IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY
This Document Relates To: All Actions	

MEMORANDUM IN SUPPORT OF CLASS PLAINTIFFS'
MOTION FOR A NEW TRIAL PURSUANT TO FED. R. CIV. P. 59

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I. INTRODUCTION

The Nexium purchasers seek a new trial.

The fundamental role of antitrust law is to preserve free and undeterred competition. In many of its applications – determining anticompetitive effects, assessing procompetitive assertions, and estimating the consequences of a violation – antitrust law looks to objective evidence of what free market conditions would have produced in the absence of collusive or other anticompetitive behavior. Because in every antitrust inquiry the defendants' actions have arguably distorted the operation of a free market, many facts on the ground may simply be consequences of the violation, not of a free market. And so antitrust law requires careful attention to market facts uninfluenced by the particular defendants' conduct, and it often looks to (sometimes complex) economic modelling to show how a competitive market would have behaved.

In this case, and for the first three questions it answered, the jury had a correctly framed question, an adequate charge, and ample objective economic evidence based on facts untainted by AstraZeneca's and Ranbaxy's wrongdoing. In answering "yes" to Questions 1, 2, and 3, the jury found that (i) AstraZeneca exercised market power within the relevant market, (ii) the settlement of the AstraZeneca-Ranbaxy patent litigation included a large and unjustified payment by AstraZeneca to Ranbaxy, and (iii) AstraZeneca's Nexium settlement with Ranbaxy was unreasonably anticompetitive (*i.e.*, that the anticompetitive effects of that settlement outweighed any procompetitive justifications). Sound economic evidence, coupled with facts untainted by the Defendants' actions, permitted the jury to reach the legally relevant conclusion that the large and unjustified payment by AstraZeneca had actual anticompetitive effects, which the Court correctly explained meant a delay in the date of generic entry.

On the other hand, the circumstances for the jury's answer of "no" to Question 4 are the opposite. The question was incorrectly framed, rewritten by the Court the day before the jury charge, and asked not about what entry date would have resulted from competitive economic conditions but about AstraZeneca's subjective desires if it could not pay off Ranbaxy. The charge was confusing, saying the standard is objective but then instructing the jury to consider what AstraZeneca itself, rather than a reasonable manufacturer in AstraZeneca's position, would have done. And the Court wrongly excluded *all* objective economic evidence of how free market conditions would have achieved a violation-free result, evidence directly relevant to the jury's analysis of Question 4. When the Court, two weeks earlier, asked for the Plaintiffs' views regarding a mistrial, neither the language of Question 4 nor the corresponding charge was known, and the parties could reasonably expect the Court to permit competent evidence regarding competitive market behavior (in the absence of Defendants' actions) to be introduced as the trial continued so as to cure the earlier mistakes in the way the trial was conducted. But that "curing" never occurred.

These failings, coupled with juror confusion arising from the seismic shift in the Court's framing of issues to be tried, along with shifting instructions on the role of patents on liability and causation issues, led the jury to answer "no" to Question 4 (*i.e.*, that AstraZeneca would not have agreed to an earlier entry date), an answer that *directly contradicts* its answer to Question 3 (*i.e.*, that AstraZeneca's Nexium settlement with Ranbaxy in fact harmed competition). These contradictory answers cannot be reconciled. A new trial should be ordered.

First, Question 4 was incorrectly framed, was disclosed for the first time on December 2, 2014 (the day before the jury was charged), and the clerk informed the parties that the Court would entertain no argument on it. Question 4 should have asked the jury what competitive

conditions would have resulted absent the unlawful conduct – *i.e.*, absent the large and unjustified payment, what competitively-derived entry date would have been agreed to by two reasonable companies obeying the law. Instead, the jury was incorrectly asked only about AstraZeneca's subjective desires, *i.e.*, "would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch . . . before May 27, 2104." But the body of well-settled antitrust law may not be reduced to the absurd proposition that competitive conditions should be measured by the antitrust violator's *post hoc* self-serving statements about what it would have done had it not violated the law.

Second, the charge on Question 4 failed to explain that the impact of the large and unjustified payment should be measured against what would be achieved by two competitive brand and generic companies seeking to reach a competitively-derived, agreed entry date. Despite the Court's assurance that it would instruct the jury that Question 4 should turn on what reasonable companies would have done, the Court created confusion by also instructing the jury to consider what *AstraZeneca thought it* would have done.

Third, the Court wrongly excluded all competent economic evidence concerning what competitive result would have occurred were it not for the "large and unjustified" payment the jury found AstraZeneca made to Ranbaxy. Such evidence would have helped the jury answer a correctly framed Question 4, but none was adduced by the parties. Plaintiffs' evidence was excluded; the Defendants chose to introduce none.

