noll Report); *see* CCF ¶¶ 1005-07, above). 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)).

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the payment received by the generic is greater than the sum of the litigation costs, itôs necessarily anticompetitive; right? A. Right.ò)).

2. Dr. Addanki improperly assumes that the parties could not enter any other settlement

1015. Dr. Addanki improperly assumes that the parties could not enter any other settlement. Dr. Addanki claims that there is ñno evidenceò that indicating that Endo and Impax could have agreed to enter any other settlement. (RX-547 at 0009 (¶ 11(f)) (Addanki Report)).

RESPONSE TO FINDING NO. 1015:

Complaint Counselôs Proposed Finding No. 1015 is inaccurate. The first sentence should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). The second sentence is an inaccurate representation of Dr. Addankiôs report. Specifically, Dr. Addanki opined that ñthere is no evidence indicating that Endo and Impax *would* have agreed to any hypothetical alternative term-split settlement.ò (RX-547.0009 (Addanki Rep. ¶ 11(f)) (emphasis added)). Thus, Complaint Counselôs proposed finding that Dr. Addanki ñclaimed there is óno evidenceô indicating that Endo and Impax *could*

always to get on the market as quickly as possible and stay in the market.ò); *see* Mengler, Tr. 564 (the ñonly way we make money is selling products, so the sooner

alternative settlement was possible. (Bazerman, Tr. 912-14). Professor Noll likewise admitted that a hypothetical alternative settlement between Impax and Endo may not have been possible. (*See* Noll, Tr. 1596 (ñQ. Sir, youôre not offering an opinion in this case as to whether a hypothetical alternative settlement with an earlier date would have been feasible between Impax and Endo, are you? A. No.ò); Bazerman, Tr. 914 (ñQ. And you canôt say with certainty that an alternative settlement was possible in this case, can you? A. No.ò)). Professor Noll conceded that ñImpaxô[s] attempt to get an earlier date met with complete resistance,ò and that he was ñnot aware that they actually came anywhere near agreeing on anything other than what they agreed to.ò (Noll, Tr. 1597-1600). Professor Bazerman similarly testified that he was aware of no evidence that Endo had ever offered an earlier date, and acknow

RESPONSE TO FINDING NO. 1019:

Complaint Counselôs Proposed Finding No. 1019 is inaccurate, unsupported, and misleading. The first sentence of Proposed Finding No. 1019 sh

(Noll Rebuttal Rep. ¶ 138) (ñlarge, unexplained reverse payments are *inherently* anticompetitiveò (emphasis added)); CX5004-058 (Noll Rebuttal Rep. ¶ 122) (ñthe *reverse payment itself*

3. Dr. Addanki improperly assumes that Impax could not have entered prior to January 2013

1021. Dr. Addanki assumes that Impax could not have launched generic oxymorphone ER prior to January 2013. (RX-547 at 0010 (¶ 11(i)) (Addanki Report)). There are a number of problems with that assumption. First, even if true ð which it is not ð it is irrelevant. (CX5004 at 076 (¶ 159) (Noll Rebuttal Report)). One does not need to prove an alternative entry date to conclude that a reverse-payment settlement is anticompetitive; one only needs to know that such a date was possible. (CX5004 at 076-77 (¶ 160) (Noll Rebuttal Report); CX4039 (Noll, Dep. at 58-59)). We can conclude such a date was possible because Endo otherwise would have no reason to make a large, unjustified payment to Impax to secure a result that it could have obtained by simply not settling. (Noll, Tr. 1487-88; *see also* CX5001 at 031 (¶ 57) (Bazerman Report) (ñConsidering all of the factors together, I fail to see any explanation for the No-AG agreement and the back-up Endo Credit other than to compensate Impax to accept an entry date in January 2013.ò)).

RESPONSE TO FINDING NO. 1021:

Complaint Counselôs Proposed Finding No. 1021 is inaccurate and engages in improper legal argumentation. Without determining an alternative entry date, there is no baseline against which to measure the negotiated entry date, and determine whether there was in fact a delay, and therefore whether the negotiated entry date harmed consumers. As Dr. Addanki explained, ñ[a] sound analysis of the competitive effects of the actual settlement is thus one that compares consumer benefit from the actual settlement to expected consumer benefit in a but-for world.ò (RX-547.0009 (Addanki Rep. ¶ 128)). The analysis is ñreally not any different from what we would do in any kind of rule of reason case.ò (Addanki, Tr. 2206).

Professor Nollôs conclusion as stated in Proposed Finding No. 1021 simply *assumes* consumer harm from the mere existence of an alleged ñlarge and unjustifiedòpayment, without looking at actual effects on consumers. (Noll, Tr. 1662 (ñQ. Your opinion is that once the payment is large relative to saved litigation costs and unjustified, youôre basically done from the standpoint of economics; right? A. That if itôs large and unjustified and there was a -- and precluded the possibility of earlier entry, then itôs anticompetitive.ò). As stated at trial, Professor

whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a),

of this, ñthere are sound, economic reasons for a firm in Impaxôs position to have been loath to enter at risk.ò (RX-547.0077 (Addanki Rep. ¶ 143)).

While Respondent concedes that Impax had manufactured validation batches of oxymorphone ER prior to the settlement, Impax strives to have every product in its generic pipeline ñlaunch readyò at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)). The goal of this approach is to give Impax management a full range of potential launch dates as options, and to avoid missing out on an opportunity to launch under favorable conditions because the product is not ready. (CX4030 (Hsu, Dep. at 86); CX4023 (Hildenbrand, Dep. at 140)). In order to accomplish this goal, Impax begins working towards launch preparedness eighteen months before the earliest possible launch date allowed by the Hatch-Waxman Act. (Camargo, Tr. 952-53, 958; CX4023 (Hildenbrand, Dep. at 79)). This process is routine, consistent with industry practice, and is the same for all products. (CX4023 (Hildenbrand, Dep. at 30); Koch, Tr. 271; CX3278-101).

Forecasting a launch date as part of this process does not mean that Impax has decided whether or when to launch a product. Todd Engle, Impaxôs Vice President of Sales and Marketing, would forecast poten

such risk.ò (RX-181; Camargo, Tr. 1009-10). Nonetheless, Impax undertook its normal launch preparations because the ñupside [was] substantial and [] we ma

(Hoxie, Tr. 2786). Willfulness is likely to be found only should the generic launch at risk and the district court finds that the generic is infringing a valid patent. (RX-548.0039 (Figg Rep. ¶ 85)). But Professor Nollôs exhibit 4 does not include a single case where a generic launched at risk and the district court ruled against it. (CX5004-078, 092-115 (Noll Rebuttal Rep. ¶ 164, Ex. 4)) (listing the ñstatus of litigation at time of launchò as either ñongoingò or coming after a favorable outcome at the district court)). Thus, exhibit 4 says nothing about the prevalence of treble damages in a situation where the generic loses at the district court level. And losing at the district court level was a real possibility for Impax, especially after the Courtôs decision adopting Endoôs proposed claim constructions. (*See* Figg, Tr. 1870). Therefore, the purported ñdataò in Professor Nollôs Exhibit 4 is not a useful comparison to Impaxôs situation.

Finally, Exhibit 4 does not support the proposi

at the conclusion of its original patent litigation with Endo, even assuming Impax would have prevailed in that litigation ð and none of Impaxôs experts have said anything to the contrary.

It is true that the original patent litigation between Impax and Endo would not have reached a final conclusion any sooner than late 2011 ð although it could have extended for much longer than that. (Figg, Tr. 1908-09). Even if Impax won that litigation (and there is no evidence it would have), it *still* could not have launched generic oxymorphone ER ñfree and clear of legal risk.ò That is because another patent that covered Opana ER (the ñô482 patentò) issued to Johnson Matthey *in December 2010*. (JX-003-005 (¶ 31)). In the real world, Johnson Matthey put Impax on notice of that patent by *May 2011* ð well before the original patent litigation could have been resolved. (CX3329.003-6; Snowden, Tr. 443-44). In other words, any Impax launch of oxymorphone ER in 2011 (or thereafter) would have been at-risk as to the ô482 patent.

It is nothing short of dishonest for Complaint Counsel to assert that ñImpaxôs experts agree that Impax could have launched free and clear of any patent risk in the second half of 2011, well before January 2013.ò Mr. Figg expressly stated in his report that ñthe ô482 patent would have been considered a material patent infringement risk for any company seeking to make or sell a generic version of Opana® ERò prior to 2013. (RX-548.0050-51 (Figg Rep. ¶ 113 n.19)). Dr. Addankiôs report likewise recognizes that if Impax had prevailed against Endo in the original patent litigation, it still ñmay well not have launched its generic versions of Opana ER until final adjudication of potential patent litigation regarding the ô482 patent.ò (RX-547.0082 (Addanki Rep. ¶ 152)). In fact, at trial, Dr. Addanki testified that Impax could *not* have launched generic oxymorphone in ER free from risk in November 2011 (again, assuming a litigation victory) because of the ô482 patent. (Addanki, Tr. 2362-63).

Finally, the fact that Impax instituted a Paragraph IV challenge to Endoôs original patents says

other generic companies. (Snowden, Tr. 442-43; RX-127 (Endoôs February 2011 evaluation of the Johnson Matthey patent); Addanki, Tr. 2362; Figg, Tr. 1949; *see also* RX-495 (Endo complaint alleging, among other things, infringement of the ó482 patent); RX-497 (same); RX-498 (same)).

Second, the assumption that ñsellers of the patent would obtain the greatest value by selling exclusively to Endo aloneò is not subject to reasonable dispute. Professor Noll himself repeatedly asserts that a brand company would pay more to preserve its exclusivity than a

Finally, Complaint Counselôs implicit suggestion that Endo paid Impax ñ$112 millionò at the time of settlement is simply false. The SLA did not require Endo to pay Impax anything at the time it was signed, and the $10 million payment that Endo made under the DCA was justified as fair value compensation for the bundle of rights Endo received. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided); Cobuzzi, Tr. 2564). The fact and amount of the ultimate Endo Credit payment were unknown at the time of settlement, and resulted from an unforeseen ñperfect stormò of events. (Addanki, Tr. 2354-56; *see* Noll, Tr. 1612 (ñWhether the Endo credit would be paid or the amount that would be paid depends on contingent events.ò)). As Professor Noll acknowledged, the Endo Credit payment could have been zero. (Noll, Tr. 1479-80).

4. Dr. Addanki uses an unworkable framework for assessing the size of a reverse payment

1028. Dr. Addanki presents a conceptually flawed and unworkable framework for assessing the size of a reverse payment. Rather than assessing the value of the payment when the agreement is entered into, Dr. Addanki urges assessing the value of the payment based on subsequent information. (CX 4044 (Addanki, Dep. 49) (ñQ. Right. So if you, Dr. Addanki, were hired in June of 2010 on behalf of Impax to assess the expected value of continued litigation, you might come up with one number in June of 2010 and if you were asked to assess that again in 2017 knowing what happened, you might come up with a different number; is that accurate? A. Yes, in other words, different information ï the availability of different information will change your calculations.ò)).

RESPONSE TO FINDING NO. 1028:

Complaint Counselôs Proposed Finding No. 1028 is inaccurate and grossly misstates Dr. Addankiôs deposition testimony. As is evident from the face of the cited transcript, Dr. Addanki was discussing how to calculate the

Thatôs correct.ò (emphasis added)). In determining the expected outcome of continued litigation, it only makes sense to ñuse all of the information we have,ò including real-world. (CX4044 (Addanki, Dep. at 48-49)). As better information about comes to light, that information can lead to different conclusions about the probabilities underlying expected values. (CX4044 (Addanki, Dep. at 49)). In this context, ñexpectedò does not refer to ñthe sense of the English meaning of the word[,] as in anticipated,ò but rather to its technical meaning of mathematically resolving uncertainty by assigning probabilistic values. (CX4044 (Addanki, Dep. at 45-46)).

As Dr. Addanki stated in his report, the value of a reverse payment should be assessed *ex ante*, as of the time of the settlement. (*See* RX-547.0066-70 (Addanki Rep. ¶¶ 125-27)).

> 1029. Dr. Addankiôs framework is conceptually flawed. The relevant question in determining whether a reverse-payment agreement is anticompetitive is whether the brand-name firm provided the generic firm with a large enough payment to [illegible]

(emphasis added)); CX5004-058 (Noll Rebuttal Rep. ¶ 122) (ñthe *reverse payment itself* is a reliable index of the welfare loss of consumers due to a reverse-payment settlementò (emphasis added)); CX4039 (Noll, Dep. at 26-27) (testifying that if a settlement includes a payment in excess of saved litigation costs, ñ*it's a hundred percent certain it's anticompetitive*ò (emphasis added)); CX4039 (Noll, Dep. at 27) (ñQ. So if itôs ð under your test, if itôs greater than the combined ð if the payment received by the generic is greater than the sum of the litigation costs, itôs necessarily anticompetitive; right? A. Right.ò)).

This proposed test is wrong as a matter of economics. As Dr. Addanki explained at trial, ñwhether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it.ò (Addanki, Tr. 2205). The analysis is ñreally not any different from what we would do in any kind of rule of reason case.ò (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, ñ[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive.ò (Addanki, Tr. 2205).

> 1030. Moreover, Dr. Addankiôs framework is unworkable. According to Dr. Addanki, the payment could have one value in 2010, another value in 2017 following a trial court decision, and yet another value once the Court of Appeals has rendered a decision. (CX 4044 (Addanki, Dep. 49-50) (ñQ. And if subsequent to today, there were reversals by the Court of Appeals on certain patent cases that are between ï that relate to Endoôs patents, that could cause you, yet, to have a third calculation of expected values of continued litigation, correct? A. If you have more information and you perform the analysis at a later time for the benefit of more information, you may have different conclusions.ò)). Following this approach would mean the legality of a reverse-payment agreement would

fluctuate ð an agreement could be unlawful when entered into, lawful after a district court decision, and perhaps unlawful again after an appellate court decision.

RESPONSE TO FINDING NO. 1030:

Complaint Counselôs Proposed Finding No. 1030 is inaccurate, unsupported, and misleading. As an initial matter, the first and final sentences of Proposed Finding No. 1030 should be disregarded because they violate the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). These proposed ñfindingsò are not facts, but rather unsupported argumentation.

Proposed Finding No. 1030 grossly misrepresents Dr. Addankiôs deposition testimony. As is evident from the face of the cited transcript, Dr. Addanki was discussing how to calculate the *expected outcome of continued litigation*, which requires one to calculate the probabilities associated with the various possible outcomes, and not the value of ñthe payment.ò (*See* CX4044 (Addanki, Dep. at 44-51) (ñQ. So the probabilities that youôre looking at . . . *are the probabilities of who's going to win the patent case; is that right?* A. Thatôs correct.ò (emphasis added)). In determining the expected outcome of continued litigation, it only makes sense to ñuse all of the information we have,ò including real-world. (CX4044 (Addanki, Dep. at 48-49)). As better information about comes to light, that information can lead to different conclusions

XII. The payments to Impax are not justified

A. The No-AG/Endo Credit payment was not justified

1. Endo did not get any product or service for the No-AG/Endo Credit payment (other than the entry date)

1031. The combination of the No-AG provision and the Endo Credit provided Impax with considerable value from Endo, either by Endo forgoing profitable sales of an authorized generic or by Endo paying Impax if Endo reformulated Opana ER and moved

204-06); CX4002 (Smolenski, IHT at 128-30); Cuca, Tr. 628-29; CX4017 (Levin, Dep. at 143-44)).

Both Complaint Counsel and Professor Noll admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 (ñJUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? Youôre going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldnôt have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.ò); Noll, Tr. 1654 (ñQ. And that example where you get zero of both, you didnôt include that on your demonstrative of scenarios, did you? A. No, I didnôt.ò)).

1032. Other than agreeing not to sell generic Opana ER until January 2013, Impax provided nothing to Endo in exchange for the No-AG/Endo Credit payment. (*See* CCF ¶¶1033-1043).

RESPONSE TO FINDING NO. 1032:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1033. Under the SLA, Impax does not pr

a) The No-AG/Endo Credit payment was directly linked to the January 2013 entry date

1034. From the start of negotiations, a No-AG provision was coupled in the settlement discussions between Impax and Endo with a 2013 entry date, and the Endo Credit evolved to protect the value of the period of No-AG exclusivity. (*See* CCF ¶¶ 10351039). The No-AG/Endo Credit payment imposes costs on Endo that can only be explained by Endo receiving a later entry date than it could have expected to get without such a payment. (*See* CCF ¶¶ 1040-1043). Further, the No-AG/Endo Credit payment explains why Impax was willing to forgo sales of generic Opana ER until January 2013. (*See* CCF ¶¶ 1044-1047).

RESPONSE TO FINDING NO. 1034:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1035. Before Impax and Endo started having substantive negotiations in May 2010, Impax executives were concerned about postponing its projected oxymorphone ER entry date beyond 2010, but were willing to do so for a settlement with a No-AG provision. (CX0505 at 001 (May 14, 2010 Mengler/Hsu email chain) (showing generics division president objecting to ñpostponing the launch of Oxymorphoneò until Impax CEO suggested a settlement ñwith No AGò)).

RESPONSE TO FINDING NO. 1035:

Complaint Counselôs Proposed Finding No. 1035 is inaccurate and misleading. The only document cited for this proposition is an email in which Dr. Hsu stated, ñI want to consider pros and cons on postponing[illegible]ry "

oxymorphone ER, not the absence of an authorized generic. (CX4030 (Hsu, Dep. at 76-77); CX4014 (Hsu, IHT at 68-69) (if no authorized generic means you ñdelay the entry date, thatôs a different story. . . . Because there is a very important factor here, which is . . . to have an entry date, have a launch as soon as possibleò); Mengler, Tr. 528-30 (Impax derives value ñby selling the drug [] with or without anò authorized generic)).

1036. The first written proposal Endo and Impax exchanged ð draft term sheets sent on May 26, 2010 ð included an agreement that Impax would not sell generic Opana ER until 2013 and a No-AG provision that lasted until the end of Impaxôs first-filer exclusivity period. (CX0320 at 009-010 (Ex. A, Draft License Agreement, §§ 1(a)-(b), 2(a))).

RESPONSE TO FINDING NO. 1036:

Respondent has no specific response other than to note that the term sheet contained no ñagreements,ò it contained on partyôs proposed terms for negotiation.

1037. Every subsequent written proposal between Impax and Endo contained provisions keeping Impax off the market until 2013 and some form of the No-AG/Endo Credit payment. (CX0321 at 001-02 (May 27, 2010 Mengler/Levin email) (launch date of January 1, 2013 and ñno authorized genericò); CX0323 at 003-04,

that it couldnôt have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.ò); Noll, Tr. 1654 (ñQ. And that example where you get zero of both, you didnôt include that on your demonstrative of scenarios, did you? A. No, I didnôt.ò)).

Impax initially sought a market degradation trigger, which would have allowed Impax to

RESPONSE TO FINDING NO.

by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

> 1042. The cost of the Endo Credit was the cash payment that Endo would have to make to Impax if sales declined following a reformulation, which turned out to be approximately $102 million paid by Endo. (*See* CCF ¶¶ 431-433, 439-444).

RESPONSE TO FINDING NO. 1042:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

> 1043. What Endo received in exchange for the No-AG/Endo Credit payment was the ability to sell branded Opana ER without generic competition until January 2013. (CX5001 at 029, 031 (¶¶ 54, 57) (Bazerman Report)). The payment resulted in a later entry date than what Endo could expect without a payment. (CX5001 at 035 (¶ 66) (Bazerman Report)).

RESPONSE TO FINDING NO. 1043:

Complaint Counselôs Proposed Finding No. 1043 violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See also* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)).

The first sentence of Proposed Finding No. 1043 is also wrong. It was *Endo's patents* that allowed it to sell branded Opana ER without generic competition until *September 2013*. (Hoxie, Tr. 2834 (testifying that if Impax lost the litigation it would ñnot be able to market its oxymorphone ER product until at least September 2013 when the patents expiredò)). The second

sentence of Proposed Finding No. 1043 is also inaccurate because had Endo prevailed in the underlying litigation, Impax could not have entered until September 2013, eight months later than the licensed-entry date in the SLA. (Hoxie, Tr. 2834). Further, the second sentence assumes Endo expected to make a ñpayment,ò which was not the ca

1046. Staying out of market would impose costs on Impax, including lost or delayed sales of generic Opana ER and uncertainty about the market opportunity for Impaxôs product in 2013. (CX0505 at 001 (Mengler/Hsu email chain describing the cost of ñpostponing the launch of Oxymorphoneò as ñlost/delayed salesò); Mengler, Tr. 527 (ñthe biggest concern that Opana ER somehow in its original form disappears or becomes so insignificant, because . . . the way generic drugs are sold is by having a substitute, and if thereôs no substitute, I get nothingò)).

RESPONSE TO FINDING NO. 1046:

Complaint Counselôs Proposed Finding No. 1046 is incomplete and misleading. First, Proposed Finding No. 1046 inappropriately assumes Impax would have entered the market at-risk, but no record evidence supports that proposition. (*See, e.g.*, Koch, Tr. 324-25). Second, had Impax continued to litigate with Endo, it was more likely than not to lose on the merits. (Figg, Tr. 1870, 1884, 1904). Third, continuing to litigate created uncertainty and imposed costs on Impax, including the likelihood that Impax would be precluded from selling oxymorphone ER for a much longer period of time. (Figg, Tr. 1972 (testifying that but for the settlement Impax would likely be enjoined from selling oxymorphone ER until 2029)).

1047. The No-AG/Endo Credit payment compensated Impax for the costs of waiting until January 2013, either through increased revenues from generic Opana ER during Impaxôs first-filer exclusivity period or a cash payment to replicate the value that Impax would have earned during that 180-day period. (Reasons, Tr. 1215 (ñHaving a no-AG provision, Impax could charge a higher price for generic Opana ERò); Mengler, Tr. 533 (describing the Endo Credit as being ñmade whole for the profits that we would have

that the Endo Credit and No-Authorized Generic provisions could have resulted in zero value to Impax. (Court, Tr. 71, 75 (ñJUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? Youôre going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldnôt have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.ò); Noll, Tr. 1654 (ñQ. And that example where you get zero of both, you didnôt include that on your demonstrative of scenari

intended to disincentivize Endo from degrading the opportunity for Impax to enter with an AB-substitutable generic version of Opana ER, and to incentivize Endo to make investments in its original Opana product. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit ñintended to disincentivize Endo fromò introducing a reformulated product)).

accelerated licensed-entry date would depend on a number of factors, including how quickly Endo switched products and how quickly Impax could launch its product.

1051. When Endo rejected the acceleration trigger, the parties moved instead to what eventually became the Endo Credit. (Snowden, Tr. 385).

RESPONSE TO FINDING NO. 1051:

Respondent has no specific response.

1052. Under the Endo Credit, Endo paid Impax rather than face earlier entry through an acceleration provision. If the SLA contained a 50% acceleration trigger (like the trigger in the Endo Credit formula), Impax mar x m % h p y

Preparation and launch readiness and [the] ability to launch wasnôt factored in. And then if you ask me about others, then there is the same issue. I donôt know a whole lot about them. In fact, some of them still havenôt launched for reasons I donôt understand.ò (CX4003 (Snowden, IHT at 197)). There is no indication that the parties ever discussed a 50 percent threshold for an acceleration trigger or that the term would have been accepted as part of any settlement. Indeed, the record is clear that Endo refused to discuss an acceleration trigger outright. (Koch, Tr. 314-16; Snowden, Tr. 432; Mengler, Tr. 581). Any suggestion that the parties would have agreed to a settlement that was materially different from the settlement they actually agreed to, the one before us, is pure speculation.ò (Addanki, Tr. 2359). ñTo hypothesize a settlement and say they would have agreed to it would be the purest speculation.ò (Addanki, Tr. 2374).

The third sentence of Proposed Finding No. 1052 is inaccurate and misleading in its suggestion that the parties agreed to, or knew the size of, any payment at the time of settlement. Impax never analyzed or forecasted whether it would receive a payment under the Endo Credit at the time of settlement, and it knew the Endo Credit could result in zero value. (Reasons, Tr. 1219; Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88)). Endo similarly had no ñexpectation that a payment would have to be made.ò (CX4017 (Levin, Dep. at 99-100) (ñat the time the

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Endo rejected an acceleration trigger outright. (Koch, Tr. 237-38; Snowden, Tr. 432; Mengler, Tr. 532; RX-318.0001).

1054. With the No-AG/Endo Credit payment, Endo received what it barga

view held only by Impax. (Cuca, Tr. 613-14 (Endo employee and author of the Endo Credit explained that ñthe mirror image of the Endo Creditò was the royalty provision); CX4017 (Levin, Dep. at 120-21) (Endo CFO explained that the Endo Credit and Royalty Provision ñwere intended to be looked at hand in handò); CX4001 (Koch, IHT at 44) (explaining ñwe agreed to pay them a royalty on the sales of our generic if the market was robust at the time of our launch in 2013, and we struck a penalty if the market wasnôt robustò and ñwe tried to find economic reasons for them to develop and enhance, grow the market for Opanaò); CX4001 (Koch, IHT at 81) (ñwhat we tried to come up with were economic reasons why they would continue to develop the market, and the economic reasons we came up with were we would pay them a royalty if the market is robust, or they pay us a penalty if it isnôtò)).

> 1056. But at the time of settlement, Impax viewed the Endo Credit as market protection, not as part of a ñcarrot and stickò approach. (*See* CCF ¶¶ 1057-1058). Moreover, the Endo Credit functioned ð as it was designed ð to reimburse Impax, not to deter Endo. (*See* CCF ¶¶ 1059-1063). Finally, the royalty provisions were not designed to act as a ñcarrotò because they still imposed costs on Endo through forgone sales of an authorized generic. (*See* CCF ¶¶ 1064-1065).

RESPONSE TO FINDING NO. 1056:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

> 1057. ñCarrot and stickò was not a concept that Impax used at the time it was negotiating the SLA. For example, Meg Snowden ð Impaxôs chief in-house lawyer and one of Impaxôs lead negotiators ð could not recall anybody using the term ñstickò or the phrase ñcarrot and stickò during the period of negotiations to refer to the Endo Credit. (Snowden, Tr. 391). Indeed, no documents from the period of negotiations refer to the ñcarrotò or the ñstickò now alleged by Impax. (*See* CCF ¶¶ 1059 (showing that, rather

than using the term ñcarrot and stick,ò Impaxôs documents refer to the Endo Credit as a ñmake whole provisionò or a ñmake goodò payment)).

1058.

peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales divided by 100, and (2) the number of percentage points under 50)). There is no indication that such potential liabilities under the Endo Credit are approximations of Impaxôs expected net profits over six months.

> 1063. Consequently, the Endo Credit did not deter Endo from reformulating and transitioning sales to the new product. (CX3241 at 001 (June 14, 2012 Endo Press Release, ñEndo Completes Transition of OPANA® ER Franchise to New Formulation Designed to be Crush Resistantò)). Instead, Endo paid the Endo Credit amount of approximately $102 million, much less than what Endo made in a single year of Reformulated Opana ER sales. (CX0333 at 002 (notice of wire transfer of $102,049,199.64 on April 18, 2013); CX3215 at 010 (Endo 10-K for 2012 showing Opana ER annual sales of $299.3 million, including sales after ñEndo transitioned to the crush-resistant formulation in March 2012ò)).

RESPONSE TO FINDING NO. 1063:

The first sentence of Complaint Counselôs Proposed Finding No. 1063 is misleading and not supported by the cited evidence. There is no indication that the Endo Credit failed to deter Endo. In fact, Endo had no ñexpectation that a payment would have to be madeò when it entered the settlement agreement. (CX4017 (Levin, Dep. at 99-100) (ñat the time the transaction was inked I did not expect that Endo would have to make a payment under this provisionò); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was ñprobable and estimableò at settlement); *see*M ξ D ŎM

RX-108.0002 at 10). When the Novartis plant at which Endo manufactured original Opana ER shut down at the end of 2011, Endo was forced to rush the launch reformulated Opana ER and the FDA ordered Endo to stop selling original Opana ER. (CX4017 (Levin, Dep. at 136-39, 155) (ñsupply chain crisisò altered Endoôs plans); RX-094.0003-04; RX-100.0001 (ñSeveral of [Endoôs] strategies envisioned [Endo] selling both [original and reformulated Opana ER] products at the same time. It was only upon [Endoôs] discussions with the FDA in February [2012] that they told [Endo] not to do this in order to avoid patient confusion.ò)). Professor Bazerman, one of Complaint Counselôs own experts, admits that the FDAôs actions shutting down Novartisô plant ñtook matters out of [Endoôs] hands.ò (Bazerman, Tr. 923-24).

distributed, the email also included the first term sheet for the DCA. (CX0320 (May 26,

Proposed Finding No. 1069 also ignores the record, which makes clear that while Mr. Mengler was the point of contact for negotiations, ñImpax had separate teams for each of the projects because one [DCA] was brand and one was generic [SLA].ò (Koch, Tr. 245-46). Impaxôs negotiating positions regarding and analysis of the DCA came from Michael Nestor, the President of Impaxôs Branded Division, and his team. (Mengler,

Finally, the fourth sentence of Proposed Finding No. 1070 is not supported by the cited testimony, in which Dr. Cobuzzi stated ñI wasnôt privy to all the reasons why we were doing it,ò but that he knew ñthey were being done together.ò (Cobuzzi, Tr. 2633). Dr. Cobuzzi said nothing about how the deals were being negotiated.

