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



In the Matter of:

IMPAX LABORATORIES, INC.,  
  
a corporation.

Docket No. 9373

**INTERVENOR ENDO PHARMACEUTICALS INC.'S  
OPPOSITION TO COMPLAINT COUNSEL'S FINDINGS AND PROPOSED RELIEF  
REGARDING THE ENDO-IMPAX 2017 SETTLEMENT AGREEMENT**

Intervenor Endo Pharmaceuticals Inc. (“Endo”) hereby opposes Complaint Counsel’s proposed nullification of the August 7, 2017 Settlement Agreement (“2017 Settlement”) between Endo and Respondent Impax Laboratories, Inc. (“Impax”) and any related proposed Findings of Fact and Conclusions of Law. Complaint Counsel’s effort to nullify the 2017 Settlement, depriving Endo of its rights under that agreement, violates the most basic principles of due process and is a brazen attempt at governmental overreach. The 2017 Settlement was not, and has never been, one of the agreements challenged in this proceeding. Nor has it been the subject of a Federal Trade Commission (“FTC”) inquiry or investigation. Before post-trial briefing in this proceeding (which relates to two different agreements from 2010), Complaint Counsel never challenged the 2017 Settlement, never attempted to make the 2017 Settlement part of this proceeding, never requested that Endo provide any information about that agreement, and never notified Endo that they had concerns about it.

Complaint Counsel, however, now seek to “*specifically nullify the [2017 Settlement].*” Br. at 76; *see also* Proposed Order § II.B-D. They assert that the 2017 Settlement

because it supposedly

*Id.* But Endo was not a party to this proceeding and Complaint Counsel never

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provided Endo with an opportunity to challenge these bald, unsupported assertions or otherwise defend its rights under the 2017 Settlement. In addition, Complaint Counsel did not—indeed, could not—establish a record to support their baseless contentions regarding that agreement. *Id.*

Complaint Counsel’s attempt to nullify the 2017 Settlement—a contract to which Endo is a party—without properly raising a challenge to that agreement and giving Endo an opportunity to present relevant evidence, expert testimony, and argument tramples Endo’s right to due process. That fact alone requires summary rejection of Complaint Counsel’s requested relief. In addition, however, as a result of the complete lack of any process, let alone due process, related to the 2017 Settlement, Complaint Counsel have failed to develop a record to support the relief that they seek.

Complaint Counsel cannot save their requested relief by claiming it is “ancillary.” Labeling relief ancillary does not permit Complaint Counsel to deprive non-party Endo of its rights under the 2017 Settlement without due process. Moreover, nullification of the 2017 Settlement, retrospective relief that would deprive a non-party of its contractual rights under an agreement, is not proper ancillary relief. And even ancillary relief must be supported by an appropriate record, which is absent here. Accordingly, Endo opposes Complaint Counsel’s proposed relief insofar as it relates to the 2017 Settlement and opposes any related and similarly unsupported proposed Findings of Fact and Conclusions of Law.

### **BACKGROUND**

#### **I. The Current Action Relates Solely to the 2010 Agreements.**

This administrative action involves two agreements between Endo and Impax: (1) a 2010 Settlement and License Agreement which resolved patent litigation between Endo and Impax and provided Impax with a broad license to sell generic Opana ER starting in January 2013, and (2) a 2010 Development and Co-Promotion Agreement for a potential new drug for the treatment of Parkinson’s Disease (collectively the “2010 Agreements”). *See generally* Jan. 23, 2017 Compl.,

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FTC No. 9373. No other agreements have been challenged in this action.

The challenge to the 2010 Agreements was the product of a three and one-half year investigation and administrative process related to those agreements. The FTC first issued a civil investigative demand to Endo related to the 2010 Agreements on February 20, 2014. Before deciding whether to formally challenge the 2010 Agreements, the FTC Staff engaged in an extensive investigation over a period of more than two years. During that investigation, Endo produced more than 400,000 documents from dozens of custodians, made eight witnesses available for questioning at investigational hearings, submitted two White Papers addressing the 2010 Agreements, held multiple meetings with the FTC Staff (including meetings with the Director of the Bureau of Competition) and, ultimately, made presentations to each of the Commissioners.

