

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

IN RE OPANA ER ANTITRUST  
LITIGATION

MDL No. 2580

Lead Case No. 14-cv-10150

THIS DOCUMENT RELATES TO:

Hon. Harry D. Leinenweber

ALL CASES

**PLAINTIFFS' POST-TRIAL MOTION FOR JUDGMENT  
AS A MATTER OF LAW OR FOR A NEW TRIAL**

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In accordance with Fed. R. Civ. P. 50(b), all Plaintiffs renew their motion made at the close of the evidence that the Court: (1) find that Endo failed to identify any legally cognizable justification for its reverse payments to Impax and (2) enter judgment for Plaintiffs that Endo violated Section 1 of the Sherman Act.<sup>1</sup> In the alternative, pursuant to Fed. R. Civ. P. 59, Plaintiffs move for a new trial to correct: (1) the flawed jury instructions on the procompetitive justification of reverse payments including the least restrictive means of achieving any such benefits; (2) the failure of the verdict form to require consideration of a less restrictive means of achieving procompetitive benefits; and (3) the admission of irrelevant, prejudicial post-agreement events.

### **INTRODUCTION**

In this case, Plaintiffs alleged that Endo made a large reverse payment to Impax consisting of a no-authorized generic agreement, the Endo Credit, and a \$10 million nonrefundable upfront cash payment under the Development and Co-Promotion Agreement (“DCA”), which was expressly incorporated into the Settlement and License Agreement (“SLA”). Plaintiffs alleged that Endo’s large reverse payment was anticompetitive under the antitrust rule of reason that the Supreme Court held to be applicable to reverse payments in *FTC v. Actavis, Inc.*, 570 U.S. 136, 156 (2013).

Under the rule of reason, Plaintiffs had the initial burden of demonstrating anticompetitive effects by proving that Endo had market power and made a large payment to Impax. *See In re Opana ER Antitrust Litig.*, 2021 WL 2291067, at \*24 (N.D. Ill. June 4, 2021) (“*Opana ER IP*”); *see also In re Impax Labs., Inc.*, 2019 WL 1552939, at \*15 (FTC Mar. 28,

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<sup>1</sup> Judgment should also be entered establishing Endo’s violation of the state laws asserted by the End-Payor Plaintiffs (“EPPs”) because Endo agreed that a violation of Section 1 of the Sherman Act would necessarily violate the state antitrust, consumer protection, and unjust enrichment laws asserted by the EPPs.

2019), *review denied*, 994 F.3d 484 (5th Cir. 2021), *cert. denied*, 142 S. Ct. 712 (2021); *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015) (“*Lamictal*”), *cert. denied*, 137 S. Ct. 446 (2016). Upon such proof, the burden shifted to Endo to show that its reverse payment was justified by procompetitive benefits. *See Opana ER II*, 2021 WL 2291067, at \*24; *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 719 (N.D. Ill. 2016) (“*Opana ER I*”); *Lamictal*, 791 F.3d at 412. Finally, if Endo demonstrated legitimate procompetitive benefits, the jury had to balance the anticompetitive harms against the legitimate procompetitive benefits. *See Opana ER II*, 2021 WL 2291067, at \*24. However, at this final step of the rule of reason, if the claimed procompetitive benefits could be achieved by some means less restrictive of competition, those benefits could not justify the reverse payment. *See Agnew v. NCAA*, 683 F.3d 328, 336 (7th Cir. 2012); *Impax*, 2019 WL 1552939, at \*15.

After almost three weeks of trial, the jury found that Endo possessed market power in a relevant market and that the settlement between Endo and Impax included a reverse payment. ECF No. 1005. In other words, the jury found that Plaintiffs had satisfied the first step of the rule of reason. However, the jury further found that the anticompetitive effects of the settlement with the reverse payment did not outweigh Endo’s claimed procompetitive justifications. *Id.* The Court should enter judgment for Plaintiffs under Fed. R. Civ. P. 50(b) that Endo violated the antitrust laws because, at the second step of the rule of reason, Endo did not offer any legally cognizable procompetitive justifications to offset the anticompetitive effects of the reverse payment found by the jury.

At trial, Endo’s only claimed procompetitive justification was the so-called “broad license.” As Plaintiffs explained at the close of the evidence, that procompetitive justification



failed for three separate and independent reasons. Tr. 2437:20-2444:5.<sup>2</sup> First, the competitive effects of any agreement under the antitrust laws must be assessed as of the date of the agreement, and neither Endo nor its experts identified any evidence that Endo's reverse payment was procompetitive on or about June 2010 when Endo agreed to make the reverse payment to Impax in the SLA and DCA.

Second, any procompetitive benefits must explain or justify the challenged reverse payment as procompetitive, not the settlement as a whole. Endo offered no evidence that the broad license was linked in any way to its reverse payment to Impax. The broad license was an additional benefit that Endo granted to Impax at Impax's insistence; it did not explain Endo's reverse payment as anything other than a payment to avoid the risk of competition.

Third, even if the broad license were a legally-cognizable procompetitive benefit, Plaintiffs' evidence demonstrated that a less restrictive means of settling with the same broad license would have been for Endo and Impax to settle their patent lawsuit *without* any reverse payment. Because Endo did not offer any evidence that the reverse payment and the broad license were linked, there is no legal or economic reason that would have prevented a settlement with the broad license but without any reverse payment. Endo's evidence that it never offered Impax an entry date prior to January 1, 2013 did not establish that a less restrictive no-payment settlement with an earlier entry date was not available; it was merely evidence that Endo, like any brand company making a reverse payment, preferred to pay Impax to delay its entry rather than compete vigorously.

Accordingly, pursuant to Fed. R. Civ. P. 50(b), the Court should enter judgment for Plaintiffs establishing that Endo violated Section 1 of the Sherman Act (and the state laws

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<sup>2</sup> Citations to "Tr. \_\_" refer to the trial transcript found at ECF Nos. 1009-1038.

asserted by EPPs) because Endo presented no evidence that the reverse payment found by the jury had any legally cognizable procompetitive justifications that could not have been achieved by a less restrictive means.

As an alternative, Plaintiffs request that the Court order a new trial pursuant to Fed. R. Civ. P. 59. The Court's jury instructions and verdict form were erroneous. The jury instructions did not tell the jury that, under the Sherman Act, competitive effects must be assessed as of the time of the agreement; did not explain that it was Endo's burden to identify a procompetitive justification for the reverse payment, not the settlement as a whole; did not identify the competitive harm of reverse payments that Endo had to justify as the avoidance of the *risk* of competition; nor did they explain how to evaluate less restrictive means under the rule of reason. In addition, the verdict form omitted any reference to the less-restrictive-means analysis, suggesting that the jury's only task was to balance anticompetitive effects against procompetitive justifications.

Collectively, and individually, these critical flaws left the jury without any understanding of the procompetitive justifications permitted by law or how to evaluate any claimed procompetitive justification. Endo took full advantage of these errors, improperly arguing that the jury should assess Endo's June 2010 agreement in hindsight and find it to be procompetitive because, absent the broad license that it included, Endo would have been able to stop Impax from selling generic Opana ER using patents Endo obtained years after agreeing to pay Impax. But under *Actavis*, the "relevant anticompetitive harm" is the avoidance of the *risk* of competition. *Actavis*, 570 U.S. at 157. Risk is not evaluated based on what ultimately occurs after a challenged agreement. Rather, risk must be evaluated *at the time of the challenged agreement*. A retrial is necessary to permit a jury to properly assess the competitive harm caused by the

reverse payment that the jury found (and then to determine whether the violation caused Plaintiffs any injury).

Retrial is also necessary to exclude Endo's evidence of the three later-issued patents and related litigation. Endo did not obtain these patents or sue to enforce them until years after it paid Impax to avoid the risk of competition. At the time that Endo agreed to pay Impax in June 2010, no one knew if or when any of the pending applications would ever issue as patents, what subject matter they would cover if they issued, or what a license to any such later patents might be worth. As a result, the later-issued patents were entirely irrelevant to the question of whether Endo's reverse payment was anticompetitive *at the time* that Endo agreed to pay Impax to avoid the risk of competition. Nor were the later-issued patents relevant to the question of causation because Plaintiffs' sole theory of causation was that, absent the illegal reverse payment, Endo and Impax would have entered an alternative settlement agreement with an earlier generic entry date. Because that alternative settlement agreement would have had the same license found in the SLA, the evidence presented at trial regarding the later-issued patents and the litigation concerning them was irrelevant and unduly prejudicial. Nevertheless, these later-issued patents were the centerpiece of Endo's defense and were undoubtedly the reason that the jury found in Endo's favor despite Endo's failure to identify any cognizable procompetitive benefits at the time of Endo's agreement to pay Impax.

### **LEGAL STANDARD**

Federal Rule of Civil Procedure 50(b) provides that a party may renew a pre-verdict motion for judgment as a matter of law made under Rule 50(a). Under Rule 50(b), the Court can direct the entry of judgment as a matter of law for the moving party or order a new trial. *See* Fed. R. Civ. P. 50(b).