> 1071. The timing of the negotiation of the two agreements further supports the linkage between payments under the DCA and the January 2013 entry date in the SLA. Impax and Endo first discussed collaborating on a potential business opportunity in 2009, but they only discussed entering into a business development opportunity at the same time as discussing settlement of the patent litigation. (CX1301 at 110-112 (Endo Response to February 20, 2014 Civil Investigative Demands, Response No. 2, Attachment C) (showing discussions of ñpotential settlementò and ñpotential transaction involving Impax developmental productò occurring between September 1, 2009 and December 7, 2009); CX0310 at 003-004 (Impax Narrative Response to CID Specifications, Response No. 5 (showing two discussions in October 2009 relating to settlement of the Opana ER patent litigation and potential areas of mutual business interest)).

RESPONSE TO FINDING NO. 1071:

The first sentence of Complaint Counselôs Proposed Finding No. 1071 is not supported by any evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

The remainder of Complaint Counselôs Proposed Finding No. 1071 is inaccurate, inconsistent with record evidence, and unsupported by the evidence citjst ı evi و ind ذ n

potential settlement of the patent infringement litigation.ò Nor is there any record testimony suggesting that Impax and Endo discussed a Frova transaction as part of a potential settlement.

> 1072. These discussions halted simultaneously and there were no discussions on either agreement again until May 2010, approximately six months later. (CX0310 at 003-004 (Impax Narrative Response to CID Specifications, Response No. 5) (showing no discussions of potential settlement or potential transaction after December 2009 until May 2010); Koch, Tr. 242-43 (Impax had not talked to Endo about the DCA before entering into patent set

the DCA and SLA are in clear c

in contact with Penwest, now part of Endo, as early as 2006 regarding potential collaborations. (RX-296 (Email from L. Zhu to A. Baichwal re: Interested in Partnership Opportunities)).

> 1080. The relationship that did exist between Impax and Endo appeared to be negative. They were adversaries in a high stakes patent litigation. (JX-003 at 003 (¶ 9)). During settlement negotiations, Impax directly accused Endo of lying about its post-settlement plans. (CX4032 (Snowden, Dep. at 113-14)). Endo employees called Impax ñpiggyò and ñOinkpaxò due to the ñporcine nature of the requests thus farò while negotiating the DCA. (CX2534 at 001 (June 6, 2010 Levin/Cobuzzi email chain)).

RESPONSE TO FINDING NO. 1080:

The first sentence of Proposed Finding No. 1080 is not supported by any record evidence and violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Respondent has no specific response to the second, third, and fourth sentences of Proposed Finding No. 1080.

> 1081. The adversarial relationship between Impax and Endo would have made independently negotiating the DCA highly unlikely, unless the business transaction was linked to settlement discussions. (CX5001 at 021-22 (¶ 43) (Bazerman Report)).

RESPONSE TO FINDING NO. 1081:

Complaint Counselôs Proposed Finding No. 1081 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Proposed Finding No. 1081 is also contrary to the record. Impax and Endo communicated regarding a potential collaboration

well before any settlement discussions with Endo had begun. (*See* RX-234; CX2927-020; RX-393.0014). Impax had also been in contact with Penwest, now parm Į O

In fact, a $10 million upfront payment did not reappear until June 2, 2010, when Chris Mengler indicated that the proposal then on the table included a $10 million upfront payment as well as an option for Endo to purchase IPX-203, retain profits from 10 percent of all sales (not just those generated by non-neurologists), or retain 100 percent of profits from sales generated by non-neurologists, all with no license fee to Impax. (CX0406).

The third sentence of Complaint Counselôs Proposed Finding No. 1082 is vague and inconsistent with record evidence. It is unclear what constitutes a ñtypical case.ò But whatever Dr. Geltosky considers typical, he has never worked for Endo and has not had any contact with the individuals involved in the negotiation and review of the DCA. (Geltosky, Tr. 1129). Dr. Cobuzzi, Endoôs Senior Vice President of Corporate Development, testified that he did not view the payment terms of the DCA as unusual, and that he believed the terms mitigated Endoôs financial risk by capping its exposure at pre-determined payment amounts and requiring demonstrable progress before additional payments came due. (Cobuzzi, Tr. 2543). Moreover, Dr. Geltoskyôs report hardly mentions Impax at all, and he offers no opinions about Impaxôs practices, procedures, or intent. (*See generally* CX5003 (Geltosky Rep.); Geltosky, Tr. 1129 (noting Dr. Geltosky had not met or spoken to any Impax employees); Geltosky, Tr. 1183 (testifying that his criticisms do not apply ñto anything that Impax didò)). Dr. Geltosky, moreover, lacks any significant experience with net buyers similar to Endo, or with discovery-stage development candidates like IPX-203. (Geltosky, Tr. 1143, 1177).

Finally, Proposed Finding No. 1082 is inconsistent with the record to the extent it implies the ñfocus of the DCAò was ever IPX-066. As Ms. Snowden testified, ñEndo was interested in the Parkinsonôs space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasnôt interested in doing the deal on IPX-066. So

there wasnôt actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only inter

1084. Contemporaneous Endo and Impax documents explicitly link the DCA to protection of Opana ER revenues. A July 2010 Corporate Development Update prepared by Robert Cobuzzi, one of Endoôs primary negotiators of the DCA, stated that the ñImpax deal adds significant topline revenue for Opana.ò (CX1701 at 005 (July 2010 Endo Corporate Development Update)). The Impax deal for an early stage asset to treat Parkinsonôs disease can ñadd significant topline revenue for Opanaò a pain relief product, only because it is directly linked to Impaxôs willingness to accept the January 2013 entry date for oxymorphone ER. (CX1701 at 005 (July 2010 Endo Corporate Development Update)). In a 2010 budget update following the Endo settlement, Impax listed the $10 million it received under the DCA as [redacted] (CX2701 at 004 (2010 Budget Update And 2011 Budget Preview)).

RESPONSE TO FINDING NO. 1084:

The first sentence of Complaint Counselôs Proposed Finding No. 1084 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

The second and third sentences of the Proposed Finding should be disregarded as a mischaracterization of the document and improper speculation. Complaint Counsel cites no evidence for the naked assertion that the ñonlyò reason the language identified would appear in CX1701 is that the DCA was linked to the SLA. Complaint Counsel never asked Dr. Cobuzzi (or any other witness, for that matter) what he actually meant with these six words. (Cobuzzi, Tr. 2568-2574).

The third sentence of Proposed Finding No. 1084 is misleading, given that no witness has been able to speak to the meaning of the two words Complaint Counsel identifies (ñEndo settlementò). Art Koch, Impaxôs former CFO and the only witness Complaint Counsel asked about the meaning of this shorthand reference, did not recognize the document. Mr. Koch also testified that the document did not appear to be an accounting document, and that other aspects of the document were inconsistent with Impaxôs common budgeting practices. (CX4018 (Koch, Dep. at 148)).

2. At the time the DCA was entered into, early-stage Parkinson's disease treatments were not a focus of Endo's corporate strategy

1085. [redacted] (Cobuzzi, Tr. 2621 (*in camera*); Geltosky, Tr. 1092) (*in camera*)).

RESPONSE TO FINDING NO. 1085:

Respondent has no specific response.

1086. At the time of the DCA, Endoôs business was not focused on pursuing Parkinsonôs disease treatments. (*See* CCF ¶¶ 1087-1095).

RESPONSE TO FINDING NO. 1086:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1087. In 2010, Endo had a new CEO, whose primary areas of interest were urology, endocrinology, and oncology. (Cobuzzi, Tr. 2519). Endoôs business focused on those therapeutic areas, as well as pain, a long-standing area of interest. (CX1001 at 015-25 (Feb. 2010 Endo Corporate Development Update)).

RESPONSE TO FINDING NO. 1087:

Complaint Counselôs Proposed Finding No. 1087 is misleading and incomplete to the extent that it implies the identified areas of focus were Endoôs only areas of interest in 2010. Dr. Cobuzzi testified that, in 2010, Endo continued to be interested in ñcompatible markets for the pharmaceutical sales force to sell products.ò (Cobuzzi, Tr. 2518-19). At that time, Endo still had a pain medication sales force, and was therefore still interested in products that could be marketed to the same audience. (Cobuzzi, Tr. 2519). Dr. Cobuzzi further testified that Endo was specifically interested in Parkinsonôs disease products because they had ñpossible utility or

RESPONSE TO FINDING NO. 1091:

Complaint Counselôs Proposed Finding No. 1091 is misleading to the extent that it implies that ñ[g]eneric competition was viewed as undesirableò by Endo (rather than by L.E.K.). There is no indication that Endo adopted or agreed with the L.E.K. rationale described in the cited document. Elsewhere in this same document, by contrast, L.E.K. explicitly identifies Endo as the source of other bases for excluding drugs from the list of potential candidates. (CX1005-063 (ñEndo is not interested in ex-U.S. Pre-Reg./ Reg productsò)). Moreover, Dr. Robert Cobuzzi ð who actually works for Endo ð explained why generic competition did *not* make improved carbidopa-levodopa formulations like IPX-066 or IPX-203 less attractive to Endo. (Cobuzzi, Tr. 2634-37 (IPX-203 likely more effective than other treatments); Cobuzzi, Tr. 2622-23 (

)).

1092. Both IPX-066 and IPX-203 were Parkinsonôs disease treatments containing carbidopa and levodopa from Impax Laboratories. IPX-066 and IPX-203 both would have been excluded from consideration by Endo under the L.E.K. rational, because they would not meet the selection criteria. (Cobuzzi, Tr. 2579-80; CX1005 at 064 (May 2008 L.E.K Transaction Opportunities Update for Endo)).

RESPONSE TO FINDING NO. 1092:

Complaint Counselôs Proposed Finding No. 1092 is misleading to the extent it implies Endo ever adopted or implemented the L.E.K. recommendations or the rationale L.E.K. used for identifying investment candidates. No record evidence suggests as much.

1093. Prior to 2010, Endo considered a potential acquisition or deal regarding clinical stage Parkinsonôs disease treatments with an Italian company known as Newron, and also a Finnish company. (CX4016 (Cobuzzi, IHT at 109-110)). However,

[redacted]

[redacted]

RESPONSE TO FINDING NO. 1093:

Respondent has no specific response.

1094. Prior to 2010, Endo had limited experience with marketing a Parkinsonôs disease treatment. For a time, Endo marketed a generic immediate release version of the Parkinsonôs disease treatment, Sinemet. (CX3161 at 040 (Endo White Paper to FTC); CX1007 at 001 (May 25, 2010 Cobuzzi email); Cobuzzi, Tr. 2633). Endo discontinued sales of generic Sinemet IR by the time the DCA was negotiated. (Cobuzzi, Tr. 2524; CX1209 at 003 (Endoôs Final Opportunity Evaluation Worksheet for IPX-203) (Endo used to sell the IR formulation for Sinemet)).

RESPONSE TO FINDING NO. 1094:

Complaint Counselôs Proposed Finding No. 1094 is not supported by the cited evidence to the extent it attempts to suggest Endoôs experience marketing Parkinsonôs disease treatments was ñlimited.ò Complaint Counsel cites no evidence regarding the extent to which Endo marketed generic Sinemet, and thus has no basis to claim it was limited. And the Endo White Paper listed in the Proposed Finding is not admitted into evidence in this matter. (*See* JX-2). In any event, the actual evidence in the record is clear: ñthis is an area we know well as a company both in terms of past evaluati

RESPONSE TO FINDING NO. 1095:

Respondent has no specific response.

3.

RESPONSE TO FINDING NO. 1097:

Respondent has no specific response.

1098. IPX-203, the ultimate subject product of the DCA, did not fit Endoôs profile for a market-ready product that would provide near term revenues. IPX-203 was still conceptual, and Impax did not yet have a final formulation. (Nestor, Tr. 2945-46). (Cobuzzi, Tr. 2612 (*in camera*); CX1209 at 012 (Endoôs Final Opportunity Evaluation Worksheet for IPX-203)).

RESPONSE TO FINDING NO. 1098:

The first sentence of Complaint Counselôs Finding No. 1098 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). The Proposed Finding is also misleading and inconsistent with the documents cited to the extent that it refers to ñEndoôs profileò for market-ready products. The documents Complaint Counsel cites identify investment in such products as one of several corporate development goals, not a specific profile for every investment. (CX1002-005 (Mar. 2010 Endo Corporate Development & Strategy document stating that one of Endoôs business development goals was to complete in-license or acquisition transaction(s) for marketed/market-ready assets representing more than $100 million in net sales in 2010); CX1701-005 (July 2010 Endo Corporate Development Update); CX1001-009 (Feb. 2010 Endo Corporate Development Update)). Indeed, Dr. Cobuzzi testified that because Endo has ñno discovery pipeline ourselves in place,ò Endo must also enter ñvery early, very speculative agreementsò for promising drugs. (Cobuzzi, Tr. 2516).

4. Endo's desire to enter a deal on a product that it could promote alongside its marketed migraine drug, Frova, would not be satisfied by IPX-203

1099. Endo expressed interest in entering a deal with Impax on a product that its existing sales force could promote alongside Endoôs migraine treatment Frova. (CX3010 at 001-02 (May 2010 Cobuzzi email chain)).

RESPONSE TO FINDING NO. 1099:

Complaint Counselôs Proposed Finding No. 1099 is misleading and incomplete in its description of CX3010. In addition to expressing an interest in an Impax product Endo could promote alongside Frova, the document describes other strategic needs and notes that ñwe would consider other alternatives to get neurology assets that meet our needs, if not IPX066.ò (CX3010-002).

1100. [redacted] (Cobuzzi, Tr. 2611 (*in camera*); CX1208 at 003) (Opportunity Evaluation Worksheet for IPX-066)). When Frovaôs patent protection expired and generic competition entered, Endo likely would have stopped promoting Frova. (CX2607 at 021 (¶ 50) (Lortie Declaration) (ñIn essence, it is not cost effective to invest in promotion of a branded drug in the face of generic competition because the promotional effort benefits the generics more than the branded product.ò)).

RESPONSE TO FINDING NO. 1100:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 1100. The second sentence of Proposed Finding No. 1100 lacks foundation, is speculative, and is not supported by the documents cited. The sole document cited for this proposition ð a declaration by Brian Lortie discussing pharmaceutical marketing generally ð does not say anything about what Endo intended to do with respect to Frova.

1101. In 2010, IPX-066 was scheduled to enter the market in late 2012. (CX1208 at 007-08 (Opportunity Evaluation Worksheet for IPX-066)). Because IPX-066 would come to market while Endoôs sales force was still promoting Frova, IPX-066 could be detailed alongside Frova. (CX3010 at 001-02 (May 2010 Cobuzzi email chain) (ñIPX-066 . . . would be a great addition for a sales force that will still be selling Frova at a time when it comes to market. As, such, IPX-066 is my first choice for Endoò)).

opinions regarding the typical diligence timeline is his experience. (Geltosky, Tr. 1063, 1128, 1140). Yet Dr. Cobuzzi, who himself has over two decades of pharmaceutical industry experience, (CX4016 (Cobuzzi, IHT at 12-13)), testified that there is no typical, one-size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). Nor does Dr. Geltosky have any significant experience with pharmaceutical collaborations in which the net buyer ð i.e., the party performing the diligence ð is a small or mid-sized company. (Geltosky, Tr. 1141-43, 1171). Indeed, Dr. Geltosky testified that, as a consultant, his clients hire him for his knowledge of how big pharmaceutical companies approach collaborations. (Geltosky, Tr. 1180).

1106. Endoôs documents reflected a process for evaluating pharmaceutical development assets consistent with the industry standards. (CX2784 at 033, 034, 036, 038, 048 (Aug. 2009 Endo Business Development Process Orientation document)).

RESPONSE TO FINDING NO. 1106:

Complaint Counselôs Proposed Finding No. 1106 is inaccurate and unsupported by the cited evidence in its suggestion that multiple Endo documents reflect a particular process. The Proposed Finding cites a single document. Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are ñideal stateò procedures ñalmost neverò implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 2573).

1107. Endoôs documents explained that due diligence is a ñ[t]horough evaluation of all aspects of [an] asset.ò Due diligence should address the question of whether an asset can ñbe successfully developed, manufactured & commercialized for the stated indication.ò (CX2784 at 033 (Aug. 2009 Endo Business Development Process Orientation document)).

that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are ñideal stateò procedures ñalmost neverò implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 257

collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). He also explained that Endo regularly reviews potential agreements in ñvery, very short periods of time,ò and that he could not identify ñany instance where [Endo] followed the perfect sequenceò when conducting due diligence. (Cobuzzi, Tr. 2566, 2627). And Dr. Cobuzzi testified that Endo had sufficient time to assess IPX-203 before entering into the Development and Co-Promotion Agreement, particularly in light of Dr. Cobuzziôs and Endoôs familiarity with Parkinsonôs disease treatments and the detailed nature of the information Impax provided on IPX-066. (Cobuzzi, Tr. 2543, 2625).

1112. Dr. John Geltosky is an expert in pharmaceutical business development with over 35 years of experience. Dr. Geltosky holds a Ph.D. in biochemistry from the California Institute of Technology and has worked at numerous pharmaceutical companies, including Smithkline Beecham Pharmaceuticals, Bristol Myers Squibb, and Johnson and Johnson. As the Vice President and Director of Scientific Licensing at Smithkline Beecham Pharmaceuticals, Dr. Geltosky managed the identification of and technical due diligence for all in-licensed compounds. As the Vice President of External Science, Technology, and Licensing at Bristol Myers Squibb, Dr. Geltosky directed all evaluation activities for compounds in all stages of development. Since 2008, Dr. Geltosky has been the Managing Director of JEG and Associates Biotech and Pharmaceutical Development Consulting. At JEG, Dr. Geltosky has provided licensing and business advice to biotech firms, including strategic input on research, development, marketing, and negotiations with other pharmaceutical companies. (CX5003 at 003-004 (¶¶ 2-7) (Geltosky Report)). Over the course of his career, Dr. Geltosky has been involved in evaluating thousands of potential pharmaceutical development opportunities. (Geltosky, Tr. 1054-55).

RESPONSE TO FINDING NO. 1112:

Respondent has no specific response.

1113. In Dr. Geltoskyôs 35-plus years of experience in the industry, he has not been involved in a licensing, co-development, or co-promotion deal that has taken less than six months to negotiate and finalize. (CX5003 at 017 (¶ 27) (Geltosky Report); Geltosky, Tr. 1064 (stating that the deals he recalls seeing taking less than 12 months have been completed in 9 months)).

RESPONSE TO FINDING NO. 1113:

Respondent has no specific response other than to clarify that Dr. Geltoskyôs 35 years of experience do not include any significant experience with pharmaceutical collaborations in

which the net buyer was a small or mid-sized pharmaceutical company, or experience with more than a ñhandfulò of discovery-stage development deals. (Geltosky, Tr. 1141-45, 1177).

1114. After initial discussions in 2009, Impax and Endo resumed settlement discussions and negotiation of a potential business transaction on or around May 19, 2010. (CX1301 at 112 (Endo Response to Feb. 20, 2014 and Mar. 25, 2014 Civil Investigative Demands, Response No. 2, Attachment B)).

RESPONSE TO FINDING NO. 1114:

Respondent has no specific response.

1115. When Endo and Impax resumed negotiations in May of 2010, the parties were discussing a potential deal relating to IPX-066, Impaxôs Parkinsonôs disease treatment, which was in the Phase III stage of development. (CX0320 at 002 (May 26, 2010 Draft Term Sheet between Impax and Endo); Cobuzzi, Tr. 2583-84)).

RESPONSE TO FINDING NO. 1115:

Complaint Counselôs Proposed Finding No. 1115 is inaccurate and not supported by the documents cited. Dr. Cobuzzi testified that ñEndo was initially discussing a product called IPX-066ò ñwith respect to Impax.ò (Cobuzzi, Tr. 2583-84). Dr. Cobuzzi does not state that it ever discussed a potential deal regarding that product *with* Impax. And while Endo proposed a potential deal regarding the entire IPX-066 franchise in its initial draft term sheet, Impax immediately rejected the proposal. (CX0320; CX0502; CX1305). As Ms. Snowden testified, ñEndo was interested in the Parkinsonôs space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasnôt interested in doing the deal on IPX-066. So there wasnôt 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.ò (Snowden, Tr. 405-06).

1116. Phase III development is the last stage of pharmaceutical development before submitting an application to the FDA. (Nestor, Tr. at 3003; CX 5003 at 007-08 (¶ 15)

(Geltosky Report)). [redacted] (Nestor, Tr. at 2959 [redacted] (*in camera*)).

RESPONSE TO FINDING NO. 1116:

Respondent has no specific response.

1117. On or about May 27, 2010, Impax informed Endo that any development and co-promotion agreement negotiated between the parties would relate to Impaxôs Parkinsonôs disease treatment known as IPX-203, which was in the early stages of development. (CX1305 at 001 (Mengler email noting ñR&D Collaboration: for a product I will designate as 066a. This is our next generation of 066.ò); Nestor, Tr. 2945 (IPX-066a was the initial name for IPX-203)). [redacted] (Nestor, Tr. 2959 (*in camera*)).

RESPONSE TO FINDING NO. 1117:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 1117. The second sentence of Proposed Finding No. 1117 provides a misleading paraphrase of Mr. Nestorôs testimony. [redacted] (Nestor, Tr. 2959; RX-387 (Mr. Nestor explaining that risk associated with IPX-203 development in 2010 was simply ñpart of the processò)). Dr. Geltosky acknowledged that the risks associated with early-stage development candidates do not stop companies from collaborating on such candidates ñall the time,ò and that all stages of pharmaceutical development carry an inherent level of risk. (Geltosky, Tr. 1134).

1118. Despite the change in product, as of June 1, 2010, Dr. Cobuzzi, Endoôs Senior Vice President of Corporate Development, still believed that Endo and Impax were discussing a deal on IPX-066. (Cobuzzi, Tr. 2594).

RESPONSE TO FINDING NO. 1118:

Respondent has no specific response.

three-week period. (CX2784 at 050, 054 (August 2009 Endo Business Development Process Orientation document, stating it takes approximately ñ≤ 4 monthsò to reach a ñdiligence outputò and approximately ñ6 months-1 year from initial evaluation to deal close.ò)).

RESPONSE TO FINDING NO. 1121:

Complaint Counselôs Proposed Finding No. 1121 is inaccurate. D

(Cobuzzi, Tr. 2543). This is particularly true for discovery-stage development collaborations, with which Dr. Geltosky has virtually no experience. (Geltosky, Tr. 1144-45). Finally, the Proposed Finding is misleading to the extent it implies Endo spent insufficient time evaluating IPX-203 or the DCA. Dr. Cobuzzi testified that he had sufficient time to analyze the opportunity, particularly in light of the information regarding IPX-066 Endo received. (Cobuzzi, Tr. 2543, 2625; CX2748-001 (June 7, 2010 email from Robert Cobuzzi noting that the attached IPX-203 opportunity evaluation worksheet ñprovides adequate and fair representation of what I would define as a good deal for Endoò)). In fact, Endo had been assessing information that was ñtremendously helpfulò in evaluating IPX-203 and the DCA since May 2010. (Cobuzzi, Tr. 2525-26, 2602, 2625).

> 1123. Endo did in fact violate its own processes by evaluating, negotiating, and finalizing a development and co-promotion deal for Impaxôs early stage product, IPX-203, in three days. (CX2784 at 050, 054 (August 2009 Endo Business Development Process Orientation document, stating it takes approximately ñ≤ 4 monthsò to reach a ñdiligence outputò and approximately ñ6 months-1 year from initial evaluation to deal close.ò)).

RESPONSE TO FINDING NO. 1123:

Complaint Counselôs Proposed Finding No. 1123 is inaccurate and misleading to the extent it refers to procedures described in a single Endo document as Endoôs ñown processes.ò Complaint Counsel identifies no further evidence suggesting that this single document embodies procedures ever implemented or followed at Endo. To the contrary, Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are ñideal stateò procedures ñalmost neverò implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 2573).

Proposed Finding No. 1123 is also inaccurate to the extent that it describes Endo ñevaluating, negotiating, and finalizing a development and co-promotion deal for Impaxôs early

RESPONSE TO FINDING NO. 1125:

Complaint Counselôs Proposed Finding No. 1125 is misleading and unsupported by the cited documents to the extent that it characterizes the timing of Endoôs efforts as ñrushed.ò The cited documents indicate that Endo proceeded on a ñcondensed timelineò and that the efforts needed to be completed within a certain amount of time, but do not speak to whether or not Endo was ñrushed.ò In fact, Dr. Cobuzzi testified that Endo had sufficient time to assess IPX-203 before entering into the Development and Co-Promotion Agreement, particularly in light of Dr. Cobuzziôs and Endoôs familiarity with Parkinsonôs disease treatments and the detailed nature of the information Impax provided on IPX-066. (Cobuzzi, Tr. 2543, 2625).

1126. Similarly, when engaging the Equinox Group consulting firm to help with the valuation of the IPX-066 opportunity, Endoôs Director of Corporate Development, Sam Rasty, requested an abbreviated version of a full financial analysis. He described an ñurgent forecasting needò and noted that ñ[t]here is no time for market research on this as we need the forecast by Wed. of next week (thatôs right, ï p T M

RESPONSE TO FINDING NO. 1128:

Complaint Counselôs Proposed Finding No. 1128 is inconsistent with record evidence and based on unreliable expert testimony. Proposed Finding No. 1128 relies exclusively on the opinions of Dr. Geltosky, who acknowledges that the sole basis for his opinions regarding the typical diligence timeline is hi

RESPONSE TO FINDING NO.

wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasnôt interested in doing the deal on IPX-066. So there wasnôt 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.ò (Snowden, Tr. 405-06). Indeed, when Endo initially proposed a collaboration covering IPX-066 and ñall improvements, modifications, derivatives, formulations and line extensions thereof,ò which would have included IPX-203, Impax immediately rejected the proposal. (CX0502; CX0320). The President of Impaxôs branded drug division, Michael Neoxe " covld ha Ind b a te " tr Ø l ɔ y So, ȳ e exȝste' hfler N

(Geltosky, Tr. 1095 (*in camera*)).

RESPONSE TO FINDING NO. 1132:

Complaint Counselôs Proposed Finding No. 1132 is misleading in its suggestion of an industry standard. Dr. Cobuzzi testified that there is no typical, one-size-fits-all process for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). Moreover, the Proposed Finding relies exclusively on the opinions of Dr. Geltosky, who acknowledges that the sole basis for his opinions regarding the typical diligence timeline is his personal experience. (Geltosky, Tr. 1063, 1128, 1140). Yet Dr. Geltosky does not have any [illegible]

RESPONSE TO FINDING NO. 1135:

Respondent has no specific response.

1136. Technical due diligence is conducted by a team of experts representing all disciplines applied to the development of a pharmaceutical drug product: pharmacology, toxicology, process development, formulation development, manufacturing, and quality. It is a rigorous and careful examination of key study reports that the originator firm provides to the investing firm. In addition to providing these important documents, originator firms usually give detailed presentations of the drug development program. Intense Q&A between the originator firm and investing firm is often a part of this exercise. (CX5003 at 011-13 (¶ 20) (Geltosky Report)).

RESPONSE TO FINDING NO. 1136:

Complaint Counselôs Proposed Finding No. 1136 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Cobuzzi testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1137. For an early stage product, technical due diligence focuses on the ñpreclinical proof of conceptò for the drug candidate, which refers to data regarding the pharmacology, efficacy, and toxicity of the drug candidate. The preclinical proof of concept addresses whether the drug works as predicted in validated animal models and is acceptably safe. A firm evaluating a pharmaceutical development opportunity would also want to consider the feasibility of manufacturing the potential drug candidate as part of the technical due diligence. (CX5003 at 011-13 (¶ 20) (Geltosky Report)).

RESPONSE TO FINDING NO. 1137:

Complaint Counselôs Proposed Finding No. 1137 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr.

Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Cobuzzi testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1138. Similar to industry standards, Endoôs own business development process identified several areas for evaluation when conducting a technical due diligence of an asset, including pharmacology, toxicology, Chemistry, Manufacturing and Control (CMC), regulatory, manufacturing, analytical and packaging. (CX2784 at 034 (Aug. 2009 Endo Business Development Process Orientation document); CX5003 at 13 n.50 (definition of ñChemistry, Manufacturing, and Controlò)).

RESPONSE TO FINDING NO. 1138:

Complaint Counselôs Proposed Finding No. 1138 is inaccurate and unsupported by the cited evidence in its suggestion that Endo had a set ñdevelopment process.ò Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are ñideal stateò procedures ñalmost neverò implemented outside of large pharmaceutical companies. (Cobuzzi, Tr. 2626-27; 2573). He also testified that there is no typical, one-size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1139. During the due diligence process and before it signed the DCA, Endo obtained very little scientific information on the composition, pharmacokinetics, mechanism of action, and manufacture of IPX-203. (*See* CCF ¶¶ 1140-1167).

RESPONSE TO FINDING NO. 1139:

The proposed summary finding should be disregarded because it violates the Courtôs

individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1140. [redacted] (CX5003 at 009 (¶ 17) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1140:

Complaint Counselôs Proposed Finding No. 1140 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò

1141. [redacted] (CX1209 at 003 (Endoôs Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*); Nestor, Tr. 3004 (stating that the levodopa compound is approximately 50 years old); Cobuzzi, Tr. 2524 (original formulation of carbidopa and levodopa was a drug named Sinemet)).

RESPONSE TO FINDING NO. 1141:

Respondent has no specific response.

1142. [redacted] (CX1209 at 003 (Endoôs Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*)).

RESPONSE TO FINDING NO. 1142:

Respondent has no specific response.

1143. [redacted] (Geltosky, Tr. 1097 (*in camera*)). [redacted] (Geltosky, Tr. 1100-101 (*in camera*)).