After that extensive investigation, the FTC formally challenged the 2010 Agreements. *See* Compl., *FTC v. Endo Pharma. Inc.*, No. 16-1440 (E.D. Pa. March 30, 2016). Endo ultimately settled with the FTC, and on January 23, 2017 Complaint Counsel filed an administrative complaint relating to the 2010 Agreements against Impax only.<sup>1</sup> *See* Jan. 23, 2017 Compl. The filing of that complaint triggered additional procedural safeguards, including further document discovery, depositions, expert discovery, a twelve-day evidentiary hearing, and post-trial briefing, all related to the 2010 Agreements.

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<sup>1</sup> The FTC filed a complaint in the U.S. District Court for the Eastern District of Pennsylvania on March 30, 2016, challenging two settlements involving two different drugs—Opana ER and the lidocaine patch Lidoderm. Defendants moved to sever the FTC's claims on June 23, 2016, and the court severed the Opana and Lidoderm actions on October 20, 2016. The FTC chose to withdraw its complaint on October 25, 2016. The FTC and Endo entered into a settlement agreement on January 23, 2017, and the U.S. District Court for the Northern District of California entered a Stipulated Order for Permanent Injunction on February 2, 2017. *See* Order, *FTC v. Endo Pharma. Inc.*, No. 17-312 (N.D. Cal. Feb. 2, 2017). When the FTC announced the Endo settlement, Complaint Counsel re-filed this action involving Opana ER as an administrative complaint against Impax only.

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### **II. Complaint Counsel Are Attempting to Use Post-Trial Briefing in this Action to Mount an Improper and Unsupported Collateral Attack on the 2017 Settlement.**

The process provided during the investigation and challenge to the 2010 Agreements—conducted in compliance with the FTC Act—stands in stark contrast to the complete absence of process in the FTC’s attack on the 2017 Settlement.

The 2017 Settlement resolved litigation between Endo and Impax related to the payment of royalties by Impax for its sales of extended release oxymorphone hydrochloride. *See generally* CX3275 (2017 Settlement). In a May 6, 2016 complaint, Endo alleged that Impax breached an obligation to negotiate and pay royalties based on patents issued to or acquired by Endo after the parties’ 2010 Agreements. *See* Compl., *Endo Pharm. Inc. v. Impax Labs., Inc.*, No. 16-2526 (D.N.J). Specifically, Endo alleged that Impax failed to negotiate in good faith regarding a royalty for Opana ER patents issued to or acquired by Endo after 2010, which Endo successfully asserted against others seeking approval to market generic oxymorphone ER products. *Id.* at 8-9, 11-12. According to Complaint Counsel, the royalty litigation could have resulted in Impax being ordered to withdraw its oxymorphone products from the marketplace. Findings of Fact and Conclusions of Law (“CC Findings”) ¶ 1430.

Under the 2017 Settlement, however, Impax continues to sell its version of generic oxymorphone and is required to pay royalties to Endo as compensation for rights under the later-obtained patents. *See* CX3275. If another oxymorphone ER product were to enter the marketplace, Impax would no longer be required to pay royalties. *Id.* Notably, the agreement has no impact on when Impax can sell oxymorphone products, contains no “reverse payment” (the basis for the FTC’s challenge of the Settlement Agreements), does not prevent Impax from continuing to sell its oxymorphone products, and does not prevent others from selling oxymorphone.

Complaint Counsel have been on notice of the 2017 Settlement since August 7, 2017, when

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Impax announced the settlement in a press release and Impax's counsel disclosed the terms of the settlement to Complaint Counsel. The 2017 Settlement was also filed with the FTC under the Medicare Modernization Act on August 16, 2017.