Dr. McGuire was prepared to offer extensive economic evidence on this key issue. This included evidence of the value of the no-authorized-generic ("No-AG") clause to Ranbaxy (including that it was worth more to Ranbaxy than even winning the patent case); its cost to AstraZeneca; and manufacturers' historical use of No-AG clauses to delay generic entry. All of

this would have supported the conclusion that Dr. McGuire would have given: *"Only when … the delay is very long* would Ranbaxy require such a massive financial transfer to agree to the delay in entry."[1]

The Court stated it would be "simply unfair"[2] to permit Dr. McGuire to testify "simply [to] … the enormous value of the AstraZeneca-Ranbaxy settlement to AstraZeneca."[3] But why? Isn't the enormous value to a brand company from a payment-laden settlement precisely one of the issues *Actavis* suggests as critical in these cases?[4] Doesn't the size of a payment directly relate to the extent to which an agreed entry date has been postponed? Can't evidence of the huge size of the agreement's benefits to the brand company undermine self-serving statements by the brand's executives that they would have been unwilling to accept less?

Plaintiffs offered evidence of the payment's benefits to each party to show the value of the settlement to both AstraZeneca and Ranbaxy and to prove the fundamental point that a large payment *moves back the generic entry date*. That, of course, is the very subject of what would later become Question 4. And evidence of the huge benefits inuring from the illegally achieved settlement would undermine an antitrust violator's self-serving claim that nothing less would have been accepted. To the extent that the Court would later in the proceeding – the day before the final jury charge – decide to charge the jury on AstraZeneca's subjective willingness to move the agreed entry date earlier, the evidence of the agreements' huge benefits to both Defendants would have been highly relevant and not "simply unfair."

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[1] Report of Richard G. Frank and Thomas G. McGuire, Economic Analysis of the Nexium Settlement Agreements, Aug. 23, 2013 ("August 23, 2013 Report"), at ¶ 180 (emphasis added), attached as Exhibit A to Plaintiffs' Evidentiary Proffer as to Dr. Thomas G. McGuire (ECF No. 1282).

[2] 11/20/14 Trial Tr. (ECF No. 1424) at 84:9.

[3] *Id*. at 84:15-17.

[4] *FTC v. Actavis, Inc*., 133 S. Ct. 2223 (2013).

At the time the Court asked Plaintiffs whether they pressed for a mistrial based on the Court's Veteran's Day weekend change of position, Plaintiffs could not predict the Court would exclude all further economic evidence of any kind at any stage, nor anticipate the Court would instruct the jury that antitrust injury should be determined based on AstraZeneca's self-serving "we would not have done a different deal" evidence.. Although the Court noted that its exclusion of Dr. McGuire's testimony "may change the plaintiffs' position on mistrial,"[5] Plaintiffs reasonably believed some reasonable rebuttal evidence would be permitted in due course, and no one could have predicted that antitrust injury would be based on evidence of the violator's self-serving statements about how it would have refused any other deal. In short, by its exclusion rulings the Court demonstrated it misunderstood that evidence of the huge size of the payments addressed key issues, *i.e.*, that pay equals delay; that the larger the payment, the longer the delay; and that evidence of huge benefits from a deal undermines self-serving testimony from brand executives that they would not have taken anything less.

Dr. McGuire (and Dr. Leffler) would also have testified to a *specific* entry date to which rational, profit maximizing management for AstraZeneca, owing a fiduciary duty to its shareholders, would have agreed in the absence of an unlawful payment. Competent economic evidence of an objective, competitive entry date would address correctly framed Questions 4 and 5. Dr. McGuire's event study used the changes in the market reaction to news of Defendants' anticompetitive agreement as a demonstrable, objective proxy for what reasonable management would have done had they not violated the law. This was a proper subject of both direct and rebuttal testimony. Dr. Leffler's testimony, too, would have aided the jury in understanding objectively what would have occurred absent a large and unjustified payment. In addition, the

[5] *Id.* at 84:23-24.

excluded FTC study (Exh. FAX) would have presented an unbiased comparison of payment-free to payment-laden settlements. And since both Dr. McGuire and Dr. Leffler empirically establish what would be the most economically advantageous course for each of AstraZeneca and Ranbaxy – had the large and unjustified reverse payment not been included in the settlement agreement – their testimony would have directly challenged the credibility of AstraZeneca and Ranbaxy's witnesses' self-serving testimony about what they would have done absent a payment. The Court's erroneous exclusion of both Dr. McGuire and Dr. Leffler thus doubly crippled Plaintiffs' case – the jury was prevented from hearing critical evidence that both affirmatively supported Plaintiffs and additional evidence that contradicted Defendants' self-serving statements.