The standard for judgment as a matter of law under Rule 50(b) “‘mirrors’ the standard for

granting summary judgment.” *Surgery Ctr. at 900 N. Michigan Ave., LLC v. Am. Physicians Assurance Corp.*, 922 F.3d 778, 784 (7th Cir. 2019) (quoting *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000)). If “no rational jury could have found for” the nonmovant, the Court should grant the Rule 50(b) motion. *Venson v. Altamirano*, 749 F.3d 641, 646 (7th Cir. 2014). When a party challenges the sufficiency of evidence supporting a jury verdict, the Court must determine “whether a reasonable jury would have ‘a legally sufficient evidentiary basis to find for the [nonmoving] party on that issue.’” *Empress Casino Joliet Corp. v. Balmoral Racing Club, Inc.*, 831 F.3d 815, 822 (7th Cir. 2016) (quoting *Lawson v. Sun Microsystems, Inc.*, 791 F.3d 754, 761 (7th Cir. 2015)). “Without assessing credibility or weighing evidence,” the Court must nevertheless review the basis for the jury’s decision, because “a verdict supported by no evidence or a mere scintilla of evidence will not stand.” *Martin v. Milwaukee Cnty.*, 904 F.3d 544, 550 (7th Cir. 2018) (citing *Thorne v. Member Select Ins. Co.*, 882 F.3d 642, 644 (7th Cir. 2018)).

Alternatively, under Federal Rule of Civil Procedure 59(a)(1), a “new trial is appropriate if the jury’s verdict is against the manifest weight of the evidence or if the trial was in some way unfair to the moving party.” *Venson*, 749 F.3d at 656. The Court should grant a new trial based on improper jury instructions “if the instructions did not sufficiently inform the jury of the applicable law *and* the instructions prejudiced the [movant].” *EEOC v. AutoZone, Inc.*, 809 F.3d 916, 922 (7th Cir. 2016) (citing *Rapold v. Baxter Int’l Inc.*, 718 F.3d 602, 609 (7th Cir. 2013)). A party suffers prejudice if “considering the instructions as a whole, along with all of the evidence and arguments, the jury was misinformed about the applicable law.” *Sansone v. Brennan*, 917 F.3d 975, 983 (7th Cir. 2019) (quoting *Susan Wakeen Doll Co., Inc. v. Ashton-Drake Galleries*, 272 F.3d 441, 452 (7th Cir. 2001)). *See also Pittman v. Cnty. of Madison, Ill.*,

970 F.3d 823, 828 (7th Cir. 2020) (granting plaintiff new trial where jury instructions misstated legal standard and defendants “argued and presented evidence” based on the incorrect standard).

A new trial is also appropriate when the verdict form contained an “incorrect statement of the law” that did “not accurately and correctly present the key issue[s] to the jury.” *Umpleby v. Potter & Brumfield, Inc.*, 69 F.3d 209, 213-15 (7th Cir. 1995). The relevant question is “whether the jury was misled in any way and whether it had [an] understanding of the issues and its duty to determine those issues.” *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 827 (7th Cir. 2010) (citation omitted). A verdict form that “fails to accurately reflect the controlling law” is “reversible error.” *Umpleby*, 69 F.3d at 214.

Finally, when a Rule 59 motion challenges improperly admitted evidence, the Court should grant a new trial “if the improperly admitted evidence had ‘a substantial influence over the jury,’ and the result reached was ‘inconsistent with substantial justice.’” *Shick v. Ill. Dep’t of Human Servs.*, 307 F.3d 605, 611 (7th Cir. 2002) (quoting *Agushi v. Duerr*, 196 F.3d 754, 759 (7th Cir. 1999)). This standard is satisfied when there is a “significant chance” that the evidence “affected the outcome of the trial.” *Id.* (quoting *Hasham v. Cal. State Bd. of Equalization*, 200 F.3d 1035, 1048 (7th Cir. 2000)). *See also Cullen v. Olin Corp.*, 195 F.3d 317, 324-25 (7th Cir. 1999) (granting defendants’ motion for new trial when plaintiff’s “most compelling and supportive evidence,” referenced in opening and closing statements and in cross-examination, was irrelevant and prejudicial and should not have been admitted), *cert. denied*, 529 U.S. 1020 (2000).

## **ARGUMENT**

### **I. PLAINTIFFS ARE ENTITLED TO JUDGMENT AS A MATTER OF LAW BECAUSE ENDO FAILED TO IDENTIFY ANY COGNIZABLE PROCOMPETITIVE JUSTIFICATION.**

Under the first step of the rule of reason, an antitrust plaintiff must prove market power

and a reverse payment by a brand manufacturer to a generic manufacturer to settle patent litigation. Here, the jury found that Plaintiffs proved both elements. As a result, the burden shifted to Endo to prove procompetitive benefits for its reverse payment.<sup>3</sup> Based on Endo's evidence at trial, no reasonable jury could have found that Endo had any procompetitive justification that outweighed the anticompetitive effects of its reverse payment for the three separate and independent reasons that Plaintiffs identified at the close of the evidence.

**A. Endo Offered No Evidence That Its Reverse Payment Was Procompetitive at the Time of Its Agreement With Impax.**

Plaintiffs are entitled to judgment as a matter of law that Endo violated the Sherman Act because Endo failed to rebut Plaintiffs' *prima facie* evidence under the first step of the rule of reason by identifying any evidence showing that its reverse payment was procompetitive *at the time of its agreement with Impax*.

Under the Sherman Act, the competitive effects of an agreement must be determined as of the date of the agreement. This Court recognized that bedrock principle in its summary judgment opinion. *Opana ER II*, 2021 WL 2291067, at \*28. It is the unambiguous law of this Circuit. *See Polk Bros. v. Forest City Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985) (holding that a "court must ask whether an agreement promoted enterprise and productivity *at the time it was adopted*") (emphasis added); *Blackburn v. Sweeney*, 53 F.3d 825, 828 (7th Cir. 1995) ("*Polk* teaches that courts must look to the time an agreement was adopted in assessing its potential for

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<sup>3</sup> In Question 3 on the Verdict Form, the Court correctly recognized that a "yes" answer to Questions 1 and 2 would establish anticompetitive harm, leaving only the question of whether that harm was outweighed by Endo's asserted procompetitive justification: "Was the settlement between Endo and Impax with the reverse payment unreasonably anticompetitive? *That is*, did the anticompetitive effects of that settlement outweigh any procompetitive justifications?" ECF No. 1005, at 2 (emphasis added). Question 3 did not ask the jury to consider the existence of "anticompetitive effects of the settlement" that followed from its answers to the first two questions, only whether those effects were outweighed by Endo's asserted justification.

promoting enterprise and productivity . . .”). In addressing the same June 2010 settlement agreement at issue here, the Fifth Circuit explicitly rejected Impax’s argument “that the [June 2010] settlement does not look anticompetitive in hindsight” because “it is a basic antitrust principle that the impact of an agreement on competition is assessed as of the time it was adopted.” *Impax Labs., Inc. v. FTC*, 994 F.3d 484, 496 (5th Cir.), *cert. denied*, 142 S. Ct. 712 (2021). As the Fifth Circuit specifically recognized: “That approach also makes sense in reverse payment cases.” *Id.*

Other courts considering challenges to reverse payments both before and after *Actavis* have similarly recognized that the competitive effects of an agreement must be assessed at the time it was made. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003) (pre-*Actavis* reverse payment case refusing to consider post-settlement patent ruling finding patent at issue invalid because “the reasonableness of agreements under the antitrust laws [is] to be judged at the time the agreements are entered into”), *cert. denied*, 543 U.S. 939 (2004); *In re Cipro Cases I & II*, 348 P.3d 845, 870 (Cal. 2015) (holding that justification of reverse payment “will not turn on whether the patent would ultimately have been proved valid or invalid” because “[a]greements must be assessed as of the time they are made, at which point the patent’s validity is unknown and unknowable”) (citing *Valley Drug*, 344 F.3d at 1306); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 241 (D. Conn. 2015) (“The salient question is not whether the fully-litigated patent would ultimately be found valid or invalid – that may never be known – but whether the settlement included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid the risk of competition.”); *Apotex, Inc. v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 611 (E.D. Pa. 2017) (“[T]he *Actavis* rule of reason analysis is focused on whether the settlements were reasonable at the time they were entered into . . .”).

The FTC and DOJ agree that competitive effects must be assessed as of the date of a challenged agreement. *See* FTC & DOJ, *Antitrust Guidelines for Collaborations Among Competitors* § 2.4 (2000) (specifying that the agencies “assess the competitive effects of a relevant agreement as of the time of possible harm to competition”). Commentators agree. P. AREEDA & H. HOVENKAMP, *ANTITRUST LAW* ¶ 2046e1 (4th & 5th eds. 2015-2021) (explaining that the “reasonableness of a patent settlement agreement cannot be made to depend on an *ex post* determination” of validity or infringement); A. Edlin, S. Hemphill, H. Hovenkamp & C. Shapiro, *The Actavis Inference: Theory and Practice*, 67 RUTGERS U.L. REV. 585, 617 (2015) (“[T]he antitrust analysis of a reverse-payment settlement should be made on an *ex ante* basis, as of the date of the settlement itself.”).