Neither Complaint Counsel nor any member of the FTC Staff raised any questions, issues, or concerns with Endo regarding the 2017 Settlement. Likewise, Endo has never been asked to answer any questions or provide any information related to that agreement. Nor did Complaint Counsel challenge the 2017 Settlement, either by amending their Complaint in this action or by filing a separate complaint.

In short, before Complaint Counsel's post-trial brief in this administrative proceeding challenging the 2010 Agreements, they made no mention of seeking relief specifically nullifying the 2017 Settlement in this or any other proceeding. Indeed, at the opening of the hearing in this proceeding, Complaint Counsel represented to the Court that they did not intend to seek any *retrospective relief*, but rather sought only to "prohibit Impax from entering into reverse payment settlements *in the future*." Trial Tr. at 13:10-12 (emphasis added); *see also id.* at 81:25-82:2 ("[W]e also ask the court to issue an order prohibiting Impax from entering reverse payment settlements in the future . . ."). In making this representation, Complaint Counsel presented the following slide to the Court, which referenced only two elements of relief: (1) a finding that the **2010** settlement violates the FTC Act and (2) prospective relief prohibiting Impax from entering into agreements "like [the 2010 Agreements]" (i.e., "reverse payment" agreements, which the 2017 Settlement is not) in the future:

A presentation slide with a dark blue header containing the FTC logo and the text "Remedies Sought". The slide lists two items: "1. Settlement violates Section 5 of the FTC Act" and "2. Order prohibiting Impax from entering into settlements like this in the future". The number "40" is in the bottom right corner.

Remedies Sought

1. Settlement violates Section 5 of the FTC Act
2. Order prohibiting Impax from entering into settlements like this in the future

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Despite these representations, in their post-trial briefing Complaint Counsel now seek—for the first time and without prior notice—to “*specifically nullify* the 2017 agreement between Impax and Endo,” even though the 2017 Settlement is not a “reverse payment” agreement. Br. at 76; *see also* Proposed Order § II.B-D. They also seek a finding that the [REDACTED] [REDACTED] CC Findings ¶ 1485. According to Complaint Counsel, the 2017 Settlement [REDACTED] [REDACTED] CC Findings ¶ 1490. Complaint Counsel, however, never sought any information from Endo regarding its intent or incentives with respect to oxymorphone ER or how, if at all, the 2017 Settlement might have affected those incentives (it did not). Tellingly, the only record citation Complaint Counsel offers is the 2017 Settlement itself, which offers no support for Complaint Counsel’s contention that it will suppress competition.

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### III. Impax Is the Only Seller of Extended Release Oxymorphone on the Market, but That Is Not Because of the 2017 Settlement.

Although Impax is the only generic pharmaceutical company selling oxymorphone ER, that is not because of the 2017 Settlement. Instead, this circumstance results from other, unrelated factors that pre-dated the 2017 Settlement. These factors highlight why it would be manifestly inappropriate to condemn the 2017 Settlement in this proceeding or otherwise.

First, the exclusion of other generic oxymorphone products from the market is the consequence of independent judicial action, not the 2017 Settlement. After the 2010 Agreements, Endo succeeded in obtaining several new patents that covered both Opana ER and Impax's generic oxymorphone ER product: U.S. Patent No. 8,309,122 ("the '122 patent"), U.S. Patent No. 8,329,216 ("the '216 patent"), and U.S. Patent No. 8,871,779 ("the '779 patent"). Endo has successfully enforced these patents against other potential generic entrants, which, unlike Impax, did not have licenses to Endo's later-acquired patents. On August 14, 2015, the U.S. District Court for the Southern District of New York found the '122 and the '216 patents valid and infringed by the defendants' generic oxymorphone products and entered an injunction prohibiting defendants in that case from selling such products until those patents expire in 2023. *See Order, Endo Pharma. Inc. v. Teva Pharma. USA, Inc.*, No. 12-8060 (S.D.N.Y. Aug. 14, 2015). Likewise, the U.S. District Court for the District of Delaware held that the '779 patent was valid and infringed by the several defendants' generic oxymorphone products and entered an injunction prohibiting defendants in that case from selling such products until that patent expires in 2029. *See Endo Pharm. Inc. v. Amneal Pharm., LLC*, 224 F. Supp. 3d 368, 378 (D. Del. 2016); *Endo Pharm. Inc. v. Actavis Inc.*, No. 14-1381, 2017 WL 3731001 \*16 (D. Del. Aug. 30, 2017).<sup>2</sup>

