PUBLIC

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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**

RESPONDENT IMPAX LABORATORIES, INC.'S
OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO DESIGNATE
FORMER EMPLOYEES OF THIRD PARTY ENDO PHARMACEUTICALS, INC.
AS ADVERSE TO COMPLAINT COUNSEL

INTRODUCTION

There is no lost love between Impax Laboratories, Inc. ("Impax") and Endo Pharmaceuticals, Inc. ("Endo"). As one of Complaint Counsel's experts recently testified, the companies have had a "fairly negative adversarial relationship."[1] The past decade has been pockmarked by frequent clashes. When Impax was preparing to begin selling generic Opana ER, for instance, Endo first filed a Citizen Petition with the FDA, and then sued the FDA, seeking to force it to withdraw or suspend its approval of Impax's generic product.[2] Impax ardently opposed the Citizen Petition and succeeded in intervening and defeating Endo's lawsuit against the FDA.[3] The companies spent years litigating Endo's patents and Impax's ANDA for reformulated Opana ER.[4] Most recently, Endo sued Impax regarding royalties it believed Impax owed under the settlement at issue in these proceedings.[5] That breach-of-contract litigation was ongoing when Complaint Counsel deposed Endo's witnesses this past summer.

Even in the context of this litigation, Impax and Endo have taken markedly different paths. Endo settled with the FTC before Complaint Counsel filed its Part III Complaint. Pursuant to the Stipulated Order, Endo agreed to certain cooperation provisions respecting this

[1] *See* Bazerman Dep. 144:25-145:3 ("Q. . . . You view the parties as having been in a fairly negative adversarial relationship; right? A. I do. I see substantial evidence of that."). Impax will provide a copy of the deposition transcript at the Court's request.

[2] Endo Pharm., Inc. Citizen Petition at 1, Dkt. FDA-2012-P-0895 (Aug. 10, 2012); Compl., *Endo Pharm. v. FDA*, No. 12-cv-1936 (D.D.C. Nov. 30, 2012).

[3] Impax Labs., Inc. Comment re Oxymorphone HCl Extended-Release Tablets, Dkt. FDA-2012-P-0895 (Dec. 9, 2012); Order, *Endo Pharm. v. FDA*, No. 12-cv-1936 (D.D.C. Dec, 19, 2012).

[4] *See Endo Pharm. Inc. v. Impax Labs., Inc.*, No. 12-cv-8317 (S.D.N.Y.) (litigation alleging that Impax's ANDA for reformulated Opana ER infringed Endo's patents).

[5] *See Endo Pharm. Inc. v. Impax Labs., Inc.*, No. 16-cv-2526 (JLL) (D.N.J.).

action.[6] Impax took a different course, choosing to litigate this case on the merits and prove that its conduct was not just legal, but procompetitive and good for consumers. It should come as no surprise, therefore, that Impax and Endo do not have a joint defense or common interest agreement in this proceeding.[7]

Given this history, Complaint Counsel's assertion that Impax and Endo have "similar, if not identical interests"[8] is implausible, and cannot justify Complaint Counsel's request that this Court preemptively and categorically designate Endo's former employees, Demir Bingol and Roberto Cuca, as adverse witnesses. *See, e.g.*, *SEC v. World Info. Tech., Inc.*, 250 F.R.D. 149, 151 (S.D.N.Y. 2008) (denying as premature SEC's motion to declare a defendant who had settled with the SEC an adverse witness, holding that ultimate decision would hinge on whether "the witness evidences hostility, bias, or recalcitrance during his testimony" at trial).

Complaint Counsel's Motion is wrong on the law. The Motion essentially ignores the governing Rule of Practice, and it is easy to see why. Rule 3.41(d) authorizes the categorical use of leading questions only with respect to "[a]n adverse ***party***, or an officer agent, or employee thereof." 16 C.F.R. § 3.41(d) (emphasis added). In all other circumstances, leading is inappropriate unless the witness actually "***appears*** to be hostile, unwilling, or evasive" at trial. *Id.* (emphasis added). Because neither Endo nor its former employees constitute "adverse parties" in this proceeding, this Court may not declare Mr. Bingol and Mr. Cuca adverse to Complaint Counsel before either of them even takes the stand.

