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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

Commissioners: **Maureen K. Ohlhausen, Acting Chairman**
Terrell McSweeny

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

COMPLAINT COUNSEL'S REPLY IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY DECISION

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Complaint Counsel's partial summary decision motion presents a straightforward and narrow question: whether certain specific procompetitive justifications that Impax has identified to date are legally cognizable under *FTC v. Actavis*, 133 S. Ct. 2223 (2013). Impax's response largely avoids this question in favor of erroneous arguments about what Complaint Counsel must show to establish its prima facie case.

Nonetheless, what Impax does say in its response confirms that its patent-related justifications ignore or contradict *Actavis*. First, Impax's claim that *Actavis* deemed entry before patent expiration to be procompetitive ignores plain language in that opinion distinguishing settlements that include a payment to the generic patent challenger to stay off the market. Second, instead of explaining how the challenged payment provision promotes a legitimate procompetitive objective, Impax incorrectly denies that it must do so. Third, Impax urges an unworkable rule to retroactively justify anticompetitive reverse-payment agreements on the basis of patent rulings that occurred years after the settlement and relate to patents not in existence at the time of the settlement. After addressing these issues, we explain Impax's fundamental errors concerning the nature of Complaint Counsel's burdens under the rule of reason analysis *Actavis* mandates.

I. *Actavis* forecloses Impax's three patent-related justifications

Under the well-established structured rule-of-reason framework, asserted procompetitive effects of an agreement are weighed against anticompetitive harm if the defendant proffers a cognizable, legitimate procompetitive objective and the challenged restraint promotes, and is reasonably necessary to achieve, that legitimate objective. Memorandum of Law in Support of

Complaint Counsel's Motion for Partial Summary Decision, Aug. 3, 2017 ("Br.") at 8.[1] Impax's response demonstrates that its asserted justifications cannot satisfy this standard.

A. Entry before patent expiration is not a cognizable justification

Complaint Counsel's brief showed that a reverse-payment settlement cannot be justified by the fact that it permits some generic entry before patent expiration. A court cannot "answer the antitrust question" raised by reverse-payment settlements by comparing the agreed-upon generic entry date to the exclusion that might occur if the patent were found valid and infringed. *Actavis*, 133 S. Ct. at 2231. As the Supreme Court explained, "[t]he patent [] may or may not be valid, and may or may not be infringed." *Id*. Treating entry before patent expiration as a cognizable procompetitive justification would thus effectively revive the "scope-of-the-patent" test that *Actavis* rejected. *See* Br. at 10-12. Courts applying *Actavis* have consistently concluded that permitting entry before patent expiration is not a cognizable defense in a reverse-payment case. *Id*.

Impax's one-paragraph response does not directly address these arguments. *See* Respondent Impax Laboratories, Inc.'s Memorandum of Law in Opposition to Complaint Counsel's Motion for Partial Summary Decision, Aug. 31, 2017 ("Opp.") at 24-25. Instead, Impax merely quotes one sentence from the *Actavis* decision: "We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also

[1] This structured framework applies in both "quick look" and non "quick look" cases. *See e.g.*, *United States v. Brown Univ. in Providence in R.I.*, 5 F.3d 658, 669 (3d Cir. 1993) (in case rejecting quick-look analysis, stating that defendant must "show that the challenged conduct promotes a sufficiently pro-competitive objective"); *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 834-35 (6th Cir. 2011) (declining to apply quick look analysis and rejecting free-rider justification "as not 'legitimate, plausible, substantial and reasonable'" because free-riding was unconnected to challenged website policies (quoting *In re Detroit Auto Dealers Ass'n*, 955 F.2d 457, 470 (6th Cir. 1992)); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 243 (2d Cir. 2003) (non-quick-look case rejecting justification for challenged restrictions on cross-issuance because restraint was not necessary to "network cohesion").

bring about competition, again to the consumer's benefit." *Id.* (quoting 133 S. Ct. at 2234). But Impax ignores the Court's next sentences, which highlight the fundamental difference between settlements with payments to induce the generic patent challenger to settle and settlements without such payments:

> We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit. *But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market*—simply keeps prices at patentee-set levels . . . while dividing that [monopoly] return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses.

133 S. Ct. at 2234-35 (emphasis added). The Court made the same basic distinction later, observing that drug companies "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, *without the patentee paying the challenger to stay out prior to that point*." *Id*. at 2237 (emphasis added).