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<sup>2</sup> The cases against three of the defendants were the subject of these trials. The cases against the remaining four defendants were stayed, with the parties agreeing to be bound by the results of

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Second, Endo itself stopped selling oxymorphone ER prior to, and for reasons entirely unrelated to, the 2017 Settlement. Endo withdrew original Opana ER from the market in 2012, after developing a reformulated version of the product, which was intended to be less crushable as a means of deterring abuse. CX4017. Endo argued, in a Citizen Petition submitted to the FDA, that the withdrawal of the original formulation should be deemed to have been done for safety reasons. CX3203. (Endo’s Citizen Petition). Five years later, in June 2017 (before the 2017 Settlement), the FDA requested that Endo voluntarily withdraw the reformulated version of Opana ER from the market, in light of concerns about the public health consequences of abuse. (JX-001-012 (¶ 52)). The FDA stated that if Endo refused to comply, it would take steps to require Endo to do so. CX6048. On July 6, 2017, Endo publicly announced that it would comply with the FDA’s request. (JX-001-012 (¶ 53)). As of September 1, 2017, Endo stopped selling reformulated Opana ER, leaving Impax as the only supplier of an oxymorphone ER product. *Id.* ¶ 54.

## **ARGUMENT**

Complaint Counsel do not have *carte blanche* to nullify an agreement based on an unsupported and unilateral declaration that the agreement reduces competition, particularly when doing so would eviscerate the rights of a non-party and the agreement has never been at issue in this proceeding. Rather, basic principles of due process and the Federal Trade Commission Act (“FTC Act”) demand notice and an evidentiary hearing before any action that would deprive a party of its rights under an agreement. Complaint Counsel here have afforded Endo neither notice nor a hearing, instead seeking to shoehorn nullification of the 2017 Settlement into the post-trial stage of an action challenging two different agreements reached more than seven years earlier.

Moreover, Complaint Counsel cannot justify ignoring Endo’s due process rights by arguing

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the trials in the other cases.

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that relief related to the 2017 Settlement is “ancillary.” Ancillary relief is proscriptive of otherwise permissible acts that are connected to acts found to be illegal. Here, Complaint Counsel’s proposed relief is no such thing. Indeed, where courts have permitted ancillary relief, such relief, consistent with due process, was prospective and impacted only the respondent in the action, not non-parties. Moreover, ancillary relief must still be supported by a factual record demonstrating that it will remedy the anticompetitive effects of the challenged conduct (here, the 2010 Agreements). Complaint Counsel have not even attempted to develop an appropriate record to support their proposed findings or relief related to the 2017 Settlement, relying on nothing more than their own naked characterization of that agreement.

### **I. Complaint Counsel’s Collateral Challenge of the 2017 Settlement Violates Non-Party Endo’s Due Process Rights.**

A government agency cannot act to deprive a party of its rights under a contract without due process of law. *See Mathews v. Eldridge*, 424 U.S. 319, 902 (1976) (“[S]ome form of hearing is required before an individual is finally deprived of a property interest.”); *Anglemyer v. Hamilton Cnty. Hosp.*, 155 F.3d 1193, 1206 (10th Cir. 1995) (explaining that express or implied contracts give rise to protected property interests). The fundamental requirement of due process is the opportunity to be heard “at a meaningful time and in a meaningful manner.” *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965); *see also Fuentes v. Shevin*, 407 U.S. 67, 80 (1972) (“For more than a century the central meaning of procedural due process has been clear: Parties whose rights are affected are entitled to be heard; and in order that they may enjoy that right they must first be notified.”).<sup>3</sup> Procedural due process is required in administrative proceedings. *Standard Oil v.*