Fourth, at various times throughout the trial, the Court improperly instructed the jury that the mere existence of patents that expire in the future may influence its decision making. When interjected on matters of liability, as a matter of law those instructions contradicted the *Actavis* holding discarding the "scope of the patent" test; antitrust scrutiny of patent settlements does not rest on the existence of "presumptively valid" patents, but on the presence of payments that influence agreed entry dates. When interjected on matters of causation, as a matter of fact the instructions contradicted the evidence; each defendant conceded its settlement decisions were not based on patent merits evaluations, all parties conceded the patents were subject to litigation placing AstraZeneca at serious risk, and no party saw a need to litigate the patent merits. The Court's interjections were an improper suggestion of AstraZeneca's litigation position, and they became an invitation to the jury to conclude that AstraZeneca might not change its position even if it were not paying off Ranbaxy for a later agreed entry date. In sum, the jury was prevented from hearing Plaintiffs' sound economic evidence about how competitive actors would have

achieved a competitive entry date. And the Defendants, for their own account, did not introduce any economic or other objective evidence on the topic. Instead, the jury was left with sporadic, self-interested statements by AstraZeneca and Ranbaxy making the subjective claim that the large and unjustified payment did not cause them to delay the entry date. And the incorrect framing of Question 4 as focusing solely on AstraZeneca's subjective desires played right into that.

The result, in the end, is that the jury's answer to Question 4 both contradicts its answers to Questions 1, 2, and 3 and simply answers the wrong question. The "yes" answers to the first three questions established the objective economic facts that the AstraZeneca-Ranbaxy agreement was unreasonably anticompetitive, *i.e.*, that it delayed the agreed entry date for the first-to-file generic Nexium. The "no" answer to Question 4 (i) if taken as an objective question, means there was no delay in the agreed entry date and so contradicts the "yes" answer to Question 3, or (ii) if taken as a subjective question, means AstraZeneca did not want to give Ranbaxy an earlier agreed entry date, which is the wrong question. Either way, the answer to Question 4 cannot serve as the basis for a judgment in Defendants' favor. The situation is directly attributable to the series of unfortunate evidentiary and other mistakes that unfolded over the course of the trial. These circumstances compel a new trial.

II. LEGAL STANDARD[6]

Pursuant to Fed. R. Civ. P. 59(a), a new trial is warranted for reasons including "substantial errors in admission or rejection of evidence or instructions to the jury." "[A] trial court must act to resolve a conflict-ridden verdict, irrespective of its cause."[7]

[6] A detailed Procedural and Factual History, with citations to the trial record, is attached as Appendix A. Appendices B – D contain additional record citations by topic. Exhibits referenced herein are attached to the accompanying Declaration of Thomas M. Sobol.

It is a "trial court's duty to set aside the verdict when the verdict . . . will result in a miscarriage of justice."[8] A court may grant a new trial where the "trial was not fair to the party moving . . . and may raise questions of law arising out of alleged substantial errors in admission or rejection of evidence or instructions to the jury."[9] A new trial is appropriate when verdicts in the same case are inconsistent and indicate either confusion or abuse on the jury's part.[10] The First Circuit has stated:

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[7] *Downs v. Gulf Western Mfg. Co., Inc.* 677 F. Supp. 661, 672 n.24 (D. Mass. 1987) (citing *Saunders v. State of Rhode Island*, 731 F.2d 81, 84 (1st Cir. 1984)).

[8] *Boston Gas Co. v. Century Indem. Co.*, 708 F.3d 254, 260 (1st Cir. 2013) (quoting *Mayo v. Schooner Capital Corp.*, 825 F.2d 566, 570 (1st Cir. 1987) (alteration and internal quotations omitted)). *See also Amgen, Inc. v. F. Hoffman La Roche Ltd.*, 581 F. Supp. 160 (D. Mass. 2008) (in *Amgen*, this Court cited the following cases as the "First Circuit standards in reviewing motions for a new trial": *Z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340 (Fed. Cir. 2007); *Fernandez v. Leonard*, 963 F.2d 459 (1st Cir. 1992); *Castillo v. Autokirey, Inc*., 379 F.3d 4 (1st Cir. 2004)).