The ABA Model Antitrust Jury Instructions, which Endo urged the Court to adopt in almost all other respects, recognize this bedrock rule. *See* ABA SECTION OF ANTITRUST LAW, MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES Instr. 4(B)(3) (2016 ed.) (in cases involving agreements about patents, rule of reason must consider whether “agreement unreasonably restrained trade *at the time it was made*”) (emphasis added). Jury instructions in another reverse-payment case identified the time of the agreement as the relevant time to assess the competitive effects of reverse payments. *See, e.g.*, Final Jury Instructions, ECF No. 155, *Walgreen Co. v. Cephalon, Inc.*, No. 09-cv-3956, at 15 (E.D. Pa. July 6, 2017) (explaining that “the rule of reason analysis . . . is conducted on an ‘ex ante’ basis, meaning considering the facts and circumstances as they existed as of” the date on which the challenged settlement agreement was executed).

In reverse-payment cases, the time for evaluating competitive effects is critical. As the Supreme Court explained, the antitrust concern when a brand manufacturer makes a reverse



payment is that it “is using its monopoly profits to avoid the *risk* of patent invalidation or a finding of noninfringement.” *Actavis*, 570 U.S. at 156 (emphasis added). The relevant anticompetitive harm occurs when the payment “likely seeks to prevent the risk of competition.” *Id.* at 157. As the Fifth Circuit explained, “[t]he fact that generic competition was possible, and that Endo was willing to pay a large amount to prevent that *risk*, is enough to infer anticompetitive effect.” *Impax*, 994 F.3d at 495 (emphasis added); *see also Impax*, 2019 WL 1552939, at \*16 (“And *Actavis* makes clear that eliminating the risk of competition is a cognizable harm under the antitrust laws.”); *Aggrenox*, 94 F. Supp. 3d at 245 (identifying the question under *Actavis* as “whether a large and unjustifiable reverse payment was made in order to avoid the risk of patent invalidation”); *Opana ER II*, 2021 WL 2291067, at \*26 (quoting *Aggrenox* with respect to *Actavis*’s concern about risk avoidance). After the fact, later events may make it possible to assess how the litigation was likely to have turned out absent the agreement. But that is not the competitive harm that *Actavis* identified.<sup>4</sup> *Actavis* considers the *potential* for competition, and “paying a potential competitor not to compete is so detrimental to competition that normally it is a *per se* violation of the antitrust laws.” *Impax*, 994 F.3d at 493 (citing *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 48-49 (1990)).<sup>5</sup> A legal rule that considered developments after the fact, as Endo argued extensively to the jury, would make the competitive effects of the agreement hinge on the date of the antitrust trial. Had the trial in this case occurred

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<sup>4</sup> The *Actavis* dissent may have accepted Endo’s hindsight analysis of the competitive effects of reverse payment settlements. *See Actavis*, 570 U.S. at 172-73 (Roberts, C.J., dissenting) (criticizing the *Actavis* majority’s concern with the risk of competition because it could lead to what it characterized as “absurd results” in hindsight if, after making a reverse payment to one generic competitor, the brand litigates its patent and wins against another generic competitor, thereby establishing the validity of its patent). But the dissent’s opinion is not the law.

<sup>5</sup> “Normally,” of course, refers to cases outside the scope of *Actavis*. Because of the unique context of Hatch-Waxman patent litigation, *Actavis* held that reverse payments by brand manufacturers to their generic competitors are judged under the rule of reason. *Actavis*, 570 U.S. at 155-56.

*before* Endo obtained the later patents (or before Endo asserted them against other generic companies), Endo would have had no evidence that the broad license had any procompetitive effects. Endo was only able to claim procompetitive benefits from the broad license because the trial in this case took place *after* it had prevailed against other generic manufacturers on the later-issued patents. The question of whether a pharmaceutical manufacturer violated the antitrust laws should not depend upon when the case against it is tried.

The relevant economic analysis of reverse payments also addresses the facts as they exist at the time of the agreement. As Dr. Keith Leffler, one of Plaintiffs' economists, testified at trial, cases settle based on the parties' *expectations* at the time of settlement. Tr. 1135:4-1136:16, 1164:22-24. A large reverse payment, if unexplained, is anticompetitive because it is *expected* to delay the generic entry date that the brand and generic negotiate. Tr. 1150:18-20. Professor Thomas McGuire, another of Plaintiffs' economists, demonstrated that at the time of the actual settlement, Endo and Impax could have resolved the risk of the litigation without a reverse payment, and that it would have been profitable for them to agree to an earlier entry date *without* a reverse payment. Tr. 1682:14-19. As a matter of economics, Dr. Sumanth Addanki, Endo's expert economist, agreed. Although he claimed that parties that settled with a reverse payment might not be able to reach an alternative agreement without a reverse payment, he agreed that if they could reach settlement agreements with and without a payment, the agreement with a reverse payment would have a later entry date. Tr. 2122:18-2123:22.

Despite the law and economics of reverse payments, Endo failed to offer any evidence from which a reasonable jury could conclude that Endo's reverse payment was procompetitive *at the time* that Endo agreed to make it. Instead, Endo argued that the settlement *later* turned out to be procompetitive because the license in the SLA permitted Impax to stay on the market when

Endo acquired patents years after entering into the reverse-payment agreement that it successfully asserted to prevent other generic manufacturers from selling generic Opana ER. In closing, Endo's counsel did not identify any evidence to show that the reverse payment was procompetitive *at the time* of the agreement. To the contrary, Endo's counsel told the jury that on the question of competitive effects, "there are really three things to remember that are important":

Impax generic has been on the market so far for nine-and-a-half years with another seven years to go under the broad license while the patents are still in effect.

So, that would not have been possible without this license. That's the second thing. The sole reason for that 16-and-a-half years during the patent's life is the broad license.

And I think the third thing to remember – and you saw the evidence – is every other generic was ordered off the market by the courts when the additional patents came along. You heard the evidence that that is what would have happened to Impax without that broad license.

Tr. 2726:23-2727:11.

None of these points showed that the reverse payment found by the jury was procompetitive at the time that Endo agreed to make it. Dr. Addanki, Endo's only expert to address purported procompetitive effects, admitted that he did not identify *any* procompetitive effects as of the time of the reverse-payment agreement. In fact, he testified that he only considered competitive effects as of the time that he issued his expert report in 2019. Tr. 2130:15-16 ("I analyzed the settlement agreement as a whole, but I didn't do it as of any time except the time I did my report."); *id.* at 2126:8-14 (agreeing that his analysis of competitive effects was as of the date of his report in 2019). He further told the jury that an analysis of competitive effects at the time of the agreement (the analysis required by the law) was "needless speculation because we know what actually happened." Tr. 2126:23-2127:1.

Endo's claimed procompetitive justification failed to address the relevant issue in *Actavis*. Endo claimed that its settlement as a whole was procompetitive in hindsight because subsequent events showed that Impax would have been found to infringe patents that were issued years after Impax agreed to delay its launch of generic Opana ER. Because Endo's claimed procompetitive justification did not address the relevant issue in *Actavis* at the relevant time, Plaintiffs are entitled to judgment as a matter of law that Endo violated Section 1 of the Sherman Act by agreeing to make an anticompetitive reverse payment.

**B. Endo Offered No Evidence of Any Procompetitive Justification Resulting From the Reverse Payment Found by the Jury.**

Endo's evidence also failed to rebut the anticompetitive effects of the reverse payment that the jury found for the separate and independent reason that none of its evidence explained the *reverse payment* or in any way showed that the *reverse payment* had any legitimate procompetitive justification. Instead, Endo only sought to show that its *settlement* with Impax was procompetitive because it contained the broad license that allegedly permitted Impax to continue to operate after Endo secured the later-issued patents years later.

Impax made the same argument in the FTC's case challenging Endo's reverse payment. While an Administrative Law Judge ("ALJ") agreed with Impax (and Endo's trial argument here) that the license in the SLA "benefitted competition and salvaged the entire agreement from antitrust condemnation," the Commission rejected that argument as a legal matter. As the Commission explained:

Impax failed adequately to link the alleged procompetitive justifications to the challenged restraint, which – as the ALJ acknowledged – was the use of a reverse payment to eliminate the risk of generic entry before January 2013. Impax does not make any argument that the No-AG Commitment or Endo Credit (or any portion of the \$10 million DCA payment) have *themselves* protected Impax from the threat of patent litigation or that it needed to accept these payments in order to enjoy the procompetitive benefits of the patent license. Impax thus fails to overcome the anticompetitive effect, which *Actavis* anticipated, from reverse

payments “independen[t] from other services for which it might represent payment,” and “lack[ing] [] any other convincing justification.”