RESPONSE TO FINDING NO. 1143:

Complaint Counselôs Proposed Finding No. 1143 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò

1144.

(Nestor, Tr. 3042 (*in camera*); Cobuzzi, Tr. 2532) (*in camera*)).

RESPONSE TO FCt

1153.

(CX3163 at 014 (¶ 60) (Impax Answer); Cobuzzi, Tr. 2613 (*in camera*); CX1209 at 007 (Endoôs Final Opportunity Evaluation Worksheet for IPX-203)). As of June 4, 2010, IPX-203 was in the beginning of the formulation stage. (Nestor, Tr. 3030-31).

RESPONSE TO FINDING NO. 1153:

Respondent has no specific response.

1154. Because IPX-203 was due to launch years after IPX-066 was already established on the market, a thorough scientific analysis of the potential deal with Impax would need to include an assessment of whether IPX-203 functioned better than IPX-066. (CX5003 at 027 (¶ 42) (Geltosky Report)).

RESPONSE TO FINDING NO. 1154:

Complaint Counselôs Proposed Finding No. 1154 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Cobuzzi testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). In the case of the DCA, Endo had sufficient information to analyze the opportunity and conclude that the deal was ñwhat I would define as a good deal for Endo.ò (CX2748-001; Cobuzzi, Tr. 2533-37, 2563 (Endo had adequate time and ñthe information we neededò to evaluate IPX-203)).

1155.-2̇ ĤP d̰ ∫̰ 0 -st X " X Ц Ґ ⱪM ъ ɹ ŕ

Geltoskyôs opinion with respect to how Medicare and third party payors purportedly would react to a particular drug is outside the scope of his tendered expertise in ñwhether the overall strategic fit, negotiation history, due diligence efforts, and terms of the development and co-promotion agreement between Endo and Impax are consistent with the usual and expected practice in the pharmaceutical industry.ò (Geltosky, Tr. 1058).

1158.

(CX5003 at 027-28 (¶ 42) (Geltosky Report) (*in camera*); CX4033 (Nestor, Dep. at 30) (ñ[T]he objective with IPX203 would be to offer even better symptom control for Parkinsonôs patients, which is critical for them, than Rytary . . . .ò).

RESPONSE TO FINDING NO. 1158:

Complaint Counselôs Proposed Finding No. 1158 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò The Proposed Finding is also inaccurate. That the objective of IPX-203 was to develop a better version of IPX-066! ľ Ů ă Ń ould be h P l D ’ Ɛ ɪ M ʌ я o ɱ ss Ȯ v þ ʁ e# þ’ ʌ ʁ l ƛ ɔ ʌ T M ҷ ʌ ɣ O ƥ MM þ m ʊ ɣ ɿ cy! ʻ ~ þ ʌ ʁ M l Ƀ M ξ ˛ ˗ Ó 9 ʻ ʻ § ʻ §

1159.

(Cobuzzi, Tr. 2635 (stating ñ[w]e had no empiric

[redacted] (Geltosky, Tr. 1092-93 (*in camera*); CX1209 at 006-07 (Endoôs Final Opportunity Evaluation Worksheet for IPX-203) (no discussion of Teva and Lundbeck study in scientific opportunity summary section of OEW)).

RESPONSE TO FINDING NO. 1160:

Complaint Counselôs Proposed Finding No. 1160 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò Proposed Finding No. 1160 is also improper and inadmissible. The Proposed Finding purports to summarize academic literature that is not in evidence and, if it were, that literature would be the best evidence of its contents. In any event, Dr. Geltosky acknowledged the purported study did not test the specific improvements Endo and Impax believed IPX-203 would achieve. (*See* CX3181-005 ([redacted]); Geltosky, Tr. 1194-1196 ([redacted]); Geltosky, Tr. 1117-18 ([redacted])).

1161. As of April of 2013, almost three years after signing and entering into the DCA, Impax had yet to complete a pharmacokinetic study for IPX-203. (Nestor, Tr. 3034).

RESPONSE TO FINDING NO. 1161:

Complaint Counselôs Proposed Finding No. 1161 is inaccurate, inconsistent with record evidence, and unsupported by the testimony cited. Impaxôs internal documents, specifically R&D presentations and detailed time entry records, reflect that Impax [redacted] and spent a substantial amount of

61; CX0310-026-27; RX-242 (reflecting pharmacokinetic study work on various formulations in 2011, 2012, and 2013); CX3166-039-42 ([redacted])).

Proposed Finding No. 1161 is also misleading in its description of the timeline for Impaxôs development work on IPX-203, because it ignores the fact that some work was temporarily 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 ñ[c]ouple yearsò); CX4033 (Nestor, Dep. at 135-36)). Bryan Reasons, Impaxôs current Chief Financial Officer, explained that when IPX-066 was delayed, ñresources 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.ò (Reasons, Tr. 1237-38).

1162. Since IPX-203 had not yet been formulated, Endo reviewed the clinical data on IPX-066 as a ñsurrogate.ò (CX1209 at 007 (Endoôs Final Opportunity Evaluation Worksheet for IPX-203) (ñAlthough IPX-203 has not yet been formulated . . . Endo has had the opportunity to review the clinical data on IPX-066 as a surrogate.ò)).

RESPONSE TO FINDING NO. 1162:

Complaint Counselôs Proposed Finding No. 1162 is misleading and incomplete in its description of the manner in which the Endo diligence team utilized IPX-066 clinical data when assessing IPX-203. Dr. Cobuzzi and his team used information about IPX-066 to supplement the research Endo had received describing the IPX-203 program and product concept. (Cobuzzi, Tr. 2533, 2625).

1163. [redacted]

(CX5003 at 027 (¶ 41)
(Geltosky Report); Geltosky, Tr. 1101 (*in camera*)).

RESPONSE TO FINDING NO. 1163:

Complaint Counselôs Proposed Finding No. 1163 is inconsistent with the record. Both Dr. Geltosky and Dr. Cobuzzi agree that the use of comparator or benchmark drugs in assessing pharmaceutical development candidates is commonplace. (Geltosky, Tr. 1155-56; Cobuzzi, Tr. 2624). Endo does this ñall the timeò and it makes the assessment ñmuch easier.ò (Cobuzzi, Tr. 2624-25). Dr. Geltosky acknowledged that information about IPX-066 would inform ñkey parametersò in an assessment of IPX-203 and the DCA, including the parameters of the project and the burdens associated with it. (Geltosky, Tr. 1153). Consistent with this, Dr. Cobuzzi and his team found information about IPX-066, including clinical information, ñtremendouslyò helpful in assessing IPX-203 and supplementing the research Endo had received describing the IPX-203 program and product concept. (Cobuzzi, Tr. 2533, 2625).

1164.
(Geltosky, Tr. 1101) (*in camera*)).

(Geltosky, Tr. 1101) (*in camera*)).

RESPONSE TO FINDING NO. 1164:

Complaint Counselôs Proposed Finding No. 1164 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò

1165. Outside of conducting the relevant testing on a specific formulation of IPX-203, there was no way for Endo to ∝ þ

RESPONSE TO FINDING NO. 1165:

Complaint Counselôs Proposed Finding No. 1165 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò

Proposed Finding No. 1165 is also misleading and inconsistent with the record. Endo knew ñthe underlying molecules, the carbidopa and levodopa, and we looked at a number of Parkinsonôs opportunities in the past, so we knew the general landscape of the area in which we

RESPONSE TO FINDING NO. 1167:

Respondent has no specific response.

1168. Endo recognized that it had insufficient information about the stability and feasibility of manufacture of IPX-203, prior to entering into the DCA. (CX1209 at 009) (Endoôs Final Opportunity Evaluation Worksheet for IPX-203) (ñ[B]ecause of the limited amount of information, potential issues around manufacturing and stability could not be fully determined . . . insufficient information has been prom˜ (Enien. i! nunim(° unt "

1169. [redacted] (CX5003 at 28 (¶ 43) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1169:

Complaint Counselôs Proposed Finding No. 1169 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò

b) Given the lack of technical information available about IPX-203, Endo did not appropriately account for the scientific risks associated with the DCA prior to agreeing to pay $10 million in upfront payments and potentially $30 million in additional milestone payments

1170. [redacted] (Nestor, Tr. 2959 (*in camera*); CX4033 (Nestor, Dep. at 95); Geltosky, Tr. 1092 (*in camera*), 1146-47)).

RESPONSE TO FINDING NO. 1170:

The first sentence to Complaint Counselôs Proposed Finding No. 1170 should be disregarded because it is not supported by any record evidence and violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). The second sentence of Proposed Finding No. 1170 is inaccurate and misleading because it incorrectly paraphrases Mr. Nestorôs testimony. Mr. Nestor explained that [redacted] (Nestor, Tr. 2959-60). Indeed, in a contemporaneous document, Mr. Nestor described the risk associated

with IPX-203ôs development as simply ñpart of the process.ò (RX-387). Dr. Geltosky similarly acknowledged that the risks associated with early-stage development candidates do not stop companies from collaborating on such products ñall the time,ò and that *all* stages of pharmaceutical development carry an inherent level of risk. (Geltosky, Tr. 1134).

> 1171. , a firm would not take for granted that an untested compound like IPX-203 would be superior to a known compound such as IPX-066. (CX5003 at 028 (¶ 43) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1171:

Complaint Counselôs Proposed Finding No. 1171 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò Proposed Finding No. 1171 is also inaccurate. Endo

universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky similarly has no basis for speculating about what Endo ñshould have doneò in its diligence of IPX-203 and the DCA. Dr. Geltosky has no expertise in ð and was not offered as an expert regarding ð Endoôs strategic business goals, Endoôs negotiation strategies, Endoôs finances, or Endoôs development pipeline, all of which affect what Endo ñshould doò when performing due diligence. Nor does Dr. Geltosky have experience with more than a few deals involving a net buyer similar to Endo in size and research and development capability. (Geltosky, Tr. 1143, 1177). Dr. Cobuzzi, an actual Endo employee, testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1173. The customary approach in the pharmaceutical industry to mitigate substantial uncertainty and risk is to provide payments commensurate with progress on the program. (CX5003 at 029 (¶ 45) (Geltosky Report)).

RESPONSE TO FINDING NO. 1173:

Complaint Counselôs Proposed Finding No. 1173 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177).

1174. Endo could have made a smaller upfront payment at signing, when risk was at its highest, and then offered more money if and when pharmacokinetic studies showed improved effectiveness of IPX-203. (CX5003 at 029 (¶ 45) (Geltosky Report); *see also* CX4016 (Cobuzzi, IHT at 69-70) (ñif you pay too much up front, you may never actually get to the point of realizing that value.ò)). [redacted] (Geltosky, Tr. at 1100 (*in camera*); (CX5003 at 029 (¶ 45) (Geltosky Report)).

RESPONSE TO FINDING NO. 1174:

Complaint Counselôs Proposed Finding No. 1174 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò Proposed Finding No. 1174 also lacks foundation and is not supported by the record. Dr. Geltosky was not tendered to offer opinions on possible alternative DCA structures Endo could have pursued. (*See* Geltosky, Tr. 1058). The alternative structure suggested in the Proposed Finding, moreover, was not viable for Impax, given its difficulty funding IPX-203; had Impax waited until later in development to receive funding, it likely would not have been able to pursue IPX-203 at all. (Nestor, Tr. 3052-53).

1175. Endo did not take any of these steps. Instead, Endo chose to enter the DCA with minimal scientific information about IPX-203 and without applying any risk mitigation strategies. (CX5003 at 029 (¶ 45) (Geltosky Report)).

RESPONSE TO FINDING NO. 1175:

Complaint Counselôs Proposed Finding No. 1175 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò Proposed Finding No. 1175 is also inaccurate. Dr. Cobuzzi, who was responsible for the overall evaluation of the IPX-203 opportunity, testified that Endo understood the risks associated with IPX-203, and that those were accounted for and mitigated in the DCA deal structure. (Cobuzzi, Tr. 2523, 2543; *see also* Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)).

c) Endo did not appropriately account for the regulatory risks

1176. Under industry standards, analysis of the regulatory risks is a key component of the due diligence process of evaluating a pharmaceutical development opportunity. Regulatory risks determine the likelihood and timing of FDA approval, timing of product launch, and the potential for any development costs. (CX5003 at 029-30 (¶ 46) (Geltosky Report)).

RESPONSE TO FINDING NO. 1176:

The first sentence of Complaint Counselôs Proposed Finding No. 1176 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage 76

1181.

(CX2780 at 024 (June 3, 2010 Impax IPX-203 presentation)
(*in camera*)).
(Geltosky, Tr. 1098 (*in camera*)).

(Geltosky, Tr. 1098 (*in camera*)); CX2780 at 058 (June 3, 2010 Impax IPX-203 presentation)
(*in camera*); CX3167 at 048 (Aug. 2010 Impax Brand R&D presentation)
(*in camera*)).

RESPONSE TO FINDING NO. 1181:

Respondent has no specific response to this proposed finding.

1182. To obtain NDA approval, the FDA ma

1185. Endo also noted potential [redacted] (CX1209 at 009 (Endoôs Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*)).

RESPONSE TO FINDING NO. 1185:

Respondent has no specific response.

1186. [redacted] (CX5003 at 035 (¶ 57) (Geltosky Report) (*in camera*)). Nor did Endo account for the possibility that IPX-203 would not receive NCE status. (CX4031 (Bradley, Dep. at 121-22)).

RESPONSE TO FINDING NO. 1186:

The first sentence of Complaint Counselôs Proposed Finding No. 1186 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs, which prohibits using ñexpert testimony to support factual propositions that should be established by fact witnesses or documents.ò The second sentence of Proposed Finding No. 1186 is not supported by the cited evidence. Mr. Bradley did not say anything about whether Endo did or did not account for the possibility IPX-203 would not receive NCE status.

d) Endo did not conduct a freedom to operate analysis or independent assessment of the intellectual property covering IPX-203

1187. A comprehensive patent review, including a freedom to operate analysis (ñFTOò) and an assessment of the strength of the patents covering the product in question, is normally conducted as part of the due diligence evaluation of a pharmaceutical product development opportunity. (CX5003 at 031 (¶¶ 49, 50) (Geltosky Report)). A freedom to operate analysis is an assessment of whether a firm may make, use or sell the product with the freedom from being sued for patent infringement. (Hoxie, Tr. 2712; Figg, Tr. 1936; Geltosky, Tr. 1080).

RESPONSE TO FINDING NO. 1187:

The first sentence of Complaint Counselôs Proposed Finding No. 1187 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with

patent exclusivity and extensionò are ñ[o]ther [c]ritical [o]utputs [e]xpected [f]rom [d]iligenceò)).

RESPONSE TO FINDING NO. 1189:

Complaint Counselôs Proposed Finding No. 1189 is incomplete. The cited document (CX1209) states that

(CX1209-013-14 (instructions state ñSummarize the IP statusò)).

1190. Endo also failed to independently conduct an assessment of the strength of the patents covering the product to determine how long those patent

Cobuzzi, an actual Endo employee, testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

e) Endo's rushed financial analysis did not provide an accurate valuation of the deal

1191.

expert on this topic. (*See* Geltosky, Tr. 1058). Dr. Geltosky has never personally performed a financial analysis, (Geltosky, Tr. 1146, 1179-80), nor does he hold any degrees in finance, accounting, or business, (Geltosky, Tr. 1149). Moreover, Dr. Geltosky admitted that there are numerous approaches to performing financial valuation analyses. (Geltosky, Tr. 1149; CX4042 (Geltosky, Dep. at 135-36)).

1194. NPV and IRR values are used heavily in the pharmaceutical industry to make investment decisions. (CX5003 at 015 (¶ 24) (Geltosky Report); Geltosky, Tr. 1082). It is critical to have high quality and carefully vetted numbers to enter into the analysis. (CX5003 at 015 (¶ 24) (Geltosky Report); CX4031 (Bradley, Dep. at 53-54) (stating that that if the assumptions that went into the valuation were not accurate, ñgarbage in, garbage out, right?ò)).

RESPONSE TO FINDING NO. 1194:

Respondent has no specific response.

1195. Firms rely on a number of assumptions and adjustments to prepare realistic NPV and IRR values. (CX5003 at 015 (¶ 24) (Geltosky Report). A thorough financial analysis would include sensitivity analyses and probability adjustments to account for the uncertainties and risks associated with the transaction. (CX5003 at 015 (¶ 24) (Geltosky Report)).

RESPONSE TO FINDING NO. 1195:

Complaint Counselôs Proposed Finding No. 1195 is based on improper and unreliable expert opinion. Dr. Geltosky has no expertise in financial analyses, nor was he tendered as an expert on this topic. (*See* Geltosky, Tr. 1058). Dr. Geltosky has never personally performed a financial analysis, (Geltosky, Tr. 1146, 1179-80), nor does he hold any degrees in finance, accounting, or business, (Geltosky, Tr. 1149). Moreover, Dr. Geltosky admitted that there are numerous approaches to calculating a risk-adjusted internal rate of return, calculating a net present value, and performing financial valuation analyses. (Geltosky, Tr. 1149; CX4042 (Geltosky, Dep. at 135-36) (discussing various approaches for conducting financial analysis of a

pharmaceutical collaboration)). Endo, for its part, would only ñsometimesò conduct sensitivity analyses. (CX4031 (Bradley, Dep. at 38, 41)).

> 1196. A firm will conduct sensitivity analyses of a pharmaceutical asset by considering multiple scenarios involving clinical parameters, such as number of pills for dosing and onset and duration of action. (CX5003 at 015 (¶ 24) (Geltosky Report)). These variables can then be weighted to ltr , wou

RESPONSE TO FINDING NO. 1197:

Complaint Counselôs Proposed Finding No. 1197 is based on improper and unreliable expert opinion. Dr. Geltosky has no expertise in financial analyses, nor was he tendered as an expert on this topic. (*See* Geltosky, Tr. 1058). Dr. Geltosky has never personally performed a financial analysis, (Geltosky, Tr. 1146, 1179-80), nor does he hold any degrees in finance, accounting, or business, (Geltosky, Tr. 1149). Moreover, Dr. Geltosky admitted that there are numerous approaches to calculating a risk-adjusted internal rate of return, calculating a net present value, and performing financial valuation analyses. (Geltosky, Tr. 1149; CX4042 (Geltosky, Dep. at 135-36) (discussing various approaches for conducting financial analysis of a pharmaceutical collaboration)). Finally, Proposed Finding No. 1197 is misleading in its selective quotation of Mr. Cobuzzi, who actually testified,

(Cobuzzi, Tr. 2620 (emphasis added)).

> 1198. Similar to industry standards, Endoôs own business development processes recognized the importance of conducting a financial analysis of a pharmaceutical product development opportunity. Endo stated that ñ[c]ritical [o]utputs [e]xpected Į ж Î rir Î

also Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)). Moreover, Endo did perform valuation analyses and concluded that they were an ñadequate and fair representation of what I would define as a good deal for Endo.ò (CX2748-001 (June 7, 2010 email from Robert Cobuzzi to Endo management); *see* Cobuzzi, Tr. 2563 (Endo had adequate time and ñthe information we neededò to evaluate IPX-203)).

1200. In May of 2010, when the parties were still discussing IPX-066 as a potential product for a development deal, Endo engaged a consulting firm, the Equinox Group, to provide an abbreviated market analysis. (CX1009 at 005 (May 21, 2010 Rasty/Equinox Group email); Cobuzzi, Tr. 2587 (ñ[W]e didnôt even ask for a fully vetted sales forecast.ò)).

RESPONSE TO FINDING NO. 1200:

Complaint Counselôs Proposed Finding No. 1200 is inaccurate to the extent it suggests the parties were ñdiscussing IPX-066 as a potential product for a development deal.ò As Ms. Snowden testified, ñEndo was interested in the Parkinsonôs space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasnôt

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1201. Using assumptions from the Equinox analysis, Endo prepared a discounted cash flow and determined NPV values and IRR values for a deal on IPX-066. (CX4031 (Bradley, Dep. at 25, 62, 64, 86-87, 97, 161); CX5003 at 032 (¶ 52) (Geltosky Report)).

RESPONSE TO FINDING NO. 1201:

Respondent has no specific response.

1202. When Impax changed the focus of the DCA from IPX-066 to IPX-203, Endo did not ask Equinox to provide a new market analysis. (Cobuzzi, Tr. 2587-88).

RESPONSE TO FINDING NO. 1202:

Complaint Counselôs Proposed Finding No. 1202 is inaccurate to the extent it suggests the parties were ñdiscussing IPX-066 as a potential product for a development deal.ò As Ms. Snowden testified, ñEndo was interested in the Parkinsonôs space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasnôt interested in doing the deal on IPX-066. So there wasnôt 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.ò (Snowden, Tr. 405-06). When Endo proposed a collaboration covering IPX-066 and ñall improvements, modifications, derivatives, formulations and line extensions thereof,ò which would have included IPX-203, Impax immediately rejected the

RESPONSE TO FINDING NO. 1205:

(Geltosky, Tr. at 1090 (*in camera*); CX5003 at 033-34 (¶ 54) (Geltosky Report) (*in camera*)).

(Geltosky, Tr. at 1089-90 (*in camera*)).

(CX4031 (Bradley, Dep. at 116-17); Geltosky, Tr. at 1090 (*in camera*)).

RESPONSE TO FINDING NO. 1207:

Complaint Counselôs Proposed Finding No. 1207 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side

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(*Compare* CX1208 at 014 (Endoôs Opportunity Evaluation Worksheet for IPX-066) to CX1209 at 016 (Endoôs Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*); Geltosky, Tr. 1091 (*in camera*).

(CX2780 at 023 (Impax Powerpoint presentation on IPX-203 (*in camera*)).

(CX5003 at 034 (¶ 54) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1210:

Complaint Counselôs Proposed Finding No. 1210 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Proposed Finding No. 1210 is also speculative, lacks foundation, and is inaccurate. Both Endo and Impax appropriately looked to assumptions about IPX-066 when

witness for facts.ò)). Proposed Finding No. 1211 is also inaccurate. Dr. Cobuzzi, who was responsible for the overall evaluation of the IPX-203 opportunity, testified that Endo did understand the risks associated with IPX-203, and that those risks were accounted for and mitigated in the DCA deal structure. (Cobuzzi, Tr. 2523, 2543; *see also* Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)). And Endo did perform valuation analyses, which Dr. Cobuzzi concluded were an ñadequate and fair representation of what I would define as a good deal for Endo.ò (CX2748-001 (June 7, 2010 email from Robert Cobuzzi to Endo management); *see* Cobuzzi, Tr. 2563 (Endo had adequate time and ñthe information we neededò to evaluate IPX-203)).

1212. Similar to the standard practice in the industry, Mr. Bradley, stated that when performing valuations of other D O _H @P € @ ð O 1Í\ H G L O p € ` p P À ð° k TPP € • `

[redacted] (CX5003 at 035 (¶ 57) (Geltosky Report) (*in camera*)). Although an earlier valuation of IPX-066 included a sensitivity analysis around the discount rate and terminal growth rate to assess the risk that revenues might be lower than anticipated, Mr. Bradley did not include any sensitivity analysis in his final valuation of IPX-203. (CX4031 (Bradley, Dep. at 86-89, 157-58)).

RESPONSE TO FINDING NO. 1213:

The first sentence of Complaint Counselôs Proposed Finding No. 1213 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 1213 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)).

The third sentence of Proposed Finding No. 1213 is inaccurate and misleading in its attempt to suggest that Endo did not account for risk when assessing the DCA. Mr. Bradley testified that there are ñ[v]arious waysò one can attempt to account for that uncertainty and that he would only ñsometimesò conducts sensitivity analyses. (CX4031 (Bradley, Dep. at 38, 41); *see* Cobuzzi, Tr. 2620 ([redacted])). Dr. Cobuzzi, who was responsible for the overall evaluation of the IPX-203 opportunity, testified that Endo did understand the risks associated with IPX-203, and that those risks were accounted for in the DCA deal structure. (Cobuzzi, Tr. 2523, 2543; *see also* Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)).

1214. The only variable that Endo considered in its financial analysis of IPX-203 was the length of exclusivity that IPX-203 would enjoy: seven years of exclusivity as the base case; five years of exclusivity in the conservative case; and thirteen years in the

testified only that he may not have included all risks in one aspect of Endoôs valuation modelling. But Dr. Cobuzzi testified

uncertainties and risks associated with the early stage IPX-203 opportunity. Using these analyses would help to develop probability adjusted NPV an IRR values to accurately reflect the significant risks

1179-80). Dr. Geltosky consequently has no basis to opine about the accuracy of Endoôs valuation analyses, and his opinions are pure speculation. By contrast, Endo did perform valuation analyses and concluded that they were an ñadequate and fair representation of what I would define as a good deal for Endo.ò (CX2748-001 (June 7, 2010 email from Robert Cobuzzi to Endo management); *see* Cobuzzi, Tr. 2563 (Endo had adequate time and ñthe information we neededò to evaluate IPX-203)).

7. In light of the high risks and uncertainty associated with an early development stage product like IPX-203, the terms of the DCA are not consistent with the usual and expected practice in the industry

1219. Given the high risks and uncertainties associated with an early stage development product such as IPX-203, the terms of the DCA are not consistent with industry standards. (CX5003 at 042 (¶ 71) (Geltosky Report)). The $10 million in upfront payments by Endo to Impax is unusually large and the contingency milestones decrease as development progresses. (*See* CCF ¶¶ 1220-1228**;** CX5003 at 042 (¶ 71) (Geltosky Report)). Some deal terms are ambiguous and do not precisely state the partiesô rights. (*See* CCF ¶¶ 1229-1232**;** CX5003 at 042 (¶ 71) (Geltosky Report)). Other terms heavily favor Impax and leave Endo with little opportunity for input despite making a $10 million investment in the project. (*See* CCF ¶¶1233-1245**;** CX5003 at 042 (¶ 71) (Geltosky Report)).

RESPONSE TO FINDING NO. 1219:

Complaint Counselôs Proposed Finding No. 1219 is inaccurate. Dr. Cobuzzi, Endoôs 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, and that he did not view the payment as unusual, particularly in light of the profit-sharing rights Endo received in return. (Cobuzzi, Tr. 2543, 2559, 2564). The DCA, moreover, is a bundle of rights and burdens. Endo believed several terms were favorable to it and mitigated its risks, including that Endo received profit-sharing rights, did not have to perform any development work, was required to contribute a capped, pre-determined amount to Impaxôs development work, and was only obligated to pay anything beyond the initial payment

performed additional development work on IPX-203 to seek a partner, Impax likely would not have been able to fund the development of IPX-203)).

Dr. Geltosky did not conduct any valuation analysis of the DCA or estimate the net present value of the DCA at the time it was executed. (Geltosky, Tr. 1125). And he did not address whether Endoôs profit-sharing rights justified its DCA payment obligations. (Geltosky, Tr. 1124). Endoôs diligence team, by comparison, concluded that IPX-203 would be a ñgreater improvement in disease control and ease of use relative toò other drugs. (RX-080.0011). It also determined that the DCA and IPX-203 had a ñgoodò and ñvery reasonable rate of returnò [redacted] (Cobuzzi, Tr. 2560). [redacted] (Cobuzzi, Tr. 2536-37). For this reason, Endo viewed the DCA payment obligations as justified. (Cobuzzi, Tr. 2564).

> 1221. Endoôs $10 million upfront payment to Impax represented 25% of the dealôs $40 million precommercialization milestones, a very high percentage for an early stage molecule. (Geltosky, Tr. 1073). Based on Dr. Geltoskyôs 35 plus years of experience in the pharmaceutical industry, he would expect to see upfront payments reflecting 5% to 10% of the total deal value for an early stage compound like IPX-203. (Geltosky, Tr. 1073).

RESPONSE TO FINDING NO. 1221:

Complaint Counselôs Proposed Finding No. 1221 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky points to the risk associated with discovery-stage development as the primary reason he believes the DCA payment structure was unusual. (Geltosky, Tr. 1073). But Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr. Geltosky did not compare the DCA with any other discovery-stage development

But Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr. Geltosky did not compare the DCA with any other discovery-stage development agreements, or quantify any purported risk. (Geltosky, Tr. 1140-41, 1147). Moreover, Dr. Geltoskyôs report hardly mentions Impax at all, and he offers no opinions about Impaxôs practices, procedures, or intent. (*See generally* CX5003 (Geltosky Rep.); Geltosky, Tr. 1129 (noting Dr. Geltosky had not met or spoken to any Impax employees); Geltosky, Tr. 1183 (testifying that his criticisms do not apply ñto anything that Impax didò)). The Proposed Finding is also inconsistent with Dr. Cobuzziôs testimony that Endoôs $10 million payment was not usual or an ñuncharacteristically large amount of money.ò (Cobuzzi, Tr. 2543-44).

> 1224. Typically, firms looking to acquire an early stage asset would much prefer to ñbackloadò payments because of the unpredictability inherent in an early stage program. (CX5003 at 043-44 (¶ 74) (Geltosky Report); (Geltosky, Tr. 1075-76). Contingency milestone payments are a way for firms in the pharmaceutical industry to achieve this goal. (CX5003 at 043-44 (¶ 74) (Geltosky Report). Contingency milestone payments assure that payments are tied to achieving tangible and identifiable goals on the project. (CX5003 at 043-44 (¶ 74) (Geltosky Report); Geltosky, Tr. 1074).
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> **RESPONSE TO FINDING NO. 1224:**

Complaint Counselôs Proposed Finding No. 1224 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147). By contrast, Endo regularly enters ñvery early, very speculative agreementsò for promising drugs. (Cobuzzi, Tr. 2516). Dr.