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<sup>3</sup> Based on these same fundamental principles of due process, parties to a contract at issue in a lawsuit are considered indispensable and must be joined under Rule 19 of the Federal Rules of Civil Procedure before the court may rescind or nullify the contract. *Downs v. Andrews*, 639 F. App’x 816, 822 (3d Cir. 2016) (finding a party to the contract underlying the plaintiffs’ claims indispensable under Rule 19 and dismissing under Rule 12(b)(7)); *E.E.O.C. v. Peabody W. Coal*

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*FTC*, 475 F. Supp. 1261, 1272 (N.D. Ind. 1979).

The FTC Act also mandates certain procedural requirements before imposing upon a party a remedy for conduct challenged as an unfair method of competition. *Cf. Calif. Lumberman's Council v. FTC*, 103 F.2d 304, 304 (9th Cir. 1939) (finding that the Commission's cease and desist order violates due process if there is not a "fair trial" with a sufficient record). Specifically, Section 5(b) of the FTC Act provides that, before the Commission imposes a remedy upon a company based on an unfair method of competition, the Commission must *first* serve that company with a complaint stating the charges *and* provide at least 30 days' notice before holding a hearing on those charges. 15 U.S.C. § 45(b). These procedures not only help safeguard due process, but are also required by the Administrative Procedure Act, which demands that those whose conduct is challenged by the FTC (or any federal agency) not only have a hearing but also be afforded full opportunity to justify their conduct. *See* 5 U.S.C. § 554(b); *L.G. Balfour Co. v. FTC*, 442 F.2d 1, 17 (7th Cir. 1971); *see also Nat'l Labor Relations Bd. v. Mackay Radio & Tele. Co.*, 304 U.S. 333, 350 (1938).

Complaint Counsel cannot seek a finding on an issue, such as the purported competitive effect of the 2017 Settlement, or obtain a remedy based on such a finding, that was not litigated in the administrative proceeding. If an issue is *not litigated in an administrative proceeding*, and "the party proceeded against was not given an opportunity to defend himself, *an adverse finding on that issue by the agency does violate due process.*" *Golden Grain Macaroni Co. v. FTC*, 472 F.2d 882, 886 (9th Cir. 1972) (emphasis added); *cf. Sims v. Greene*, 161 F.2d, 87, 89 (3d Cir. 1947)

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*Co.*, 610 F.3d 1070, 1082 (9th Cir. 2010) ("No procedural principle is more deeply imbedded in the common law than that, in an action to set aside a...contract, all parties who may be affected by the determination of the action are indispensable."); *U.S. ex rel. Hall v. Tribal Dev. Corp.*, 100 F.3d 476, 479 (7th Cir. 1996) (same); *Davis Companies v. Emerald Casino, Inc.*, 268 F.3d 477, 484 (7th Cir. 2001) ("a contracting party is the paradigm of an indispensable party").

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(“It has never been supposed that a temporary injunction could issue under the Clayton Act without giving the party against whom the injunction was sought an opportunity to present evidence on his behalf.”). Here, the proceeding did not even include one of the parties necessary to litigate issues related to the 2017 Settlement, namely Endo.

In short, to satisfy due process, an agency attempting to deprive a party of its property rights under a contract must first offer notice and an opportunity to be heard. With respect to the 2017 Settlement, Complaint Counsel followed *none* of the procedures specified in the FTC Act and required by basic principles of due process. For that reason alone, Complaint Counsel’s requested nullification of the 2017 Settlement should be summarily rejected.

