PUBLIC

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

ORIGINAL

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

NON-PARTY ENDO PHARMACEUTICALS INC.'S UNOPPOSED MOTION FOR LIMITED INTERVENTION AND MEMORANDUM IN SUPPORT

Non-party Endo Pharmaceuticals Inc. ("Endo") moves, pursuant to 16 C.F.R. § 3.14(a), for leave to intervene in this action for the limited purpose of participating in post-trial briefing to protect its due process rights, and its contract rights under an August 7, 2017 Settlement Agreement ("2017 Settlement") between Endo and Respondent Impax Laboratories, Inc. ("Impax"). The 2017 Settlement resolved litigation between Endo and Impax related to whether Impax was obligated to negotiate and pay royalties based on its sales of extended release oxymorphone hydrochloride products. The 2017 Settlement was not, and has never been, one of the agreements challenged in this proceeding.

In their December 22, 2017 Post-Trial Brief, however, Complaint Counsel seeks to expand the scope of this action by requesting relief that would "***specifically nullify the [2017 Settlement]***." Br. at 76; *see also* Proposed Order § II.B-D. Although the relevant portions of the public version of Complaint Counsel's Post-Trial Brief are heavily redacted,[1] presumably they are now asserting that the 2017 Agreement "prevents, restricts or disincentives competition for oxymorphone ER."

[1] Endo requested, with Impax's consent, unredacted versions of the relevant sections of the Post-Trial Brief and Findings of Fact. Complaint Counsel refused, instead requiring Endo to file a motion to access the briefing related to the 2017 Settlement. Endo will do so promptly.

Id. at 75. Complaint Counsel apparently links the fact that "Endo has not re-introduced a branded or authorized generic version of Original Opana ER" to the 2017 Settlement. CC Findings of Fact, 1491. Complaint Counsel, however, never sought any information—let alone introduced any evidence—from Endo, a non-party in this action, related to these assertions, i.e., demonstrating how, if at all, the fact that Endo has not reintroduced a version of Opana ER is related to the 2017 Settlement (it is not, as explained below).

To date, the 2017 Settlement has not been the subject of any inquiry, investigation or charge from Complaint Counsel or Commission Staff. As a result, Endo has not had an opportunity to develop or present any evidence, expert testimony, or argument related to the 2017 Settlement. Had Endo been able to do so, it would have demonstrated that the 2017 Settlement is pro-competitive, that it merely resolved the parties' royalty litigation, and that it is not a so-called "pay for delay" settlement. To the contrary, under the 2017 Settlement, Impax will continue to sell oxymorphone hydrochloride, but be required to pay royalties to Endo. Moreover, the 2017 Settlement has not prevented or deterred Endo or any other competitor from entering the marketplace. At this point of this proceeding, however, Endo does not seek to intervene to litigate whether the 2017 Settlement was pro-competitive. Rather, Endo merely raises issues related to the merits of the 2017 Settlement because they demonstrate why this proceeding is not the place for relief related to that agreement.

The relief requested in Complaint Counsel's Post-Trial Brief suggests that they have a different view of the 2017 Settlement, albeit one uninformed by investigation or factual development. But that is precisely the point. If Complaint Counsel had concerns regarding the 2017 Settlement, the appropriate process would have been to initiate an investigation, develop the facts related to the potential competitive effect of that agreement, and give Endo an opportunity to

be heard on the issues. Complaint Counsel, however, chose to conduct this proceeding without properly raising a challenge to the 2017 Settlement (by, for example, amending their Complaint), without providing Endo with the notice and opportunity to be heard required by basic principles of due process and without creating an evidentiary record regarding the competitive effect of the 2017 Settlement. Instead, in their Post-Trial Brief, they attempt to mount a collateral attack on the 2017 Settlement without the due process provided for by the Federal Trade Commission Act ("FTC Act"), including the safeguards of notice and a hearing.