[9] *Castillo*, 379 F.3d at 13 (citations omitted). *See, e.g., Boston Gas Co.*, 708 F.3d at 268-69 (affirming the trial court's decision to vacate a damages award and grant a motion for a new trial in light of the court's determination that it was "[u]nable to reconcile the damages award with the arguments and evidence presented at trial"); *Amgen, Inc. v. F. Hoffman La Roche*, 580 F.3d 1340 (Fed. Cir. 2009) (vacating trial court's grant of summary judgment and JMOL to plaintiff of no invalidity for obviousness-type double patenting of certain claims and grant of JMOL to defendant of non-infringement of a certain patent claim and remanding for a new trial on infringement of that claim); *Blake v. Pellegrino*, 329 F.3d 43, 46 (1st Cir. 2003) (vacating in part and remanding for new trial where "the district court had erred in redacting the death certificate, and, moreover . . . the timing of the court's actions—allowing [plaintiffs] to introduce the unredacted death certificate, publish it to the jury, and build their case around it, and then striking the pivotal language -- had doomed their chances of prevailing.").

In *Blake*, the First Circuit addressed, *inter alia*, the timing of the evidentiary issue on which the motion for a new trial was based. In that case, after the plaintiffs rested their case following fifteen days of trial, the court excised key words from the "centerpiece" of plaintiffs' evidence and around which their theory of the case was tried. 329 F.3d at 45. As to the timing, the First Circuit stated:

> [T]he timing of the redaction – on the seventeenth day of a twenty day trial and after the plaintiffs had rested – magnifies the prejudice occasioned by the [error]. The plaintiffs had . . . built their case around the redacted language—a reasonable tactic . . . . The court then abruptly reversed direction and sawed the limb off at the eleventh hour, bringing the plaintiffs' case down with it. It is difficult to imagine a more prejudicial turn of events.

Id. at 49.

[10] *See generally, Downs, supra*, note 13. *See also* 3 MOTIONS IN FEDERAL COURT § 9:50 (3d ed.) (citing *Hopkins v. Coen*, 431 F.2d 1055 (6th Cir. 1970); *Frain v. Andy Frain, Inc.*, 660 F. Supp. 97 (7th Cir. 1987); *Global Van Lines, Inc. v. Nebeker*, 541 F2d 865 (10th Cir. 1976)).

In *Frain*, 660 F. Supp. at 101, 103, the court held that the jury made inconsistent findings that corporations breached their fiduciary duties, but had not violated securities law or committed common law fraud, and ordered a new trial because it was apparent that the jury was "either confused, inaccurately instructed as to the law, or both," and that "permitting the verdict . . . to stand would be a miscarriage of justice." In so ruling, the *Frain* Court

> [a] federal trial court has broad discretion to refuse to accept a general verdict and to order a new trial when it believes that the ends of justice so require. [Citations omitted.] This discretion encompasses the power to refuse to accept a jury's answers to special interrogatories.[11]

If there is uncertainty or contingency to the finality of the jury's determination, or when a court cannot reconcile verdict inconsistencies, the trial court may grant a timely motion for a new trial.[12] At least one court has noted that "the legal error resulting from entry of a judgment based on inconsistent special interrogatories is one which undermines the validity and integrity of the judgment and may, in fact, run afoul of the Seventh Amendment by allowing the District Court to usurp the jury's function."[13]

In *Downs v. Gulf Western*, the United States District Court for the District of Massachusetts (Garrity, J.) granted a new trial because "the conflict in the jury's findings [were] irreconcilable," and rose "to the level of being 'seriously erroneous' and a 'clear miscarriage of justice."[14] Judge Garrity cautioned: "a trial court should not sidestep a possibly serious conflict in a jury's answers to interrogatories by confining its attention to only one portion of a special verdict"[15] and noted that the First Circuit "has ordered a new trial when acceptance of answers to some interrogatories required the trial court to ignore answers to others."[16]

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deemed it improper to "resolve an inconsistent verdict by reconciling it on a theory that was never present to the jury."

[11] *Downs*, 677 F. Supp. at 672 (citing *Atlantic Tubing & Rubber Co. v. International Engraving Co.*, 528 F.2d 1272, 1276 (1st Cir. 1976). *See also Cone v. Beneficial Standard Life Ins. Co.*, 388 F.2d 456, 460 ("If the verdict is perverse because of inconsistency with special findings a new trial may be ordered.").

[12] *See Downs*, 677 F. Supp. at 666. *See also* 3 MOTIONS IN FEDERAL COURT § 9:50 (3d ed.).

[13] *Mercer v. Long Mfg. N.C., Inc.*, 671 F.2d 946, 948 n.1 (5th Cir.1982) (*per curiam*).

[14] *Downs*, 677 F. Supp. at 664, 667.

[15] *Downs*, 677 F. Supp. at 666 (citing 6A MOORE'S FEDERAL PRACTICE ¶ 59.08 [4] at 59–127, 59–128).