*Impax*, 2019 WL 1552939, at \*30 (citing and quoting *Actavis*, 570 U.S. at 157, 159). Endo’s assertion of the same claimed procompetitive justification fails for the same reason.

In *Actavis*, the Supreme Court identified the “specific restraint at issue” as “a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed.” *Actavis*, 570 U.S. at 153-54. It further explained that a “payment in return for staying out of the market” would “keep[] prices at patentee-set levels,” allowing brand and generic manufacturers to divide the brand’s continued monopoly. *Id.* at 154. The Court did not hold that all Hatch-Waxman *settlements* risked antitrust liability. To the contrary, it explained that “the fact that *a large, unjustified reverse payment* risks antitrust liability does not prevent litigating parties from settling their lawsuit” by agreeing on a generic entry date without any payment. *Id.* at 158 (emphasis added). As the Supreme Court explained, a defendant’s burden under the rule of reason is to justify the reverse payment, not the settlement containing the reverse payment: “[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it . . . .” *Id.*; see also *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 256 (3d Cir. 2017) (holding that “defendants have the burden of justifying the rather large reverse payment here, and they offer no reason why those other elements of the settlement agreement do so”), *cert. denied*, 138 S. Ct. 983 (2018). A defendant like Endo cannot simply point to unrelated terms in its settlement agreement to justify its payment but rather must justify “the presence of the *challenged term* and show[] the lawfulness of *that term* under the rule of reason.” *Actavis*, 570 U.S. at 156 (emphasis added). It must explain the reason for the payment because the “likelihood of a reverse payment

bringing about anticompetitive effects depends upon,” *inter alia*, “its independence from other services for which it might represent payment and the lack of any other convincing justification.” *Id.* at 159.

The requirement that a defendant establish a specific link between a challenged restraint and any claimed procompetitive justification is well-established. In *NCAA v. Board of Regents of the University of Oklahoma*, 468 U.S. 85 (1984), the Supreme Court rejected a claim that a restraint on televised college football games could be justified by a legitimate interest in adopting rules to promote “competitive balance” among football teams. The Court held that the specific restraint was “not even arguably tailored” to serve the identified interest. *Id.* at 117-19. To establish a procompetitive justification, a defendant must instead show that the restraint bears a “logical nexus to [the] claimed efficiencies.” *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 368 (5th Cir. 2008), *cert. denied*, 555 U.S. 1170 (2009). Claimed efficiencies that do not “result from or are [not] in any way connected to” the restraint cannot be used to justify the restraint. *Id.* at 369. *See also Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 835 (6th Cir. 2011) (affirming FTC’s finding that the respondent had not “demonstrated a connection” between the restraint and the proffered rationale), *cert. denied*, 565 U.S. 942 (2011); *United States v. Visa USA, Inc.*, 344 F.3d 229, 238, 243 (2d Cir. 2003) (explaining that defendants “must provide a procompetitive justification for the challenged restraint” and sustaining the district court’s finding that “no evidence” showed that the restraint advanced the proffered justifications), *cert. denied*, 543 U.S. 811 (2004); *In re Polygram Holding, Inc.*, 136 F.T.C. 310, 347 (2003) (requiring defendant to “articulate the specific link between the challenged restraint and the purported justification”), *review denied*, 416 F.3d 29 (D.C. Cir. 2005); P. AREEDA & H. HOVENKAMP, *supra*, ¶¶ 1505a, 1511c (explaining that defendants’ claimed justifications are “entirely immaterial” unless they

“are actually promoted significantly by the restraint”).

Like Impax in the FTC litigation, Endo did not offer a shred of evidence that the no-AG agreement, Endo Credit, or the \$10 million nonrefundable payment under the DCA protected Impax from future patent infringement suits. To the contrary, Dr. Addanki, Endo’s economist, admitted that *none* of his opinions about purported procompetitive effects was dependent on whether there was a reverse payment by Endo to Impax (Tr. 2084:21-24) and that he had no opinion that the broad license explained the no-AG agreement, the Endo Credit, or the \$10 million payment under the DCA (*id.* at 2185:7-14). He did not even offer an opinion that the no-AG agreement or the Endo Credit were necessary for Endo and Impax to reach a settlement of their patent litigation. *Id.* at 2185:15-20.

Nor did any fact witness establish such a link. For example, Margaret Snowden, Impax’s former Vice President of Intellectual Property, could not identify anything that Impax gave to Endo in exchange for the broad license. *Id.* at 612:7-9 (“Q: What did Impax give to Endo to get that broad license? A: I don’t – I don’t know that there was a horse trade for that. We just dug in and insisted on it.”). Neither the reverse payment nor the January 2013 entry date changed after Endo and Impax agreed to the broad license. *Id.* at 498:22-500:9 (entry date); *id.* at 503:23-505:4 (components of the reverse payment).

Unable to link the broad license to the reverse payment as required by the law, Endo argued to the jury that the evidence showed that it never would have offered a settlement to Impax with an earlier entry date and the broad license. Tr. 2729:10-23, 2733:23-2734:3. But, like Impax’s argument to the FTC that Impax would not have settled without the broad license, Endo’s argument does not address the correct legal question. *See Impax*, 2019 WL 1552939, at \*36. As the FTC explained, the “appropriate question is whether Endo and Impax could have

reached a similar licensing agreement without a *reverse payment* for delayed generic entry.” *Id.*

On this question, the FTC found that because “both the payment and the license were benefits flowing to Impax, Impax readily could have accepted the license without also accepting a payment.” *Impax*, 2019 WL 1552939, at \*36 (citation omitted). This Court made the same point in denying Defendants’ motion for summary judgment, explaining:

Defendants would like to use the Broad License as a counterbalance to the reverse payment, but the Broad License is a concession in the same direction as the reverse payment – from Endo to Impax. As a result, while the Broad License has potentially beneficial effects to consumers, it does not counterbalance the \$102 million reverse payment from Endo to Impax. Instead, the Broad License concession serves only to highlight how much Endo valued Impax’s delayed start, suggesting monopolistic effects instead of procompetitive ones.

*Opana ER II*, 2021 WL 2291067, at \*25.

At trial, Prof. McGuire also made that point, explaining that the broad license was a benefit to Impax under the settlement agreement and that it did not make economic sense to conclude that an alternative settlement that removed one benefit to Impax (the reverse payment) would *also* eliminate an additional benefit to Impax (the broad license). Tr. 1684:9-1685:16. In response, Dr. Addanki testified that Prof. McGuire’s opinion did not “make sense at all” because any “alternative agreement has to be agreeable to both parties.” *Id.* at 2078:18-19. But Dr. Addanki’s response was the same legally deficient argument that the FTC rejected when Impax made it. The issue is not what Endo was willing to offer when it had the opportunity to pay Impax to delay its entry. The issue is whether it was economically rational for Endo and Impax to agree to an earlier entry, or, as the FTC put it, whether they “could” enter into an agreement with an earlier entry date without a reverse payment. *Impax*, 2019 WL 1552939, at \*36.

Because Endo failed to identify any evidence at trial linking the broad license to the reverse payment found by the jury, the broad license cannot justify Endo’s reverse payment as a matter of law. Endo obviously did not pay Impax to take the broad license. The broad license



was a separate provision that Impax demanded to settle the patent litigation. It was not tied in any respect to the reverse payment. Endo's failure to identify any procompetitive benefit to justify the reverse payment found by the jury requires judgment as a matter of law in Plaintiffs' favor.

**C. Endo Offered No Evidence to Rebut Plaintiffs' Showing That a Settlement Without a Reverse Payment Was a Less Restrictive Means of Achieving the Benefits of Settlement.**

Finally, even if the broad license could be a legally cognizable procompetitive justification, Endo failed to rebut Plaintiffs' evidence that there was a less restrictive means of obtaining its benefits by settling with the same broad license but without the challenged reverse payment. Endo did not identify any evidence that the broad license was conditioned on Endo's reverse payment or anything else in the SLA. Thus, even if Endo preferred to pay Impax to avoid the risk of competition, there was nothing preventing it legally or economically from agreeing to an entry date without a reverse payment and the same broad license that it actually granted. As the FTC held, such a settlement agreement "is a practical, less restrictive alternative." *Impax*, 2019 WL 1552939, at \*39.

In *NCAA v. Alston*, 141 S. Ct. 2141 (2021), the Supreme Court recently agreed with the conclusion of a prominent antitrust treatise that a "legitimate objective that is not promoted by the challenged restraint can be equally served by simply abandoning the restraint, which is surely a less restrictive alternative." *Id.* at 2162 (quoting P. AREEDA & H. HOVENKAMP, *supra*, ¶ 1505). That is certainly true here. As discussed above, there is no evidence that any benefits from the broad license were promoted by or tied to the reverse payment from Endo to Impax. *See supra* pp. 13-17. Endo did not offer any evidence that the benefits of the broad license were linked in any way to the reverse payment found by the jury. Dr. Addanki did not opine that the broad license explained Endo's reverse payment (Tr. 2185:7-14) nor did he suggest that the no-AG

agreement or the Endo Credit were necessary for Endo and Impax to settle the patent litigation (*id.* at 2185:15-20). It is entirely illogical to believe that Endo paid Impax in order to convince it to accept the benefits of the broad license. In almost three weeks of trial testimony, no fact or expert witness made such a claim.