B. The challenged restraint must promote and be reasonably necessary to achieve a legitimate, procompetitive objective

The law clearly places the burden on the defendant to justify "the challenged term," in this case, the payment: "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby *explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason*." *Actavis*, 133 S. Ct. at 2236 (emphasis added); *see also King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 416 (E.D. Pa. 2015) (finding that "the defendant bear[s] the burden of providing evidence that the reverse payment is justified by procompetitive considerations"). Impax references this very quote from *Actavis* in its brief (Opp. at 25), but then makes no attempt to explain the connection between Endo's payments and the asserted settlement benefits. Instead, it contends

that "[t]here are no limitations on the benefits that can be considered, or from where in the settlement agreement they may flow." Opp. at 25; *see also Id*. at 25-26 (all benefits from the settlement "as a whole" are "relevant").

Impax cites only two cases for its "all benefits are relevant" argument, and neither supports its claim. First, Impax incorrectly asserts that, in *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447 (1986), the Supreme Court "considered" all of the Federation's "countervailing procompetitive virtues." Opp. at 26. Not so. In that case, the Court found there were no cognizable procompetitive benefits because the Federation's asserted quality-of-care justification for withholding dental x-rays from insurers was fundamentally an argument that competition would harm rather than promote quality. *Ind. Fed'n of Dentists*, 476 U.S. at 463.

Nor does then-Judge Sotomayor's concurrence in *Major League Baseball Props., Inc v. Salvino, Inc.*, 542 F.3d 290, 338 (2d Cir. 2008) (Sotomayor, J. concurring), support Impax's argument. That opinion, as Impax notes, assessed the alleged procompetitive benefits of Major League Baseball clubs' joint licensing venture as a whole. But what Impax fails to note is that the concurrence considered the benefits of the joint venture as a whole only because the challenged provisions were deemed "reasonably necessary to achieve MLBP's efficiency-enhancing objectives." *Id.* at 340. Indeed, the opinion specifically stated that "when a challenged restraint is not reasonably necessary to achieve any of the efficiency-enhancing purposes of a joint venture, it will be evaluated apart from the rest of the venture." *Id*. at 338.

Although Impax points to its license to future Endo patents as a procompetitive benefit of the settlement, it does not explain how the challenged *reverse payment* promoted a legitimate procompetitive objective or how the payment could, as a matter of logic, be reasonably necessary to achieve that benefit. Indeed, Impax does not, and cannot, deny that Endo's willingness to give

Impax a broad license to future Endo patents *and* a substantial reverse payment necessarily means that Endo also would have been willing to give Impax the license without a payment.

And even if Impax were to argue that the challenged payment was reasonably necessary to reach settlement, Impax's desire to be paid to accept an otherwise unacceptable entry date is not a legitimate procompetitive justification. As the Commission observed in its *Wellbutrin XL* amicus brief, a justification that rests on the premise that the generic would not have agreed to the settlement without being paid "irrationally turns proof of the plaintiff's case—the use of a reverse payment to induce an entry-restricting settlement—into a defense."[2] The California Supreme Court has similarly observed that drug companies may not "use money to bridge their differences over the point when competitive entry is economically desirable, for that gap is not one that antitrust law permits would-be competitors to bridge by agreement." *In re Cipro Cases I & II*, 348 P.3d 845, 869 (Cal. 2015). Indeed, even though "some settlements might no longer be possible absent a payment in excess of litigation costs," that fact "is no concern if the ones barred would simply have facilitated the sharing of monopoly profits." *Id*.

C. Post-settlement patent rulings cannot retroactively justify a reverse payment

Complaint Counsel's opening brief explained that Impax's effort to justify the challenged reverse-payment agreement with post-settlement patent rulings is inconsistent with *Actavis* and with post-*Actavis* decisions that specifically reject reliance on such rulings. Br. at 15-18. The appropriate antitrust analysis focuses on the circumstances at the time the relevant harm to competition occurs.[3] *Actavis* makes clear that "the relevant anticompetitive harm" occurs when

[2] Brief of Federal Trade Commission as Amicus Curiae in Support of No Party at 24, *In re Wellbutrin XL Antitrust Litig.*, Nos. 15-3559, 15-3591, 15-3681 & 15-3652 (3d Cir. Mar. 11, 2016).