### **II. Complaint Counsel Did Not Develop A Record That Supports Nullifying The 2017 Settlement**

There is also a second, independent reason why Complaint Counsel’s proposed relief must be rejected: Complaint Counsel failed to develop any evidentiary record supporting nullification of the 2017 Settlement. Proposed relief must be supported by a clear “factual basis” based on findings and an adequate record. *Massachusetts v. Microsoft Corp.*, 373 F.3d 1199, 1222 (D.C. Cir. 2004) (“*Microsoft IP*”); *United States v. Microsoft Corp.*, 253 F. 3d 34, 101, 103 (D.C. Cir. 2001) (“*Microsoft I*”) (explaining that “judicial resolution of disputed facts” is essential to determine “appropriate relief”); *cf.* Fed. R. Civ. P 65 (requiring an evidentiary hearing for the imposition of any injunctive relief beyond a temporary restraining order). This applies regardless of whether the relief is directly tied to liability or constitutes “ancillary relief” designed to remedy the effects of the challenged conduct. *See, e.g., Ford Motor Co. v. United States*, 405 U.S. 562, 571 (1972) (emphasizing that the court held *nine days of factual hearings on the appropriate remedy*, which included “ancillary measures”).

Here, Complaint Counsel seek to “specifically nullify” the 2017 Settlement on the grounds

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that it “disincentivizes Endo from launching or authorizing an Opana ER AG” and thus “reduces competition for . . . the product at issue in this case.” Br. 75-76 But whether the 2017 Settlement “disincentivizes Endo” from launching an Opana ER AG or “reduces competition” for oxymorphone ER are two disputed questions of fact that cannot be answered from the record in this proceeding—a proceeding challenging the 2010 Agreements in which no evidence was introduced regarding the competitive effects of the 2017 Settlement.<sup>4</sup> Indeed, Complaint Counsel did not even attempt to create such a record.

As a result, although Complaint Counsel *assert* that the 2017 Settlement reduces competition, they cite no evidence supporting that assertion. The only evidence Complaint Counsel cite for their assertions is the 2017 Settlement itself. They cite no testimony, no supporting documents and no expert opinion. In effect, Complaint Counsel suggest that the 2017 Settlement should be deemed anticompetitive on the face of the agreement alone. But only a very limited set of conduct is subject to such a *per se* rule. *See Texaco v. Dagher*, 547 U.S. 1, 5 (2006) (“*Per se* liability is reserved for only those agreement that are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality.”) (internal quotations omitted).

The 2017 Settlement does not fall into that limited category of conduct and therefore cannot be deemed anticompetitive from the face of the agreement alone. *Id.*; *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) (explaining that *per se* liability is inappropriate where the economic impact of practices or agreements is unclear). If they wanted to prove that the 2017 Settlement lessens competition, Complaint Counsel should have formally challenged it, developed a full record regarding its competitive impact, and given not only Impax but also Endo an opportunity to

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<sup>4</sup> Endo, as an intervenor in this action, is not addressing whether the record is sufficient to establish liability or remedies as to the 2010 Agreements.

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respond. They failed to do any of these things, and their proposed Findings and relief related to the 2017 Settlement must be denied on that ground.

Moreover, Complaint Counsel's assertion that the royalty provision in the 2017 Settlement [REDACTED] ignores a number of material facts (noted above) which Complaint Counsel could not reasonably dispute:

*First*, in 2012, Endo argued to the FDA in a Citizen Petition that original Opana ER had been withdrawn for safety reasons. Although Endo's Citizen Petition was denied, the premise of the FTC's theory—that, absent the 2017 Settlement, Endo would have had an incentive to reintroduce a product that it argued to the FDA had been withdrawn for safety reasons—is absurd.

*Second*, prior to the 2017 Settlement, Endo withdrew reformulated Opana ER at the FDA's request. As a result, Endo cannot re-introduce reformulated Opana ER.

*Third*, each of the other potential generic entrants is currently enjoined from launching its generic version of original or reformulated Opana ER by courts as a result of Endo's successful enforcement of its patents, and those injunctions were entered long before the 2017 Settlement. Endo would have no incentive to license those potential entrants and had no such incentive at the time of the 2017 Settlement.