Endo therefore seeks to intervene for the limited purpose of responding to Complaint Counsel's Post-Trial Brief and Proposed Order and opposing (1) any findings related to the alleged competitive effects of the 2017 Settlement[2] and (2) the requested nullification of the 2017 Settlement, or any remedy that would affect Endo's rights under that agreement. If permitted to intervene, Endo will submit briefing explaining why Complaint Counsel's relief, as it relates to the 2017 Settlement, is improper in this action and should be summarily rejected. In short, that relief (a) would nullify non-party Endo's rights under that agreement without providing Endo with the most basic elements of due process; and (b) is not supported by an evidentiary record in this action. In addition, Endo will also explain why the remedy requested with respect to the 2017 Settlement is not the type of ancillary relief sometimes permitted in FTC enforcement actions.

[2] Complaint Counsel raised the specter of seeking findings and retrospective relief related to existing agreements in its Pretrial Brief, but the proposed relief identified did not specifically mention the 2017 Settlement. Moreover, at trial, Complaint Counsel disclaimed any intention to seek retrospective relief nullifying existing agreements. Complaint Counsel specifically stated in opening argument that they sought to "prohibit Impax from entering into reverse payment settlements ***in the future***." 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…"). It is only in its Post-Trial Brief that Complaint Counsel for the first time specifically seeks relief related to the 2017 Settlement.

Impax has consented to Endo's intervention, and Complaint Counsel has represented that they will not object to the motion on the condition that Endo files its substantive brief by January 16, 2018 (which is acceptable to Endo).

BACKGROUND

Complaint Counsel's administrative action challenged only 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. *See generally* Jan. 23, 2017 Compl. No other agreements were challenged at any time during this proceeding.

In August 2017, more than seven years after the 2010 agreements that are the subject of this action, Endo and Impax entered into the 2017 Settlement. The 2017 Settlement resolved litigation between Endo and Impax regarding whether the 2010 Settlement and License Agreement required Impax to negotiate and pay royalties for later-acquired patents. *See Endo Pharmaceuticals Inc. v. Impax Labs., Inc.*, No. 16-2526 (D.N.J.). In the 2017 Settlement, Impax agreed to pay a royalty to Endo based on Impax's sales of extended release oxymorphone. If any other company lawfully enters the market for extended release oxymorphone, Impax will no longer be required to pay Endo a royalty.

Complaint Counsel has been on notice of the 2017 Settlement since August 7, 2017, when 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 Commission Staff has raised any questions, issues or concerns with Endo regarding the 2017

Settlement, or given Endo the opportunity to present any facts or argument related to that agreement.

Instead, in a back-door challenge to the 2017 Settlement, Complaint Counsel now seeks to "***specifically nullify*** the 2017 agreement between Impax and Endo." Br. at 76; *see also* Proposed Order § II.B-D. Any assertion that the 2017 Settlement prevents, restricts, or disincentivizes competition is a flagrant mischaracterization, uninformed by an appropriate investigation or the development of a factual record. Had the FTC staff bothered to inquire, they would have learned from Endo that nothing in the 2017 Settlement has prevented Endo or any other potential competitor from entering the marketplace. Although Impax is currently the only company marketing an extended-release oxymorphone hydrochloride product, that fact is not due to the 2017 Settlement, but rather to factors unrelated to that agreement, which were known to Endo when it entered into the agreement.

First, Endo withdrew its ***original*** Opana ER product from the market in 2012, and argued (unsuccessfully) in a Citizen Petition filed with the FDA that it should be deemed to have withdrawn original Opana ER for safety reasons. Although the FDA denied Endo's Citizen Petition in 2013, if the FDA had granted it, generic versions of the original Opana ER product would have been required to be withdrawn. Thus, the apparent premise of the Complaint Counsel's attack on the 2017 Settlement—that Endo might, but for the royalty provision in the 2017 Settlement, decide to reintroduce a branded or authorized generic version of a product that it argued to the FDA should be withdrawn for safety reasons—is absurd on its face.