On the last page of its Motion, Complaint Counsel further asks this Court to bar Impax

[6] *See* Stipulated Order for Permanent Injunction § VIII, *FTC v. Endo Pharm. Inc.*, No. 17-cv-00312 (N.D. Cal. Jan. 23, 2017), ECF No. 4-2.

[7] *See* Feb. 16, 2017 Ini. Pretrial Conf. Tr. 12:18-13:20, 15:17-21.

[8] Complaint Counsel's Oct. 4, 2017 Motion (the "Motion" or "Mot.") at 5.

from asking Messrs. Bingol and Cuca any leading questions—even, apparently, under circumstances where Rule 3.41(d) would otherwise permit leading. This request is improper and premature. The trial itself is the appropriate venue for deciding whether and to what extent Impax—and Complaint Counsel, for that matter—may lead an Endo witness.

This Court should deny Complaint Counsel's requests **(1)** to categorically designate Endo's former employees as adverse, and **(2)** to preclude Impax from asking any leading questions to Endo's former employees.[9]

ARGUMENT

I. The Rules of Practice Do Not Permit Complaint Counsel to Categorically Treat Former Endo Employees as Adverse Witnesses.

Complaint Counsel contends that Endo's former employees should be designated as adverse witnesses because their "interests [are] aligned with Impax." (Mot. at 1.) This argument fails for the simple reason that it applies the wrong rules. While Complaint Counsel cites Rule of Practice 3.41(d) in passing, it relies all but entirely on Federal Rule of Evidence 611(c) and its predecessor in the Federal Rules of Civil Procedures, and exclusively cites case law applying the federal rules. (Mot. at 3 n.1; *see id.* at 2-8.) In so doing, Complaint Counsel evades a critical distinction between Federal Rule of Evidence 611(c) and Rule of Practice 3.41(d): whereas Rule 611(c) allows an examiner to pose leading questions to "a hostile witness, an adverse party, ***or a witness identified with an adverse party***," Fed. R. Evid. 611(c)(2) (emphasis added), Rule 3.41(d) does ***not*** permit the use of leading questions as to a witness who is merely "identified with" an adverse party.[10] Rather, Rule 3.41(d) limits categorical leading to an "adverse party"

[9] Impax does not oppose Complaint Counsel's request to designate current and former Impax employees as adverse witnesses.

[10] Complaint Counsel also cites Rule of Evidence 611(c)'s predecessor, the former Federal Rule of Civil Procedure 43(b). (Mot. at 3 n.1.) Similar to Rule of Practice 3.41(d), the former Federal

and its officers, agents, or employees. 16 C.F.R. § 3.41(d). Leading is otherwise improper, unless a witness actually "appears to be hostile, unwilling, or evasive." *Id.*

Because Complaint Counsel does not (and could not) contend that Endo or any of its former employees is an "adverse party" in this action—Endo settled with the FTC before the Part III Complaint was filed, and thus was never named as a party—the plain terms of Rule 3.41(d) preclude Complaint Counsel from categorically treating Mr. Bingol and Mr. Cuca as adverse. And since the trial has not yet begun, it remains to be seen whether Mr. Bingol or Mr. Cuca will "appear[] to be hostile, unwilling, or evasive." (Complaint Counsel deposed Messrs. Bingol and Mr. Cuca, but tellingly does not cite to or rely upon their deposition transcripts to attempt to establish hostility, unwillingness, or evasiveness.[11]) Complaint Counsel can make the argument at trial if it so chooses, but Rule 3.41(d) does not permit the preemptive designation sought in Complaint Counsel's Motion.

Given that Rule of Practice 3.41(d) differs materially from Federal Rule of Evidence 611(c), federal court decisions interpreting the latter rule carry no persuasive value.[12] Ignoring

Rule of Civil Procedure 43(b) limited leading questions to "adverse part[ies]" and their "officer[s], director[s], or managing agent[s]," except where a witness actually presented as "unwilling or hostile." (*See id.*) While Complaint Counsel cites a handful of cases decided under the former Rule 43(b), as shown below, ***all*** of these cases involved witnesses who were either employed by, or themselves constituted, "adverse parties." *See infra* pages 5-6 & n.15 (discussing the *Uarte*, *Melton*, *Union P.R.*, and *Kador* cases). As neither Endo nor its former employees are "adverse parties" in this proceeding, these cases are inapposite.