[3] *See generally* Federal Trade Commission and U.S. Dept. of Justice, Antitrust Guidelines for Collaborations Among Competitors § 2.4 (April 2000).

drug companies agree "to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market" and thereby "prevent the risk of competition." *Actavis*, 133 S. Ct. at 2236.[4] That happens at the time of the settlement. The Complaint in this case alleges that "[t]he agreement between Impax and Endo precluding Impax from launching a generic version of Opana ER until January 2013 harmed competition and consumer welfare by eliminating the risk that Impax would have marketed its generic version of Opana ER before that date." Compl. ¶ 94. Thus, the relevant anticompetitive harm in this case occurred before Endo had even obtained the subsequent patents Impax relies on—let alone prosecuted them in any court.[5]

Allowing post-settlement patent rulings to justify a reverse-payment settlement is simply an unworkable way to assess the legality of such agreements. Br. at 15-18. Under Impax's approach, the antitrust legality of a reverse-payment settlement would fluctuate: for example, a settlement may be unlawful when entered but later become lawful if a district court upholds the brand's patent—and then perhaps become unlawful again if the Federal Circuit reverses. How can pharmaceutical companies assess the antitrust risks associated with a settlement if a patent ruling years in the future can dramatically change that analysis? Impax then augments this inadministrable approach with a bold "heads-I-win-tails-you-lose" framework: According to Impax, post-settlement rulings of validity and infringement can justify an otherwise unlawful

[4] *See also* 133 S. Ct. at 2235 (antitrust "concern" is that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement).

[5] Impax acknowledges that *Actavis* rejected an analysis that "***presume[es]***" patent validity and infringement, and emphasizes that here "Impax is relying on an actual ***adjudication*** of validity." Opp. at 29 (emphasis in original). But all of the adjudications it points to involve patents that Endo obtained years after the settlement. Thus, its arguments do not rest on the validity of the patent actually disputed in the Impax-Endo patent litigation, which was never resolved.

reverse-payment agreement, but a later finding of patent *invalidity* cannot make a "good faith" settlement unlawful. *See* Opp. at 17-18.

This one-sided rule does not square with the essential teaching of *Actavis* – that antitrust analysis of reverse-payment agreements accepts the uncertainty about patent validity or infringement at the time of settlement. This principle has been repeatedly recognized in post-*Actavis* reverse-payment cases. Br. at 12, 15-18. As the Third Circuit put it, *Actavis* "embraces" the fact that at the time of settlement a patent "may or may not be valid, and may or may not be infringed." *King Drug Co. of Florence, Inc. v. Smithkine Beecham Corp.*, 791 F.3d 388, 410 (3d Cir. 2015) ("*Lamictal*"); *see also Cipro*, 348 P.3d at 870 ("Agreements must be assessed as of the time they are made, at which point the patent's validity is unknown and unknowable." (internal citation omitted)).

Impax contends that the Supreme Court's sole reason for rejecting an inquiry into the patent merits was to avoid a patent mini-trial within the antitrust case. *See* Opp. at 27. But *Actavis* did not reject an assessment of the patent merits simply because it would be a difficult task. It rejected such an assessment because the appropriate antitrust analysis turns on whether the parties are agreeing to share the rewards of avoiding the risk of competition, not on the outcome of the patent case. *Actavis*, 133 S. Ct. at 2236 (antitrust concern is that "the patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement"); *see also Cipro*, 348 P.3d at 870 ("[C]onsideration of whether the agreement is justified as procompetitive will not turn on whether the patent would ultimately have been proved valid or invalid.").

Finally, Impax's reliance on post-settlement patent rulings would improperly import into this government enforcement action the injury-in-fact requirement that applies only in private

suits. Br. at 16-17. Proof of an antitrust violation and proof of actual injury are "distinct matters that must be shown independently." *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016) (quoting *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990)). Impax's arguments about the "actual" competitive effects of its challenged conduct reflect its erroneous continued merging of these two distinct inquiries.

II. Impax's view of the rule of reason analysis misunderstands *Actavis* and longstanding antitrust precedent

Complaint Counsel's motion for summary decision focused on the narrow issue of whether certain of Impax's alleged justifications are cognizable. The majority of Impax's opposition brief ignores those arguments and instead makes erroneous arguments about the nature of Complaint Counsel's burden in its prima facie case. Specifically, Impax contends that Complaint Counsel must show that the "reverse-payment settlement actually delayed generic competition or resulted in any actual harm to consumers." Opp. at 20. This approach fundamentally misunderstands the applicable rule of reason analysis. Thus, although Complaint Counsel's motion did not ask the Commission to address the prima facie case under *Actavis*, we explain Impax's three basic errors here.