In addition, even if Endo had the incentive (or ability) to reintroduce original or reformulated Opana ER, the 2017 Settlement does not prohibit it from doing so directly or through a licensee. There is nothing in the record regarding the circumstances under which it would (or would not) be profitable to do so.<sup>5</sup>

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<sup>5</sup> Complaint Counsel's theories regarding the 2017 Settlement are also internally inconsistent. Although they assert, without support, that the 2017 Settlement reduced competition, they also assert that, without the 2017 Settlement, Impax's oxymorphone products could have been removed from the marketplace. See CC Findings ¶ 1430 (proposing finding that, in the litigation resolved by the 2017 Settlement, Impax could have been required to withdraw its oxymorphone

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In sum, before any condemnation of the 2017 Settlement, these issues—and many others—would need to be explored on a fully developed evidentiary record, and both parties whose contractual rights would be affected would need to be afforded appropriate due process. Complaint Counsel did neither and their effort to use the post-trial briefing in this proceeding to skirt those basic requirements is wholly improper.

**III. Nullification of the 2017 Settlement Agreement is Not Proper Ancillary Relief.**

Complaint Counsel characterize the proposed relief related to the 2017 Settlement as “ancillary relief,” i.e., relief prohibiting conduct that falls within the category of “otherwise permissible practices connected with the acts found to be illegal” that “must sometimes be enjoined.” Br. at 75 (quoting *United States v. Loew’s, Inc.*, 371 U.S. 38, 53 (1962)). Apparently, Complaint Counsel believe that, by invoking this term, they can nullify the 2017 Settlement—an entirely different agreement than the 2010 agreements at issue in this proceeding—without providing Endo with basic due process and without creating an evidentiary record supporting the proposed relief.

The relief Complaint Counsel seek with respect to the 2017 Settlement is not ancillary. Ancillary relief is typically limited to *prospective* remedies that impact the respondent(s) in an action, not the retrospective nullification of an existing agreement with a non-party, like the 2017 Settlement. Moreover, labelling relief as “ancillary” cannot justify ignoring Endo’s due process rights. Finally, even ancillary relief must be supported by an adequate record demonstrating a

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ER product from the market). They also propose a finding that, [REDACTED]  
[REDACTED]  
[REDACTED] *Id.* at ¶ 1492. Thus, Complaint Counsel assert both that the 2017 Settlement reduced competition *and* [REDACTED]  
[REDACTED]

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reasonable relationship with the anticompetitive effects of the challenged conduct (i.e., the 2010 Agreements), which is entirely lacking in this case.

- A. Nullification of the 2017 Settlement is not proper ancillary relief because it is retrospective and impacts the rights of a non-party.

Complaint Counsel’s proposed retrospective nullification of the 2017 Settlement is not the type of relief that courts have deemed to be ancillary. Such retrospective remedies for alleged anticompetitive conduct cannot extend beyond the issues of liability contemplated in the underlying administrative proceeding. *See Microsoft II*, 373 F.3d at 1215, 1222, 1224. Here, the issues of liability contemplated in the administrative proceeding did not include the 2017 Settlement, which is not even alleged to be a “reverse payment” agreement.

By contrast, the case law that allows for ancillary restrictions clearly contemplates *prospective* restrictions on *future* conduct by the *respondent*. *See FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965) (explaining that ancillary relief allows the Commission to “prevent respondents from engaging in similarly illegal practices in future [conduct]”); *Telebrands v. FTC*, 457 F.3d 354, 357 & n.5 (4th Cir. 2006) (“Fencing-in remedies are designed to prevent future unlawful conduct.”); *see also Nat’l Soc. of Prof. Eng’rs*, 435 U.S. at 697 (explaining that courts are “empowered to fashion appropriate restraints on [respondent’s] future activities both to avoid a recurrence of the violation and to eliminate its consequences...”); *Microsoft II*, 373 F.3d at 1215-16 (explaining that “forward looking provisions” may restrain otherwise lawful but related conduct).