[16] *Downs*, 677 F. Supp. at 666 (citing *Saunders v. State of Rhode Island*, 731 F.2d 81, 84 (1st Cir. 1984)).

The *Downs* Court rejected an argument that the movant for a new trial had waived its grounds of inconsistent verdict answers and stated that Fed. R. Civ. P. 49(a) applied and permitted "the trial court to give [the requested]

The jury's answers on a verdict form are irreconcilably inconsistent if they are logically incompatible.[17] Verdict inconsistencies include inconsistent answers to jury interrogatories.[18] The ordinary remedy for irreconcilable verdicts is a new trial.[19]

III. ARGUMENT

A. The framing, timing, and instructions on Question 4 were improper.

The Court first shared Question 4 with the jury on the day of the charge, improperly framing the issue (for the first time) as a purely subjective question about whether antitrust violator AstraZeneca would wish to have agreed on an earlier entry date.

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relief" (and citing, among other cases, *Mercer*, 671 F.2d at 947-48, n.1 (finding no waiver in a Rule 49(a) case)). The *Downs* Court further observed that under Rule 49(a) *or* Rule 49(b) post-trial relief would not be foreclosed because "there was virtually no consideration of the inconsistent special verdicts among the court and the parties when the jury returned its answers" and the court "should have moved more decisively . . . [and] did not elicit the views of both counsel directly, or address clearly the problem of inconsistent special findings." Last, the *Downs* court noted that the trial court has long-standing discretion to "order a new trial *sua sponte* in the interest of justice, whatever its precise grounding," including where a jury has rendered inconsistent verdict answers. *Id*. at 671-672 and accompanying notes.

Cases where the First Circuit has held that a party waived the issue of inconsistency in the verdict by not raising the issue before the jury was discharged are distinguishable. For example, *Howard v. Antilla*, 294 F.3d. 244 (1st Cir. 2002), involved a general verdict, not special interrogatories under Fed. R. Civ. P. 49(a), and the *Antilla* Court relied, in part, on *Austin v. Lincoln Equip. Associates, Inc.*, 888 F.2d 934, 939 (1st Cir. 1989), where "[t]he court also allowed time for motions after the jury announced its verdict and before the jury was dismissed." No such time was provided here. Moreover, a court can, regardless, correct its error *sua sponte* by ordering a new trial.

[17] Federal Trial Handbook, Section 79:2 (4th ed.).

[18] 3 MOTIONS IN FEDERAL COURT § 9:50 (3d ed.). *See also Downs*, 677 F. Supp. at 667 n.11 (granting a new trial, and noting that "it must be deemed inconsistent . . . for a jury to find that a product was not defective for purposes of strict liability, and yet that the product was negligently designed . . . ." (quoting *Witt v. Norfe, Inc.*, 725 F.2d 1277, 1279 (11th Cir. 1984)). *See also Cipriano v. State of Rhode Island*, 738 F.2d 535, 537-38 (1st Cir. 1984) (affirming trial court's remedy of addressing inconsistent verdict answers by altering the judgment pursuant to Fed. R. Civ. P. 59(e)).

[19] *Downs*, 677 F. Supp. at 667 and n.11 (citing *Ladnier v. Murray*, 769 F.2d 195, 198 (4th Cir. 1985); *Atlantic Tubing & Rubber*, 528 F.2d 1272, 1276–77 (1st Cir. 1976); 5A MOORE'S FEDERAL PRACTICE ¶ 49.03[4] at 49–31, 49–32; *Witt v. Norfe, Inc.*, 725 F.2d 1277, 1279 (*per curiam*) (11th Cir. 1984) .

1. The evolution of Question 4.[20]

Before and during trial, every iteration of what became Question 4 (except the last) correctly sought to have the jury determine what the objective, economic facts would have been absent the Defendants' wrongdoing.

The first proposed verdict slip was submitted by the Plaintiffs during the December 11, 2013 hearing. Plaintiffs suggested asking the jury for a reasonable, objective, estimate of the month and year when generic Nexium would have otherwise been available:

> [***Question 7***] (***a***) ***(Period of generic Nexium foreclosure):*** If the defendants had not entered into an agreement to delay the entry of generic Nexium, what is your reasonable estimate (please provide month and year) as to when Ranbaxy (acting alone or with others) would have begun to sell a less expensive generic version of Nexium?[21]

Before trial, during the October 15, 2014 charge conference, the Court distributed a verdict sheet that asked, "5. Had there been no violation of the antitrust laws, a generic version of Nexium would first have come to market on [Month], [Year]."[22]

And again, on the first day of evidence (October 21, 2014), the Court distributed to the jury a verdict slip that against asked a similar objective question about competitive, "but for" facts: "5. Had there been no violation of the antitrust laws, a generic version of Nexium would first have come to market on [Month], [Year], and would an authorized generic have entered thereafter? [y/n]"[23]

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[20] *See also* Appendix A at Section B.