In *Actavis*, the Supreme Court recognized the ability of parties to settle without reverse payments. *See Actavis*, 570 U.S. at 158 (“[P]arties may well find ways to settle patent disputes without the use of reverse payments.”); *id.* (recognizing that parties in Hatch-Waxman litigation may settle without risking antitrust liability simply by “allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without . . . paying the challenger to stay out prior to that point”). Indeed, the “premise” behind *Actavis* “is that there are better, less anticompetitive ways to settle these disputes.” P. AREEDA & H. HOVENKAMP, *supra*, ¶ 2046c2. All of the economic experts who testified at trial – including Dr. Addanki, Endo’s economist – recognized that a reverse payment delays the entry date that a brand and generic would otherwise negotiate. *See supra* pp. 10-11.

At trial, Endo argued that it never offered a payment-free settlement to Impax or to any other generic company that contained both an earlier entry date and a broad license. Tr. 2729:10-23; 2733:23-2734:3. But this argument does not rebut the existence of a less restrictive alternative. To rebut a less restrictive alternative, a defendant must show that “the proffered alternative is either unworkable or not less restrictive” based on the evidence. P. AREEDA & H. HOVENKAMP, *supra*, ¶ 1914c; *see also Wilk v. Am. Med. Assoc.*, 671 F. Supp. 1465, 1483 (N.D. Ill. 1987) (concluding that defendant had failed to establish that an alternative was impractical or unworkable), *aff’d*, 895 F.2d 352 (7th Cir. 1990), *cert. denied*, 496 U.S. 927 (1990). *Cf. United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 91 (D.D.C. 2011) (rejecting a proffered efficiency

for a merger where defendant failed to present evidence of why an alternative would not be feasible).

Endo's desire to keep generics off the market until January 1, 2013 does not establish that a no-payment settlement with a broad license was not workable or practical. Rather, all that Endo's evidence demonstrated was that Endo preferred to pay Impax to refrain from competing until January 1, 2013. That is unsurprising. As the evidence showed, Endo expected to make \$20 million a month for every month that it delayed generic entry. *See* PTX-0078, at 78.0005; ECF No. 961, at 15. The fact that Endo would earn less in profits under a less restrictive settlement without a reverse payment does not make that alternative unworkable. Competitors always make more by conspiring with each other to limit competition. *See United States v. Consolidated Packaging Corp.*, 575 F.2d 117, 128 (7th Cir. 1978) ("If the conspirators could make the conspiracy work and minimize price competition, all conspirators could expect a more profitable survival . . . ."); *In re Surescripts Antitrust Litig.*, 2022 WL 2208914, at \*13 (N.D. Ill. June 21, 2022) (antitrust conspiracies are "premised on the . . . logic" that "it is better to divide a bigger pie of monopoly profits by agreement than to compete to win a larger share of a smaller pie of competitive profits"). *See also* H. Hovenkamp, *Antitrust & the Patent System: A Reexamination*, 76 OHIO ST. L.J. 467, 493 (2015) ("Dividing the monopoly proceeds is virtually always more profitable than competing, even within a duopoly."); P. AREEDA & H. HOVENKAMP, *supra*, ¶ 2002c ("Rivals are naturally more receptive to an invitation to participate in monopoly profits as opposed to an action directed at eliminating their profits . . . ."). When a less restrictive alternative reduces prices as expected, it does not mean that the less restrictive alternative is unworkable or not feasible.

Endo's failure to identify any link between the broad license and the reverse payment or

any other evidence that a payment was necessary to settle with a broad license requires entry of judgment as a matter of law in Plaintiffs' favor. Endo's preference for a reverse-payment settlement only shows that it preferred to act anticompetitively rather than to compete against lower-priced generic Opana ER. That is not sufficient to rebut Plaintiffs' evidence of the availability of a less restrictive alternative settlement without a reverse payment.

**II. IN THE ALTERNATIVE, PLAINTIFFS ARE ENTITLED TO A NEW TRIAL TO CORRECT THE COURT'S ERRONEOUS JURY INSTRUCTIONS, VERDICT FORM, AND EVIDENTIARY RULINGS.**

While the Court should enter judgment as a matter of law for Plaintiffs because no reasonable jury could find that Endo identified any cognizable procompetitive justification for its reverse payment, Plaintiffs alternatively request a new trial because the Court did not properly instruct the jury on the law governing Endo's claimed procompetitive justification, omitted the possibility of a less restrictive alternative from the verdict form, and permitted Endo to offer irrelevant and highly prejudicial evidence about the later-issued patents that Endo obtained after paying Impax to delay its generic entry.

**A. The Jury Instructions and Verdict Form Were Contrary to the Law Governing the Competitive Effects of a Reverse Payment.**

Plaintiffs' proposed instructions and arguments during the charge conference repeatedly asked the Court to instruct the jury on key legal principles governing Endo's claim that the broad license was procompetitive. *See, e.g.*, ECF No. 991-1 (proposed instructions); Tr. 2509:4-20, 2521:22-2522:18, 2574:16-19, 2577:18-2578:3. Individually, and as a whole, the Court's omissions from the jury instructions and verdict form left the jury without a proper understanding of the applicable law and substantially prejudiced Plaintiffs. *See AutoZone*, 809 F.3d at 922.

### **1. Time for Assessment of Competitive Effects**

A central issue in this case was the relevant time for consideration of the competitive effects of Endo's reverse payment. Plaintiffs' proposed Instruction No. 8 in part asked the Court to instruct the jury that: "Under the antitrust laws, the competitive effects of agreements are evaluated at the time that they were formed. Accordingly, in applying the rule of reason, you should only consider the facts known or that could have been known to the parties in June 2010." Instr. No. 8 (ECF No. 991-1, at 16) (citing, *inter alia*, *Opana ER II*, 2021 WL 2291067, at \*28). Plaintiffs extensively argued at the charge conference for an instruction informing the jury that the competitive effects of a reverse payment must be assessed at the time of the reverse payment agreement. Tr. 2518:24-2519:18, 2521:22-2511:18, 2529:5-2530:5, 2533:2-21, 2536:10-2537:5.

As discussed above, there should have been no dispute about this bedrock legal principle of antitrust law. *See supra* pp. 8-11. The Seventh Circuit unambiguously held that courts in antitrust cases must ask "whether an agreement promoted enterprise and productivity *at the time it was adopted*," *Polk*, 776 F.2d at 18 (emphasis added); this Court specifically cited that law in its summary judgment opinion; the Fifth Circuit relied on it in rejecting Impax's challenge to the FTC's finding that Endo's reverse payment violated the antitrust laws; various other courts have stated and applied this principle; the DOJ and FTC Merger Guidelines recognize it; the ABA Antitrust Model Jury Instructions have adopted it; jury instructions in other reverse payment cases have explained it; and commentators agree. *See supra* pp. 7-9.

However, at Endo's urging, the Court refused to instruct the jury that it was required to consider competitive effects at the time of the agreement and instead told the jury: "When deciding as to whether there was an unreasonable restraint on trade, you should take into consideration a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and

effect.” See Instr. 8 (ECF No. 1004, at 9). This instruction was based on language from this Court’s summary judgment and *Daubert* opinion citing *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997). See *Opana ER II*, 2021 WL 2291067, at \*23.

*Khan* addressed whether vertical maximum price fixing was illegal *per se* under the Sherman Act. In the passage that the Court quoted, *Khan* cited *Chicago Board of Trade v. United States*, 246 U.S. 231 (1918), the very first Supreme Court case describing the rule of reason. Under that hundred-year old formulation, the rule of reason considers “a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.” *Id.* at 238. But this general statement of the rule of reason fails to identify significant refinements of the rule of reason in the hundred years since *Chicago Board of Trade*. As then-Professor Frank Easterbrook noted in criticizing the *Chicago Board of Trade* formulation of the rule of reason as “empty,” “[w]hen everything is relevant, nothing is dispositive.” F. Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1, 12 (1984). Since *Chicago Board of Trade*, the rule of reason has been significantly refined—most notably, through development of the “three-step, burden-shifting framework.” *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). See also *Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I.*, 373 F.3d 57, 68 (1st Cir. 2004) (describing *Chicago Board of Trade* is a “warhorse” that should not be taken literally as “an endorsement of kitchen-sink antitrust in which anything that might alarm a jury is made admissible”); P. AREEDA & H. HOVENKAMP, *supra*, ¶ 1505 (explaining that the Court’s modern cases represent a “significant improvement over” *Chicago Board of Trade*, where “the parties were invited to throw in everything relevant to the business and see what sticks”).