Cobuzzi testified that Endoôs $10 million payment was not usual or an ñuncharacteristically large amount of money.ò (Cobuzzi, Tr. 2543-44). And Endo viewed the DCA payment structure as mitigating the risks associated with IPX-203ôs early stage of development, with Impax bearing most of the risk. (CX1209-003 ([redacted] (emphasis added)); Cobuzzi, Tr. 2543-44).

1225. Contingency milestone payments typically increase as development of the product proceeds. (CX5003 at 045 (¶ 76) (Geltosky Report); Geltosky, Tr. 1074-75). Increasing contingent payments reflects the idea that every step forward in development reduces the overall risk and therefore creates value, which is reflected in the magnitude of the milestone. (CX5003 at 045 (¶ 76) (Geltosky Report); Geltosky, Tr. 1072 (ñ[T]he milestone payments actually, in every agreement that Iôve ever seen, increase as risk is taken out of the program. Value is created. The originator then is sort of rewarded with a larger milestone payment reflecting that increased value by taking risk out.ò)).

RESPONSE TO FINDING NO. 1225:

Complaint Counselôs Proposed Finding No. 1225 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147). By contrast, Endo regularly enters ñvery early, very speculative agreementsò for promising drugs. (Cobuzzi, Tr. 2516). And Endo viewed the DCA payment structure as mitigating the risks associated with IPX-203ôs early stage of development, with Impax bearing most of the risk. (CX1209-003 ([redacted] (emphasis added)); Cobuzzi, Tr. 2543-44).

1226. The DCA contained up to $30 million in milestone payments contingent upon the development and forecasted sales of IPX-203. (RX-365 at 0009 (DCA, §§3.2, 3.3 (ñMilestone Fees,ò ñForecast Net Salesò)). But, the magnitude of the development contingent milestone payments in the DCA decreased as IPX-203 moved closer to FDA approval: $10 million for successful completion of Phase II, $5 million for successful completion of Phase III, $2.5 million for NDA acceptance, $2.5 million for FDA approval. (RX-365 at 0009 (DCA, §3.2 (ñMilestone Feesò). Structuring the contingency milestone payments in the DCA to decrease as development of IPX-203 progresses is unusual and does not reflect industry standards. (CX5003 at 045 (¶ 77) (Geltosky Report)).

RESPONSE TO FINDING NO. 1226:

Respondent has no specific response to the first and second sentences of Complaint Counselôs Proposed Finding No. 1226. The third sentence of Proposed Finding No. 1226 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147). By contrast, Endo regularly enters ñvery early, very speculative agreementsò for promising drugs. (Cobuzzi, Tr. 2516). And Endo viewed the DCA payment structure as mitigating the risks associated with IPX-203ôs early stage of development, with Impax bearing most of the risk. (CX1209-003 ([redacted] (emphasis added)); Cobuzzi, Tr. 2543-44).

1227. Firms frequently mitigate the risks inherent in a particular transaction by structuring the deal as an option agreement. (CX5003 at 044 (¶ 75) (Geltosky Report); Geltosky, Tr. 1076 (stating that option agreements are ña great risk mitigator. Youôre not putting a lot of money at risk until you see something that convinces you it has a higher probability of successò)). An exclusive option agreement is one where the potential licensee or partner usually pays the other party a nominal sum to hold the asset (not shop it to other potential acquirers) for a given period of time while the licensee decides on

products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147).

The record, moreover, reflects that the DCA joint development committee meetings were intended to be ñ[e]ssentially a progress report on clinical development by Impax.ò (CX3345-006). Michael Nestor, the president of Impaxôs brand division, testified that

1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147).

> 1235. The DCA also does not expressly state whether Endo has the right to co-promote IPX-203 if the sales forecast is less than $175 million or how much time after receiving the forecast Endo would have to decide whether to co-promote IPX-203. (CX5003 at 47 (¶ 81) (Geltosky Report); RX-365 at 0009 (DCA §3.3 (ñForecast Net Salesò))). The DCA does not contain any language addressing Endoôs right to appeal the forecast. (CX5003 at 047 (¶ 81) (Geltosky Report); RX-365 at 0009 (DCA §3.3 (ñForecast Net Salesò))). The sales forecast term disfavors Endo because it gives very little time to prepare to promote IPX-203. (CX5003 at 047 (¶ 81) (Geltosky Report)). Considerable time is required to prepare marketing materials for

remainder of Complaint Counselôs Proposed Finding No. 1237 is incomplete, inaccurate, and misleading. Mr. Nestor testified that Impax expected IPX-203 to offer a real and significant clinical improvement compared to IPX-066. (Nestor, Tr. 2938-39 (ñSo we envision IPX-203 being a better product, a much better product than not only immediate-release carbidopa-levodopa but also Rytaryò)). For that reason, Impax planned to limit the ability of IPX-066 to compete with IPX-203 by ñpulling all promotion, all sampling from Rytaryò and ñdevot[ing] all of our sales force attention, all of our marketing attention, all of our sampling attention to IPX-203, to build the demand for IPX-203 *and allow Rytary to have its natural decline*.ò (Nestor, Tr. 2937 (emphasis added)). Mr. Nestor explained IPX-203ôs commercial success was ñvery important in terms of ensuring that [Impaxôs brand division] had a longer term business foundation established.ò (Nestor, Tr. 2939; *see* Cobuzzi, Tr. 2536-37, 2622-23 ([redacted])).

1238. The DCA limited Impax to promoting IPX-203 to neurologists. (RX-365 at 0005 (DCA § 1) (definition of ñImpax Audienceò)). However, there was no apparent restriction on Impaxôs ability to promote IPX-066 to Endoôs target audience (non-neurologists). (RX-365 at 0023 (DCA § 12.1 (ñNoncompeteò))). In the event that issues over supply, distribution, or pricing of IPX-203 arise, Impax could have favored its own wholly-owned product, IPX-066. (CX5003 at 048 (¶ 82) (Geltosky Report)).

RESPONSE TO FINDING NO. 1238:

Respondent has no specific response to the first sentence of Proposed Finding No. 1238. The second sentence of Proposed Finding No. 1238 is an improper legal conclusion, not a fact. The third sentence of Proposed Finding No. 1238 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò The third sentence also ignores the record, which is clear that Impax planned to limit the ability of IPX-066 to compete with IPX-203 by ñpulling all promotion, all sampling from Rytaryò and ñdevot[ing] all of our sales force

attention, all of our marketing attention, all of our sampling attention to IPX-203, to build the demand for IPX-203 *and allow Rytary to have its natural decline*.ò (Nestor, Tr. 2937 (emphasis added)). Mr. Nestor explained IPX-203ôs commercial success was ñvery important in terms of ensuring that [Impaxôs brand division] had a longer term business foundation established.ò (Nestor, Tr. 2939; *see* Cobuzzi, Tr. 2536-37, 2622-23 ([redacted])).

> 1239. Under the DCA, Impax held control over all aspects of the development and commercialization of IPX-203. (RX-365 at 0002 (DCA, ñRecitalsò) (ñImpax has the exclusive right to develop, market, promote and sell the Productò). Acceding this degree of control to Impax, without any other obligations to develop IPX-203, put Endo at a competitive disadvantage. (CX5003 at 048 (¶ 82) (Geltosky Report)).

RESPONSE TO FINDING NO. 1239:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 1239. The second sentence of Proposed Finding No. 1239 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò Proposed Finding No. 1239 is also based on improper expert opinion. Dr. Geltosky has no expertise in contract interpretation, nor has he been tendered to offer opinions regarding the interpretation of pharmaceutical agreement terms generally or the DCAôs terms specifically. (*See* Geltosky, Tr. 1058). Finally, Proposed Finding No. 1239 ignores the record, which reflects that it has long been Impaxôs ñstrategy to continue to grow and extend the duration of our Parkinsonôs franchise.ò (Reasons, Tr. 1238 (noting also that IPX-203 is Impaxôs ñlead compound on the brand sideò); *see* Nestor, Tr. 2935-37 (Impax long planned to withdraw promotion and sampling of IPX-066 once IPX-203 reached the market to ensure Impaxôs sales force could focus on IPX-203 and extend Impaxôs Parkinsonôs franchise)).

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individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

a) Impax and Endo did not appear interested in moving quickly to develop IPX-203

1247. In stark contrast to the timeline of deal negotiations, the parties did not appear interested in moving quickly to develop IPX-203. Impax was slow to conduct the necessary studies to develop IPX-203 and the parties never established a Joint Development Committee as required by the DCA. (*See* CCF ¶¶ 1248-1255).

RESPONSE TO FINDING NO. 1247:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1248. [redacted] (CX2928 at 011; (Impax Response to Interrogatory No. 17) (*in camera*)). [redacted] (CX2928 at 011 (Impax Response to Interrogatory No. 17) (*in camera*)). [redacted] (CX2928 at 011 (Impax Response to Interrogatory No. 17) (*in camera*)).

RESPONSE TO FINDING NO. 1248:

Respondent has no specific response.

1249. [redacted] (Geltosky, Tr. 1103 (*in camera*)).

RESPONSE TO FINDING NO. 1249:

Complaint Counselôs Proposed Finding No. 1249 is misleading and based on unreliable expert opinion. Dr. Geltoskyôs ñ35 plus years of experienceò involve only a ñhandfulò of deals related to discovery-stage development assets. (Geltosky, Tr. 1144-45). Dr. Geltosky also has very little experience with deals in which the net buyer is a mid-sized pharmaceutical company like Endo, as opposed to a big pharmaceutical company like Bristol-Meyers Squibb or SmithKline Beecham. (Geltosky, Tr. 1141, 1143, 1177). Indeed, Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). By contrast, Endo regularly enters ñvery early, very speculative agreementsò for promising drugs. (Cobuzzi, Tr. 2516).

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

1250. When the DCA was signed in June of 2010, IPX-203 was in the ñfeasibility studyò phase of development. (Nestor, Tr. 3034). The feasibility study phase refers to a phase of development that is prior to locking in a final formulation of the drug product. (Nestor, Tr. 3033).

RESPONSE TO FINDING NO. 1250:

Respondent has no specific response.

1251. Pharmacokinetic studies are part of the feasibility study phase of development. (Nestor, Tr. 3034). [redacted] (CX3167 at 048 (Aug. 2010 Impax Brand R&D presentation) (*in camera*)). However, as of April 2013, nearly three years after entering into the DCA, Impax had still not conducted a pharmacokinetic study of IPX-203, and the product was still in the feasibility study phase of development. (Nestor, Tr. 3034).

RESPONSE TO FINDING NO. 1251:

Respondent has no specific res

not that it had never completed one. (Nestor, Tr. 3034). In this respect, the Proposed Finding misunderstands the role of pharmacokinetic studies in pharmaceutical development generally, and the development work on IPX-203 specifically.

(Nestor, Tr. 2962-61; CX0310-026-27; RX-242 (reflecting pharmacokinetic study work on various formulations in 2011, 2012, and 2013); CX3166-039-42 (

)).

The third sentence of Proposed Finding No. 1251 is also misleading in its description of the timeline for Impaxôs development work on IPX-203, because it ignores the fact that some work was temporarily 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 ñ[c]ouple yearsò); CX4033 (Nestor, Dep. at 135-36)). Bryan Reasons, Impaxôs current Chief Financial Officer, explained that when IPX-066 was delayed, ñresources were put to focus on the approval of Rytary [IPX-066] so that we coulteslMiva]i ɜ m

experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a ñhandfulò of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of small or mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1141, 1143, 1177).

b) Despite having already paid Impax $10 million upfront, Endo terminated the agreement in 2015 when Impax attempted to modify the DCA

1256. [redacted] (CX3166 at 038 (Jan. 2013 Impax Pharmaceutical R&D presentation) (*in camera*)).

RESPONSE TO FINDING NO. 1256:

Respondent has no specific response.

1257. [redacted] (CX2928 at 012) (Impax Response to Interrogatory No. 18) (*in camera*)). A target product profile categorizes key performance parameters of a drug, such as effectiveness, safety, dosage and stability. (CX5003 at 037 (¶ 61) (Geltosky Report). [redacted] (Nestor, Tr. 2960-61 (*in camera*)).

RESPONSE TO FINDING NO. 1257:

Respondent has no specific response.

1258. Eventually, Impax discontinued the levodopa-ester/carbidopa program because it did not meet the target product profile to be categorized as a competitive product. (CX2747 at 001 (Oct. 29, 2014 Macpherson/Ailinger email)).

RESPONSE TO FINDING NO. 1258:

Complaint Counselôs Proposed Finding No. 1258 is inaccurate and misleading in its suggestion that Impax had a ñlevodopa-ester/carbidopa programò or that IPX-203 was discontinued. [redacted]

(Nestor, Tr. 2962 (

); Nestor, Tr. 2935

(ñIPX-203, 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.ò)).

1259.

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

RESPONSE TO FINDING NO. 1259:

Respondent has no specific response.

1260.

(Nestor, Tr. 2961 (*in camera*); CX2928 at 012 (Impax Response to Interrogatory No. 18) (*in camera*)).

RESPONSE TO FINDING NO. 1260:

Respondent has no specific response.

1261.

(Nestor, Tr. 3045 (*in camera*)). The new

(Nestor, Tr. 2963 (*in camera*); CX2747 at 001 (Oct. 29, 2015 Macpherson/Ailinger email)).

RESPONSE TO FINDING NO. 1262:

While Respondent does not dispute that the formulation for IPX-203 was not covered by the definition of the product in the DCA, or that Impax approached Endo about amending the agreement, Proposed Finding No. 1262 is inaccurate in its claim that discussions about an amendment first occurred in the fall of 2015.

(Nestor, Tr. 2963-64; RX-208). During that conversation, Impax offered to amend the DCA (Nestor, Tr. 3057; CX2928-013).

RESPONSE TO FINDING NO. 1266:

Complaint Counselôs Proposed Finding No. 1266 is inaccurate and misleading in its suggestion that Endo did not assess information regarding the likelihood that IPX-203 would offer a superior clinical benefit compared to IPX-066.

(Cobuzzi, Tr. 2532-37 (

); RX-080.0011 (Endo diligence team concluding that IPX-203 would be a ñgreater improvement in disease control and ease of use relative toò IPX-066)).

Proposed Finding No. 1266 is also incorrect and unsupported by the cited evidence with respect to Endoôs purported views about competition. The cited portion of the Endo Opportunity Evaluation Worksheet describes Endoôs belief that it would successfully capture market share

XIII. The other justifications offered by Impax for the payment are not cognizable and do not undermine the conclusion that Endo's payment to eliminate the risk of competition is anticompetitive

A. The reverse-payment settlement did not result in a better outcome for consumers

1268. Impax has offered the purported justification that the settlement with Endo resulted in a better outcome for consumers than continued patent litigation because the litigation was likely to take years to conclude, and Impax was likely to lose. (RX-548 at 0058 (¶ 136) (Figg Report)).

RESPONSE TO FINDING NO. 1268:

Respondent has no specific response.

1. The outcome of the underlying patent litigation was highly uncertain

1269. The outcome of patent litigation generally is uncertain. (Snowden, Tr. 483 (ñpatent litigation is uncertainò); Snowden, Tr. 563 (ñPatent challenges are inherently risky because they involve uncertain outcomes with court decisionsò); Figg, Tr. 2006-07; CX5007 at 025 (¶ 51) (Hoxie Report); Noll, Tr. 1644, 1645). It is not possible to assign a percentage to the likely outcome of patent litigation. (CX4045 (Figg, Dep. at 152)).

RESPONSE TO FINDING NO. 1269:

Respondent has no specific response.

1270. The ultimate outcome of the underlying patent litigation on the ô456 and ô933 patents was uncertain. (Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644).

RESPONSE TO FINDING NO. 1270:

Respondent has no specific response.

1271. In January 2008, Endo sued Impax, alleging that Impaxôs ANDA for the 5, 10, 20, 30, & 40 mg dosages of generic oxymorphone ER infringed the ô456 and ô933 patents. (JX-001 at 007 (¶¶ 13, 15)). Impax raised a number of counterclaims and defenses, including that Endoôs patents were invalid and that Impaxôs product did not infringe the patents. (RX-454 at 0004-07 (answer, affirmative defenses, and counterclaims of defendant Impax Labs, Inc., in Endo v. Impax) (admitted for the fact of the assertion, not for truth of the matter asserted)).

RESPONSE TO FINDING NO. 1271:

Respondent has no specific response.

1272. Among the issues contested in the patent litigation was the construction of certain claims found in the ô456 and ô933 patents. (RX-484 at 0001-03 (amended order on claim construction, in Endo v. Impax) (admitted for the fact of the statement, not for truth of the matter asserted); CX5007 at 029 (¶ 55) (Hoxie Report); RX-548 at 0013-14 (¶¶ 27-28) (Figg Report)).

RESPONSE TO FINDING NO. 1272:

Respondent has no specific response.

1273. Patent claims define the scope of the patent holderôs right to exclude, and inform the public on what they are precluded from doing by this patent. Patent claims often contain technical terms, and the parties may dispute the meanings of some or all of the claims in a particular patent. One of the roles the court undertakes is to rule on what various terms in the claims mean. (Figg, Tr. 1861-62).

RESPONSE TO FINDING NO. 1273:

Respondent has no specific response.

1274. In claim construction proceedings, often referred to as Markman proceedings, the court typically sets a schedule and puts forth a procedure for the parties to exchange the list of claims they think require interpretation and explain each partyôs proffered interpretation of those claims. These interpretations will be explained in briefing, which is sometimes supported by expert testimony. (Figg, Tr. 1862).

RESPONSE TO FINDING NO. 1274:

Respondent has no specific response.

1275. Once the parties have completed briefing on their claim constructions, the court typically holds a hearing, called the claim construction hearing or Markman hearing. (Figg, Tr. 1862-63).

RESPONSE TO FINDING NO. 1275:

Respondent has no specific response.

1276. After the claim construction hearing, the court issues a claim construction order or Markman order, which defines the terms of the claims for purposes of determining infringement or invalidity. (Hoxie, Tr. 2671). The claim construction order lays the groundwork for the attorneys on both sides to determine whether the accused product infringes the claims and also whether the claims are invalid. (Hoxie, Tr. 2671). In some circumstances, the claim construction order can be dispositive. (Hoxie, Tr. 2671-72; Figg, Tr. 1863).

RESPONSE TO FINDING NO. 1276:

Respondent has no specific response.

1277. In the ô456 and ô933 patent litigation, the parties contested the proper construction of the terms ñhydrophobic materialò and ñsustained releaseò as used in the claims of the ô456 and ô933 patents. (RX-484 at 0003 (amended order on claim construction, in Endo v. Impax) (admitted for the fact of the assertion, not for truth of the matter asserted); CX5007 at 029 (¶ 55) (Hoxie Report); RX-548 at 0016 (¶ 36) (Figg Report)).

RESPONSE TO FINDING NO. 1277:

Respondent has no specific response.

1278. The district court held Markman hearings in the ô456 and ô933 patent litigation on December 21, 2009 and March 19, 2010. (JX-003 at 004 (¶ 18)). The court issued its claim construction order on March 30, 2010 (RX-483 (order on claim construction, in Endo v. Impax) (admitted for the fact of the statement, not for truth of the matter asserted); RX-548 at 0013-14 (¶ 28) (Figg Report)), and issued a slightly modified claim construction order on April 5, 2010 (RX-484 (amended order on claim construction, in Endo v. Impax) (admitted for the fact of the statement, not for truth of the matter asserted); CX5007 at 029 (¶ 55) (Hoxie Report); RX-548 at 0013-14 (¶ 28) (Figg Report)).

RESPONSE TO FINDING NO. 1278:

Respondent has no specific response.

1279. The district court adopted the claim constructions advocated by Endo for the terms ñhydrophobic materialò and ñsustained releaseò. (Hoxie, Tr. 2670-71; Figg, Tr. 1867, 1868).

RESPONSE TO FINDING NO.

1280. The district court construed ñhydrophobic materialò to mean ña material which is effective to slow the hydration of the gelling agent without disrupting the hydrophilic matrix.ò (RX-484 at 0003 (amended order on claim construction, in Endo v. Impax)

a variety of patent licensing, prosecution, and litigation issues for both branded and generic products. Mr. Hoxie was with Novartis Group from 1992 to 2004, where he held a number of positions, including Head of Intellectual Property for North America, and Head of Global IP Litigation/Head of Patents, Global Pharma Markets. His responsibilities included negotiating patent license agreements, including patent litigation settlements, reviewing all major patent licenses for Novartis worldwide, and managing all intellectual property litigation for Novartis globally. Mr. Hoxie also served on committees including the executive committee and the portfolio review committee, where he was involved in decisionmaking related to product development and commercialization, as well as other global business decisions. (Hoxie, Tr. 2645-46). Since 2004, Mr. Hoxie has led his own firm, now Hoxie & Associates LLC, which specializes in in patent matters relating to pharmaceuticals, chemicals and biotechnology, including patent licensing in these areas. (CX5007 at 003-05 (¶

construction was a functional definition, which means that the claim was defined by what function the material or ingredient is performing in the formulation, as opposed to a definition based on its chemical and physical properties. (CX5007 at 029 (¶ 56, n.69) (Hoxie Report)).

RESPONSE TO FINDING NO. 1284:

Complaint Counselôs Proposed Finding No. 1284 is inaccurate and is based on unreliable expert testimony. The courtôs claim construction of ñhydrophobic materialò was the *verbatim*

(ô933 Patent) (admitted for the fact of the statement, not for the truth of the matter asserted); RX-453 at 0016 (ô456 Patent) (admitted for the fact of the statement, not for the truth of the matter asserted); RX-260 at 0017 (Impaxôs pre-trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for the truth of the matter asserted); CX5007 at 032 (¶ 61) (Hoxie Report)). Endoôs expert in the patent litigation, Dr. Lowman, admitted the solid dosage form recited in the claims of the ô933 and ô456 patents refers to a single tablet. (RX-260 at 0017 (Impaxôs pre-trial brief, in Endo v. Impax) (admitted for the fact of the statement, not for the truth of the matter asserted); CX5007 at 032 (¶ 61) (Hoxie Report)). The claims are not related to a method of administering many tablets over many twelve-hour periods to reach a steady-state blood level that would provide a therapeutic effective amount. (Hoxie, Tr. 2674-75). This means that the sustained release element of maintaining therapeutically effective blood levels for over twelve hours needed to be achieved by administration of one tablet of Impaxôs product. (CX5007 at 032 (¶ 61) (Hoxie Report)).

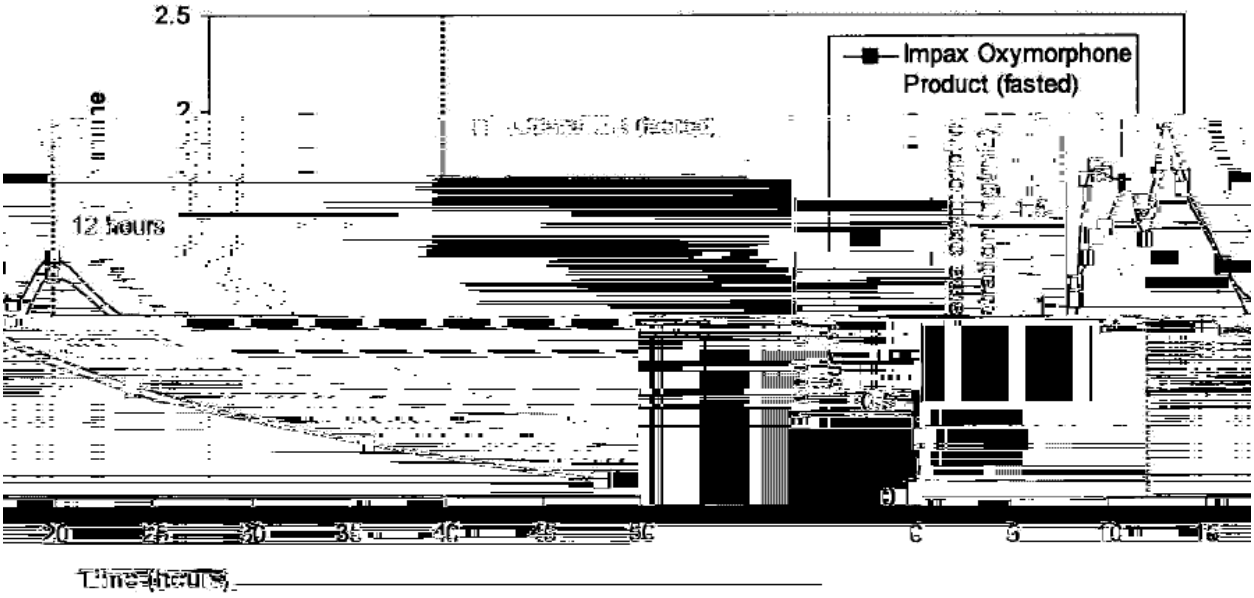
RESPONSE TO FINDING NO. 1286:

Complaint Counselôs Proposed Finding No. 1286 is inaccurate, misleading, and not based on reliable expert testimony. The courtôs claim construction of ñsustained releaseò did not pose problems for Endo; indeed the construction adopted by the court was the *verbatim* construction *advocated by Endo*. (Figg, Tr. 1868; Hoxie, Tr. 2836).

The rest of Proposed Finding No. 1286 is irrelevant because even if ñsustained releaseò required only a ñsingle tablet,ò Impax offered no expert testimony in support of that position, and therefore the issue likely would not have been available for Impax to argue at trial. (RX-548.0017 (Figg Rep. ¶ 38 n.3)). Indeed, Impax did not even contest ñsustained releaseò infringement in its non-infringement, not for [illegible]

1287. Impaxôs generic Opana ER product, however, was designed to be used in a twice-daily dosage regimen, not as a single daily dose. (RX-230 at 0001 (Oxymorphone ER label)). When Impax pointed out that there was no evidence that a single tablet of its product would provide therapeutically beneficial blood levels of the medicament over a period of at least twelve hours, Endo responded by arguing that Impax had not provided expert evidence to the contrary. (RX-260 at 0017-18 (Impaxôs pre-trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for the truth of the matter asserted); RX-261 at 0013 (Endoôs trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for the truth of the matter asserted)). But the burden of proving infringement rested on Endo: Endo needed to show that a single tablet of Impaxôs product met this limitation. (CX5007 at 033 (¶ 62) (Hoxie Report)). Endo did not have any experimental data to prove that a single tablet of Impaxôs product would provide a therapeutically effec

period as Endoôs product. (*See* RX-261.0013-14 (Endoôs pre-trial brief, in *Endo v. Impax*) (admitted for the fact of the assertion, not for the truth of the matter asserted)). Endo even submitted a chart showing that Impaxôs product had slightly more blood plasma concentration after twelve hours with the administration of *only a single tablet* than Opana ER did as part of its pre-trial briefing.



(*See* RX-261.0014 (Endoôs pre-trial brief, in *Endo v. Impax*) (admitted for the fact of the assertion, not for the truth of the matter asserted)). Thus, even under a new ñsingle tabletò theory, Endo had significant clinical evidence to support its infringement case with regard to the ñsustained releaseò construction, including pharmacokinetic data submitted to the FDA *by Impax*. Furthermore, this evidence was cited by Endoôs expert, Dr. Lowman, in Paragraph 48 of his expert report, contrary to the assertion in Proposed Finding 1287. (RX-469.0016 (¶48) (admitted for the fact of the assertion, not for the truth of the matter asserted)).

The last sentence of Proposed Finding No. 1287 should be disregarded because it relies on a quotation of three words from Dr. Lowmanôs deposition cherry-picked entirely out of

context. Mr. Hoxie did not even review Dr. Lowmanôs deposition transcript before relying on this phrase. (*See* CX4043 (Hoxie, Dep. at 291) (noting he only reviewed ñthat particular quoteò from the briefing); *see also* CX5007-050-53 (Hoxie Rep., Ex. B) (not listing Dr. Lowmanôs deposition transcript as a material considered)). Without knowing the context or how Dr. Lowman clarified the testimony at his deposition, Mr. Hoxieôs assertion that Dr. Lowman admitted that Impaxôs product did not infringe lacks foundation, is unreliable, and should be disregarded. To the contrary, Mr. Figg, relying on his 30-years of experience in Hatch-Waxman litigation, opined that ñEndo would have prevailed on proving infringement based on the construction[] of . . . ósustained release.ôò (Figg, Tr. 1884).

Finally, it is telling that despite the purported criticisms in Proposed Finding No. 1287, Complaint Counselôs patent expert, Mr. Hoxie, stopped short of opining that Impax would have prevailed on the infringement issue. (Hoxie, Tr. 2841). Indeed, Mr. Hoxie offers no opinions on the likely outcome of the Endo-Impax litigation. (Hoxie, Tr. 2751-52).

1288. Moreover, a therapeutically effective dosage of oxymorphone varies very much from patient to patient. (Hoxie, Tr. 2675) The blood levels a p ic |

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0020, 022, 025 (¶¶ 45, 49, 56) (Figg Report)). The courtôs claim construction order also raised issues for Endoôs defense against Impaxôs invalidity case on each of these grounds. (Hoxie, Tr. 2679-93; CX5007 at 035 (¶ 65) (Hoxie Report)).

RESPONSE TO FINDING NO. 1289:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 1289.

The second sentence of Proposed Finding No. 1289 is inaccurate because Endo prevailed on the claim construction issues by convincing the court to adopt is constructions of ñsustained releaseò and ñhydrophobic materialò verbatim. (Hoxie, Tr. 2836; Figg, Tr. 1868).