[21] Direct and End-Payer Purchaser Class Plaintiffs' Proposed Special Jury Verdict Form for the Liability (Non-Damages) Trial Phase, attached as Exhibit A to the Declaration of Thomas M. Sobol ("Sobol Declaration"), filed herewith.

[22] *See* draft Jury Verdict slip distributed on October 15, 2014, attached as Exhibit C to the Sobol Declaration.

[23] *See* draft Jury Verdict slip provided to the jury on October 21, 2014, attached as Exhibit D to the Sobol Declaration.

Even on November 18, 2014 – when the Court explained that, after ruminating on the case over the weekend, the Court would "jimmy" the verdict slip,[24] and outlined the Court's plan for a new verdict sheet – the Court's statements indicated that the jury would still be asked only a general question about when generic Nexium would have launched, and included no mention of a question seeking AstraZeneca's subjective desires.

> But I look at it like this, "Is there monopoly power?" "No." "Yes." "Did AstraZeneca, in settling with Ranbaxy, make to Ranbaxy a large and unjustified payment?" "No." "Yes." If "no," you can jump then to Teva. But if "yes," "Did the anticompetitive effects outweigh the procompetitive effects?" "No." "Yes." Then the same questions for Teva. "Forget the conspiracy question," then ***"Could they have partnered, gotten on the market earlier? If so, when?" "If they did, would there be a" -- "would there be an authorized generic?"***[25]

Consistent with the Court's remarks, on November 21, 2014 the Court distributed to the parties – but not the jury – a revised verdict sheet which *again* included only a question about the objective facts whether and when generic Nexium would have launched absent Defendants' wrongdoing:

> 6. Had it not been for either or both of these agreements, would a generic version of Nexium have come to the market prior to May 27, 2014?
>
> _____ no _____ yes
>
> 7. If so, when? [month], [Year].[26]

It was not until the conclusion of the evidence that the Court, at the final charge conference on December 2, advised the parties of a reshaped question that simply asked the jury

[24] 11/18/14 Trial Tr. (ECF No. 1420) at 4:20-23.

[25] *Id.* at 6:10-20 (emphasis added).

[26] *See* draft Jury Verdict slip provided to counsel on November 21, 2014, attached as Exhibit E to the Sobol Declaration.

to answer a question about AstraZeneca's subjective desires:[27] "Had it not been for the unreasonably anticompetitive settlement, would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?" Plaintiffs objected.

During the charge conference, the Court said that "even if they answer 'no' to Question 4, I'm going to tell them I want an answer to Question 6, 'Had it not been for the unreasonably anticompetitive settlement, would Ranbaxy have agreed with Teva to launch a generic version of Nexium before May 27th, 2014?'"[28] The Court acknowledged that in order to have "an adequate record upon which to be reviewed . . . if they answer 'no' to 4, they don't have to answer 5. But I also want them to answer 6. If they answer 'yes' to 6, I want to know when."[29] The Court, however, did not follow its own guidance, failing to charge the jury to answer Question 6 regardless of its answer to Question 4, and failing to direct the jury to continue deliberating to answer Question 6. This compounded the other errors and now leaves "an [*in*]adequate record upon which to be reviewed."

Later on December 2, the same day the Court first revealed Question 4, Plaintiffs filed two briefs objecting to the subjective phrasing of Question 4.[30]

On December 3, the Court gave the jury copies of the final verdict slip,[31] including the subjectively framed Question 4 ("Had it not been for the unreasonably anticompetitive settlement, would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?") and charged the jury.

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[27] *See* draft Jury Verdict slip provided to counsel on December 2, 2014, attached as Exhibit F to the Sobol Declaration.

[28] 12/02/14 Charge Conf. Tr. (ECF No. 1437) at 6:7-12.

[29] *Id.* at 14:8-10.

[30] *See* ECF Nos. 1358-59, discussed below.

[31] *See* final Jury Verdict slip provided to jury on December 3, 2014, attached as Exhibit G to the Sobol Declaration.

2. Question 4 was improperly framed.

As ultimately presented to the jury, Question 4 read subjectively: "Had it not been for the unreasonably anticompetitive settlement, would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?" Plaintiffs objected to this question repeatedly during the charge conference,[32] as soon as Question 4 was first presented, raising their concern that Question 4 should, instead, be presented as an objective question – *i.e.*, what reasonable companies in AstraZeneca and Ranbaxy's positions would have agreed to. But, unfortunately, the question was presented in its subjective form and (as addressed below) accompanied by jury instructions that confusingly referred to both objective and subjective considerations.