One of the refinements of the rule of reason in the century since *Chicago Board of Trade*

is that the competitive effects of agreements must be assessed as of the date that they are made. *See supra* pp. 8-9. *Chicago Board of Trade*'s passing reference to business "before and after" does not squarely address this issue and provides no reason to reject the consistent subsequent rulings made by courts (including the Seventh Circuit) in the years since the Supreme Court's first rough articulation of the rule of reason. Given *Actavis*'s central concern with whether the brand made a reverse payment to avoid "the risk of competition," it was particularly prejudicial for the Court to fail to instruct the jury that it must consider that risk at the time that Endo agreed to make the reverse payment and to permit Endo to argue that the effects of the challenged restraint could be assessed at some later time.

The Court's failure to instruct on this central issue was directly relevant to the verdict question that the jury decided against Plaintiffs – *i.e.*, whether the anticompetitive effects outweighed Endo's procompetitive justification. In closing, Plaintiffs correctly argued that the jury had to assess competitive effects at the time of the agreement. Tr. 2648:3-22, 2744:15-17, 2750:9-13. In response, Endo's counsel told the jury that Plaintiffs' focus on the effects of the reverse payment at the time of agreement was wrong. Tr. 2686:7-22. She then emphasized the "before and after" language from Instruction No. 8 based on *Khan* and *Chicago Board of Trade* to argue that the jury should consider competitive effects long after the date of Endo and Impax's agreement:

But your consideration is not limited to one moment in time. The Court will give you instructions later this afternoon, and those instructions will tell you what you surely already know by now because you have heard so much about the events that happened after the settlement. You are allowed to consider *before and after*. Those patents are evidence in the case that you can consider. And I will show you why they make such a difference to the questions that you'll be asked to answer at the end of the case.

Tr. 2686:14-22 (emphasis added). Instruction No. 8 based on *Chicago Board of Trade* together with the Court's failure to instruct the jury that competitive effects must be considered as of the

date of the agreement misstated the law.

The relevant question under *Actavis* is not whether Endo's later acquisition of patents showed that the June 2010 SLA was procompetitive compared to the result that would have resulted from litigation in the absence of a settlement. The question is whether a brand manufacturer agreed to pay its generic competitor to eliminate the risk of competition. *Actavis*, 570 U.S. at 156. Given the specific emphasis that Endo's counsel put on this erroneous instruction, the Court's failure to instruct the jury that competitive effects must be considered on the date of the agreement must be found to have prejudiced Plaintiffs.

## **2. Need to Justify the Reverse Payment**

Plaintiffs also asked the Court to instruct the jury that the challenged restraint consisted of Endo's reverse payment, and that, under the second step of the rule of reason, Endo had to show that its reverse payment was procompetitive. Plaintiffs' proposed Instruction No. 8 provided in part: "[I]f you find that Plaintiffs satisfy the first step [of the rule of reason], the burden shifts to the Defendants to show the challenged payments to be justified by one or more procompetitive objectives. Again, Defendants must show that the challenged reverse payments, not the overall agreement between the Defendants, enhanced or helped competition." Pl. Prop. Instr. No. 8 (ECF No. 991-1, at 15); *see also* Pl. Prop. Instr. No. 17 (ECF No. 991-1, at 36) ("If you find that Plaintiffs satisfied the first step of the rule of reason, the burden shifts to Defendants to show that the challenged reverse payments were justified by some procompetitive objective. The second step of the rule of reason requires Defendants to establish that the challenged reverse payments, not the overall agreement between the Defendants, enhanced competition."); Pl. Prop. Instr. No. 19 (ECF No. 991-1, at 40) ("[Y]ou may not consider procompetitive effects unless Defendants can show a specific link between the challenged reverse payments and the purported justification.").



In contrast, the Court’s instructions did not identify the reverse payment as the restraint nor explain that it was Endo’s burden in the second step of the rule of reason to justify the reverse payment. Rather, the Court’s instruction told the jury that its duty was to “decide whether the settlement agreement imposed an unreasonable restraint on trade” and that “the burden shifts to the defendants to show procompetitive benefits of the restraint.” Instr. No. 7 (ECF No. 1004, at 8). The third question in the court’s verdict form compounded the problem by failing to ask whether Endo had justified the reverse payment. Instead, it asked: “Was the settlement between Endo and Impax with the reverse payment unreasonably anticompetitive? That is, did the anticompetitive effects of that *settlement* outweigh any procompetitive justifications?” Verdict Int. No. 3 (ECF No. 1005, at 2) (emphasis added).

Without a clear instruction that the *reverse payment* was the relevant restraint, and that the *reverse payment* was what Endo had to justify, the jury was free to accept Endo’s argument that the broad license justified the settlement as a whole. This is the same legal error that the ALJ made in finding in favor of Impax in the FTC’s case. In reversing its ALJ, the Commission explained that the broad license could not explain the reverse payment: “For purposes of procompetitive justifications, we look at the specific restraint, not the agreement as a whole. Even if an agreement between competitors generally benefits competition, this does not validate a restraint that ‘makes no significant contribution to the alleged justification.’” *Impax*, 2019 WL 1552939, at \* 31 (quoting P. AREEDA & H. HOVENKAMP, *supra*, ¶ 1505a). The failure to instruct the jury that the law required Endo to connect its alleged procompetitive justification to the reverse payment rather than to the settlement as a whole allowed the jury to make the same error as the ALJ.

In its *Daubert* and summary judgment opinion, this Court recognized that Plaintiffs

challenged Endo’s reverse payment, *Opana ER II*, 2021 WL 2291067, at \*18, and that the broad license could not explain why Endo paid Impax. *Id.* at \*25 (“[W]hile the Broad License has potentially beneficial effects to consumers, it does not counterbalance the \$102 million reverse payment from Endo to Impax.”). However, the Court did not instruct the jury about the law that it cited in its own *Daubert* and summary judgment opinion.

Whether Endo had to justify its payments or the settlement agreement as a whole was not a factual issue for argument by the parties. *See, e.g.*, Tr. 2485:16-20 (Court’s concern about “overloading the jury with instructions on reverse payments” and desire to provide “some relatively innocuous description of what *Actavis* provides and let the jury then take the facts as they heard them and apply *Actavis* . . . .”); *id.* at 2573:25-2576:12 (Endo’s counsel arguing that whether the reverse payment or the settlement as a whole must be shown to be unreasonably anticompetitive is “something that can be argued”). It was a legal issue on which an instruction was necessary, especially given Endo’s claim that the broad license was a procompetitive justification. *Actavis* unambiguously recognized that reverse payments are the challenged term in cases like this one, and that defendants must justify that term. *See supra* pp. 12-17. This approach is consistent with settled law under the rule of reason that only considers the competitive effects of the specific challenged contractual term, not the contract as a whole. *Id.* While some district court opinions have permitted defendants to rely on procompetitive justifications unrelated to a challenged reverse payment,<sup>6</sup> those decisions are erroneous because they fail to appreciate that *Actavis* identifies reverse payments, not patent settlements, as the anticompetitive restraint, and that settled rule-of-reason precedent requires the challenged

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<sup>6</sup> *See, e.g., In re Glumetza Antitrust Litig.*, 2021 WL 3773621, at \*8 (N.D. Cal. Aug. 25, 2021); *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 317 (D.R.I. 2019); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 734655, at \*4 (D. Mass. Feb. 6, 2018).

restraint to be justified.

The absence of any instruction explaining that any procompetitive justification must have a nexus to the challenged reverse payment prejudiced Plaintiffs. Endo's entire defense was built on the broad license, a contractual term that did not explain or even relate to Endo's reverse payment. The Court's instructions left the jury completely unaware of the need to identify such a nexus.

### **3. Avoidance of Risk of Competition**

Relatedly, the Court's instructions failed to explain the relevant competitive harm that Endo had to justify.

Plaintiffs asked the Court to instruct the jury that: "The anticompetitive harm of a reverse payment is that it eliminates the risk of competition. The fact that the settlement permitted generic entry before the expiration of patents asserted in litigation does not justify this anticompetitive effect." Pl. Prop. Instr. 24 (ECF No. 991-1, at 46); *see also* Pl. Prop. Instr. 16 (ECF No. 991-1, at 34-35) ("[I]t is an antitrust violation for a brand manufacturer to pay a generic manufacturer to avoid the risk of losing a patent case, no matter how small the risk of losing. A reverse payment is unlawful if it is made 'to prevent the risk of competition' or to 'avoid the risk of patent invalidation or a finding of noninfringement.'") (quoting *Actavis*, 570 U.S. at 156-57)); Pl. Prop. Instr. 20 (ECF No. 991-1, at 41) ("If the brand company pays the generic company more than the fair value of the services, that overpayment may be a hidden reverse payment to avoid the risk of competition (and delay generic entry)."); Pl. Prop. Instr. 21 (ECF No. 991-1, at 44) ("A payment made to 'prevent the risk of competition' or because the Defendants were 'risk averse' constitutes the anticompetitive harm of a reverse payment, not a legitimate justification." (quoting *Actavis*, 570 U.S. at 157)); Pl. Prop. Instr. 25 (ECF No. 991-1, at 47) ("[T]he question is whether Endo sought to pay Impax to avoid the risk of competition.").