1290. ñóAnticipationô requires that a single prior art reference disclose (explicitly, implicitly, or inherently) every element of the claim, arranged as in the claim. A claim

1292. Endoôs arguments that MCC served as the hydrophobic material in Impaxôs product opened the door to a number of prior art references that could have invalidated the ô933 and ô456 patents. 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

prove that MCC was hydrophobic. (RX-261 at 0027 (Endoôs trial brief, in Endo v. Impax) (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 Endoôs 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 Impaxôs product was hydrophobic. (RX-261 at 0027 (Endoôs trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for the truth of the matter asserted); *see also* Hoxie, Tr. 2679-81; CX5007 at 036-37 (¶¶ 67-68) (Hoxie Report)).

RESPONSE TO FINDING NO. 1293:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 1293.

Complaint Counselôs assertion in the second sentence of Proposed Finding No. 1293 that Endoôs arguments ñcreated inconsistencies in Endoôs caseò is false and based on unreliable expert testimony. Both patent experts agree that the courtôs claim construction of ñhydrophobic materialò was a ñfunctionalò construction, and thus required testing. (Figg, Tr. 1873-75; Hoxie, Tr. 2836). Further, the burdens of proof differ between infringement and invalidity: Endo needed only to prove infringement by a preponderance of the evidence, whereas Impax needed to show that prior art anticipated the claim by clear and convincing evidence. (Hoxie, Tr. 2850; Figg, Tr. 1872, 1885). Endo provided tests in support of its infringement case, (Figg, Tr. 1874; Hoxie, Tr. 2836 (ñEndoôs attorneys commissioned certain tests.ò)), but Impax did not offer any tests related to the prior art, (Figg, Tr. 1874 (ñImpax did not do any tests of its own.ò); Hoxie, Tr. 2839), and therefore Impax could not meet the clear and convincing standard to show the prior art anticipated the patents. Tellingly, Mr. Hoxie did not opine that he believed Impax would have prevailed on the validity arguments, including anticipation. (Hoxie, Tr. 2845). Indeed, Mr. Hoxie did not offer any opinion on the outcome of the Endo-Impax litigation. (Hoxie, Tr. 2751-52).

1294. Impaxôs second grounds for invalidity ð obviousness ð requires demonstration that ñthe differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art to which the subject matter pertains.ò (RX-548 at 0022 (¶ 49) (Figg Report); Hoxie, Tr. 2677; Figg, Tr. 1897). Impax argued that the asserted claims of the ô933 patent were invalid under 35 U.S.C. §103 as obvious. (RX-468 at 0029-39 (¶¶ 110-133) (Expert Report of Edmund J. Elder from Endo v. Impax) (admitted for the fact of the assertion, not for truth of the matter asserted); RX-548 at 0022 (¶ 49) (Figg Report)).

RESPONSE TO FINDING NO. 1294:

Respondent has no specific response.

1295. The courtôs claim construction order raised issues for Endoôs defense against Impaxôs invalidity case on the basis of obviousness. Impax argued that MCC is a well-known excipient and therefore, there was a large volume of prior art references that could have potentially invalidated Endoôs patents under an obviousness theory. (RX-260 at 0009-10, 0027-28 (Impaxôs pre-trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for truth of the matter asserted)).

RESPONSE TO FINDING NO. 1295:

Complaint Counselôs Proposed Finding No. 1295 is misleading and inaccurate. The first sentence of Proposed Finding No. 1295 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). In any event, the Courtôs claim construction order did not ñraise[] issues for Endoôs defense against Impaxôs invalidity case on the basis of obviousness.ò Instead, the claim construction ð adopting a functional claim that required testing ð made it very difficult for Impax to meet its burden of showing that the prior art references could have invalidated Endoôs patents under an obviousness theory because Endo had submitted to testing the function of the MCC in the referenced prior art. Accordingly, Impax was not likely to meet its burden under the ñclear and convincing evidenceò standard. Tellingly, Mr. Hoxie did not opine that Impax would have prevailed on the validity arguments, including obviousness. (Hoxie, Tr. 2845).

1296. To overcome Impaxôs obviousness claims, Endo argued that secondary indicia of nonobviousness (also known as ósecondary considerationsô) 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)).

RESPONSE TO FINDING NO. 1296:

Respondent has no specific response to Complaint Counselôs Proposed Finding No. 1296, except to clarify that the secondary indicia were not Endoôs only arguments regarding obviousness. (RX-261.0030-32 (Endoôs trial brief, in *Endo v. Impax*) (admitted for the fact of the assertion, not for truth of the matter asserted)).

1297. 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 038-39 (¶ 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)).

RESPONSE TO FINDING NO. 1297:

Respondent has no specific response.

1298. As a result, Endo may have encountered problems trying to ñsuccessfully rely on secondary considerations or objective indicia of non-obviousnes

after Impaxôs initial ANDA filing in June 2007. (JX-001 at 006-07 (¶¶ 9, 11); CX5007 at 039 (¶ 72) (Hoxie Report)).

RESPONSE TO FINDING NO. 1298:

Complaint Counselôs Proposed Finding No. 1298 is incomplete and inaccurate. Endo was more likely than not to prevail on the obviousness issue. (Figg, Tr. 1897-98).

The final two sentences of Proposed Finding No. 1298, moreover, do not accurately reflect Impaxôs obviousness arguments. Impax never once mentioned the Orange Book or the timing in which Endo listed the ó933 and ó456 patents in its pre-trial briefing. (RX-260.0027-36 (Impaxôs pre-trial brief, in Endo v. Impax) (admitted for the fact of the statement, not for the truth of the matter asserted)). Thus, this argument is a post-hoc rationalization created by Complaint Counselôs expert for purposes of this Part III proceeding, and it would not have been raised or considered during the actual Endo-Impax patent trial. Further, Proposed Finding No. 1298 ignores significant evidence that secondary factors supported Endoôs argument of non-obviousness, including (1) the fact Endoôs product was commercially successful with hundreds of millions of dollars of sales; and (2) that Opana ER was the only extended-release version of oxymorphone on the market despite the fact oxymorphone IR had been available for many years. (Figg, Tr. 1899). Moreover Endo would have enjoyed a presumption of a nexus between the inventions and the commercial su

rational party would advocate for claim constructions that most favor their position and disfavor the positions of the opposing party. (*See* Hoxie, Tr. 2833 (Q. And you agree that each party would advocate for a claim construction that would be most advantageous for their case going forward; correct? A. Yes.ò)).

> 1304. If Endo and Impax had not entered into a settlement, the trial on the ô933 and ô456 patents would have continued. If litigation continued, Impax may have ñobtained a favorable judgmentò at the district court. (CX5007 at 044 (¶ 82) (Hoxie Report); Figg, Tr. 2017).

RESPONSE TO FINDING NO. 1304:

Respondent has no specific response to Complaint Counselôs Proposed Finding No. 1304, except to note that Complaint Counsel offers no evidence regarding the likelihood that Impax would have obtained a favorable judgment or the strength of either partyôs litigation positions. (Hoxie, Tr. 2693, 2752-53, 2835).

> 1305. If litigation continued, Impax lost at the district court, and appealed that decision, the outcome of any such appeal was uncertain. (Figg, Tr. 2007-08; Hoxie, Tr. 2694; CX5007 at 041-42 (¶¶ 76-79) (Hoxie Report)). Endo faced a significant risk of loss on appeal. (CX5007 at 041-42 (¶ 76) (Hoxie Report)).

RESPONSE TO FINDING NO. 1305:

Respondent has no specific response to the first sentence of Complaint Counselôs Proposed Finding No. 1305.

The assertion in the second sentence of Proposed Finding No. 1305 is based on unreliable expert testimony. Mr. Figg explained that even though there was a theoretical risk that Endoôs victory could be reversed and remanded, Mr. Figg would give the edge to Endo on appeal because Impax would have to ñconvince the appeals court that that judge made a mistake even though itôs de novo review.ò (Figg, Tr. 2019).

gelling agent without disrupting the hydrophilic matrix,ò (RX-484 (Amended Order on Claim Construction)), after reviewing numerous briefs and conducting two days of hearings, (*see* RX-

therapeutically beneficial blood levels of the medicament are maintained over a period of at least 12 hours,ò (RX-484 (Amended Order on Claim Construction)), after reviewing numerous briefs and conducting two days of hearings, (*see* RX-462; RX-464; RX-465 (claim construction briefing)). Accordingly, the court disagreed with Mr. Hoxieôs conclusions as advanced in Proposed Finding No. 1308, and Mr. Hoxie offers no basis for why his opinion should be accepted over that of a federal judge who heard similar arguments to those offered by Mr. Hoxie.

Respondent has no specific response to the final sentence of Proposed Finding No. 1308 other than to clarify that Mr. Figg testified he would give the edge to Endo on appeal because Impax would have to ñconvince the appeals court that that judge made a mistake even though itôs de novo review.ò (Figg, Tr. 2019). Further, Complaint Counselôs Proposed Finding No. 1308 is based on unreliable expert testimony.

2. The elephant in the room: Endo did not pay Impax to accelerate the expected date of generic oxymorphone ER entry

1309. Impax has proffered as an alleged procompetitive benefit of the settlement that the SLA allowed it to enter earlier than it could have under continued litigation. In particular, Impax asserts that absent the settlement, it not only would have lost the ô933 and ô456 patent litigation, but it would have faced additional patent infringement litigations on later-issued patents that it would have lost as well. (Figg, Tr. 1904-05, 1963-64, 1971-72).

RESPONSE TO FINDING NO. 1309:

Complaint Counselôs Proposed Finding No. 1309 is misleading. Impax does not assert that absent the settlement it ñwould haveò lost the ó933 and ó456 patent litigation. (RX-548.0005, 28-31 (Figg Rep. ¶¶ 4(a),.63-71); *see also* Figg, Tr. 1870, 1904).

1310. This justification is implausible because it means that ñEndo made a charitable contribution to Impax by paying Impax over $100 million AND allowing Impax to enter earlier than otherwise would have been likely.ò (CX5004 at 059-60 (¶ 125) (Noll Report); Noll, Tr. 1487-88). The purported justification is also inconsistent with the facts. *See* CCF ¶¶ 1311-27.

RESPONSE TO FINDING NO. 1310:

Complaint Counselôs Proposed Finding No. 1310 should be disregarded because it is based on nothing but unreliable expert testimony. What is more, the SLA did not require Endo to pay anything to Impax at the time it was executed. And the evidence is clear that Endo had no expectation that it would make a payment under the Endo Credit anytime thereafter, until a supply disruption forced it to launch reformulated Opana ER sooner than planned and to withdraw original Opana ER at the request of the FDA. (CX4017 (Levin, Dep. at 99-100, 131); Cuca, Tr. 677; RX-094.0003-06 (ñPrior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012ò); RX-100.0001 (ñSeveral of [Endoôs] strategies envisioned [Endo] selling both [original and reformulated Opana ER] products at the same time. It was only upon [Endoôs] discussions with the FDA in February [2012] that they told [Endo] not to do this in order to avoid patient confusion.ò)).

The second sentence of Proposed Finding No. 1310 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

a) Outcomes of the settlement for Endo and Impax

1311. The settlement agreement produced the following outcomes for Endo and Impax. For Endo, the settlement guaranteed that generic entry on the five dosages of Opana ER that accounted for more than 90% of sales would not occur until about eight months before the expiration of the patents that were at issue in the Endo/Impax patent infringement litigation. (RX-364 at 0010-11 (SLA §§ 4.1(c), 4.2 (ñLicense; Covenant Not to Sueò and ñLicense Termò)); CX0203 (Nov. 11, 2009 Mengler/Smolenski email); Noll, Tr. 1456-57; CX5000 at 146-47, 163 (¶¶ 335, 366) (Noll Report); CX5004 at 060 (¶ 127) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1311:

Respondent has no specific response.

1312. Because of Impaxôs 180-day exclusivity period as a first filer, the settlement agreement also guaranteed Endo that no other generic entry would occur until, at the earliest, only ten weeks before these patents expired. (*See* CCF ¶¶ 378-87, above; CX5004 at 060 (¶ 127) (Noll Rebuttal Report)). This agreement preserved Impaxôs 180-day exclusivity period, but guaranteed that entry would not occur for two and a half years after Impax received FDA approval to enter. (*See* CCF ¶¶ 332-87, above; CX5004 at 060 (Noll Rebuttal Report)). Thus, the earliest possible date of entry was substantially delayed by the agreement. (*See* CCF ¶¶ 332-87, above; CX5004 at 060 (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1312:

Complaint Counselôs Proposed Finding No. 1312 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posen " e "

1314. One benefit to Impax was the value of Endoôs commitment not to

1315. In fact, Endo intended to launch an authorized generic and was prepared to do so. In late 2009 Endo began preparing to launch an AG if Impax launched generic oxymorphone ER. Endo knew that Impax was likely to receive final approval for its generic by June 2010, and so began to prepare for an AG launch in the summer of 2010. (CX2576 at 001, 003 (Feb. 2010 Endo email)). Endoôs latest estimate of the date that Impax would launch was mid-2011, when Endo expected that the appellate decision on the infringement case would be issued. (CX3001 at 001 (Endo Launch scenario); CX2576 at 001 (Feb. 2010 Endo email); CX2573 at 004 (Feb. 2010 EN3288 Commercial Update Presentation); *see* CCF ¶¶ 58, 64, above).

RESPONSE TO FINDING NO. 1315:

The first sentence of Complaint Counselôs Proposed Finding No. 1315 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). The documents cited in support of Proposed Finding No. 1315 indicate only that Endo forecast the possibility of an authorized generic in the 2010 through 2011 time frame, and do not indicate that Endo would actually have launched an authorized generic. Indeed, Endo looked at an authorized generic as ñanother scenario that you go through, just like when youôre making an assumption around potential launch dates.ò (CX4025 (Bingol, Dep. at 180)). Finally, Complaint Counselôs failure to cite any testimony from any Endo witnesses is telling, especially since all Endo witnesses testified that Endo had no intention of launching an authorized generic. (*See* Bingol, Tr. 1337-39 (testifying that an authorized generic ñwas never, to my knowledge . . . fully realized as a plan or an ideaò); CX4019 (Lortie, Dep. at 118-19) (ñwe never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didnôt want to.ò); CX4031 (Bradley, Dep. at 198) (ñI donôt recall having any conversation with any colleagues regarding the launch of an authorized generic.ò)).

1316. To prepare for an AG launch, Endo took a number of steps, including designing tablets, receiving labels, and creating SKUs for its AG oxymorphone ER product. Endo made one batch of each strength of its AG product, and had manufactured enough to support a June 2010 launch, if necessary. Endo also informed drug wholesalers about its

intentions to launch an AG, [redacted] (*See* CCF ¶¶ 86-90, above) (*in camera*).

RESPONSE TO FINDING NO. 1316:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1317. Endoôs financial analyses estimated that an Impax launch in mid-2010 would cause Endo to lose $45.6 million in ñProduct Contributionò in 2010, but that Endo could recoup $17.7 million by launching an AG. (CX3009 at 003 (June 2010 Endo email attaching P&L scenarios)); *see* CCF ¶ 84, above)).

RESPONSE TO FINDING NO. 1317:

Respondent has no specific response.

1318. Endo and Impax settled the infringement case on June 8, 2010. (JX-001 at 009 (¶ 33)). Three days later Endo employees concluded that Endo could make arrangements to destroy its generic oxymorphone ER inventory. (CX3000 (June 2010 Endo email)).

RESPONSE TO FINDING NO. 1318:

Respondent has no specific response.

1319. The value to Impax of Endoôs agreement not to launch an authorized generic is reflected in Impaxôs documents. Impax executives estimated that if Original Opana ER were still on the market and Endo launched an AG when Impax entered, Endoôs AG would capture roughly half of sales and cause substantially lower generic prices during the exclusivity period than would be the case if Impax sold the only generic. (CX0202 at 001 (July 2009 Impax email); CX2825 at 008 (Feb. 2010 Impax email attaching 5-year forecast); CX4037 (Smolenski, Dep. at 52-54, 149-50); CX4002 (Smolenski, IHT at 80-81, 94-95)).

RESPONSE TO FINDING NO. 1319:

Complaint Counselôs Proposed Finding No. 1319 is incomplete and misleading because it ignores the testimony of Mr. Smolenski, who explained that the figure was simply ñwhat I was assuming in this particular email,ò not a detailed analysis of the marketplace. (CX4037 (Smolenski, Dep. at 53) (discussing CX0202)). Further, whether a No-Authorized Generic provision had any value depends entirely on whether Endo intended to launch an authorized generic but-for the term, and Endo employee testimony demonstrates Endo did not. (CX4019 (Lortie, Dep. at 117-18) (testifying it would be ñmorally very difficult to justify at the same time having a crushable authorized generic productò and a non-crushable branded product); Bingol, Tr. 1337-39 (testifying that an authorized generic ñwas never, to my knowledge . . . fully realized as a plan or an ideaò); CX4019 (Lortie, Dep. at 118-19) (ñwe never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didnôt want to.ò)). Finally, Professor Noll did not calculate the expected value of any provision in the

one document. That document (CX0222) was never shown to any fact witness and there is no explanation regarding the meaning of the document.

> 1321. In the Upside case, after AG entry Impaxôs share of generic sales is estimated to fall to 60% and average price to fall by 36%. (CX0222 at 004 (May 2010 Impax email attaching 5-year forecast)). As a result, AG entry during the exclusivity period causes Impaxôs revenues to fall by 61.6%, amounting to $5 million per month or a reduction of about $23 million in the four and a half months after AG entry. (CX5000 at 155 (¶ 350) (Noll Report)). In the Base case, Endoôs AG enters simultaneously with Impax and captures half of the market while causing prices to fall by the same 36%. (CX0222 at 005 (May 2010 Impax email attaching 5-year forecast)). These estimates imply that simultaneous AG entry would reduce Impaxôs revenues by 68.0% during the exclusivity period, or about $33 million for a launch on June 14, 2010. (CX5000 at 155-56 (¶ 350) (Noll Report)).
>
> **RESPONSE TO FINDING NO. 1321:**
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> Complaint Counselôs Proposed Finding No. 1321 is lacks foundation and is misleading. The cited document (CX0222) was never shown to any fact witness and there is no explanation regarding the meaning of the document, despite Complaint Counselôs efforts to use their economic expert to testify about the purpose and nature of figures within the document, which violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Moreover, any purported estimates of how much an authorized generic would reduce Impaxôs revenues is based on the false premise that Endo would launch an authorized generic, which Endo did not intend. (*See* CX4019 (Lortie, Dep. at 117-18) (testifying it would be ñmorally very difficult to justify at the same time having a crushable authorized generic productò and a non-crushable branded product); Bingol, Tr. 1337-39 (testifying that an authorized generic ñwas never, to my knowledge . . . fully realized as a plan or an ideaò);

CX4019 (Lortie, Dep. at 118-19) (ñwe never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didnôt want to.ò)).

1322. The value of the ñNo AG Provisionò would be higher in the future if the revenues from Original Opana ER continued to increase. Sales of Original Opana ER grew from $240 million in 2010 to $384 million in 2011 and, after the switch to Reformulated Opana ER in 2012, Opana ER revenues remained at $299 million. (CX3215 at 010 (Mar. 1, 2013 SEC Form 10-K, Endo Health Solutions, Inc.); CX5000 at 156 (¶ 351) (Noll Report)). These data imply that the value of the ñNo AG Provisionò for entry would have been approximately 60% greater (over $50 million) in 2011 and at least 25% greater (over $40 million) in 2012. (CX5000 at 156 (¶ 351) (Noll Report)).

RESPONSE TO FINDING NO. 1322:

Complaint Counselôs Proposed Finding No. 1322 lacks foundation and is misleading. Professor Noll calculated neither the expected value of any provision in the Settlement and License Agreement, nor the overall expected value of the Settlement and License Agreement. (Noll, Tr. 1613, 1651-52). Moreover, any speculation about how much the absence of an authorized generic would be worth is based on the false premise that Endo would launch an authorized generic, which Endo did not intend. (*See* CX4019 (Lortie, Dep. at 117-18) (testifying it would be ñmorally very difficult to justify at the same time having a crushable authorized generic productò and a non-crushable branded product); Bingol, Tr. 1337-39 (testifying that an authorized generic ñwas never, to my knowledge . . . fully realized as a plan or an ideaò); CX4019 (Lortie, Dep. at 118-19) (ñwe never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didnôt want to.ò)).

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RESPONSE TO FINDING NO. 1323:

Complaint Counselôs Proposed Finding No. 1323 should be disregarded because it only cites expert testimony for propositions of fact. (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Further, Proposed Finding No. 1323 is based on unreliable expert testimony. In any event, there is nothing in the record to support the proposition that the Endo Credit had any value at the time of settlement. Professor Noll did not calculate the expected value of any provision in the Settlement and License Agreement, or the overall expected value of the Settlement and License

RESPONSE TO FINDING NO. 1324:

Respondent has no specific response.

1325. The ñEndo Creditò provision was designed to insulate Impax against a substantial decrease in sales of Opana ER. (Cuca, Tr. 617). At the time the parties were negotiating the terms of the ñEndo Creditò provision, Endo was developing a reformulated version of Opana ER, the introduction of which could lead to such a decrease in the sales of Original Opana ER. (Cuca, Tr. 618-19; *see also* CCF ¶¶ 246-50, 253-75, above).

RESPONSE TO FINDING NO. 1325:

Complaint Counselôs Proposed Finding No. 1325 is incomplete and misleading. The Endo Credit was designed to deter Endo from introducing a reformulated product. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122) (the Endo Credit was designed to act as ña deterrent to prevent [Endo] from switching the market.ò); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit ñintended to disincentivize Endo fromò introducing a reformulated product)). Respondent has no specific response to the second sentence of Proposed Finding No. 1325.

1326. Endo later introduced Reformulated Opana ER and discontinued selling Original Opana ER. (JX-001 at 011-12 (¶¶ 48-50)). As a result, sales of Original Opana ER did decrease substantially ð falling to zero ð which triggered the payment of the ñEndo Creditò. Ultimately, Endo paid Impax $102 million under the ñEndo Credit.ò (JX-001 at 011 (¶ 45); CX1216 (Apr. 2013 email requesting payment); CX5000 at 161-62 (¶ 362) (Noll Report)).

RESPONSE TO FINDING NO. 1326:

Respondent has no specific response other than to note that to the extent Complaint Counselôs Proposed Finding No. 1326 attempts to suggest that a substantial decrease in original Opana ER sales was planned or anticipated, it is inaccurate and misleading. Indeed, the first time that Endo knew its sales would be zero was in the last quarter of 2012, after the Novartis plant shutdown and resulting supply interruption. (Cuca, Tr. 615, 617, 677 (ñI donôt know that

anyone was anticipating a change in the marketplaceò); RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)). Until that point, Endo expected to sell Opana ER through the fourth quarter of 2012. (CX4017 (Levin, Dep. at 131); RX-094.0006 (ñPrior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012ò); RX-108.0002 at 10).

1327. Another benefit of the settlement to Impax was an upfront payment of $10 million dollars for a co-development and co-promotion agreement that was then terminated. (RX-365 at 0009 (DCA § 3.1); *see also* CCF ¶¶ 320, 1246, above; CX5003 at 052 (¶ 87) (Geltosky Report); CX5000 at 162 (¶ 363) (Noll Report); CX5004 at 060 (¶ 128) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1327:

b) The question not answered by Dr. Addanki and Mr. Figg

1328. Dr. Addanki and Mr. Figg have offered the opinion that, if Impax had not entered into this settlement with Endo, it would have been prevented from entering the market until at least mid-2013, and possibly still would not be on the market today. (Figg, Tr. 1971-72; Addanki, Tr. 2376-77 *see, also* CCF ¶¶ 1021, above).

RESPONSE TO FINDING NO. 1328:

Respondent has no specific response.

1329. According to their opinions, therefore, Impaxôs entry date under continued litigation was not likely to occur until a number of months later than the January 2013 generic entry date in the SLA, and possibly still would not have occurred at all. (RX-548 at 0038 (¶ 83) (Figg Report); Figg Tr. 1971-72).

RESPONSE TO FINDING NO. 1329:

Respondent has no specific response.

1330.

The first sentence of Proposed Finding No. 1331, moreover, should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings shall be supported by specific references to the evidentiary record,ò and prohibits citations ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)).

> 1332. Rather than answer the question of why Endo paid so much to settle with Impax, Respondent asserts that a finding that a settlement is anticompetitive depends on addressing two considerations. One is whether an alternative no-payment settlement is feasible. (RX-547 at 0009-10 (Addanki Report)). The other is the probability that Endo would prevail in the patent infringement litigation. (RX-547 at 0009-10 (Addanki Report)).

RESPONSE TO FINDING NO. 1332:

Complaint Counselôs Proposed Finding No. 1332 is misleading and inaccurate. Mr. Figg answered this exact question at trial, where he explained litigation is uncertain and that ñthings could have gone the other direction as well.ò (Figg, Tr. 2046). Yet even under the Settlement and License Agreement, whether and how much Endo would pay was uncertain and outside of Endoôs control. (*See* Bazerman, Tr. 923 (testifying Endo did not have control over the events leading to the Endo Credit payment)). And the record is clear that Endo did not expect to make any payment, and did not book a reserve for any payment. (Cuca, Tr. 664-65; CX4017 (Levin, Dep. at 125-26)). Brian Lortie, Endoôs Senior Vice President for Pain Solutions at the time of settlement, explained that Endo ñintended to replace one product with the other, and that would be the only product that we had on the market,ò (CX4019 (Lortie, Dep. at 117-18)), but Endo still ñdid not expect to make a payment to Impax,ò (CX4017 (Levin, Dep. at 126)). Further, ñ[t]he test of whether the agreement at issue is anticompetitive [] is a test of whether consumers would have been better off had the parties eschewed settlement and proceeded with litigation,ò

(RX-547.0021 (Addanki Rep. ¶ 36)). That test involves more than two considerations, but is not something that Complaint Counsel considered because they offer no evidence regarding the but-for world.

> 1333. Economic analysis of reverse-payment settlements shows that, by definition, the very existence of a large reverse-payment settlement rules out the possibility that the settlement benefits consumers. (CX5000 at 120 (¶ 271) (Noll Report); CX5004 at 061-62 (¶ 130) (Noll Rebuttal Report)). This conclusion is derived from a comparison between the settlement agreement that would maximize expected consumer welfare, regardless of whether such a settlement is feasible, and the expected consumer welfare arising from a settlement. (CX5000 at 120 (¶ 271) (Noll Report); CX5004 at 061-62 (¶ 130) (Noll Rebuttal Report)). The settlement that maximizes expected consumer welfare is one in which the expected profits of the brand-name and generic firms are the same as the expected profits from litigating the case to conclusion, which is why a settlement in which the brand-name firm pays more than saved litigation cost is anticompetitive. (CX5000 at 120 (¶ 271) (Noll Report); CX5004 at 061-62 (¶ 130) (Noll Rebuttal Report)).
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> **RESPONSE TO FINDING NO. 1333:**

Complaint Counselôs Proposed Finding No. 1333 is an improper legal conclusion, not a fact, and is based on unreliable expert testimony. In any event, Proposed Finding No. 1333 is inaccurate because it deliberately ignores real-world considerations. Indeed, Professor Noll admitted that he ñdo[es] not measure the actual anticompetitive harm in the market.ò (Noll, Tr. 1665). Instead, Professor Noll believes that ñone can infer whether a settlement is anticompetitive from the terms of the agreement,ò (Noll, Tr. 1663), and that he need not ñactually model whatôs going to actually happen in the market,ò (Noll, Tr. 1661). Professor Nollôs purported test has never

1334. As explained in Section XI above, the conclusion that large, unexplained reverse-payment settlements are anticompetitive does not depend on the feasibility of a no-payment settlement or the probability that the brand-name firm will win the infringement

RESPONSE TO FINDING NO. 1336:

Complaint Counselôs Proposed Finding No. 1336 is inaccurate. Complaint Counsel should cite Dr. Addanki to describe Dr. Addankiôs ñmethod.ò Dr. Addankiôs test is a simple one: ñwhether consumers would have been better off had the parties eschewed settlement and proceeded with litigation.ò (RX-547.0021 (Addanki Rep. ¶ 36)). ñSuch a comparison would involve evaluating likely consumer benefits in light of the various events that may have transpired had the parties continued litigating the patent case instead of reaching the settlement at issue.ò (RX-547.0010 (Addanki Rep. ¶ 11(h))). Further, Dr. Addanki testified that his ultimate conclusion was not based on the outcome of the ô456 and ô933 patent litigation. (Addanki, Tr. 2383 (ñQ. [D]oes your opinion in any way depend on how the patent suits between Endo and Impax would ultimately been resolved? A. No.ò); Addanki, Tr. 2418).

> 1337. Dr. Addanki ignores, however, the underlying economics of settlements of patent infringement cases in the pharmaceutical industry. A small probability that the generic firm will win the infringement litigation is inconsistent with a large reverse-payment settlement because a brand-name firm has nothing to gain by paying off a generic firm that is highly likely to lose the infringement case. Thus, the very existence of a large reverse-payment settlement rules out the possibility that the settlement benefits consumers, making assessing the merits of the infringement case unnecessary in determining whether a reverse-payment settlement causes anticompetitive harm to consumers. (CX5000 at 120 (¶ 271) (Noll Report)).

RESPONSE TO FINDING NO. 1337:

Complaint Counselôs Proposed Finding No. 1337 is misleading because it prioritizes an untested and never-accepted mathematical theory of harm over real-world evidence of consumer welfare. (Noll, Tr. 1642). With regard to the ñprobability that the generic firm will win the infringement litigation,ò Professor Noll admitted that this is an economic *assumption*, not a real-world fact. (Noll, Tr. 1634 (ñQ. But you donôt calculate, for example, the net probability of winning the Endo-Impax patent litigation[?] A. No. Iôm entering assumptions in the model.ò)).