Second, Endo launched a ***reformulated*** version of Opana ER in 2012, but—on June 8, 2017, prior to the 2017 Settlement—the FDA asked Endo to withdraw that version of Opana ER from the market due to particular abuse and misuse of the product. The FDA also publicly

announced that if Endo failed to comply with its request to withdraw reformulated Opana ER, the agency would take steps to require Endo to do so. On July 6, 2017, one month before the 2017 Settlement, Endo publicly announced that it would comply with the FDA request and withdraw reformulated Opana ER from the market. Thus, regardless of the royalty provisions in the 2017 Settlement, Endo could not launch or license an authorized generic of the reformulated version of Opana ER either and had no such incentive at the time that it entered into the agreement in August 2017.

Finally, other potential generic entrants are subject to court orders, each entered before the 2017 Settlement, enjoining them from entering the marketplace as a result of Endo's successful assertion of patent infringement claims.

These points illustrate why relief related to the 2017 Settlement is inappropriate in this proceeding. Endo is entitled to the due process contemplated by the FTC Act—including notice, an opportunity to be heard, and a fully-developed record related to these points, among others—before potential condemnation of the 2017 Settlement is even considered.[3] Complaint Counsel would prefer to take a short-cut and use this proceeding to deprive Endo of its due process rights. Endo seeks to intervene to prevent that from happening.

ARGUMENT

The FTC Act provides that any non-party "may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person" upon "good cause shown." 15 U.S.C. § 45(b); *see* 16 C.F.R. § 3.14(a) ("The Administrative Law Judge or the Commission may by order

[3] In addition, even if (contrary to the facts) Endo had an incentive to launch or authorize an authorized generic version of Opana ER, the 2017 Settlement does not prevent it from doing so. Developing this point, however, would require additional facts and, potentially, expert testimony that are not in the record of this action.

permit the intervention to such extent and upon such terms as are provided by law or as otherwise may be deemed proper."). Good cause exists when a non-party demonstrates that it "desire[s] to raise substantial issues of law or fact which would not otherwise be properly raised or argued; and that the issues raised are of sufficient import to warrant additional expenditure of Commission resources…." *In re Polypore Int'l, Inc.*, Dkt. 9327, 2009 WL 3138657, at *1 (F.T.C. Sept. 23, 2009) (citing *In re Kentucky Movers Household Carriers Ass'n*, Dkt. 9309, 2004 FTC LEXIS 84, at *3). Here, Complaint Counsel's requested relief unquestionably affects Endo's contractual rights under the 2017 Settlement—Complaint Counsel seeks to nullify the agreement. In addition, by avoiding the Commission's established procedures for challenging conduct, set forth in Section 5 of the FTC Act, Complaint Counsel has denied Endo its right to due process.

I. Endo Has Good Cause to Intervene in the Instant Action Because Complaint Counsel's Proposed Remedy Is Intended to Nullify Its Contractual Rights.

When relief sought by Complaint Counsel may impact the contract rights of a non-party to an administrative hearing, good cause exists for the non-party to intervene in the proceeding. *See In re Polypore Int'l, Inc.*, 2009 WL 3138657 at *2; *see also PepsiCo, Inc. v. Federal Trade Com'n*, 472 F.2d 179, 184 (2d Cir. 1972) (finding that intervention should be a matter of right where "the intervenors are persons whose contract rights are at stake"); *In re Heublein, Inc.*, 82 F.T.C. 1826, 1973 WL 165230, at *2 (1973) (allowing a non-party cooperative to intervene in an administrative proceeding for the purposes of adequately representing itself on the issue of relief when Complaint Counsel's proposed relief impacted its contractual interests).

Complaint Counsel now, after the conclusion of the administrative hearing, seeks to nullify the 2017 Settlement. Br. at 76. But, as explained above, Complaint Counsel sought no information, let alone admissible evidence, regarding Endo's intentions with respect to original Opana ER or how the 2017 Settlement would, if at all, affect its incentives. Any relief premised

on the alleged competitive effect of the 2017 Settlement therefore jeopardizes Endo's contractual rights without a fully-developed record and without Endo having had an opportunity to be heard.