Plaintiffs' briefs, filed the same day (December 2), outlined an "expansive body of case law demonstrat[ing] that the construction of the antitrust hypothetical scenario, necessitated by Defendants' unlawful behavior, is based on objective factors, *not* on what Defendants say they would have done had they not broken the law,"[33] and explaining that the "less restrictive alternative" available to reasonable companies in Defendants' position would be a "no-payment

[32] 12/02/14 Charge Conf. Tr. (ECF No. 1437) at 8:25-9:20.

[33] Plaintiffs' Submission Regarding Jury Instructions (ECF No. 1359), at 4, and cases cited therein at 1-4, including cases which demonstrate a jury's determination of what would have occurred is an objective analysis, not a subjective one. *See e.g., Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 264 (1946); *Dolphin Tours, Inc. v. Pacific Creative Serv., Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985) ("In economic terms, the amount of damages is the difference between what the plaintiff could have made *in a hypothetical free economic market* and what the plaintiff actually made in spite of the anticompetitive activities.") (emphasis added); *Los Angeles Memorial Coliseum Comm'n v. National Football League*, 791 F.2d 1356, 1367 (9th Cir. 1984) (same); *National Farmers' Organization, Inc. v. Associated Milk Producers, Inc.*, 850 F.2d 1286, 1306 (8th Cir. 1988) ("At base, an antitrust plaintiff's 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) (emphasis added); *Been v. O.K. Indus. Inc.*, 398 Fed. Appx. 382, 396 (10th Cir. 2010) ("district court did not err in allowing the jury to calculate damages based on the profits that the Growers actually received in comparison to profits in a *hypothetical competitive market*") (emphasis added).

[settlement with] an earlier entry date."[34] This no-payment settlement would "provide the same benefits – by removing the risk of the patent litigation – in a less restrictive manner, *i.e.*, without the delay bought by the reverse payment."[35]

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[34] Plaintiffs' Submission Regarding Objective Standard on Jury Verdict Form (ECF No. 1358), at 1 (and quoting *Sullivan v. NFL*, 34 F.3d 1091, 1103 (1st Cir. 1994) ("One basic tenet of the rule of reason is that a given restriction is not reasonable, that is, its benefits cannot outweigh its harm, if a reasonable, less restrictive alternative to the policy exists that would provide the same benefits as the current restraint."). As plaintiffs explained in the brief:

> *First*, the First Circuit makes clear that "benefits cannot outweigh [the challenged] conduct's harm" if a less restrictive alternative is available. Second, the First Circuit's language is clear that the standard by which to judge less restrict[ive] alternative[s] is what is "reasonable"—*i.e.*, an *objective* standard. In Nexium, the less restrictive alternative is what is a settlement with no payment and an earlier entry date. Sullivan makes clear that this settlement is assessed using an objective standard.

Plaintiffs' Submission Regarding Objective Standard on Jury Verdict Form, ECF No. 1358, at 1.

See also, 2A Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 392b, at 379 (3d Ed.) (in the context of antitrust damages, addressing that the Eighth Circuit has observed. ". . . antitrust 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" (citing *National Farmer's Org. v. Associated Milk Producers*, 859 F.2d 1286, 1306 (8th Cir. 1988), *cert denied*, 489 U.S. 1081 (1989))); *id*. at ¶ 338, at 126-27 (citing *Irvin Indus., Inc. v. Goodyear Aerospace Corp.*, 974 F.2d 241, 245-46 (2d Cir. 1992) (in a case alleging monopolization based on predatory pricing, reversing summary judgment and refusing to base denial of injury on the defendant's speculative arguments regarding what it would have done had it not engaged in predatory conduct—i.e., that it still would have won the government contract at issue with a lawful bid—instead finding that the trier of fact could infer that "a competitor" would have behaved differently based on objective profit motivations)); 2B Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* at ¶ 422a, at 91-92 (3d Ed.) (in the context of the government's horizontal merger guidelines, addressing that the "likelihood of entry is best measured by an objective test") (citing United States Dept. of Justice and Federal Trade Commission, 1992 Horizontal Merger Guidelines, available at: http://www.ftc.gov.os/2006/03/CommentaryontheHorizontalMergerGuidelinesMarch2006.pdf; 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 706b, at 264 (noting that "objective evidence about what is reasonable under the circumstances often provides a basis for determining the reasonableness of [a patent] infringement claim" because "reliable evidence about the plaintiff's subjective mental state will [often] be unavailable"); 5 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1128b, at 97-98 (with respect to determining probable future market entrants in merger cases, noting that "[s]ubjective evidence can be helpful but will seldom be reliable," in large part because it may be motivated by a wish to influence existing or future litigation) (citing *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 568-69 (1973)); *id.* at 98 ("The firm that is sensitive to the possible future uses of subjective evidence w[ill] be tempted to phrase its internal documents and minutes in language that is always negative, or at least doubtful, until the moment of actual positive steps toward independent entry."); *id.* at 103 (concluding that evidence of subjective intent "may be given some weight when it is consistent with objective factors," but that "[i]t should be clear that affirmative proof of a subjective intention to enter the market is not a prerequisite to finding that the defendant would probably have entered the market."); *id.* at ¶ 1128c, at 104-110 (discussing objective factors that may instead be considered); 6 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1412f, at 87 (noting that, although a defendant should be free to rebut with evidence of its subjective motivations, a plaintiff may satisfy its initial burden of showing conspiratorial motivation through objective evidence).