[11] Complaint Counsel cites the witnesses' deposition testimony only in an attempt to show that their interests are aligned with those of Impax and that [redacted] (Mot. at 5, 7.) As discussed herein, Rule 3.41(d) does not apply in these circumstances. Complaint Counsel makes no attempt to argue that Messrs. Bingol and Cuca are "hostile, unwilling, or evasive," and may not raise new arguments on this front in reply. *In re N.C. Bd. of Dental Examiners*, 152 F.T.C. 640, 684 n.19 (2011); *cf.* 16 C.F.R. § 3.52.

[12] This Court has held that cases interpreting federal rules may be "useful" where the federal rules are "***similar*** to the Commission's Rules of Practice." *In re ECM BioFilms, Inc.*, Dkt. 9358,

this principle, Complaint Counsel relies heavily on *United States v. McLaughlin*, No. 95-CR-113, 1998 U.S. Dist. LEXIS 18588 (E.D. Pa. Nov. 19, 1998), a decision interpreting Federal Rule of Evidence 611. (*See* Mot. at 5, 7-8.) There, the putatively adverse witness had long been an "independent contractor . . . for the defendant's corporation," and had drafted the subject contract as part of his employment with the defendant. 1998 U.S. Dist. LEXIS 18588, at *1, *4. Given this long-running relationship and direct involvement with the matter in issue, the court held that the witness was "identified with . . . the defendant" under Rule 611(c)'s "identified with an adverse party" prong. *Id.* at *3-4 (citing Fed. R. Evid. 611(c)). Because Rule 3.41(d) has no analogue to that provision, *McLaughlin* does not in any way bolster Complaint Counsel's argument that a third-party's former employees should be categorized as adverse.

In every other case Complaint Counsel cites as putative support for declaring Messrs. Bingol and Cuca adverse, the witness constituted (or was employed by) an actual "adverse party" in the litigation. For instance, Complaint Counsel points to *United States v. Uarte*, 175 F.2d 110 (9th Cir. 1949), to argue that a party's involvement in a "parallel action" justifies treating it as adverse. (Mot. at 6.) But that is not what *Uarte* says. The witness in *Uarte* was ***himself*** a former defendant who had been dismissed on procedural grounds.[13] *Id.* at 113. He had also been a defendant in a separate state court action brought by the same plaintiff and arising from the same course of events. *Id.* In other words, the witness himself—not merely his employer—had twice been an "adverse party" to the plaintiff, including in that very action. *Id.* Further, and perhaps more importantly, ***the witness's trial testimony established that he was "unwilling."***

2014 WL 6806846, at *2 (F.T.C. Nov. 18, 2014) (quoting *In re L.G. Balfour Co.*, 61 F.T.C. 1491, 1492 (1962)) (emphasis added). Here, the rules are materially different.

[13] *See Uarte*, 175 F.2d at 113 ("McCoy had previously been a defendant in the instant action but on a motion raising the question of jurisdiction under a 'joinder' issue, he was dismissed out of this case by order[, the United] States alone being retained herein as a party defendant.").

Id. These facts do not map on to this case in the least. Here, **(1)** the witnesses have never been adverse to the FTC or Complaint Counsel in their individual capacity; **(2)** the witnesses' former employer, Endo, has never been an "adverse party" in this action, and in fact is no longer adverse to the FTC or Complaint Counsel in any sense; **(3)** unlike the plaintiff in *Uarte*, Complaint Counsel is not a party to the separate action (the *Opana ER* MDL) and has stressed that private plaintiffs and government enforcers are differently situated[14]; and **(4)** unlike the witness in *Uarte*, Messrs. Bingol and Cuca have not yet taken the stand and been deemed "hostile, unwilling, or evasive." 16 C.F.R. § 3.41(d).

In a similar vein, Complaint Counsel claims that in *Sadid v. Idaho State University*, No. 4:11-cv-00103-BLW, 2013 U.S. Dist. LEXIS 172361 (D. Idaho Dec. 5, 2013), "third parties were designated as adverse because they were defendants in [a] related action." (Mot. at 6.) Yet again, Complaint Counsel omits key facts: the witnesses in *Sadid* were not merely "third parties" who had been involved in a "related action." (*Id.*) They were also ***employees*** of the defendant, Idaho State University. 2013 U.S. Dist. LEXIS 172361, at *6-8. Thus, while the *Sadid* witnesses would constitute "officer[s], agent[s], or employee[s]" of an "adverse party" (Idaho State University) within the meaning of Rule 3.41(d), Messrs. Bingol and Cuca do not, because Endo is not and has never been an "adverse party" in this action.