Indeed, Professor Noll admits that his model does not ñactually model whatôs going to actually happen in the market.ò (Noll, Tr. 1661). Thus, Professor Nollôs theoretical approach fails to consider a number of scenarios that could have left consumers worse off but for the settlement. (*See* Noll, Tr. 1667 (ñIf [Impax] continued litigating and lost, that would make consumers worse off.ò)). Professor Noll instead contends that the ñvery existence of a large reverse-paymentò is sufficient to condemn the agreement, even though he cannot say whether or not consumers are better off with the settlement. (Noll, Tr. 1669 (ñQ. Is it fair to say you believe consumers are better off today because Impax is selling oxymorphone? A. I think thatôs an extremely difficult question to answer.ò)). To the contrary, Dr. Addanki explained that ñthere are all kinds of reasons that firms may enter int

(Addanki Rep. ¶ 36)). Proposed Finding No. 1338 consequently is incorrect because if Endo had won the underlying patent litigation, Impax would have been enjoined from selling oxymorphone ER until September 2013 at the earliest, resulting in significant consumer harm. (*See* Noll, Tr. 1667 (ñIf [Impax] continued litigating and lost, that would make consumers worse off.ò); Savage, Tr. 818, 821; Hoxie, Tr. 2834; Figg, Tr. 1972-76).

> 1339. The fundamental underlying fact is that no brand-name firm would pay a generic firm to settle a patent infringement case unless the brand-name firm expected to recover at least the cost of the settlement in increased profits from the brand-name drug. (CX5004 at 009 (¶ 14) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1339:

Complaint Counselôs Proposed Finding No. 1339 lacks foundation that there was any payment at the time of settlement and is not supported by any record evidence. (Addanki, Tr. 2353 (ñthere are all kinds of reasons that firms may enter into agreements that include payments that are nevertheless procompetitive in the effect they have on consumersò)). Professor Noll did not calculate an expected value of the challenged terms of the settlement. (Noll, Tr. 1651). Indeed, the parties knew that the settlement could have no value to Impax. (Cuca, Tr. 628-29; CX4017 (Levin, Dep. at 143-44)). In fact, ñit was not [Endoôs] expectation that a payment would have to be made.ò (CX4017 (Levin, Dep. at 99-100) (ñat the time the transaction was inked I did not expect that Endo would have to make a payment under this provisionò)). Even Professor Noll agrees that the payment pursuant to the SLA could have been zero. (Noll, Tr. 1479-80). Finally, Proposed Finding No. 1339 should be disregarded because Complaint Counsel cites only expert testimony for issues of ñfundamental underlying fact.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)).

1340. As long as entry prior to the entry date in the SLA was possible, one does not need to assess the likelihood of contingent events to conclude that the settlement was anticompetitive. (CX5004 at 058-59 (¶ 123) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1340:

Complaint Counselôs Proposed Finding No. 1340 is an improper and inaccurate conclusion of law, not a fact. Further, whether ñentry prior to the entry date in the SLA was possibleò tells one nothing about actual effects without assessing the likelihood of contingent events. Because Endo obtained additional patents, even if Impax had entered ñprior to the entry date in the SLAò it would have very likely been enjoined by those patents but for the license Impax secured in the Settlement and License Agreement, just as every other ANDA filer is now enjoined. (Figg, Tr. 1972 (testifying Impax would likely be enjoined from selling oxymorphone ER until 2029 without the SLA)).

1341. The very existence of a reverse payment indicates that the brand-name firm expects that the duration of the patent monopoly will be longer under the settlement than under continuing the infringement litigation to conclusion. Hence, the expected entry date in the settlement agreement must be later than the entry date that the brand-name firm expects to occur without a settlement. Thus, the agreement is anticompetitive because it eliminates the risk to the brand-name firm of entry occurring before the agreed date. (CX5004 at 009 (¶ 14) (Noll Report)).

RESPONSE TO FINDING NO. 1341:

Complaint Counselsô Proposed Finding No. 1341 is an improper conclusion of law, not a fact. Proposed Finding No. 1341 is also wrong because it relies solely on economic assumptions instead of real-world evidence. Professor Noll admits that his model does not ñactually model whatôs going to actually happen in the market.ò (Noll, Tr. 1661). Professor Nollôs proposed framework ñmight be something that would trigger an inquiry as to whether a settlement was anticompetitive in its effect, *but it couldn't possibly substitute for that factual inquiry*. [That] inquiry is a factual one, was monopoly power less effectively dissipated through the settlement

refused to contemplate any licensed entry date before January 1, 2013. (Koch, Tr. 239 (ñmet complete resistance to the concept of an earlier launch dateò); Mengler, Tr. 565-67; *see* Noll, Tr. 1599-1600 (ñImpaxôs attempt to get an earlier date met with complete resistance.ò)). This resistance was the same whether or not the Endo Credit and No-AG terms were included. (Snowden, Tr. 371-73, 423 (explaining Endo refused a July 2011 licensed entry date without the Endo Credit or No-AG provision)). Indeed, at no point during settlement discussions did Endo and Impax discuss Impax accepting a later entry date in exchange for something of value. (Mengler, Tr. 567-68; CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)). Tellingly, the two cited paragraphs of Professor Bazermanôs report cite no record evidence.

> 1343. Impaxôs and Endoôs documents are consistent with the logic that linking the entry date to the payment would result in a later entry date. The evidence shows that: (1) Endo and Impax had the financial incentives to reach such an agreement; (2) the branded-to-generic payments did not make sense from Endoôs perspective absent the ability to avoid the risk of competition; (3) Impax presented a risk to competition and was, in fact, preparing to be ready for a possible at-risk launch significantly before January 2013; and (4) settlements with other generic Opana ER manufacturers did not include branded-to-generic payments and had earlier entry dates (which would become effective as soon as Impax used its first-filer exclusivity). (CX5001 at 22 (¶ 45) (Bazerman Report)).

RESPONSE TO FINDING NO. 1343:

Complaint Counselôs Proposed Finding No. 1343 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). The cited paragraph of Professor Bazermanôs report also fails to cite any record evidence in support of the proposition. And witnesses from both Endo and Impax confirm that at no point during settlement discussions did Endo and Impax discuss Impax

accepting a later entry date in exchange for something of value from Endo. (Mengler, Tr. 567-68; CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)).

(1) Impax and Endo's financial incentives

1344. The amount that Endo could expect to gain from not facing generic competition until January 2013 was significantly greater than the costs to Impax of agreeing not to sell generic Opana ER until January 2013. Endo could use the profits it would generate from sales before January 2013 to compensate Impax for agreeing to abandon its patent litigation and not sell generic Opana ER until 2013. (CX5001 at 023-24 (¶¶ 46-48) (Bazerman Report)).

RESPONSE TO FINDING NO. 1344:

Complaint Counselôs Proposed Finding No. 1344 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Professor Bazerman calculated neither ñ[t]he amount that Endo could

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

> 1346. For example, Endoôs 3-year plan for 2010, circulated a few months prior to the settlement with Impax, assumes generic entry in July 2011 and estimates that Endoôs net sales will be $184.5 million lower in the four quarters after July 2011 than its net sales in the four quarters before July 2011. (CX1320 at 007 (email from Nancy Santilli to Alan Levin, et al. re: Updated Three Year Forecast 2010-2012) (sum of Net Sales for Q3ô10-Q2ô11 minus sum of Net Sales for Q3ô11-Q2ô12)). In another document, Endo indicates that it could gain hundreds of millions of dollars from not facing generic competition until January 2013. (CX1314 at 001 (June 1, 2010 Endo Cuca/Levin email) (forecasting that, in 2010 Endo ñwould lose $71.2M in branded ER sales assuming a generic launch on July 1ò)).

RESPONSE TO FINDING NO. 1346:

Complaint Counselôs Proposed Finding No. 1346 is incomplete and misleading. The first cited document (CX1320-007) simply assumes lost sales for purposes of the particular forecasts. (CX1320-007 (describing ñassumptionsò)). It was Endoôs practice to forecast different scenarios regarding the future of its Opana ER product to ñanalyze the full range of potential outcomes.ò (Cuca, Tr. 663-64). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted ña number of different potential outcomes over the course of years,ò the accuracy of which were ñalways debatable.ò (Bingol, Tr. 1292, 1303).

Similarly, Mr. Cuca, the author of the second cited document (CX1314), testified that the figures came from ñassuming some specified erosion assumption.ò (CX4035 (Cuca, Dep. at 66) (discussing CX1314)). Mr. Cuca also testified that under those assumptions, ñthe bottom-line effectò of a theoretical Impax launch ð Endoôs income before taxes, which considers revenues and expenses together ð would only be $2 million at the ñmore aggressive end of the range of

(See CCF ¶¶ 1040-42, above). The only benefit to Endo, however, flows from Impaxôs agreement not to enter until January 2013. (*See* CCF ¶ 1043, above).

RESPONSE TO FINDING NO. 1348:

The proposed summary finding should be disregarded because it v

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Endo would have to make a payment under this provisionò)). Whether Endo would eventually have to make a payment under the Endo Credit provision depended

Tr. 565-67 (Endo was ñadamant about 2013 and not getting anything into 2012ò and ñwas certainly digging in their heels with that dateò); *see* Noll, Tr. 1599-1600 (ñImpaxôs attempt to get an earlier date met with complete resistance.ò)).

1356. As discussed in greater detail above, both Impax and Endo forecasted generic entry by Impax in 2010 or 2011. (*See* CCF ¶¶ 58-64, 148-66, above). And Impax was taking steps to plan and prepare for an at-risk launch. (*See* CCF ¶¶ 168-213, above).

RESPONSE TO FINDING NO. 1356:

date allowed by the Hatch-Waxman Act, as it does with every product. (CX4023 (Hildenbrand, Dep. at 60-61, 140); CX4030 (Hsu, Dep. at 85-86)).

The second sentence of Proposed Finding No. 1357 assumes that Impax could have sold generic oxymorphone ER before January 1, 2013, but that was uncertain given the patent litigation and unlikely given Endoôs ability to obtain additional future patents. (Addanki, Tr. 2360; Figg, Tr. 1971-72). Finally, the alleged payment terms were not compensation, but a means ñto prevent [Endo] from switching the market.ò (Mengler, Tr. 582-83 (Endo Credit was not intended to generate income, it was meant to ensure Impax had a generic opportunity); CX4021 (Ben-Maimon, Dep. at 118, 122); CX4037 (Smolenski, Dep. at 244-45) (ñintended to disincentivize Endo fromò introducing a reformulated product); CX4026 (Nguyen, Dep. at 163-64) (Endo Credit was used to ñput [Endo] to [its] wordò with respect to reformulation)).

> 1358. The existence of the branded-to-generic payments implies a concern within Endo that Impax was a threat to launch at risk. If Endo believed there was no chance for Impax to launch at risk, then Endo could have converted the marketplace to Reformulated Opana ER without needing to pay Impax. It was the combination of Endo planning on launching a Reformulated Opana ER and the significant risk of Impax launching without a license in advance of the Reformulated Opana ER launch that created a strong incentive for Endo to pay Impax to agree not to enter until 2013, thereby avoiding a risk of competition to Endoôs branded product. (CX5001 at 034 (¶ 64) (Bazerman Report)).

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might launch at risk at the end of the Hatch-Waxman Actôs thirty-month stay, Endoôs lawyer laughed at the suggestion. (Snowden, Tr. 424; CX4032 (Snowden, Dep. at 26)). Endoôs lawyer responded that ñImpax never launches at risk. . . . Thatôs not a realistic date.ò (Snowden, Tr. 424). Endoôs internal documents make the same point, stating that at the time of settlement Impax was ñnot likely to launch at riskò because it had never done so before. (RX-086 at 9-10 (third-party market intelligence firm noted that ñImpax tends not to launch at riskò)). Indeed, Endo surveyed doctors, drug wholesalers, pharmacists, academics, and financial analysts and reported that each ñdoubt[s] Impax would launch at risk.ò (RX-086 at 9).

(4) Opana ER Settlements with No Payments Had Earlier Entry Dates

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(CX3383 at 002, 003

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Rep. ¶ 101); *see also* Figg, Tr. 1946-47; Bazerman, Tr. 877 (admitting that one of the reasons

RESPONSE TO FINDING NO. 1365:

Complaint Counselôs Proposed Finding No. 1365 is inaccurate and misleading. First, Mr. Figg did offer an opinion about an at-risk launch by Impax, noting that ñImpax could not have launched before a favorable decision of the Court of Appeals for the Federal Circuit without facing significant risksò and that ñit would have been prudent to wait for final resolution by the Federal Circuit to avoid the potential for lost-profit damages.ò (RX-548.0042-43 (Figg Rep. ¶¶ 90-91)). Second, the first sentence of Proposed Finding No. 1365 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Third, Mr. Figg testified that the decision to launch at-risk was a business decision, and that he had not been involved in the particular business decision, (Figg, Tr. 1979), but that Mr. Figg has been involved in Hatch-Waxman litigation in which an at-risk launch was considered, (Figg, Tr. 1828).

1366. Mr. Figg did not undertake his own quantitative analysis of how oftenidered, (ɹ ɕ ʊ ʊ ʊ ʊ ʊ

RESPONSE TO FINDING NO. 1367:

Complaint Counselôs Proposed Finding No. 1367 is incomplete and misleading. Mr. Figg testified that ñ[w]hat I try to do is advise them of what I perceive the patent risks to be, and then whether they decide to accept that risk or whether there are business considerations that influence, thatôs their decision.ò (Figg, Tr. 2061). Mr. Figg testified that a specific line in his report was an ñovergeneralization,ò but explained that ñ[m]y advice in that situation would have been that there are substantial risks if you proceed with this litigation that you will lose, and if you launch at risk, you run the risk of losing and being liable for lost profit damages to Endo.ò (Figg, Tr. 2062).

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RESPONSE TO FINDING NO. 1370:

Complaint Counselôs Proposed Finding No. 1370 is an incomplete and inaccurate summary of Mr. Figgôs testimony. The cited testimony states that Mr. Figg cannot summarize the methodology because Mr. Figg ñdoesnôt know what [Counsel] mean[s] by that,ò and that ñeverything I did here was from the perspective of someone who litigates patent cases or advises clients about issues.ò (CX4045 (Figg, Dep. at 108-09)). Mr. Figg further clarified that ñmy methodology of analyzing the facts of the case were clear from my report. And if -- therefore, I donôt really understand what youôre asking when you ask that.ò (Figg, Tr. 2003-04). Indeed, Judge Chappell noted that Complaint Counselôs questioning was ñassuming that a method is required rather than honesty and hard work.ò (Figg, Tr. 2004). Mr. Figg agreed that ñI think honesty and hard work and applying the knowledge that Iôve gained over a few decades as a patent attorney and a litigator were all part of the methodology I applied here, a careful analysis. They were all part of it.ò (Figg, Tr. 2005).

> 1371. Mr. Figgôs opinions are not reliable because his process in developing his opinions in this case deviated from his usual process as a litigator of Hatch-Waxman cases. Mr. Figg cannot remember ever litigating a Hatch-Waxman case in which he did not discuss the merits of the case with in-house counsel, but he did not talk to anyone at Impax about the merits of the patent case between Endo and Impax that settled in June 2010. (Figg, Tr. 1992).

RESPONSE TO FINDING NO. 1371:

Complaint Counselôs Proposed Finding No. 1371 is incomplete and misleading. The first sentence of Proposed Finding No. 1371 should be disregarded because it violates the Courtôs

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under the same regulatory framework, and therefore represented the most relevant cases for an objective review. Finally, while Mr. Figg has never taken a case to trial in the District of New Jersey, Mr. Figg has tried betw

1378. Mr. Figg opines that if Impax had lost in the District Court, appealed to the Federal Circuit, won its appeal, had the case remanded back to District Court, and went all the way to a new final judgment in the District Court, then a final judgment in the patent litigation could have occurred as early as May 2012. (Figg, Tr. 2045). He has no opinion about the likelihood of Impax winning its case at the end of this new trial. (Figg, Tr. 2045).

RESPONSE TO FINDING NO. 1378:

Complaint Counselôs Proposed Finding No. 1378 is incomplete. While Mr. Figg said that completing a remand by May 2012 was theoretically ñpossible,ò he clarified: ñI think that is extremely unlikely.ò (Figg, Tr. 2044-45). Mr. Figg explained that if the Federal Circuit remanded the case it was more likely that the case would not conclude until May 2013. Mr. Figg testified that ñthat remand would likely take somewhere between 6 months and 18 months. *And I tend to think more toward the latter*, because . . . the trial judge would have to schedule a new trial.ò (Figg, Tr. 1914-15 (emphasis added)).

e) Mr. Figg is not offering an opinion that Endo's patents were valid or invalid or whether Impax would have ultimately won or lost the patent case

1379. Mr. Figg is not offering any opinions as to whether, in 2010, Endoôs patents were

RESPONSE TO FINDING NO. 1382:

The first sentence of Complaint Counselôs Proposed Finding No. 1382 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Further, the phrase ñpercentage probabilityò is ambiguous and unclear.

The second sentence of Proposed Finding No. 1382 is incomplete. While Mr. Figg does not have a ñspecific percentage probability in mind,ò he clarified that his report does convey his ñlevel of confidenceò in each opinion and that ñyou would be able to ascertain [his level of confidence] from the context and the explanation in my report for how I arrived at that opinion.ò (Figg, Tr. 2011).

> 1383. Mr. Figg offers no opinion as to how the patent litigation ultimately would have turned out. He does not opine that Impax had a zero percent chance of overcoming the issues raised by the District Courtôs claim construction opinion. (Figg, Tr. 2012). There are some scenarios in which things could have gone badly for Endo in the patent litigation. (Figg, Tr. 2017-18).

RESPONSE TO FINDING NO. 1383:

The first sentence of Complaint Counselôs Proposed Finding No. 1383 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Further, Mr. Figg offers clear opinions about the likelihood that Impax would have lost the patent case with Endo. (RX-548.0058 (Figg Rep. ¶ 136) (ñI conclude that Impax was more likely than not to lose the ô933 and ô456 patent litigation with Endoò)).

Respondent has no specific response to the second and third sentences of Proposed Finding No. 1383.

1384. Mr. Figg is not offering an opinion about whether the claim construction opinion by the district court was correctly decided. (Figg, Tr. 2018). If Impax had appealed that decision, it would have been a fair issue to litigate at the appellate level. (Figg, Tr. 2018). He does not offer in his report any opinion about whether the Federal Circuit would have affirmed or reversed the claim construction opinion of the district court. (Figg, Tr. 2020-21).

RESPONSE TO FINDING NO. 1384:

While Respondent has no specific response to the first two sentences of Complaint Counselôs Proposed Finding No. 1384, the third sentence misrepresents Mr. Figgôs report and testimony. Mr. Figg testified that his report ñmake[s] it clear that [he] thought the overall outcome of the litigation was likely to be in Endoôs favor, and [he] would include in the litigation the appeal.ò (Figg, Tr. 2020). Mr. Figg reiterated that ñmy opinion was that Endo was likely to prevail in the litigation, and in my mind that would *include the appellate process*.ò (Figg, Tr. 2021) (emphasis added)).

1385. With respect to the patent case between Impax and Endo that settled in June 2010, Mr. Figg opined that Impaxôs position that its product did not infringe Endoôs patents was well-founded and made in good faith. (Figg, Tr. 2014-15; *see also* Figg, Tr. 2014 (concluding that no one would think that Impax made its non-infringement arguments in bad faith)).

RESPONSE TO FINDING NO. 1385:

Complaint Counselôs Proposed Finding No. 1385 is incomplete and misleading. Mr. Figg testified that he believed that Impaxôs infringement positions were well-founded and made in good faith *based on Impax's proposed claim constructions*, which the court ultimately *rejected*. (Figg, Tr. 2014 (ñQ. My question, sir, was, itôs your opinion that Impaxô position on noninfringement appears to have been well-founded. A. Based on its claim construction. Q. Okay. And Impax had good-faith arguments that its product did not infringe Endoôs patents? A. Based on its claim construction.ò)).

1386. Mr. Figg would not characterize any of Impaxôs arguments in the district court as being frivolous. (Figg, Tr. 2014-15).

RESPONSE TO FINDING NO. 1386:

Respondent has no specific response.

1387. Mr. Figg admits that he has been wrong about his prediction about litigation outcomes in the past. (CX4045 (Figg, Dep. at 180 (ñThere are cases I lost that I thought I should have won . . . .ò)).

RESPONSE TO FINDING NO. 1387:

Respondent has no specific response.

f) Mr. Figg's opinions about the scope of the license in the SLA and Endo's later-obtained patents are not reliable

1388. In his report, Mr. Figg opined that Impax received a license in the SLA ñensuringò it would not be sued on Endoôs later obtained patents. (RX-548 at 0006 (¶ 4.c.) (Figg Report)).

RESPONSE TO FINDING NO. 1388:

Respondent has no specific response.

1389. Mr. Figg acknowledged that opinion was not accurate. (Figg, Tr. 2046-47 (acknowledging the opinion as a ñpoor choice of wordsò and admitting that ñ[o]ne can never ensure that their competitor is not going to sue themò)).

RESPONSE TO FINDING NO. 1389:

Complaint Counselôs Proposed Finding No. 1389 is incomplete. While Mr. Figg acknowledged that using the term ñensuringò was a ñpoor choice of words,ò Mr. Figg explained that this was because ñ[i]tôs pretty easy to bring a lawsuit in this country. . . . Impax could not ensure that Endo wouldnôt sue it, but what Impax did do was it negotiated the terms of an agreement that gave it rights and freedom to operate under patents that Endo would obtain in the future.ò (Figg, Tr. 2047). Mr. Figg further explained that Impax secured a license that allowed it to come to market ñwithout the risk of another infringement lawsuit,ò but that ñ[y]ou canôt

control another person filing a lawsuit. It cost you 100 bucks or something to file a complaint.ò (CX4045 (Figg, Dep. at 262-63)).

1390. Mr. Figg did not quote or interpret the language of the license granted to Impax in the SLA in his report. (Figg, Tr. 2048; CX4045 (Figg, Dep. at 265)).

RESPONSE TO FINDING NO. 1390:

Complaint Counselôs Proposed Finding No. 1390 misrepresents Mr. Figgôs testimony. Mr. Figg never testified that he did not ñinterpret the language of the license granted to Impax in the SLA in his report.ò Mr. Figg clearly testified that he interpreted the language to mean that Impax was ñable to negotiate a broad license and covenant not to sue under later-acquired patents.ò (CX4045 (Figg, Dep. at 265); *see* Figg, Tr. 1934, 1945, 2092). Mr. Figg explained that the language of the SLA granted Impax the freedom to operate ñ[u]nder both the litigated patents as well as future patents that Endo might obtain in this area.ò (Figg, Tr. 1936-37). That Mr. Figg did not directly quote the language of the SLA in his report is irrelevant.

1391. When he submitted his expert report in this case, Mr. Figg was unaware of the subsequent litigation between Endo and Impax regarding the license to Impax in the SLA. (Figg, Tr. 2051). As a result, his opinions in this case do not take into account the subsequent litigation between Endo and Impax regarding the license to Impax in the SLA. (Figg, Tr. 2051). Mr. Figg first saw the complaint that Endo had filed against Impax alleging breach of the license and infringement of some of Endoôs later-obtained patents after he had served his expert report in this matter. (Figg, Tr. 2051). He did not review any pleadings that had to do with the sub

while Mr. Figg did not review materials from the litigation until after Mr. Hoxie raised it in his rebuttal report, Mr. Figg explained that the existence of the litigation ñdidnôt alter [his] opinion that the license agreement that Impax entered gave it a license and a covenant not to sue under patents that would subsequently issue to Endo.ò (Figg, Tr. 2052; *see also* Figg, Tr. 2092). Mr. Figg further explained: ñThe way I viewed all of this and the way it played out was, this was simply an effort by Endo to get additional money in the form of royalty payments from Impax. And the fact . . . that when Endo brought suits on the later patents against a number of other generic companies based on the original Opana ER generic product, they did not sue Impax, and the only rational reason that they would not have sued Impax was they recognized that Impax was licensed under those patents.ò (Figg, Tr. 2093-94).

1392. The District of Delaware has found one of Endoôs later obtained patents invalid, and that courtôs ruling that the ô779 patent had not been shown to be invalid is on appeal. (Figg, Tr. 2049). Mr. Figg offers no opinion as to how the appeal regarding the ô779 patent will turn out. (Figg, Tr. 2050).

RESPONSE TO FINDING NO. 1392:

Respondent has no specific response.

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under the circumstances but the SLA provided Impax and the public with a better outcome than could have reasonably been expected through litigation, namely, generic entry that occurred months—and likely many years—]

(Noll, Tr. 1665 (ñQ. You did not measure what the actual anticompetitive effects are[?] A. Thatôs correct.ò)).

> 1395. The later-issued patents that were the subject of patent infringement litigation were all issued after Impax and Endo agreed to the Impax-Endo Settlement Agreement in June 2010. The patents that were issued to or acquired by Endo were the 8,309,122, 8,329,216, and 7,851,482 patents in 2012, and the 8,808,737 and 8,871,779 patents in 2014. (*see* CCF ¶¶ 1397-1401, below).

RESPONSE TO FINDING NO. 1395:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

> 1396. At the time of the Impax-Endo Settlement Agreement, it was uncertain whether any new patents would issue that Endo might claim would cover Impaxôs generic Opana ER product. (CX3455 at 022-23 (Sep. 19, 2013 *Endo v. Actavis* transcript) (ñNobody knew for sure whether these patents were going to issue . . . . [T]he ô122 and the ô216 patent were in the Patent Office at the time that the prior case was settled. The Patent Office may never have issued the patents; the Patent Office may have issued it.ò)).

RESPONSE TO FINDING NO. 1396:

Complaint Counselôs Proposed Finding No. 1396 should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). The only citation provided by Complaint Counsel is to attorney argument at a preliminary injunction hearing, and therefore should not be admitted for the truth of the matter asserted. Further, the citation makes clear that the statement only applies to two of the relevant patents.

Agreement in June 2010. The first litigation was filed December 11, 2012 against Actavis for infringement of the newly-issued ô122, ô216, and ô482 patents. (RX-495 (*Endo v. Actavis* complaint) (admitted for the fact of the complaint, not the truth of the matter asserted).

RESPONSE TO FINDING NO. 1402:

Respondent has no specific response.

1403. Endo filed infringement suits against Teva, Sandoz, and Roxane on the ô122 and ô216 patents on May 15, 2013 (RX-501 (*Endo v. Teva* complaint) (admitted for the fact of the complaint, not the truth of the matter asserted); RX-500 (*Endo v. Sandoz*

(ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Tellingly, the cited paragraph in Professor Bazermanôs report cites no record evidence for his opinion.

> 1406. As discussed in greater detail above, the issue of including in the SLA a license to future Endo patents arose in the last few days of negotiation of the SLA. Endo and Impax had reached an agreement on the form and substance of the payments from Endo to Impax before Impax requested that a license to patents that may issue from Endoôs pending patent applications be included in the SLA. There is no indication that the payments from Endo to Impax changed in any way as a result of adding the license to potential future patents. (*See* CCF ¶¶ 279-84, above).

RESPONSE: [illegible]

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1936). Endo admitted as much. In a subsequent breach of contract action between Endo and Impax, Endo asserted that Endo would have sued Impax for infringing subsequently acquired patents but for the fact that the Endo-Impax settlement included a license to future patents.

royalties. (RX-364.0011 (SLA § 4.1(d))). This requirement does not affect the scope of the license in Section 4.1(a), which is why Endo never sued Impax for infringement regarding the generic version of original Opana ER under later-acquired patents. (Figg, Tr. 1951-52, 1964). Indeed, Complaint Counselôs own expert states that Section 4.1(d) is only ñarguably in conflict with § 4.1(a).ò (Hoxie, Tr. 2720).

> 1417. A term such as the one in Section 4.1(d) of the SLA that requires the parties to negotiate in good faith ñthe terms of the License to any patents which issue from any Pending Applicationsò is uncommon and problematic. (CX5007 at 016 (¶ 28) (Hoxie Report)).
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> **RESPONSE TO '**

RESPONSE TO FINDING NO. 1418:

Complaint Counselôs Proposed Finding No. 1418 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Proposed Finding No. 1418 is also an improper legal conclusion, not a fact. In any event, Endoôs litigation decisions with respect to its later-acquired patents indicate that Endo believed Impax had a license to those patents. (Figg, Tr. 1951-52, 1964; Hoxie, Tr. 2892-93). There is simply no explanation for why Endo would sue every other ANDA filer and not Impax if it believed Impaxôs license did not give Impax freedom to operate. (Figg, Tr. 1951-52).

1419. In January 2013, in accordance with the SLA, Impax began to sell its generic version of the Original Opana ER product. (JX-003 at 006 (¶ 40)). In October 2015, Endo reached out to Impax to negotiate a license fee for the patents that issued after the execution of the SLA and proposed a royalty of 85% of Impaxôs gross profits. (CX2938 at 004 (email chain between Impax and Endo re: Impax License Agreement); CX2942 at 003 (Oct. 1, 2015 email from Endo to Impax attaching Draft Non-Binding Term Sheet)).

RESPONSE TO FINDING NO. 1419:

Respondent has no specific response.

1420. The parties disagreed over the interpretation of 4.1(a) and 4.1(d). Impaxôs position was that the SLA did not require the parties to negotiate a license fee for the later-issued patents because the SLA granted Impax a royalty-free license that includes patents or patents issued from pending patent applications that could cover or potentially cover Impaxôs ANDA product. (CX2938 at 002 (email chain between Impax and Endo re: Impax License Agreement) (asserting that ñthe patent applications (*and any patents issued thereunder*) being the óPending Applications,ôò and that accordingly ñEndo knows that the ô122, the ô216, the ô779 and the ô737 patents all issued from the Pending Applications, and, therefore are included in Impaxôs existing license regarding its ANDA for generic original Opana ER.ò)).