First, Impax ignores the central teaching of *Actavis*: that the "relevant anticompetitive harm" from paying a generic patent challenger to stay off the market is that it "eliminate[s] the risk of competition." 133 S. Ct. at 2236. Second, Impax confuses *Actavis*'s sliding scale rule-of-reason test with a "quick look" or presumption of illegality. Third, Impax incorrectly equates proof of an antitrust violation in this government enforcement proceeding with the proof required to establish injury-in-fact in a private plaintiff damages action.

A. Under *Actavis*, the anticompetitive effect of a reverse payment is the elimination of the risk of competition

Contrary to Impax's claim, Complaint Counsel's "initial burden to show anticompetitive effects" does not require proof that the agreement "actually delayed generic competition or resulted in any actual harm to consumers." Opp. at 11, 20 (internal quotation marks and alteration omitted). The core concern in *Actavis* was that a monopolist and a potential competitor would collude to avoid the possibility of competing for some period of time and share the resulting monopoly profits. 133 S. Ct. at 2235. As the Court explained, the "anticompetitive consequence that underlies the claim of antitrust unlawfulness" is "maintain[ing] supracompetitive prices to be shared among the patentee and the challenger rather than face what *might have* been a competitive market." *Id.* at 2236 (emphasis added). In other words, the "relevant anticompetitive harm" from a reverse payment is that it can "prevent the risk of competition." *Id.* at 2237. Here the alleged anticompetitive harm is the prevention of the risk of competition to Opana ER for two and a half years, until January 2013.

Despite this clear standard, Impax insists that a reverse payment cannot be proven anticompetitive without conclusively demonstrating that generic entry would have occurred sooner had the payment not been tendered. Opp. at 19-20. [6] But *Actavis* does not require reconstruction of the hypothetical world that might have existed absent the reverse payment.

[6] Impax's reliance on *McWane* (Opp. at 23) is wholly misplaced. In *McWane*, the Commission found that Sigma, the alleged excluded competitor, "lacked the financial means" needed to enter the market, and therefore was not a potential competitor. *In re McWane*, Docket No. 9351, 2014 WL 556261 at *35 (FTC Jan. 20, 2014); *see also id*. at *10 (finding Sigma had concluded that "the entire project was found to be too overwhelming and cumbersome"). As a result, the agreement between Sigma and the Respondent did not raise the concerns about competitor collusion that the Supreme Court addressed in *Actavis*. To date, Impax has not contended that it was not a potential competitor to Endo.

Indeed, the Court observed that the removal of an uncertain risk of invalidity or non-infringement, even if small, cannot justify an otherwise unexplained large reverse payment:

> The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.

133 S. Ct. at 2236; *see also id.* at 2244 (Roberts, C.J., dissenting) (under logic of majority opinion, "taking away any *chance* that a patent will be invalidated is itself an antitrust problem"); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 240 (D. Conn. 2015) (plaintiffs "need not plead (or prove) the weakness of the [] patent because the patent's ultimate validity is not at issue").[7]

In addition, Impax incorrectly claims that "Complaint Counsel's 'elimination of risk' test captures every patent litigation settlement." Opp. at 21. This assertion, however, ignores the most important aspect of a reverse-payment claim: the *payment*. The anticompetitive harm from a reverse-payment settlement is not merely that the settlement eliminates the risk of competition, but that the brand is *paying* the generic to accomplish that end. In other words, "the patentee seeks to induce the generic challenger to abandon its claim with a share of monopoly profits that would otherwise be lost in the competitive market." *Actavis*, 133 S. Ct. at 2235. The Supreme Court made clear that there is ordinarily no antitrust problem with a settlement that "allow[s] the generic manufacturer to enter the patentee's market prior to the patent's expiration, *without* the patentee's paying the challenger to stay out prior to that point." *Id.* at 2237. As the Third Circuit elaborated, a reverse-payment agreement is categorically different from this type of pure "early

[7] Of course, if the risk of competition is so small that it results in a small payment, there would be no *Actavis* claim.

entry" settlement because "entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered." *Lamictal*, 791 F.3d at 388.