The Court's instructions failed to advise the jury that the relevant harm that Endo had to justify was the avoidance of the risk of competition. Its instructions did not even refer to the "risk of competition." But the central question in *Actavis* is whether the brand manufacturer paid to avoid the risk of competition. *See Actavis*, 570 U.S. at 157. As *Actavis* explained, "the relevant antitrust question is: What are those reasons [that the parties prefer settlements with reverse payments]? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.* at 158.

The absence of any instruction about the relevant harm of reverse payments was critical to Endo's success. Dr. Addanki, Endo's expert, made no assessment of whether Endo's reverse payment avoided the risk of competition. To the contrary, he told the jury that competitive effects are "what actually happened [in the] markets" (Tr. 2127:12-13), that the jury should not "speculate" about what would have happened as of the date of the agreement "when you know what actually happened" years later (Tr. 2127:19-20), and that the effects of the agreement "depended on facts that have developed since June 8, 2010" (Tr. 2129:13-15). Endo's counsel made the same argument, telling the jury that it should assess the effect of the settlement based on its actual, later effect on competition – *i.e.*, that Impax's generic had been on the market for nine and a half years as of the date of trial, that it would not have been on the market absent the broad license, and that every other generic was ordered off the market because of Endo's subsequently acquired patents. Tr. 2726:23-2727:9.

Endo and its expert essentially endorsed the rule of law that the Supreme Court rejected in *Actavis*. In *Actavis*, the Eleventh Circuit applied what was known as the "scope of the patent" test in which "the only pertinent question [was] whether 'the settlement agreement . . . fall[s]

within’ the legitimate ‘scope’ of the patent’s ‘exclusionary potential.’” *Actavis*, 570 U.S. at 148 (quoting *FTC v. Watson Pharms, Inc.*, 677 F.3d 1298, 1309, 1312 (11th Cir. 2012)). In other words, the patents at issue in Hatch-Waxman litigation were presumed to be valid and infringed by the generic manufacturer’s product, and so long as the negotiated entry date was within the scope of the facial, exclusionary potential of the patent, it was presumed legal. But *Actavis* flatly rejected this test and reversed the Eleventh Circuit. The Supreme Court explained that “what the holder of a valid patent could do does not by itself answer the antitrust question” because the patent at issue “may or may not be valid, and may or may not be infringed.” *Id.* at 147.

Unfettered by any instruction explaining the relevant anticompetitive harm to be the elimination of the risk of losing the patent case and facing competition, Endo took the losing argument in *Actavis* one step further. Dr. Addanki claimed that it was impossible to know if the settlement was anticompetitive until well after the date of the reverse-payment agreement when it could be known whether *any* of Endo’s patents, including those that did not even exist at the time of the reverse payment, were likely infringed by Impax. Tr. 2126:23-2127:1, 2128:19-2130:11.

Endo’s argument that the broad license was a procompetitive justification is directly contrary to the law established by *Actavis* and its progeny. The failure to instruct the jury that the central concern in reverse payment cases is whether the payment was made to avoid the risk of competition prevented the jury from properly evaluating Endo’s claimed procompetitive justification.

#### **4. Less Restrictive Means**

The Court’s instructions also provided no guidance to the jury as to how it was to assess whether any procompetitive justifications identified by Endo could be achieved using less restrictive means or the significance of a conclusion that less restrictive means existed, and the verdict form omitted the less-restrictive-means inquiry entirely.

Plaintiffs proposed that the Court instruct the jury on the less-restrictive-means analysis as part of the third step of the rule of reason:

[I]f you find that the procompetitive benefits of the reverse payments outweigh the anticompetitive harm of the reverse payments, you must consider whether the procompetitive benefits could have been achieved in some other way less restrictive of competition. If you find that the procompetitive benefits could have been achieved in some other way less restrictive of competition, the reverse payments violated antitrust law under the rule of reason.

Pl. Prop. Instr. 8 (ECF No. 991-1, at 16).

Plaintiffs also proposed a further instruction expanding on the issues relevant to determining the existence of less restrictive means:

If Plaintiffs prove that the same benefits could have been achieved by other, reasonably available alternative means that create substantially less harm to competition, then the claimed procompetitive justifications cannot and do not justify the reverse payments and the reverse payments violate the rule of reason.

For instance, if you find that Endo and Impax could have settled their patent litigation without a reverse payment, the procompetitive benefit of settlement in general cannot justify the reverse payments because the benefits could have been achieved in settlement without a reverse payment. If you find that other procompetitive benefits that Defendants have shown could have been achieved without reverse payments, those other procompetitive benefits cannot justify the reverse payments. Procompetitive benefits can only justify a reverse payment if there is no less anticompetitive way to achieve the procompetitive benefits.

Here, Plaintiffs contend that any competitive benefits from the reverse payments could have been achieved by Endo and Impax settling for an earlier generic entry date without a reverse payment. If you find that Plaintiffs have proven such an agreement to be a reasonably available alternative, then they have shown that any procompetitive efficiencies could have been reasonably achieved through less anticompetitive means and the reverse payments violated the rule of reason.

Pl. Prop. Instr. 28 (ECF No. 991-1, at 51-52).

These proposed instructions correctly state the law. They would have told the jury that, if Endo identified a valid procompetitive justification, Plaintiffs could show that the “procompetitive efficiencies could be reasonably achieved through less anticompetitive means.”

*See Alston*, 141 S. Ct. at 2160 (quoting *Am. Express Co.*, 138 S. Ct. at 2284); *Sealy Mattress*

*Mfg. Co. v. Duncan*, 1985 WL 1737, at \*3 (N.D. Ill. June 7, 1985) (“If the defendants are able to establish the existence of sufficient pro-competitive benefits to offset any anticompetitive effects of any restraints shown by plaintiffs,” plaintiffs must “show that a less restrictive (i.e., one with fewer anticompetitive effects) alternative would secure these same benefits[.]”). Plaintiffs’ proposed instructions also would have told the jury that if a plaintiff shows that a procompetitive justification for a reverse payment could be achieved with a less restrictive means, the reverse payment is anticompetitive under the rule of reason. *Agnew*, 683 F.3d at 335-36; *Impax*, 994 F.3d at 497-498 (“A restraint is unreasonable when any procompetitive benefits it produces could be reasonably achieved through less anticompetitive means,” as the “idea is that it is unreasonable to justify a restraint of trade based on a purported benefit to competition if that same benefit could be achieved with less damage to competition.”) (quotations omitted). Plaintiffs’ proposed instructions further would have explained to the jury that a less restrictive means of settling a Hatch-Waxman case is settling without a reverse payment. *See Actavis*, 570 U.S. at 158 (explaining that the fact that “a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling” because they “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”); *Impax*, 994 F.3d at 498 (noting that a settlement without a reverse payment had been recognized by the Supreme Court in *Actavis* as a viable alternative settlement); P. AREEDA & H. HOVENKAMP, *supra*, ¶ 2046c2 (recognizing that the “premise” behind *Actavis* “is that there are better, less anticompetitive ways to settle these disputes”).

In contrast, the Court’s sole instruction on less restrictive means told the jury: “If defendants prove some procompetitive benefits, then the burden shifts back to the plaintiffs to

show that the anticompetitive effects outweigh the procompetitive benefits *or that the benefits could have been achieved with less restrictive effects on competition.*” Instr. No. 7 (ECF No. 1004, at 8) (emphasis added). The failure to explain the less restrictive means test or how it fits into the rule of reason was exacerbated by the failure of the verdict form to even include it in the inquiry posed to the jury. Question 3 on the verdict form asked only: “Was the settlement between Endo and Impax with the reverse payment unreasonably anticompetitive? That is, did the anticompetitive effects of that settlement outweigh any procompetitive justifications?” ECF No. 1005, at 2. Plaintiffs specifically objected to the omission of the less restrictive means inquiry from Question 3. Tr. 2574:20-21.

Even Defendants’ proposed instructions would have told the jury that the existence of alternative less restrictive means would mean that any procompetitive justification could not justify the challenged restraint. Defendants’ Proposed Instruction 11 provided: “If plaintiffs prove that the same benefits could have been readily achieved by other reasonable or available alternative means that create substantially less harm to competition, then they cannot be used to justify their restraint.” Def. Prop. Instr. 11 (ECF No. 988-1, at 16); *see also* Tr. 2518 (Endo’s counsel agreeing that if there is a less restrictive means to achieve the procompetitive benefits identified by defendants, the procompetitive benefits “fall away”). Unlike either Plaintiffs’ or Defendants’ proposed instructions, the Court’s instructions did not explain that, if the jury found a less restrictive means, it should find the reverse payment to be anticompetitive. The Court’s final instructions also failed to explain that a less restrictive means of settling Hatch-Waxman cases is to settle without a reverse payment, a significant part of the law established by *Actavis*.