RESPONSE TO FINDING NO. 1420:

Respondent has no specific response.

1421. On May 4, 2016, Endo filed a suit against Impax in New Jersey, alleging that Impax was in breach of the SLA for failing to negotiate with Endo in good faith a royalty for the three new patents ï the ô122, the ô216 and the ô737 ï which were pending applications at the time Endo and Impax entered into the SLA. (CX2976 at 001 (*Endo v. Impax*, complaint) (admitted for the fact the complaint was filed, not truth of the matter asserted)). Endo claimed that Impaxôs refusal to negotiate a royalty under the new patents was a breach of Section 4.1(d)ôs requirement that they negotiate in good faith an amendment to the terms of the License to any patents which issue from any Pending Applications for the time period following the Exclusivity Period.ò (CX2976 at 011-012 (*Endo v. Impax*, complaint) (admitted for the fact that the allegation was made, not truth of the matter asserted); RX-364 at 0011 (SLA § 4.1(d)). Endo simultaneously sued Impax for infringement of the same patents. (CX2976 at 014-18 (*Endo v. Impax*, complaint) (admitted for the fact of the allegations, not truth of the matter asserted)).

RESPONSE TO FINDING NO. 1421:

Complaint Counselôs Proposed Finding No. 1421 is incomplete. While Endo included claims for patent infringement in its complaint, (CX2976-014-18 (admitted for the fact of the allegations, not truth of the matter asserted)), those claims were predicated on the alleged breach and termination of the contract, which purportedly would have terminated the license, (Figg, Tr. 2050-51). Whether the contract was terminated was an issue in the litigation. Endo did not seek an injunction to prevent Impax from selling oxymorphone ER. (Hoxie, Tr. 2891).

1422. Endo indicated to Impax that it hoped the patent infringement suit would lead Impax to come to terms with Endo over royalties for the newly-issued patents. (CX2944 at 001-02 (Oct. 31, 2016 email chain attaching letter from Endo to Impax re: notice of termination of the license agreement (ñhad hoped the lawsuit would prompt Impax to honor the promises it made to Endo and come to the negotiation tableò))).

RESPONSE TO FINDING NO. 1422:

Respondent has no specific response.

1423. Impax moved to dismiss for failure to state a claim upon which relief could be granted, arguing that the plain language of Section 4.1(a) of the SLA granted it a royalty-free license under the Pending Applications. (CX3356 at 011-12 (Impaxôs Motion to Dismiss) (admitted for the fact of allegation, not truth of the matter asserted)).

RESPONSE TO FINDING NO. 1423:

Complaint Counselôs Proposed Finding No. 1424 is inaccurate and misstates the arguments that Impax made in its motion to dismiss. Impax moved to dismiss on a number of grounds described in CX3356, which speaks for itself.

1424. On October 25, 2016, the judge denied the motion to dismiss except as to the ô737 patent. (CX3361 at 014 (*Endo v. Impax*, opinion) (admitted for the fact the court issued the opinion, not truth of the matter asserted)).

RESPONSE TO FINDING NO. 1424:

Respondent has no specific response.

1425. On October 31, 2016, Endo provided Impax notice of termination of the SLA due to what Endo characterized as Impaxôs material breach of the agreement. (CX2944 at 002 (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 Impaxôs infringing generic Opana ER product. (CX2944 at 003 (Oct. 31, 2016 email chain attaching letter from Endo to Impax re: notice of termination of the license agreement) (notifying Impax that ñthere is no legitimate dispute that Impaxôs current Opana ER generic tablets infringe Endoôs patentsò and demanding that ñImpax should therefore honor Endoôs patent rights and immediately cease all sales of those infringing tabletsò)). Impax continued to disagree with Endoôs interpretation of the SLA as it applied to the later-issued patents, as well as Endoôs interpretation of what constituted a material breach. (CX2939 at 003-04 (Nov. 2, 2016 email chain attaching letter from Impax to Endo)).

RESPONSE TO FINDING NO. 1425:

Respondent has no specific response.

1426.

(CX3275 at 001 (*in camera*)).

RESPONSE TO FINDING NO. 1426:

Respondent has no specific response.

1427. The 2017 Contract Settlement Agreement included

(CX3275 at 011, 013-14
(*in camera*)).

(CX3275 at 014-15
(*in camera*))).

RESPONSE TO FINDING NO. 1427:

Respondent has no specific response.

1428.

(CX3275 at 012, 014
(*in camera*)).

(CX3275 at 013
(*in camera*)).
at 0Q2

RESPONSE TO FINDING NO. 1430:

Complaint Counselôs Proposed Finding No. 1430 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Tellingly, the cited paragraph from Mr. Hoxieôs report cites no record evidence. (CX5007-020 (Hoxie Rep. ¶ 36)). Finally, Proposed Finding No. 1430 is inaccurate. Endo did not seek an injunction to prevent Impax from selling oxymorphone ER. (Hoxie, Tr. 2891).

5. There are sound reasons to expect an oxymorphone ER product be on the market today, even in the absence of the Impax-Endo Settlement Agreement

1431. At the time Impax and Endo entered into the Impax-Endo Settlement Agreement,

With respect to the fourth sentence of Proposed Finding No. 1431, while it may not be possible ñto know what the market would look like today if Impax and Endo had not settled,ò there is significant real-world evidence that indicates that if Impax had not secured a broad license from Endo, oxymorphone ER may not be on the market today, especially in generic form. First, given the courtôs claim construction in the underlying infringement case, it was more likely than not that Impax would have lost the infringement case and therefore been enjoined from selling the product. (RX-548.0058 (Figg Rep. ¶ 136); Figg, Tr. 1870). Second, Endo has aggressively and successfully asserted its patents covering oxymorphone ER and enjoined all other ANDA filers from marketing oxymorphone ER. (Figg, Tr. 1958-59, 1965-66). Third, Endo has ceased selling any oxymorphone ER product because it switched its original product to a reformulated product ð claiming the original formulation posed safety risks, (Snowden, Tr. 480) ð and then was later asked to remove the reformulated product from the market, (Snowden, Tr. 446). Finally, Impax is the only seller of oxymorphone ER on the market today. (JX-003-008 (¶ 59) (Second Set of Joint Stipulations); Addanki, Tr. 2383 (ñtoday Impax is the only seller of that productò)).

> 1432. Even today, the outcome of the litigation regarding the later-issued patents, like all patent litigation, is uncertain. If Endo had brought additional suits against Impax based on these later-issued patent, the outcome of such litigation cannot be predicted. (CX4039 (Noll, Dep. at 265-66)). To know the outcome of such a litigation would require making many assumptions about a series of events, including the date of acquisition of certain later-issued patents, Impaxôs infringement case, and the outcome of Endoôs infringement cases against other ANDA filers. (CX4039 (Noll, Dep. at 265-66).

RESPONSE TO FINDING NO. 1432:

Complaint Counselôs Proposed Finding No. 1432 is inaccurate and misleading. It is a near certainty that if Impax had not secured the license in the Settlement and License Agreement, Endo would have sued Impax on the later-acquired patents and prevailed. In fact, in a

subsequent breach of contract action between Endo and Impax, Endo asserted that it would have sued Impax for infringing subsequently acquired patents but for the fact that the Endo-Impax settlement included a license to future patents. (Hoxie, Tr. 2892-93). Mr. Figg testified that ñif Impax had not had the license to future patents in its settlement agreement, thereôs little doubt in my mind that Endo would have included claims of infringement against Impax for the original generic Opana ER.ò (Figg, Tr. 1951). Indeed, Endo *did* sue Impax for infringement of its later-acquired patents with respect to Impaxôs generic version of *reformulated* Opana ER because the license in the Settlement and License Agreement did not cover a reformulated product. (Figg, Tr. 1951-52, 1964). Endo *won* that case and has successfully *enjoined* Impaxôs reformulated product pursuant to the later-acquired patents. (*See* Figg, Tr. 1951-52; Koch, Tr. 440; RX-525).

> 1433. In the world where Impax and Endo had not entered into the Impax-Endo Settlement Agreement, and Impax and no other generics had entered with an oxymorphone ER product market, Endo may have had different incentives following its withdrawal of Reformulated Opana ER. Endo would have strong financial incentives to realize value from its Opana ER franchise and its patent portfolio relating to Opana ER. If Impax had never come on the market, Endo would have had an incentive to introduce a version of the original formulation of Opana ER when Endo knew that the FDA was considering requesting it to withdraw Reformulated Opana ER from the market. (Noll, Tr. 1575-76). In that situation, Endo might be selling its own original formulation of Opana ER.

RESPONSE TO FINDING NO. 1433:

Complaint Counselôs Proposed Finding No. 1433 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Further, Proposed Finding No. 1433 ignores significant real-world evidence that Endo would not have relaunched its original oxymorphone ER after the FDA asked it to withdraw its reformulated product. (Snowden, Tr. 446). Indeed, Endo argued that it

removed the original formulation for safety reasons. (Snowden, Tr. 480). And Endo recognized that there would be significant ñmoralò issues with bringing back a product it claimed it removed for safety reasons. (CX4019 (Lortie, Dep. at 117-18)). Accordingly, Complaint Counselôs unsupported assertion that ñEndo might be selling its own original formulation of Opana ERò is base speculation and contrary to the weight of the record.

> 1434. Even if Endo does not introduce a version of the original formulation of Opana ER, Endo has the financial incentive to maximize profits from its Opana ER franchise and its patent portfolio relating to Opana ER. (Addanki, Tr. 24

Briefs at 2). Proposed Finding No. 1435 also lacks foundation and is not supported by the record. The documents cited do not say anything about the propositions advanced. It is especially telling that Complaint Counsel does not cite a single Endo witnesses or document, despite discussing Endoôs actions, incentives, and potential plans. Proposed Finding No. 1435 is an improper attempt by Complaint Counsel to insert a new issue into the litigation that was not addressed at trial or during discovery, and it is entirely speculative.

C. The reverse payment was not necessary to achieve any of the purported procompetitive benefits of the agreement

1436. The reverse payment from Endo to Impax was not necessary to achieve either entry before patent expiration or a license to patents that had not yet issued. (*See* CCF ¶¶ 1437-59).

RESPONSE TO FINDING NO. 1436:

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1. The reverse payment was not necessary for Impax to achieve entry prior to patent expiration in September 2013

1437. The SLA restricted Impax from selling generic Opana ER for more than 30 months ð from mid-June 2010 until the end of December 2012 ð and licensed Impax to enter approximately eight months before expiration of the last patent on which Impax was sued. (RX-364 at 007 (SLA § 3.2); CX0301 (Orange Book patent data)).

RESPONSE TO FINDING NO. 1437:

While Respondent does not dispute that the Settlement and License Agreement allowed Impax to launch its generic product risk-free roughly eight months before the patents-in-suit

expired, the remainder of Complaint Counselôs Proposed Finding No. 1437 is incomplete and misleading. Impax could sell certain dosages of generic Opana ER as soon as ña Third Party commences commercial sale of an FDA approved generic extended release oxymorphone product that is AB rated to Opana ER Product.ò (RX-364.0002 (SLA § 1.1)). With respect to the rest of the dosages, the agreement allowed Impax to market and offer to sell its generic product ñthirty days prior to the anticipated applicable Commencement Date,ò which would be no later than January 1, 2013. (RX-364.0001-02, 07 (SLA § 3.2)).

1438. A pure term-split settlement between Impax and Endo was feasible. Removing the reverse payments would logically result in an entry date earlier than January 2013. (*See* CCF ¶¶ 1439-55).

RESPONSE TO FINDING NO. 1438: [illegible]

The proposed summary finding should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to those findings.

1439. Settlements of Hatch-Waxman litigation can be, and typically are, based on the merits of the patent, reduced litigation costs, and risk aversi

resisted an earlier licensed-entry date when Impax approached Endo with an entry-date only proposal. (Snowden, Tr. 371-73, 423).

Professor Bazerman conceded that he has not seen any evidence in the record that Endo offered an earlier entry date. (Bazerman, Tr. 907). Professor Bazerman did not identify a possible reservation date for Endo. (Bazerman, Tr. 913). And Professor Bazerman cannot say with any certainty that an alternative settlement was possible. (Bazerman, Tr. 914). Dr. Addanki confirms that ñ[f]rom an economic standpoint, thereôs no basisò to assume an alternative settlement was possible. (Addanki, Tr. 2359). Therefore, ñthe only real alternative we have to the settlement that we have before us is that the parties continue to litigate.ò (Addanki, Tr. 2374).

1442. Although Impaxôs economic expert, Dr. Addanki, outlines ñselected reasonsò why settlement with no reverse payments might not have been negotiated by Impax and Endo, he never concludes that such an agreement was impossible. (RX-547 at 0061-66 (¶¶ 115-24) (Addanki Rebuttal Report)). In fact, Dr. Addanki does not know whether or not there were any settlements that Endo and Impax were willing to accept absent any payments. (Addanki, Tr. 2467).

RESPONSE TO FINDING NO. 1442:

Respondent has no specific response.

1443. Dr. Addanki concedes that he lacks information to determine the earliest date of generic entry that Endo was willing to accept, also known as Endoôs reservation date. (Addanki, Tr. 2466-67 (ñI do not know what the true reservation date was for Endo or anyone negotiating on behalf of Endoò)).

RESPONSE TO FINDING NO. 1443:

Complaint Counselôs Proposed Finding No. 1443 is incomplete and misleading. While Dr. Addanki said he did not know the ñtrue reservation dateò for Endo, he states that he is ñnot aware of any evidence that Endo would have agreed to an earlier entry date, and, as an economic matter, there is no reason to expect that the parties could have agreed upon an earlier entry date.ò

(RX-547.0060 (Addanki Rep. ¶ 114)). Indeed, Professor Bazerman did not identify a possible

1448. [redacted] (CX3383 (Actavis settlement) (admitted for fact of the settlement and its terms, not truth of the matter asserted) (*in camera*)).

RESPONSE TO FINDING NO. 1448:

Respondent has no specific response.

1449. Effective April 12, 2010, Barr Laboratories, Inc. settled litigation relating to generic Opana ER with Endo and received a license to the litigated patents starting no later than September 15, 2012. The Barr-Endo settlement did not include a reverse payment. (CX3378 at 070-071 (Barr settlement, definitions of ñCommencement Dateò and ñEffective Dateò)).

RESPONSE TO FINDING NO. 1449:

Respondent has no specific response.

1450. Effective June 7, 2010, Sandoz Inc. settled litigation relating to generic Opana ER with Endo and received a license to the litigated patents starting no later than September 15, 2012. The Sandoz-Endo settlement did not include a reverse payment. (CX3378 at 092-93 (Sandoz settlement, definitions of ñCommencement Dateò and ñEffective Dateò)).

RESPONSE TO FINDING NO. 1450:

Respondent has no specific response.

1451. Effective October 4, 2010, Watson Laboratories, Inc. settled litigation relating to generic Opana ER with Endo and received a license to the litigated patents starting no later than September 15, 2012. The Watson-Endo settlement did not include a reverse payment. (CX3378 at 031 (Watson settlement, definitions of ñCommencement Dateò and ñEffective Dateò)).

RESPONSE TO FINDING NO. 1451:

Respondent has no specific response.

1452. Effective May 4, 2011, Roxane Laboratories, Inc. settled litigation relating to generic Opana ER with Endo and received a license to the litigated patents starting no later than September 15, 2012. The Roxane-Endo settlement did not include a reverse payment. (CX3452 at 115-17 (Roxane settlement, definitions of ñCommencement Dateò and ñEffective Dateò)).

RESPONSE TO FINDING NO. 1452:

Respondent has no specific response.

1453. Dr. Addankiôs failure to consider a September 2012 entry date similar to what other generics received cannot be attributed to Endoôs goal to introduce a reformulated version of Opana ER before generic entry. Around the time of settlement with Impax, Endo expected that it would get approval for and launch a reformulated oxymorphone extended-release product between December 2010 and June 2011. (CX3038 at 001 (Hogan email dated 4/2/2010 entitled ñFW: EN3288 Core Commercial Launch Team (CCLT) Updateò)). Dr. Addanki offers no analysis supporting a conclusion that paying the Endo Credit ð which was ultimately more than $102 million ð was preferable to Endo than offering Impax an entry date in September 2012 without any reverse payments. (RX-547 at 0060 (Addanki Rebuttal Report) (¶ 114) (ñI am not aware of any evidence that Endo would have agreed to an earlier entry date, and, as an economic matter, there is no reason to expect that the parties could have agreed upon an earlier entry dateò)).

RESPONSE TO FINDING NO. 1453:

Complaint Counselôs Proposed Finding No. 1453 is inaccurate and misleading because there is no evidence in the record that a ñSeptember 2012 entry dateò was possible. First, Complaint Counsel cites no evidence indicating that Endo would have agreed to a September 2012 entry date. Second, while a number of other ANDA filers obtained a September 2012 entry date in settlements with Endo ntm Ú γ l M ę x l M D m x l D M ɾ ¸ ɥ ɾ M

1454. Further, the only ñsimple settlementò without any payment and a

2. The reverse payment was not necessary for Impax to obtain a license to additional patents

1456. Under the SLA, Impax received a license to patent applications that had not issued at the time of settlement, but might issue in the future. (RX-364 at 0009 (SLA § 4.1(a))).

RESPONSE TO FINDING NO. 1456:

Respondent has no specific response.

1457. 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. (CX0324 at 030 (draft SLA § 4.1(a) (showing Impaxôs edits to the June 5, 2010 draft version to include patent applications)). 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. (CX5001 at 030 (¶ 56) (Bazerman Report)). 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 ð signed the same day as Impax ð did not include a reverse payment. (CX3378 at 092-93 (Sandoz settlement, definitions of ñCommencement Dateò and ñEffective Dateò), 100 (Sandoz settlement, § 4.4)).

RESPONSE TO FINDING NO. 1457:

The first and third sentences of Complaint Counselôs Proposed Finding No. 1457 should be disregarded because they violate the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). These sentences are also improper argument, not facts. Indeed, the cited paragraph of Professor Bazermanôs report includes no citations to record evidence to support his argument, and therefore Mr. Bazermanôs opinions are based on unreliable expert testimony.

Respondent has no specific response to the second sentence of Proposed Finding No. 1457 other than to clarify that the cited evidence says nothing about whether any term had ñvalueò to any party. Finally, the last sentence of Proposed Finding No. 1457 is incomplete and misleading. Endo never granted Sandoz a license to future patents covering generic

oxymorphone ER, which is why Endo sued Sandoz for infringement of the ó482, ó122, and ó216 patents in 2013. (RX-500 (*Endo v. Sandoz* complaint) (admitted for the fact of the complaint, not the truth of the matters asserted therein)).

> 1458. Moreover, the reverse payment was part of the settlement agreement substantially before the license to additional patents was even suggested. Impax first raised that license on June 5, 2010, whereas Impax and Endo had been discussing the reverse payment since the previous month and had even reached an agreement in principle on June 3, 2010, two days before Impax raised the license to patents not yet issued. (CX0320 at 003, 009-010 (draft terms sheets circulated on May 26, 2010, which incorporated the No-AG provision and payments under a co-promotion/licensing agreement for IPX-066, including a $10 million option fee due at signing);

RESPONSE TO FINDING NO. 1459:

Complaint Counselôs Proposed Finding No. 1459 should be disregarded because it violates this Courtôs Order on Post-Trial Briefs by citing ñto expert testimony to support factual propositions that should be established by fact witnesses or documents.ò (*See* Court, Tr. 1859 (ñ[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.ò)). Tellingly, the cited paragraph in Professor Bazermanôs report cites no evidence for the proposition. Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondentôs replies to

1462. As of February 2016, Impaxôs generics business had more than 60 products on the market and more than 40 ANDAs either in regulatory review or in development. (CX3271 at 003 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1462:

Respondent has no specific response.

1463. As of February 2016, Impax had 112 ANDAs approved by the FDA (including one with tentative approval) and the right to market and/or share in the profits of 14 approved ANDAs held by third parties. (CX3271 at 012 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1463:

Respondent has no specific response.

1464. As of February 2016, Impax had 25 applications pending at the FDA representing approximately $7.9 billion in 2015 U.S. product sales. (CX3271 at 012 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1464:

Respondent has no specific response.

1465. [redacted]
(RX-246 at 0024 (July 2015 Impax Portfolio Executive Committee (PEC) Meeting Presentation) (*in camera*); CX3271 at 011 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1465:

Respondent has no specific response.

1466. Impaxôs ñproducts and product candidates are generally difficult to formulate and manufacture, providing certain competitive advantages.ò (CX3271 at 011 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1466:

Respondent has no specific response.

1467. Impaxôs Specialty Pharma division primarily focuses on the development and promotion of ñproprietary branded pharmaceutical products for the treatment of central

RESPONSE TO FINDING NO. 1472:

Respondent has no specific response.

2. Impax regularly engages in patent litigation

1473. As a manufacturer and marketer of both generic and branded pharmaceutical products, Impax regularly engages in patent litigation. (CX3163 at 020 (¶ 100) (Impax Answer) (Impax ñis sometimes involved in patent litigation related to various drugs.ò); *see also* CCF ¶¶ 1474-1478).

RESPONSE TO FINDING NO. 1473:

Complaint Counselôs Proposed Finding No. 1473 is not supported by the cited evidence. The cited document states that ñImpax admits that it continues to develop and manufacturer pharmaceutical products, and that ð like virtually all pharmaceutical companies ð it is *sometimes* involved in patent litigation related to various drugs.ò (CX3163-020 (emphasis added)).

1474. Impax is ñinvolved in numerous patent litigationsò in which Impax ñchallenge[s] the validity or enforceability of innovator companiesô listed patents and/or their applicability toò Impaxôs generic products. (CX3271 at 030 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1474:

Respondent has no specific response.

1475. Impaxôs generic products division ñis routinely subject to patent infringement litigation brought by branded pharmaceutical manufacturers seeking to delay FDA approval to manufacture and market generic forms of their branded products.ò (CX3271 at 030 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1475:

Respondent has no specific response.

1476. Impax is ñ[a]lmost alwaysò sued any time Impax files an ANDA with a Paragraph IV certification. (CX4003 at 005 (Snowden, IHT at 15)).

RESPONSE TO FINDING NO. 1476:

Respondent has no specific response other than to clarify that Ms. Snowden was testifying about a brand suing Impax for patent infringement after Impax filed a Paragraph IV certification, not the FTC or any other party suing on the basis of antirust (or any other type of) Pen was

1482. Impaxôs current CEO and former head of several pharmaceutical companies, Paul Bisaro, has testified under oath that he ñwould like to always try to maintainò a No-AG clause ñwherever possible.ò (CX4000 at 004 (Bisaro, IHT at 33-34); Nestor, Tr. 2928 (identifying Mr. Bisaro as CEO of Impax)).

RESPONSE TO FINDING NO. 1482:

Complaint Counselôs Proposed Finding No. 1482 is inaccurate and misleading. First, Mr. Bisaro testified at an investigational hearing in 2014, when he was an employee of Actavis, another pharmaceutical company, and at which Impax was not present and had no rights. (CX4000 (Bisaro, IHT at 7)). Second, Mr. Bisaro actually testified, ñhaving grown up in the industry and knowing when the law [Hatch-Waxman] was passed, it was not supposed to have an AG, I would like to always try to maintain that, wherever possible. . . . So, I mean, they werenôt contemplated at the time the law was passed, for sure. Otherwise somebody would have said something.ò (CX4000 (Bisaro, IHT at 33-34)). Third, Mr. Bisaro stated that a No-Authorized Generic Provision is not an ñessential term,ò but rather ñwe look at the whole situation and say this is -- this is a good deal for us. And itôs a good deal for our shareholders, and itôs a good deal for consumers. And thatôs what we do.ò (CX4000 (Bisaro, IHT at 127)). Fourth, there is no evidence to suggest Mr. Bisaro, in his role at Impax, attempted to maintain a No-Authorized Generic clause. Fifth, it bears noting that at the time Mr. Bisaro gave his testimony, no Court of Appeals had ruled on the legality of a ñNo AGò provision, and multiple district courts had held that they were *lawful*. *See, e.g.*, *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 190ï95 (D.R.I. 2014), *vacated*, 814 F.3d 538 (1st Cir. 2016); *In re Lamictal Dir. Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 567ï69 (D.N.J. 2014), *vacated*, 791 F.3d 388 (3d Cir. 2015).

1483. Impaxôs former CEO, Larry Hsu, testified under oath that, ñobviously, if you have a choice, with AG, without AG, you prefer to get the no AG.ò (CX4014 at 018 (Hsu, IHT at 68)).

support the suggestion that current Impax employees view other theoretical No-Authorized Generic provisions as important in any theoretical future settlements.

B. Injunctive relief is necessary to prevent anticompetitive conduct in the oxymorphone ER market

1485. [redacted] (CX3275 at 001 (2017 Contract Settlement Agreement) (*in camera*)).

RESPONSE TO FINDING NO. 1485:

The first sentence of Complaint Counselôs Proposed Finding No. 1485 is an improper legal conclusion, not a fact. The first sentence is also unsupported by any record evidence and should be disregarded because it violates the Courtôs Order on Post-Trial Briefs, which requires that ñ[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record.ò (Order on Post-trial Briefs at 2). Respondent has no specific response to the second sentence of Proposed Finding No. 1485. Finally, Proposed Finding No. 1485 is an improper attempt by Complaint Counsel to insert a new issue into the litigation that was not addressed at trial or during discovery, and it is entirely speculative.

1486. [redacted] (CX3275 at 011 (2017 Contract Settlement Agreement) (*in camera*)).

RESPONSE TO FINDING NO. 1486:

Respondent has no specific response.

1487. [redacted]

(CX3275 at 013-14 (2017 Contract Settlement Agreement § 1(i)) (*in camera*))).

RESPONSE TO FINDING NO. 1487:

Respondent has no specific response.

1488.

(CX3275 at 013 (2017 Contract Settlement Agreement §§ 1(h), (i)) (*in camera*))).

RESPONSE TO FINDING NO. 1488:

Respondent has no specific response.

1489. Endo ceased selling Reformulated Opana ER on September 1, 2017. (JX-001 at 012 (¶ 54)).

RESPONSE TO FINDING

(CX6048-001). 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)).

1490.

(CX3275 at 013 (2017 Contract Settlement Agreement § 1(i)) (*in camera*))).

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RESPONSE TO FINDING NO. 1492:

While Respondent does not dispute [redacted] as Proposed Finding No. 1492 attempts to suggest. Moreover, Proposed Finding No. 1492 is an improper attempt by Complaint Counsel to insert a new issue into the litigation that was not addressed at trial or during discovery, and it is entirely speculative.

IMPAX'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED CONCLUSIONS OF LAW

1. Impax Laboratories, Inc., is a ñcorporationò within the meaning of Section 4 of the Federal Trade Commission Act., 15 U.S.C. § 44. JX-001 at 001 (¶ 4).

RESPONSE TO CONCLUSION NO. 1:

Respondent has no specific response.

2. Impax has engaged, and continues to engage, in commerce and act

RESPONSE TO CONCLUSION NO. 5:

Complaint Counselôs Proposed Conclusion No. 5 is incomplete.

To begin with, it is not the case that *all* alleged reverse-payment settlements are automatically subject to antitrust scrutiny under the rule of reason. As the Supreme Court stated in *FTC v. Actavis Inc.*, 133 S. Ct. 2223 (2013), a reverse-payment settlement ñcan bring with it the risk of significant anticompetitive effectsò warranting the application of antitrust scrutiny only where the reverse payment is ñlarge and unjustified.ò *Id.* at 2237.

Numerous courts have affirmed that proof of a settlement with a ñlarge and unjustifiedò reverse payment is required to trigger antitrust scrutiny in the first place. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251-52 (3d Cir. 2017), *petition for cert. filed*, No. 17-771 (U.S. Nov. 20, 2017) (only after plaintiffs have ñóallege[d] facts sufficient to support the legal conclusion that the settlemca Ê !mca Ê _ M æ u]riʃ l D Ŏ y φ

Litig., 42 F. Supp. 3d 231, 262 (D. Mass. 2014), *aff'd*, 842 F.3d 34 (1st Cir. 2016) (ñólarge and unjustifiedô reverse payments must be analyzed under the rule of reasonò). To hold otherwise ñwould compel antitrust scrutiny of a settlement regardless of whether its terms could reasonably be construed as a large and unjustified reverse payment[, . . .] ignore the limiting principles set forth in the [*Actavis*] decision, and subject virtually *any* settlement to antitrust scrutiny ð a result the [Supreme] Court could not have intended.ò

(Compl. Counsel Post-trial Br. at 47, *In re Impax Labs., Inc.*, Dkt. 9373 (F.T.C. Dec. 20, 2017) [hereinafter ñCC PTBò].)

Proving monopoly power invariably requires the plaintiff to identify and establish the existence of a cognizable relevant market. ñWithout a well-defined relevant market, a court cannot determine the effect that an allegedly illegal act has on competition.ò Initial Decision at 123, *In re 1-800 Contacts, Inc.*, No. 9372 (F.T.C. Oct. 27, 2017) [hereinafter ñ*1-800 Contacts*ò].

> 6. Under *Actavis*, a plaintiff can satisfy its ñinitial burdenò under the rule of reason by ñestablishing anticompetitive effects through market power and evidence of a large reverse payment.ò *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 416 (E.D. Pa. 2015).

RESPONSE TO CONCLUSION NO. 6:

Complaint Counselôs Proposed Conclusion No. 6 is wrong.