B. *Actavis* instructs courts to apply a sliding-scale approach in structuring the rule of reason analysis

Impax erroneously contends that any attempt to focus the rule of reason inquiry on whether the payment eliminated the risk of competition amounts to impermissible "presumptions, quick-looks, or shortcuts." Opp. at 12. The Supreme Court declined to adopt the "quick look" or "presumptively unlawful" standard requested by the FTC and used by the Third Circuit in *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012). But *Actavis* made clear that "this is not to require the courts to insist . . . that the Commission need litigate the patent's validity, empirically demonstrate the virtues or vices of the patent system, present every possible supporting fact, or refute every possible pro-defense theory." 133 S. Ct. at 2237. Instead, the Court instructed trial courts to structure the rule of reason to avoid "consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question," i.e., whether the reverse payment "maintain[s] and [] share[s] patent-generated monopoly profits" and thereby avoids the risk of competition. *Id.* at 2237, 2238. In so doing, *Actavis* expressly reaffirmed the principle that even outside the "quick look" context, in applying the rule of reason, "there is always something of a sliding scale in appraising reasonableness" and "the quality of proof required should vary with the circumstances." *Id.* at 2237-38 (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 780 (1999)).

Courts handling reverse-payment cases have consistently rejected the "kitchen sink" approach Impax proposes. For example, in *Cephalon*, 88 F. Supp. 3d 402, the Eastern District of Pennsylvania held that the plaintiff's prima facie case required a showing of market power and a large payment from the brand to the generic. The court specifically rejected the argument that the

prima facie case included "demonstrating actual anticompetitive effects, such as reduction of output, increase in price, and deterioration in quality of goods or services." *Id.* at 414. The Third Circuit outlined a similar framework: "First, to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, a payment to prevent the risk of competition." *Lamictal*, 791 F.3d 388, 412. Here, Complaint Counsel will need to prove a large reverse payment that guaranteed Impax would stay out of the market until January 2013—preventing the risk of competition prior to that point. If the plaintiff makes the required showing, the burden shifts to the defendant to provide legitimate justifications for that payment.

Contrary to Impax's assertions, this sort of structuring does not amount to a "quick look" or "presumption." As the *Cephalon* Court explained, "[t]he burden-shifting framework I have adopted does not qualify as a quick-look approach because the plaintiff still maintains the initial burden—establishing anticompetitive effects through market power and evidence of a large reverse payment." 88 F. Supp. 3d at 416.; *see also In re K-Dur Antitrust Litig.*, No. 01-cv-1652, 2016 WL 755623, at *11 (D.N.J. Feb. 25, 2016) (noting that "the rule-of-reason test puts the ultimate burden of proof to show anticompetitive conduct onto the plaintiff" whereas "the 'quick look' test, by contrast, creates the presumption that the conduct in question is in fact anticompetitive, thereby shifting the ultimate burden of proof to the defendant to show that the conduct in question is procompetitive"). Indeed, under *Actavis*, there must be "monopoly profits that would otherwise be lost in the competitive market" to create the antitrust concern in the first place. 133 S. Ct. at 2235. *See also* Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1914d, at 315 (1996) (the "main difference between the burden-shifting analysis under the 'quick look' approach and the rule of reason is that under the former the plaintiff's case does not ordinarily include proof of power or anticompetitive effects").

C. Government antitrust enforcers do not need to show "actual harm" to consumers to prove an antitrust violation

Impax's proposed requirement that Complaint Counsel "prove that a reverse-payment settlement actually delayed generic competition or resulted in any actual harm to consumers" (Opp. at 20) inappropriately conflates proof of an antitrust violation with proof of injury-in-fact. It is well established that a government antitrust enforcer can prove an antitrust violation under the rule of reason even absent "actual injury." In contrast, a private plaintiff must show "actual harm" because it must prove an injury-in-fact to proceed under the Clayton Act. *See Nexium*, 842 F.3d at 60 ("[P]rivate plaintiffs derive their authority to sue from Section 4 or Section 16 of the Clayton Act and must therefore satisfy the additional evidentiary burdens that those provisions impose."). This distinction reflects public policy: while the interest of a private plaintiff is to "remediate an injury," the interest of the government is "to prevent and restrain violations of the antitrust laws along with the attendant social costs such violations can cause." *Id.* (quoting Brief of Amicus Curiae FTC in Support of No Party at 21, *In re: Nexium Esomeprazole Antitrust Litig.*, Nos. 15-2005, 15-2006, 15-2007 (1st Cir. Feb. 12, 2016)).