Complaint Counsel's remaining cases are equally inapposite.[15] Lacking legal authority

[14] *See, e.g.*, Complaint Counsel's Motion for Partial Summary Decision at 17, *In re Impax Labs., Inc.*, Dkt. 9373 (F.T.C. Aug. 3, 2017) ("'Private plaintiffs and the FTC as government enforcer stand in different shoes.'") (quoting *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016)).

[15] *See Melton v. O.F. Shearer & Sons, Inc.*, 436 F.2d 22 (6th Cir. 1970) (witness was the defendant's employee, and thus constituted an "adverse party" and "managing agent" of defendant under former Fed. R. Civ. P. 43(b)); *Union P.R. Co. v. Ward*, 230 F.2d 287, 290 (10th Cir. 1956) (witness was a "veteran employee [of the defendant] in a supervisory position"); *Maryland Cas. Co. v. Kador*, 225 F.2d 120, 123 (5th Cir. 1955) (witness was an "adverse party"

for the relief it seeks, Complaint Counsel resorts to misdirection. The Motion characterizes Impax as "taking the anomalous position that these Endo witnesses are somehow friendly to Complaint Counsel, even though these same witnesses will be treated as adverse to plaintiffs in the private case in Chicago." (Mot. at 6.) Impax has never suggested that Messrs. Bingol and Cuca are "friendly" to Complaint Counsel—but that is beside the point. Regardless of friendliness, neither they nor Endo is an "adverse party" under Rule 3.41(d). Far from it, ***Endo has settled with the FTC***. And by the same token, regardless of which side Complaint Counsel is cheering for in the *Opana ER* MDL, it is not and has never been a party to that litigation.

Complaint Counsel has failed to provide any justification for preemptively and categorically designating Endo's former employees as adverse witnesses.

II. There Is No Basis For Categorically Barring Impax From Asking Leading Questions to Endo's Former Employees.

Complaint Counsel further contends that "Impax's counsel should not be allowed to use leading questions with its own clients," for fear that they will "'spoon-feed leading questions to their own man.'" (Mot. at 7 (quoting *McLaughlin*, 1998 U.S. Dist. LEXIS 18588, at *4-5).[16] Complaint Counsel then proceeds to argue that "[f]or the same reasons, Impax should not be allowed to lead the witnesses associated with Endo." (*Id.* at 8.) The insinuation that Impax's counsel could—or would—"spoon-feed" former Endo employees, despite the lack of a joint defense or common interest relationship in these proceedings, is baseless conjecture.

In any event, it is premature to for the Court to decide whether and to what extent Impax

under former Fed. R. Civ. P. 43(b) because he was the actual tortfeasor whose "wrongdoing [was] the gravamen of the action," and but for statute providing for a right of action against the insurer, the witness "would have been a necessary party defendant").

[16] While Impax does not presently seek leave to ask leading questions to any current or former Impax employees who may testify at trial, Impax reserves the right to seek this Court's permission to do so if and when circumstances may justify.

may pose leading questions to Mr. Bingol or Mr. Cuca. *World Info. Tech., Inc.*, 250 F.R.D. at 151. If either witness "appears to be hostile, unwilling, or evasive," Impax may appropriately seek permission to ask leading questions. 16 C.F.R. § 3.41(d). Complaint Counsel's attempt to short-circuit this routine practice before trial even begins is improper.

CONCLUSION

For the foregoing reasons, this Court should deny Complaint Counsel's requests **(1)** to categorically treat Endo's former employees as adverse witnesses, and **(2)** to bar Impax entirely from asking leading questions to Endo's former employees.

Dated: October 10, 2017

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Notice of Electronic Service

I hereby certify that on October 11, 2017, I filed an electronic copy of the foregoing RESPONDENT IMPAX LABORATORIES, INC.'S OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO DESIGNATE FORMER EMPLOYEES OF THIRD PARTY ENDO PHARMACEUTICALS, INC. AS ADVERSE TO COMPLAINT COUNSEL, with:

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