This Proposed Conclusion wholly relies on a single district court decision that may not even be good law in that district. In *King Drug Co. of Florence v. Cephalon, Inc.* (ñ*Cephalon*ò), 88 F. Supp. 3d 402 (E.D. Pa. 2015), the court began with the observation that ñ[t]he specific contours of the rule of reason analysis to be applied under *Actavis* are not . . . well-defined,ò and from there, fashioned its own framework. *See* 88 F. Supp. 3d at 412-21. Later that year, however, the Third Circuit made clear in *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.* (ñ*Lamictal*ò), 791 F.3d 388 (3d Cir. 2015), that the ñtraditional,ò ñfull-fledged,ò ñwell-established,ò ñwell-mappedò rule of reason applies. *Id.* at 398 n.15, 399, 411, 412.

As noted in Impaxôs response to Complaint Counselôs Proposed Conclusion No. 5, proof of monopoly power in a properly defined relevant market is an essential element of every rule of reason claim. *Chi. Prof'l Sports*, 95 F.3d at 600. But that does not relieve Complaint Counsel of the burden of showing actual ce pay ъ l ʁ ə *HU*

reverse payment patent settlement lawsuits, . . . market power alone cannot be sufficient to demonstrate anticompetitive effects under the rule of reason. . . . The plaintiffs, therefore, must

Salvino, Inc., 420 F. Supp. 2d 212, 220 (S.D.N.Y. 2005), *aff'd*, 542 F.3d 290 (2d Cir. 2008) (ñUnder a quick look analysis, the plaintiff is relieved of its initial burden of showing that the challenged restraints have an adverse effect on competition.ò) (quotation omitted). This is exactly what the FTC advocated for in *Actavis* ð unsuccessfully.[1]

Moreover, Complaint Counselôs Proposed Conclusion No. 6 conflates two distinct analytical questions: **(1)** whether the defendants entered into a settlement containing a ñlarge and unjustifiedò reverse payment, warranting antitrust scrutiny in the first place; and **(2)** whether the settlement is anticompetitive, as determined by the rule of reason. While proof of a settlement with a ñlarge and unjustifiedò reverse payment may be necessary to subject a challenged agreement to rule of reason scrutiny under *Actavis*, it does not substitute for proof of actual anticompetitive effects under the rule of reason. *See Sergeants Benevolent Ass'n*, 2016 WL 4992690, at *13; *Wellbutrin*, 133 F. Supp. 3d at 754-55; *Actos*, 2015 WL 5610752, at *11, *14; *United Food*, 74 F. Supp. 3d at 1065-66. As the Supreme Court stated in *Actavis*, while a ñlarge and unjustifiedò reverse payment carries ñ*risk* of significant anticompetitive effects,ò the ñbasic questionò posed by the rule of reason remains ñthat of the *presence* of significant unjustified anticompetitive consequences.ò 133 S. Ct. at 2237-38 (emphasis added).

> 7. The relevant anticompetitive effect *under Actavis* is that the reverse payment agreement interferes with the competitive process. The reverse payment agreement prevents ñthe risk of competition,ò allowing the parties ñto maintain and share patent-generated monopoly profitsò rather than ñface what might have been a competitive market ð the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.ò *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236-37 (2013). Thus, ñin the

[1] (*See* Reply Br. of FTC at 2-3, *FTC v. Actavis Inc.*, No. 12-416 (U.S. Mar. 18, 2013) (asserting that a ñlarge cash paymentò warrants óa confident conclusionô that óthe principal tendencyô . . . of a reverse-payment agreement is anticompetitive, so that the burden of identifying a procompetitive justification is properly placed on the agreeing partiesò; advocating for ñquick lookò analysis) (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999)).)

> absence of some other justification, the antitrust laws are likely to forbid the arrangement.ò *Id.* at 2237.

RESPONSE TO CONCLUSION NO. 7:

Complaint Counselôs Proposed Conclusion No. 7 is wrong. Though Complaint Counsel couches its arguments in cherry-picked snippets from *Actavis*, it mischaracterizes that decision and misstates the law.

To begin with, nowhere in *Actavis* did the Supreme Court mention the ñcompetitive process,ò much less hold that the ñrelevant anticompetitive effectò is ñinterfer[ing] with the competitive process.ò Rather, the Court made clear that Complaint Counsel must ñprove its case as in other rule-of-reason cases,ò and that the ñbasic questionò posed by the rule of reason remains unchanged: ñthat of the *presence* of significant unjustified anticompetitive consequences.ò *Actavis*, 133 S. Ct. at 2237-38 (emphasis added).

Other decisions, not cited in Complaint Counselôs Proposed Conclusion No. 7, explain that proving harm to the ñcompetitive processò does not lighten or obviate the need to show actual anticompetitive effects. As the D.C. Circuit stated in *Microsoft*, for example, to be deemed anticompetitive, a defendantôs conduct ñmust harm the competitive *process* and thereby *harm consumers*.ò 253 F.3d at 58 (latter emphasis added); *see also id.* at 59 (ñno less in a case brought by the Government, [the government] must demonstrate that the monopolistôs conduct harmed competitionò).

To the extent Complaint Counsel suggests that the *Actavis* Courtôs reference to avoiding the ñrisk of competitionò amounts to a redefinition of the term ñanticompetitive effect,ò it is incorrect. The Commission has held that where Complaint Counsel alleges an agreement ñ*eliminate[d] the risk of competition*,ò it must prove that the allegedly excluded competitorôs ñentry was reasonably probable in the absence of the [challenged agreement].ò *In re McWane*,

Inc., No. 9351, 2014 WL 556261, at *32-37 (F.T.C. Jan. 30, 2014), *aff'd*, 783 F.3d 814 (11th Cir. 2015) (emphasis added). This is in keeping with standard antitrust principles in cases where defendants allegedly excluded or avoided potential competition. *See, e.g.*, *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 862 (D.C. Cir. 2008) (in suit alleging that defendants restrained generic drug competition, plaintiff must prove that ñthe excluded firm was willing and able to supply [the generic drug] but for the incumbent firmôs exclusionary conductò); *Engine Specialties, Inc. v. Bombardier Ltd.*am m ʇ ʻ

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RESPONSE TO CONCLUSION NO. 9:

Respondent has no specific response.

10. For market definition, the relevant antitrust question is whether products are economic substitutes, not just whether they are functional substitutes. A product is a close economic substitute for another only if there is high cross-elasticity of demand between the products ð i.e., an increase in price on one product would cause a large number of consumers to switch to the other. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437-38 (3rd Cir. 1997).

RESPONSE TO CONCLUSION NO. 10:

Complaint Counselôs Proposed Conclusion No. 10 is incomplete and partially incorrect.

For purposes of identifying the relevant product market, the question is not whether products are ñcloseò substitutes, as Complaint Counsel contends. The question, rather, is whether the products are ñ*reasonable* substitutes.ò *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 25 (D.D.C. 2015) (emphasis added) (citing *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 46 (D.D.C. 1998); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1074 (D.D.C. 1997)). Or as the Supreme Court has put it, products that are ñreasonably interchangeable by consumers for the same purposesò belong to the same relevant market. *United States v. E.I. Du Pont de Nemours & Co. v. United States*, 351 U.S. 377, 395 (1956); *see In re N.C. Bd. of Dental Examiners*, 152 F.T.C. 75, 161, *aff'd*, 152 F.T.C. 640 (2011) (ñRelying on *du Pont*, courts have found the óreasonable interchangeabilityô standard to be the essential test for ascertaining the relevant product market.ò).

Reasonable interchangeability requires only that ñone product [be] roughly equivalent to another for the use to which it is put; while there may be some degree of preference for the one over the other, either would work effectively.ò *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436-37 (3d Cir. 1997); *see Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*,

838 F.3d 421, 436 (3d Cir. 2016) (ñproducts need not be perfectly fungible to be considered reasonably interchangeable for market-definition purposesò).

It is indeed true that mere functional substitutes do not necessarily compete in the same relevant market, though Complaint Counsel does not cite any authority for that proposition. *See FTC v. Swedish Match N. Am., Inc.*, 131 F. Supp. 2d 151, 156-65 (D.D.C. 2000). And while cross-elasticity of demand is part of the relevant market inquiry, Complaint Counselôs explanation is not complete. The Supreme Court has held that ñ[t]he outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.ò *Brown Shoe v. United States*, 370 U.S. 294, 325 (1962).

In addition to economic constructs like cross-elasticity and ñSSNIPò tests, courts routinely look to ñpractical indiciaò in discerning the relevant product market ð especially where statistical or econometric analyses are lacking or cannot be performed. *See Brown Shoe*, 370 U.S. at 325 (endorsing ñpractical indiciaò); *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 51 (D.D.C. 2011) (ñThese ópract

ñ[T]he determination of the relevant market in the end is óa matter of business reality ð [] of how the market is perceived by those who strive for profit in it.ôò *Cardinal Health*, 12 F. Supp. 2d at 46 (quoting *FTC v. Coca-Cola Co.*, 641 F. Supp. 1128, 1132 (D.D.C. 1986), *vacated as moot*, 829 F.2d 191 (D.D. Cir. 1987)). As this Court has recently emphasized, ñ[o]rdinary course business documents reveal the contours of competition from the perspective of the parties, who may be presumed to óhave accurate perceptions of economic realities.ôò *1-800 Contacts*, at 124-25 (quoting *FTC v. Whole Foods Mkt, Inc.*, 548 F.3d 1028, 1045 (D.C. Cir. 2008) (Tatel, J., concurring)). Because of this, ñcourts often pay close attention to the defendantsô ordinary course of business documentsò when ñdetermining the relevant product market.ò *H&R Block, Inc.*, 833 F. Supp. 2d at 52.

11. The relevant antitrust product market in which to analyze the effects of Impaxôs reverse payment agreement with Endo is extended-release oxymorphone products.

RESPONSE TO CONCLUSION NO. 11:

Complaint Counselôs Proposed Conclusion No. 11 is wrong for the reasons stated in Paragraphs 693-1009 of Impaxôs Proposed Findings of Fact and Paragraphs 498-965 of Impaxôs Replies to Complaint Counselôs Proposed Findings of Fact.

The relevant product market in this case no narrower than the market for long-acting opioids (ñLAOsò). This is so for the following reasons, at minimum:

- LAOs, including Opana ER, are ñreasonably interchangeable by consumers for the same purposesò ð namely, to treat chronic pain. *E.I. du Pont*, 951 U.S. at 395; *see Mylan*, 838 F.3d at 436-37 (oral tetracyclines were interchangeable for the treatment of acne, and belonged to same product market); *HDC Med., Inc. v. Minntech Corp.*, 474 F.3d 543, 547-49 (8th Cir. 2007) (medical products that had ñidentical usesò belonged to same relevant market); *Schering I*, 2002 WL 1488085, at *7-10, *73-78 (relevant market consisted of ñall oral potassium supplements,ò which were reasonably interchangeable).

- There is no identifiable population of patients and no medical condition for which Opana ER is the only treatment, or for which Opana ER is the superior treatment option. *See* U.S. Depôt of Justice & Fed. Trade Commôn, *Horizontal Merger*

Guidelines §§ 3, 4.1.4 (2010) (markets defined by ñtargeted customersò must be based on ñobservable characteristicsò); *In re R.R. Donnelly & Sons Co.*, 120 F.T.C. 36, 51 (1995) (ñ[A] profitable discriminatory price increase is possible, and therefore sufficient to define a relevant market,ò only if, *inter alia*, ñthe hypothetical monopolist can identify . . . customers with sufficiently inelastic demand for [the relevant product].ò).

- Endoôs and other LAO manufacturersô ordinary course business documents reflect that LAOs compete in the same market, including on the basis of price. *See 1-800 Contacts*, at 124-25 (ñOrdinary course business documents reveal the contours of competition from the perspective of the parties, who may be presumed to óhave accurate perceptions of economic realities.ôò) (quoting *Whole Foods*, 548 F.3d at 1045); *id.* at 132 (ñAnalysis of the market is a matter of business reality ð a matter of how the market is perceived by those who strive for profit in it.ò) (quoting *Coca-Cola*, 641 F. Supp. at 1132); *see also Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 497 (3d Cir. 1992) (evidence that ñChrysler dealers perceive[d] themselves as competing with dealers handling other carsò indicated that the relevant market was not limited to Chrysler cars); *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) (ñYears of internal marketing documents further confirm that tetracyclines are reasonable substitutes for one another. Defendants consistently defined the market in which Doryx competed as including other tetracyclines.ò); *Staples*, 970 F. Supp. at 1080 (relying on evidence that Staples and Office Depot ñprice check[ed] the other office superstoresò in defining relevant market as sale of consumable office suppliers through office superstores).

- ñIt is imperative that the Court, in determining the relevant market, take into account the economic and commercial realities of the pharmaceutical industry.ò *Cardinal Health*, 12 F. Supp. 2d at 46. LAOs compete on the basis of price at every level of competition in the pharmaceutical industry ð at the payor level, at the patient level, and at the prescriber level. *See United States v. Phillipsburg Nat'l Bank & Trust Co.*, 399 U.S. 350, 360 (1970) (ñthe relevant product market is determined by the nature of the commercial entities involved and by the nature of the competition that they faceò); *United States v. Continental Can Co.*, 378 U.S. 441, 457 (1964) (relevant marketôs ñcontours must, as nearly as possible, conform to competitive realityò); *Whole Foods*, 548 F.3d at 1039 (ñAs always in defining a market, we must ótake into account the realities of competition.ôò) (quoting *Weiss v. York Hosp.*, 745 F.2d 786, 826 (3d Cir. 1984)).

- Patients can and regularly do switch between LAOs, including in response to changes in relative price ð direct evidence of cross-elasticity of demand. *See Apple, Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1196 (N.D. Cal. 2008) (ñWhether products are part of the same or different markets under antitrust law depends on whether consumers view those products as reasonable subs

was the ñ[m]ost convincing[]ò proof that Doryx competed in the same market as other oral tetracyclines). The antitrust agencies recognize that real-world evidence of price-induced switching is probative of market definition. *See Horizontal Merger Guidelines* § 4.1.3 (evidence of ñhow customers have shifted purchases in the past in response to relative changes in price or other terms and conditionsò is probative of relevant market).

- The Federal Trade Commission itself has recognized that Opana ER competes against other LAOs. In the *King Pharmaceuticals* matter, the Commission identified a relevant market consisting of ñthe manufacture and sale of oral LAOs,ò which included ñorally-administered extended-release formulations of . . . oxycodone, morphine sulfate and oxymorphone.ò (Compl. ¶¶ 1, 11, *In re King Pharm., Inc. & Alpharma Inc.*, No. C-4246 (F.T.C. Feb. 2, 2009).) In its analysis published in the Federal Register, the Commission stated that although ñoral LAOs are based on distinct chemical compounds, . . . all of these products have the same mechanisms of action, similar indications, similar dosage forms and similar dosage frequency.ò King Pharm., Inc. and Alpharma Inc. Agreement Containing Consent Order to Aid Public Comment, 74 Fed. Reg. 295, 296 (Jan. 5, 2009). The Commission specifically noted that ñ*Endo Pharmaceutical's Opana ER . . . also competes in the market.*ò *Id.* (emphasis added).

Complaint Counsel has not borne its burden of proving a single-product market consisting solely of branded and generic Opana ER. *See Planetarium Travel, Inc. v. Altour Int'l, Inc.*, 97 F. Supp. 3d 424, 429 (S.D.N.Y.), *aff'd*, 622 F. Appôx 40 (2d Cir. 2015) (ñcourts routinely reject markets defined by a single productò). This is so for the following reasons, at minimum:

- Dr. Noll did not calculate cross-elasticity of demand, conduct a SSNIP test, or perform any other quantitative or statistical analysis of LAO sales. He merely inspected Opana ER sales trends for any ñvisible effectò of generic LAO entry ð a metric he never bothered to define. This does not suffice. *See Ky. Speedway, LLC v. NASCAR, Inc.*, 588 F.3d 908, 918 (6th Cir. 2009) (upholding exclusion of plaintiffôs expertôs testimony where expert did not perform ñstandard SSNIP test,ò but merely looked at average prices and attendance figures for sporting event over an eight-year period; stating that expertôs methodology ñhas not been tested; has not been subject to peer review and publication; there are no standards controlling it; and there is no showing that it enjoys general acceptance within the scientific communityò); *Schering I*, 2002 WL 1488085, at *15, *69, *80 (rejecting proposed single-product market where Complaint Counselôs expert did not ñcalculate demand elasticitiesò and ñpresented no statistical pricing studyò).

- Complaint Counsel did not demonstrate that switching costs among LAOs are high, and has not identified any patients who wanted to but were unable to switch from Opana ER to another LAO. *See SMS Sys. Maint. Servs., Inc. v. Digital*

Equip. Corp., 188 F.3d 11, 20 (1st Cir. 1999) (ñSMS has not proffered significantly probative evidence sufficient to create a fact question as to whether this alleged switching cost is materialò); *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 515 (3d Cir. 1998) (ñwe find no evidence suggesting that U.S. Healthcare members who wish to switch HMOs face switching costs significant enough to constitute a lock inò); *Comm. Data Servers, Inc. v. IBM Corp.*, 262 F. Supp. 2d 50, 68-69 (S.D.N.Y. 2003) (rejecting plaintiffôs proposed relevant market where plaintiffôs expert ñdid not try to identify any S/390 customers who wanted to leave the S/390 platform but were unable to migrate due to high switching costs, or to quantify how many such customers there might beò).

- Complaint Counsel did not demonstrate that chemical differences between Opana ER and other LAOs were economically meaningful. *See Mylan*, 2015 WL 1736957, at *8-9 (testimony that Doryx had ñunique characteristics that differentiate it from other antibiotics,ò such as its ñside-effect profile,ò did not defeat conclusion that ñall oral tetracyclines treat acne with similar effectiveness and so are interchangeable for that purposeò); *id.* at *10 (Doryxôs ñunique side effect profileò did not delineate a relevant market because ñ[i]nterchangeability is defined by rough equivalence, not perfect correspondenceò).

- Advertising and similar product differentiation efforts are consistent with competition in a relevant market consisting of multiple LAOs. *See* Phillip E. Areeda & Herbert Hovenkamp, *3KL0Y*

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As explained in Impaxôs response to Complaint Counselôs Proposed Conclusion No. 11, the relevant market in this cas

not evidence of supracompetitive pricing or monopoly power, since plaintiffs did not show that the margin was ñabnormally highò). High or not, Endoôs Lerner Index says nothing about whether it was charging supracompetitive prices or otherwise exercising monopoly power. *See*

required to prove that the challenged settlement agreement caused ñactual anticompetitive effects.ò *Wellbutrin*, 133 F. Supp. 3d at 755; *see E.W. French*, 885 F.2d at 1402 (ñIt is well established that proof of anticompetitive effect is essential to a rule of reason case.ò); *Schering I*, 2002 WL 1488085, at *88 (ñIn a rule of reason case, Complaint Counsel must prove that the challenged agreements had the effect of injuring competition.ò).

For the reasons stated in Paragraphs 1010-1438 of Impaxôs Proposed Findings of Fact and Paragraphs 966-1459 of Impaxôs Replies to Complaint Counselôs Proposed Findings of Fact, Complaint Counsel has not presented evidence of *any* actual anticompetitive effects. Because of that, its claims necessarily fail. *See Procaps S.A. v. Patheon, Inc.*, 845 F.3d 1072, 1087 (11th Cir. 2016) (affirming summary judgment for defendant on rule of reason claim where plaintiffs ñfailed to adduce concrete evidence of actual anticompetitive effectsò); *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016) (affirming summary judgment for defendant on rule of reason claim where plaintiff lacked evidence of anticompetitive effects).

> 14. If the plaintiff meets its initial burden to demonstrate likely anticompetitive effects, the burden shifts to the defendant to establish a legitimate, procompetitive justification for the challenged restraint. *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993). An antitrust defendant in a reverse payment case may show in the antitrust proceeding ñthat legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.ò *Actavis*, 133 S. Ct at 2236.

RESPONSE TO CONCLUSION NO. 14:

Complaint Counselôs Conclusion No. 14 is incomplete and partially incorrect.

As an initial matter, as stated in Impaxôs responses to Complaint Counselôs Proposed Conclusion Nos. 6, 7, and 13, a plaintiff must prove ñ*actual* anticompetitive effectsò to discharge its initial burden under the rule of reason. *Wellbutrin*, 133 F. Supp. 3d at 755 (emphasis added); *see Microsoft Corp.*, 253 F.3d at 95 (ñMeeting [the governmentôs] burden óinvolves an inquiry into the actual effectô of [the defendantsô] conduct on competition.ò) (quoting *Jefferson Par.*, 466

U.S. at 29). If the plaintiff meets its initial burden, then ñthe burden shifts to the defendant to offer evidence of the procompetitive effects of its agreement.ò *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 308 (2d Cir. 2008); *see Wellbutrin*, 133 F. Supp. 3d at 753 (second step of rule of reason asks, ñare there procompetitive justifications for the agreement[?]ò).

In a reverse-payment case, the defendant may show that the ñchallenged termò (whatever that may be[2]) is lawful under the rule of reason by demonstrating that ñ*the challenged settlement*

800 Contacts, at 166. Procompetitive benefits also include ñensuring consistent supply of [a] product,ò[3] *Wellbutrin*, 133 F. Supp. 3d at 760, and facilitating a potential entrantôs ñability to compete,ò *FTC v. AbbVie, Inc.*, 107 F. Supp. 3d 428, 437 (E.D. Pa. 2015).

In *Wellbutrin*, for instance, the defendants raised as a procompetitive justification the fact that the generic companies (Anchen/Teva) procured, as part of a settlement with GlaxoSmithKline (GSK), a sublicense to a patent (owned by Andrx) that was not at issue in the original patent litigation. 133 F. Supp. 3d at 737, 747, 759. Teva had insisted on the sublicense, on the ground that it ñneeded óthe full freedom to operateô without concern over [a] patent infringement claim by Andrx.ò *Id.* at 747. The court held that the sublicense was a cognizable procompetitive justification for the settlement, since it ñeliminat[ed] an independent and substantial hurdle to generic entry,ò and removed ñthe possibility that Andrx could prevent generic Wellbutrin XL from being marketed for the 15 years remaining on its patent.ò *Id.* at 758-59.

While Complaint Counselôs reference to the *Antitrust Law* treatise is accurate, Complaint Counsel gets the burden of proof wrong. Under standard rule of reason principles, the defendant need only come forward with evidence of procompetitive benefits, at which point it falls to the *plaintiff* to demonstrate a lack of connection between the challenged restraint and the stated benefits. *See Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 75 (3d Cir. 2010) (ñThe *plaintiff* then must demonstrate that the restraint itself is not reasonably necessary to

[3] *See also Eisai*, 821 F.3d at 403 (ñassuring [consumers] the availability of supplyò is a cognizable procompetitive benefit).

achieve the stated objective.ò) (emphasis added). This is emphatically the plaintiffôs burden. *See McWane*, 2014 WL 556261, at *36.[4]

This is evident from the *Antitrust Law* section quoted in Complaint Counselôs Proposed Conclusion No. 14. Complaint Counsel cites Paragraph 1505a, which addresses the *plaintiff's* rebuttal burden once the defendantôs comes forward with procompetitive justifications. *See* Areeda & Hovenkamp, *Antitrust Law* ¶ 1505.

Typically, to discharge its rebuttal burden at this stage of the rule of reason analysis, the plaintiff must show that the ñlegitimate objectives can be achieved in a substantially less restrictive manner.ò *O'Bannon v. NCAA*, 802 F.3d 1049, 1070 (9th Cir. 2015) (quoting *Tanaka v. Univ. of S. Cal.*, 252 F.3d 1059, 1063 (9th Cir. 2001)).

16. Respondent failed to demonstrate that the challenged restraint, the large payment from Endo to stay off the market, is connected to any procompetitive objective or provides procompetitive benefits that justify the restraintôs anticompetitive harm.

RESPONSE TO CONCLUSION NO. 16:

Complaint Counselôs Proposed Conclusion No. 16 is wrong.

To begin with, Complaint Counsel erroneously equates the ñchallenged restraintò to the ñlarge payment.ò That is wrong. A payment is *not* a restraint. To ñrestrainò means to ñbind.ò *Bd. of Trade of City of Chi. v. United States*, 246 U.S. 231, 244 (1918); *see also Standard Oil Co. of N.J. v. United States*, 221 U.S. 1, 55 (1911) (a restraint ñimped[es] the due course . . . of tradeò). A ñrestraint of tradeò is something that restricts competition. *See* Areeda &

[4] Complaint Counsel seems to be confusing the traditional rule of reason with a ñquick lookò analysis, under which the burden of ñarticulat[ing] the specific link between the challenged restraint and the purported justificationò *does* fall to the defendant. *In re Polygram Holding, Inc.*, 136 F.T.C. 310, 347 (2003), *aff'd*, 416 F.3d 29 (D.C. Cir. 2005).

Hovenkamp, *Antitrust Law* ¶ 1502. More precisely, an antitrust

Impax has presented substantial, unrebutted evidence that ñthe challenged settlement [was] in fact procompetitive.ò *Cipro*, 348 P.3d at 869-70. Specifically, as explained in Paragraphs 1439-1574 of Impaxôs Proposed Findings of Fact and Paragraphs 966-1459 of Impaxôs Replies to Complaint Counselôs Proposed Findings of Fact, the settlement permitted Impax to begin selling low-priced generic Opana ER on a sustained basis, free from patent risk, earlier than would have been possible absent the settlement. These are indisputably cognizable procompetitive effects. *See Bd. of Regents*, 468 U.S. at 102 (actions that ñenable[] a product to be marketed which might otherwise be unavailable . . . widen consumer choice . . . and hence can be viewed as procompetitive.ò); *Law v. NCAA*, 134 F.3d 1020, 1023 (10th Cir. 1998) (ñmaking a new product availableò and ñwidening consumers choiceò are procompetitive benefits); *AbbVie*, 107 F. Supp. 3d at 437 (agreement that ñfacilitat[ed] Tevaôs ability to compete in the cholesterol drug market [was] good for the consumerò and procompetitive under *Actavis*); *Wellbutrin*, 133 F. Supp. 3d at 760 (ñensuring consistent supply of product . . . to consumersò is a procompetitive justification).

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payment agreements, ña party with no claim for damages . . . walks away with money simply so it will stay away from the patenteeôs marketò); *id.* at 2234 (ñpayment in return for staying out of the market [] simply keeps prices at patentee-set levels.ò); *id.* at 2237 (ñpaying the challenger to stay out [of the market]ò risks anti-trust violation).

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The procompetitive benefits also flowed directly from the challenged ñrestraintò ð the settlement ð which ñwas negotiated as a whole, agreed to as a whole, and went into effect as a whole.ò *Wellbutrin*, 133 F. Supp. 3d at 754.

Impax more than satisfied its burden of demonstrating procompetitive justifications for the challenged settlement agreement.

17. Complaint Counsel has met its burden of proving that the Impaxôs agreement with Endo restrains competition in violation of Section 5(a) of the FTC Act, 15 U.S.0 §45(a).

RESPONSE TO CONCLUSION NO. 17:

Complaint Counselôs Proposed Conclusion No. 17 is wrong.

For the reasons stated in Impaxôs responses to Complaint Counsels Proposed Conclusion Nos. 11, 12, 13, and 16, **(1)** Complaint Counsel did not show that Impax received a ñlarge and unjustifiedò reverse payment; **(2)** Complaint Counsel failed to demonstrate that Endo possessed monopoly power in a properly defined relevant market; **(3)** Complaint Counsel did not satisfy its *prima facie* burden of proving anticompetitive effects; and **(4)** Impax put on substantial, unrebutted evidence that the settlement agreement was procompetitive.

Further, Complaint Counsel has not even attempted to identify a ñsubstantially less restrictive alternativeò to the challenged settlement agreement. *O'Bannon*, 802 F.3d at 1074. Because of this, it has fallen far short of its burden of ñmak[ing] a strong evidentiary showingò that a less restrictive alternative would not only be ñviable,ò but ñóvirtually as effectiveô in serving the [settlementôs] procompetitive purposesò and ñówithout significantly increased cost.ôò *Id.* (quoting *Cty. of Tuolumne v. Sonora Cmty. Hosp.*, 236 F.3d 1148, 1159 (9th Cir. 2001)).

Because of this, Complaint Counsel has not shown that the settlement restrains competition in violation of the FTC Act. *See N. Am. Soccer League, LLC v. U.S. Soccer Fed'n, Inc.*, No. 17-CV-05495 (MKB), ð F. Supp. 3d ð , 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 ñprovide some alternative to the [challenged restraint] that offer[ed] the same procompetitive benefits . . . ówithout significantly increased costôò; denying motion for preliminary injunction) (quoting *O'Bannon*, 802 F.3d at 1074).

> 18. Pursuant to Section 5 of the FTC Act, upon determination that the 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); *FTC v. Nat'l Lead Co.*

relief, but in its outward limits, so that parties may know[ ] their duties and unintended contempts may not occur.ò *Int'l Salt Co. v. United States*, 332 U.S. 392, 400 (1947).

To justify prospective relief, Complaint Counsel must show that ñthere exists some cognizable danger of recurrent violation.ò *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). This requires more than a ñmere possibilityò; the finding must be grounded in record fact.

Dated: February 7, 2018

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CERTIFICATE OF SERVICE

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CERTIFICATE FOR ELECTRONIC FILING

I hereby certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

DATED: February 7, 2018

/s/ *Benjamin J. Hendricks*
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Notice of Electronic Service

I hereby certify that on February 13, 2018, I filed an electronic copy of the foregoing RESPONDENT IMPAX LABORATORIES, INC.'S REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF, RESPONDENT IMPAX LABORATORIES, INC.'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, with:

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