Moreover, cases that allow for prospective ancillary relief contemplate narrow relief that is “not so expansive as to be unduly regulatory,” *Microsoft II*, 373 F.3d at 1116, and certainly not relief that impacts the rights of non-parties whose due process right to be heard as to the relief has been totally ignored. *See, e.g., id.* (allowing limited prospective ancillary relief that did not impact

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the rights of non-parties); *Ford Motor Co.*, 405 U.S. at 577 (affirming a marketing and manufacturing remedy affecting only Ford). Here, however, Complaint Counsel’s proposed relief would impact not only Respondent Impax, but would also deprive non-party Endo of its rights under the 2017 Settlement.

B. Nullification of the 2017 Settlement does not bear a reasonable relationship to the alleged anticompetitive effects of the challenged conduct.

Nullification of the 2017 Settlement also fails to qualify as ancillary relief because it does not bear a reasonable relationship to the goal of remedying the alleged anticompetitive effect of the challenged conduct, here the 2010 Agreements. *Spiegel, Inc. v. FTC*, 540 F.2d 287, 296 (7th Cir. 1976). Ancillary relief must “represent[] a reasonable method of eliminating the consequences of the illegal conduct.” *Nat’l Soc. Prof. Eng’rs*, 435 U.S. at 1369. Such relief must be based “on some clear indication of a significant causal connection between the conduct enjoined . . . and the violation found directed toward the remedial goal intended.” *Microsoft I*, 253 F.3d at 401 (internal quotations omitted) (acknowledging that prospective conduct restrictions must be based on findings).

Here, there is no record demonstrating any relationship between the 2017 Settlement and Complaint Counsel’s stated remedial goal— preventing Impax from entering into alleged reverse payment agreements in the future. Trial Tr. at 13:10-12, 81:25-82:2; *see also* Comp. Counsel Opening Slides at 40. The 2017 Settlement is not a “reverse payment” agreement, and Complaint Counsel have demonstrated no link between the 2017 Settlement and preventing the alleged harm that arises from such agreements—i.e., delayed generic entry. To the contrary, the 2017 Settlement expressly permits Impax to continue to market its generic extended-release oxymorphone products.

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**CONCLUSION**

For the reasons stated herein, Complaint Counsel's proposed Findings related to the 2017 Settlement, requested nullification of the 2017 Settlement, and any remedy that would affect Endo's rights under that agreement should be denied.

Respectfully submitted,

*/s/ Christine Levin*

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**CERTIFICATE OF SERVICE**

I hereby certify that on January 16, 2018, I caused a true and correct copy of the foregoing Opposition to be served via the FTC E-Filing System, which will send notification of such filing to all counsel of record as well as the following:

Office of the Secretary  
Federal Trade Commission  
Constitution Center, 400 Seventh Street SW  
Suite 5610  
Washington, DC 20024

The Hon. Michael D. Chappell  
Administrative Law Judge  
Federal Trade Commission  
Washington, DC 20580

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*Counsel for Non-Party Endo  
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Notice of Electronic Service

**I hereby certify that on January 16, 2018, I filed an electronic copy of the foregoing Endo Pharmaceuticals's Opposition to Complaint Counsel's Findings and Proposed Relief [Redacted], with:**

D. Michael Chappell  
Chief Administrative Law Judge  
600 Pennsylvania Ave., NW  
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Donald Clark  
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**I hereby certify that on January 16, 2018, I served via E-Service an electronic copy of the foregoing Endo Pharmaceuticals's Opposition to Complaint Counsel's Findings and Proposed Relief [Redacted], upon:**

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**I hereby certify that on January 16, 2018, I served via other means, as provided in 4.4(b) of the foregoing Endo Pharmaceuticals's Opposition to Complaint Counsel's Findings and Proposed Relief [Redacted], upon:**

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