Absent such explanation, the Court’s instructions left the jury without any understanding of how it was to determine the existence of a less restrictive alternative.



**B. The Extensive Evidence of the Later-Issued Patents and Related Litigation Should Have Been Excluded as Irrelevant and Unduly Prejudicial.**

Finally, Plaintiffs are entitled to a new trial because Endo's extensive evidence of the later-issued patents and related litigation – Endo's "most compelling and supportive evidence," *Cullen*, 195 F.3d at 324-25 – was irrelevant and never should have been admitted. Plaintiffs moved *in limine* to exclude evidence of the later-issued patents (ECF No. 806) and objected when Endo offered into evidence court opinions finding the later-issued patents to have been infringed by other generic manufacturers (Tr. 2331:8-12, 2335:20-22, 2340:16-18, 2342:8-10).

For many of the same reasons explained above, the three patents that Endo obtained years after it settled with Impax and the related litigation concerning those patents were entirely irrelevant to the question of whether Endo violated the rule of reason *at the time that Endo agreed* to pay Impax to avoid the risk of competition. As the Fifth Circuit explained in affirming the FTC's conclusion that Impax's acceptance of Endo's reverse payments violated the antitrust laws:

Impax also argues that the settlement does not look anticompetitive in hindsight. After all, since the settlement Endo has obtained more patents for Opana ER and proven their validity in court. On top of that, the product hop [to reformulated Opana ER] ended up failing once Endo had to take reformulated Opana ER off the market due to safety concerns. So Impax's generic is now the only version of Opana ER on the market.

But it is a basic antitrust principle that the impact of an agreement on competition is assessed as of "the time it was adopted."

*Impax*, 994 F.3d at 496 (quoting *Polk Bros.*, 776 F.2d at 189).

As discussed above, in its summary judgment opinion, the Court held, consistent with the Fifth Circuit, that the later-issued patents were not material to whether there is an illegal restraint of trade because a restraint of trade is "viewed at the time it was adopted." *Opana ER II*, 2021 WL 2291067, at \*28 (quoting *Polk Bros.*, 776 F.2d at 189). While the Court elsewhere cited the

general description of the rule of reason from *Khan* and *Chicago Board of Trade, Opana ER II*, 2021 WL 2291067, at \*23, the Supreme Court’s very first statement of the rule of reason over a one hundred years ago does not represent the current law under the rule of reason and certainly does not justify ignoring repeated subsequent specific rulings of the Seventh Circuit and other courts that the anticompetitive effects of agreements are to be determined at the time of the agreement. *See supra* pp. 8-9.

In addition, the later-issued patents were not relevant to Plaintiffs’ evidence of causation. The only causation benchmark that Plaintiffs presented to the jury was that, absent Endo’s reverse payments, it was in the economic interests of Endo and Impax to agree to an identical settlement agreement that included the broad license but no reverse payment. As explained at trial, such a settlement without a reverse payment would necessarily provide for an earlier generic entry date. Tr. 1149:5-1150:19 (Dr. Leffler) (“[A] reverse payment is expected to delay generic entry.”); Tr. 1682:7-19 (Prof. McGuire) (explaining that a settlement without reverse payment “could have otherwise looked like the existing settlement, except with an earlier date”). Because the but-for world must differ from the actual world only with respect to the challenged conduct, the benchmark no-payment settlement agreement must necessarily contain the same broad license as the SLA. *See Kleen Prods. LLC v. Int’l Paper Co.*, 831 F.3d 919, 927 (7th Cir. 2016) (explaining that a “plaintiff could satisfy its burden . . . [to] establish antitrust injury” through a “‘but-for’ analysis” consisting of “an expert construction of a hypothetical market free of any anticompetitive restraint”); *Nat’l Farmers’ Org., Inc. v. Associated Milk Producers, Inc.*, 850 F.2d 1286, 1306 (8th Cir. 1988) (“At base, an antitrust plaintiffs’ damages should reflect the difference between its performance in a hypothetical market free of all antitrust violations and its actual performance in the market infected by the anticompetitive conduct.”). *See also In re Zetia*

(*Ezetimibe*) *Antitrust Litig.*, 2021 WL 6690351, at \*5 (E.D. Va. Aug. 17, 2021) (collecting authorities); P. AREEDA & H. HOVENKAMP, *supra*, ¶ 392b (explaining that a but-for world should “isolate the effect of the antitrust violation” and “not include any other effects – good or bad – that influence the financial condition of the plaintiff”); ABA SECTION OF ANTITRUST LAW, PROVING ANTITRUST DAMAGES: LEGAL AND ECONOMIC ISSUES 54-55 (2d ed. 2010) (stating that “[t]o isolate the effect of the violation . . . it is important to modify the defendants’ conduct in the but-for world only to the extent necessary to comply with the law.”).

Accordingly, the later-issued patents would no more prevent Impax from launching in the but-for world without any reverse payment than they did in the actual world. Those later-patents and related litigation are therefore irrelevant and should have been excluded under Fed. R. Evid. 402.<sup>7</sup>

Even assuming *arguendo* that the later-issued patents and related litigation had some marginal relevance, they should have been excluded under Fed. R. Evid. 403 because any alleged probative value that they might have had was far outweighed by the likelihood of misleading and confusing the jury and unfairly prejudicing Plaintiffs’ case. Allowing evidence of patents that Endo did not acquire until November 2012, two and a half years after it agreed to pay Impax to avoid the risk of litigation, created a substantial risk that the jury was misled or confused about when the competitive effects of the reverse payments must be evaluated and whether the broad license covering those later-issued patents should be considered a procompetitive justification for Endo’s reverse payments. It should not.

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<sup>7</sup> Even if the law did not require the but-for settlement agreement to include the unchallenged broad license, there was no reason for the jury to hear about what the later-issued patents covered and the litigation brought to enforce them. The only relevant issue was whether a but-for settlement agreement with a no-payment entry date would also include a broad license. The details of the later-issued patents and the later litigation concerning those patents were entirely irrelevant.

The later-issued patents were the centerpiece of Endo's case. Endo's counsel featured the later-issued patents prominently in opening. Tr. 187:17-191:7, 204:11-206:22, 219:2-20, 232:2-234:1. Endo used them to cross-examine Plaintiffs' fact witnesses (Tr. 369:11-370:10, 598:11-24; ECF No. 962 at 21-27) and expert witnesses (Tr. 935:8-17, 1273:17-1278:2, 1449:20-1451:9, 1595:13-1596:14, 1602:4-1604:10, 1608:15-1609:2, 1657:21-1660:9, 1661:5-1663:7, 1748:14-1750:13, 1763:21-1765:2, 1823:3-18, 1824:12-18, 1905:17-1908:22). Over Plaintiffs' objection, Endo offered into evidence copies of both the later-issued patents and the hearsay opinions of courts finding them to be infringed by other generic manufacturers. Tr. 2329:3-20, 2337:22-2338:6 (offering into evidence the later-issued patents); Tr. 2330:22-2331:7, 2335:13-20, 2339:22-2340:15, 2341:24-2342:7 (offering court opinion from litigation surrounding those patents). In closing, Endo's counsel dwelled on the later-issued patents at length, criticizing Plaintiffs for failing to spend enough time addressing them (Tr. 2685:3-2686:2, 2687:9-10) and arguing that they showed that Endo's reverse payment settlement could not have had any adverse competitive effects (Tr. 2684:13-2685:2, 2686:23-2687:5, 2733:14-18, 2742:12-15).

The admission of this irrelevant and highly prejudicial evidence (without any limiting instructions) created a "significant chance" that the jury was influenced by improperly admitted irrelevant evidence. *Shick*, 307 F.3d at 611. Endo presented no evidence that the reverse payment was procompetitive at the time of its agreement with Impax. *See supra* pp. 8-13. The jury's finding that the anticompetitive effects of Endo's conduct did not outweigh its procompetitive justifications is thus "inconsistent with substantial justice." *Shick*, 307 F.3d at 611. If the Court does not enter judgment in Plaintiffs' favor, it should grant a new trial to correct the wrongful admission of this evidence.

### **CONCLUSION**

For the foregoing reasons, Plaintiffs request that the Court: (1) grant their Rule 50(b)

motion that Endo violated Section 1 of the Sherman Act (and the state laws asserted by EPPs) because Endo failed to identify any cognizable procompetitive justification for the reverse payment found by the jury; and (2) schedule a retrial on the questions of impact and damages. In the alternative, Plaintiffs request that the Court order a new trial under Rule 59 at which: (1) the jury will be properly instructed on Endo's claimed procompetitive justification including the less-restrictive-means inquiry; (2) the verdict form will correctly permit the jury to find a less restrictive means of settling; and (3) the irrelevant and unduly prejudicial later-issued patents and related litigation will be excluded.

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