The *en banc* D.C. Circuit decision in the *Microsoft* monopolization case illustrates the distinction between proving an antitrust violation and showing an actual injury. The D.C. Circuit explained that the antitrust violation analysis does not "turn on a plaintiff's ability or inability to reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct" because "neither plaintiffs nor the court can confidently reconstruct a product's hypothetical . . . development in a world absent the defendant's exclusionary conduct." *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (*en banc*) (citing 3 Areeda & Hovenkamp, *Antitrust Law* ¶ 651c, at 78). Instead, to establish a violation (as opposed to injury-in-fact), a plaintiff need only show that "as a general matter the [defendant's conduct] is the type of conduct that is reasonably

capable of contributing significantly to a defendant's continued monopoly power," viewed "at the time [the defendant] engaged in the anticompetitive conduct." *Id.*; *see also Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 690 (1978) (purpose of anticompetitive effects inquiry is to determine "the nature or character of the contract[]" at issue). As the D.C. Circuit explained, "to some degree, 'the defendant is made to suffer the uncertain consequences of its own undesirable conduct.'" *Microsoft*, 253 F.3d at 79 (quoting 3 Areeda & Hovenkamp, *Antitrust Law* ¶ 651c, at 78).

In cases involving reverse payments, courts have recognized the important distinction between anticompetitive effects needed to establish an antitrust violation and the specific harm required to establish an injury-in-fact. The First Circuit's decision in *In re Nexium (Esomeprazole) Antitrust Litig.* is particularly instructive. After a lengthy trial, the *Nexium* jury found that (1) the brand company, AstraZeneca exercised market power, (2) the challenged settlement included a large and unjustified reverse payment to the generic challenger, Ranbaxy, (3) the "anticompetitive effects" of the settlement "outweigh[ed] any pro-competitive justifications," and (4) AstraZeneca would not have agreed to an earlier entry date for Ranbaxy even absent the reverse payment. 842 F.3d at 49-51.

Thus, the jury concluded that Ranbaxy, as Impax claims here, would not "have launched a generic earlier than [the settlement date] but for the antitrust violation." *Id.* at 60. As the First Circuit explained, however, that did not preclude finding anticompetitive effects. The court made clear that the question of whether a reverse payment has an anticompetitive effect on the competitive process such that it violates the antitrust laws is separate from the question of whether its "actual effects" (Opp. at 13) reduce competition in the market. 842 F.3d at 60. Thus, the jury found that "some antitrust violation resulted from the AstraZeneca-Ranbaxy settlement,"

but "that *notwithstanding the existence of an antitrust violation*, the plaintiffs failed to establish an antitrust injury that entitled them to monetary relief." *Id.* (emphasis added). The First Circuit then clarified that the FTC does not need to show an actual injury. *Id.* at 60. *See also In re Wellbutrin XI Antitrust Litig.*, __ F.3d __, 2017 WL 3531069, at *18-19 (3d Cir. Aug. 9, 2017) (explaining that plaintiffs did not have standing because they "failed to show that Anchen would have been able to launch its [generic product] without running afoul" of an additional patent and thus failed to show that they suffered an injury from the settlement).[8]

In sum, the rule of reason's "anticompetitive effects" inquiry is not a free-form fishing expedition into everything that occurred in the market after an agreement was executed. It is a focused inquiry into the competitive character of the restraint and its effect on the competitive process. In the context of a reverse payment, the relevant anticompetitive effect is the elimination of the risk of competition for a period of time. That anticompetitive effect can occur regardless of whether and how competition would actually have materialized, and therefore does not depend on showing actual injury.

Conclusion

Complaint Counsel's motion presents a pure question of law that is ripe for summary disposition. Impax identifies no factual dispute that is material to assessing the legal viability of

[8] Outside the reverse payment context, courts have held similarly. In *Microbix Biosystems, Inc. v. Biowhittaker, Inc.*, 172 F. Supp. 2d 680, 695-99 (D. Md. 2000), the district court found sufficient evidence that the defendant's exclusive supply agreement violated sections 1 and 2 of the Sherman Act. But it further found that intervening events would have prevented the plaintiff—a potential competitor—from entering the market regardless of defendants' unlawful conduct. The court made clear that the inquiry into whether the plaintiff would have entered the market was "[i]n addition to proving violation of the antitrust laws." *Id.* at 696. *See also Ocean State Physicians Health Plan, Inc. v. Blue Cross & Blue Shield of R.I.*, 883 F.2d 1101, 1105-06 (1st Cir. 1989) (treating the question of whether there was an antitrust violation separately from whether injunctive or monetary relief was warranted).

the three asserted justifications addressed by this motion,[9] and its legal arguments misunderstand *Actavis* as well as well-established rule-of-reason principles. Partial summary decision is warranted.