Notably, the cases cited by Complaint Counsel in support of its position that the Court should nullify the 2017 Settlement, despite the fact that it was not the subject matter of this action, highlight the inappropriateness of its requested relief and support Endo's request to intervene. In those cases, the ancillary relief implicated ***only the rights of parties to the case***, and not those of third-parties who had no full and fair opportunity to be heard in the proceedings. *See, e.g.*, *Massachusetts v. Microsoft*, 373 F.3d 1199, 1215-16 (D.C. Cir. 2004) (affirming a disclosure remedy that affected only Microsoft); *Ford Motor Co. v. United States*, 405 U.S. 562, 577 (1972) (affirming a marketing and manufacturing remedy affecting only Ford). Further, both courts approved ancillary relief that was ***purely prospective*** and targeted at future conduct—nothing like the type of retrospective relief that Complaint Counsel seeks here, targeting a different agreement than the one at issue in the proceeding. *Id.* And in affirming limited, ancillary relief, those courts were mindful that "the remedy [must] not [be] so expansive as to be unduly regulatory." *Microsoft*, 373 F.3d at 1215.

Endo is also seeking intervention to protect its fundamental right to due process. Section 5(b) of the FTC Act provides that if the Commission wants to charge a party with engaging in 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). The procedures provided for in the FTC Act reflect basic notions of due process. *See 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."); *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). Complaint Counsel took none of these steps and, therefore, their unsupported attempt to nullify the 2017 Settlement violates these principles.

In addition, the 2017 Settlement was vigorously negotiated between Endo and Impax as litigation adversaries. Endo should not be forced to rely on Impax's post-trial briefing to protect Endo's interests in the 2017 Settlement or its right to due process. Indeed, given that Complaint Counsel's requested relief implicates Endo's right to due process and its strategy with respect to Opana ER, Impax is not in a position to adequately protect Endo's interests.

II. Endo Seeks to Intervene for a Limited Purpose.

For the reasons described above, Endo seeks to intervene for a limited purpose. Endo seeks only to oppose any findings or remedy implicating its rights under the 2017 Settlement for the reasons explained above. Moreover, Endo's proposed intervention would cause no delay. Rather, Endo's participation would be limited to post-trial briefing to be filed by January 16, 2018.

CONCLUSION

Endo respectfully requests that it be permitted to intervene in this action for the limited purpose of responding to Complaint Counsel's Post-Trial Brief and Proposed Order and opposing (1) any findings related to the alleged competitive effects of the 2017 Settlement and (2) the nullification of the 2017 Settlement, or any remedy that would affect Endo's rights under that agreement.

Date: January 2, 2018

Respectfully submitted,

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

[PROPOSED] ORDER GRANTING NON-PARTY ENDO PHARMACEUTICALS INC.'S UNOPPOSED MOTION FOR LIMITED INTERVENTION

Upon consideration of non-party Endo Pharmaceuticals Inc. ("Endo") Motion for Limited Intervention, it is HEREBY ORDERED that Endo is permitted to intervene in the above-captioned action for the limited purpose of responding to Complaint Counsel's Post-Trial Brief and Proposed Order and opposing (1) any findings related to the alleged competitive effects of the 2017 Settlement and (2) the nullification of the 2017 Settlement, or any remedy that would affect Endo's rights under that agreement. Endo's brief for this purpose shall be submitted on or before January 16, 2018.

ORDERED:

_____

D. Michael Chappell
Administrative Law Judge

CERTIFICATE OF SERVICE

I hereby certify that on January 2, 2018, I caused a true and correct copy of the foregoing Motion 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:

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Notice of Electronic Service

I hereby certify that on January 02, 2018, I filed an electronic copy of the foregoing Non-Party Endo Pharmaceutical's Unopposed Motion for Limited Intervention, with:

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I hereby certify that on January 02, 2018, I served via E-Service an electronic copy of the foregoing Non-Party Endo Pharmaceutical's Unopposed Motion for Limited Intervention, upon:

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I hereby certify that on January 02, 2018, I served via other means, as provided in 4.4(b) of the foregoing Non-Party Endo Pharmaceutical's Unopposed Motion for Limited Intervention, upon:

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