Respectfully submitted,

Dated: September 15, 2017

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[9] See Complaint Counsel's Reply To Impax Laboratories, Inc.'s "Statement Of Material Facts That Remain In Dispute" (September 15, 2017).

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Maureen K. Ohlhausen, Acting Chairman**
Terrell McSweeny

In the Matter of **Impax Laboratories, Inc.,** **a corporation.**	**Docket No. 9373**

COMPLAINT COUNSEL'S REPLY TO IMPAX LABORATORIES, INC.'S "STATEMENT OF MATERIAL FACTS THAT REMAIN IN DISPUTE"

Impax's "Statement of Material Facts That Remain in Dispute" in support of its Opposition to Complaint Counsel's Motion for Partial Summary Decision presents no dispute of material fact preventing the Commission from granting the motion.

First, Impax does not dispute Complaint Counsel's Statement of Undisputed Facts, except for a purported dispute about paragraph 10 "to the extent that it characterizes" the contents of Impax's paragraph IV certifications.[1] Impax does not identify anything wrong with Complaint Counsel's "characterization." Instead, it merely states that "Impax's Paragraph IV certifications speak for themselves." In any event, for purposes of this motion, what matters is that Impax filed paragraph IV certifications to Endo's patents. Impax does not dispute that fact and it submitted two of those certifications as exhibits along with its Statement.

[1] Respondent Impax Laboratories, Inc.'s Statement of Material Facts That Remain in Dispute, at 1 n.1 & Exhibits E, F; *see also* Complaint Counsel's Statement of Undisputed Facts at ¶ 10.

Second, the vast majority (33 out of 41) of the factual assertions Impax presents are not material to the legal question presented in Complaint Counsel's motion. Rather, they concern other issues that Impax may raise at trial, including: whether Impax would have launched at risk absent the settlement (paragraphs 1-4); court rulings prior to settlement (paragraph 5); alternative entry dates (paragraph 6); whether the settlement contained a "large" reverse payment (paragraphs 15-31); and whether a part of the alleged reverse payment that is expressly not at issue in Complaint Counsel's motion (the Development and Co-Promotion Agreement) was justified (paragraphs 32-41). These issues do not affect the legal sufficiency of the particular justifications Complaint Counsel's motion addresses. Granting Complaint Counsel's motion would not affect resolution of factual disputes as to these other aspects of the case that Impax raises.

A subset of Impax's asserted facts (paragraphs 7-14) do relate to issues implicated by Complaint Counsel's motion; specifically, the scope of the rights Endo granted to Impax relating to future Endo patents and Endo's enforcement of certain later-obtained patents. But Complaint Counsel's motion raises purely legal questions, the outcome of which do not depend on whether Impax's factual assertions in paragraphs 7-14 are true. Therefore, Complaint Counsel does not dispute those assertions for the limited purpose of this motion.[2] Complaint Counsel retains the right to dispute the statements in paragraphs 7-14 of Respondent's "Statement of Material Facts That Remain in Dispute" in all other aspects of this proceeding.

[2] Our opening brief noted that Endo sued Impax in 2016 concerning a dispute about what rights Endo granted Impax regarding future Endo patents. The brief also noted that this dispute did not bear on the legal issues presented in Complaint Counsel's motion. Br. at 4 n.1. The companies settled that lawsuit on August 7, 2017. *See* http://investors.impaxlabs.com/Media-Center/Press-Releases/Press-Release-Details/2017/Impax-Announces-Settlement-of-Contract-Litigation-on-Opana-ER-Oxymorphone-Hydrochloride-CII-Extended-Release-Tablets/default.aspx.

Respectfully submitted,

Dated: September 15, 2017

/s/ Charles A. Loughlin

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CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2017, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

September 15, 2017 By: s/ Charles A. Loughlin