See, e.g., cases in which antitrust courts also consider *objective* market conditions through expert econometric analysis that depends *not* on defendants' own hypothetical data but on *objective* data, including a benchmark of prices in similar competitive prices, various explanatory (objective) variables such as costs and demand. *See e.g.*, *In re Linerboard Antitrust Litig.*, 305 F.3d 145, 153-55 (3d Cir. 2002) ("[Plaintiffs' expert] also indicated that there are

One fundamental problem with a subjectively framed standard is that it wrongly suggests a company can make an "if we can't act in violation of the law, we won't act at all" argument. A price fixer, for example, is not permitted to argue that had it not illegally fixed prices with its competitor, it would have stopped selling the product all together and so plaintiffs would have no damages. A company that uses fraud to obtain a patent cannot defend a *Walker Process* antitrust suit by arguing that had it not committed fraud, it would never have sold the product and so plaintiffs have no damages. So too here. AstraZeneca cannot defend itself by claiming that it only settles patent lawsuits with unlawful payments. Having chosen to settle, the only relevant antitrust question is how that settlement would have looked under competitive conditions, *i.e.*, without a payment.

3. Question 4 was first disclosed to the jury and the lawyers *after* the close of evidence.[36]

The jury first saw the final verdict form on December 3, 2014, *after* the close of evidence.

On the first day of trial, the Court gave the jury a verdict sheet that asked a general question about when a generic would have entered:

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several accepted statistical or mathematical approaches that could be used to determine the percentage or absolute overcharge due because of the effect of a conspiracy to manipulate prices. She suggested that 'benchmarking,' which uses 'competitive prices for other comparable products to estimate the pattern of prices but-for the alleged misconduct[,]' could be effectively employed in this situation. Another proffered model would 'compare[ ] prices during non-conspiratorial periods with product prices during the alleged conspiracy,' and yet a third approach would use revenue, production and profit data to derive prices that are consistent with 'yardstick' competitive performance levels.") (internal citations omitted); *In re Aftermarket Auto. Lighting Prods. Antitrust Litig.*, 276 F.R.D. 364, 371 (C.D. Cal. 2011) ("A regression is a statistical tool designed to express the relationship between one variable, such as price, and explanatory variables that may affect the first variable. Regression analysis can be used to isolate the effect of an alleged conspiracy on price, taking into consideration other factors that might also influence price, like costs and demand.") (internal quotation marks and citation omitted).

[35] Plaintiffs' Submission Regarding Objective Standard on Jury Verdict Form (ECF No. 1358), at 1.

[36] And again, even if the subjective formulation were proper, the Court's exclusion of Dr. McGuire and Dr. Leffler's testimony regarding what a profit maximizing agreement – without a payment – would have looked like severely prejudiced Plaintiffs' ability to challenge the credibility of Defendants' witnesses' self-serving, *post hoc* testimony.

> 5. Had there been no violation of the antitrust laws, a generic version of Nexium would first have come to market on [Month], [Year], and would an authorized generic have entered thereafter? [y/n][37]

The jury thus listened to the evidence throughout the entire trial bearing in mind that it would ultimately be asked to answer this "month, year, and authorized generic yes/no" question.

The Court shifted its views on the verdict slip throughout the course of the trial. But the jury received the final verdict slip, with brand new Question 4, only at the very end of the case, on the same day it was charged (December 3, 2014). For all six weeks of trial, as it listened to the evidence, the jury had no idea that it would be asked to decide whether AstraZeneca would have, in the absence of a large and unjustified payment, subjectively desired to enter into a settlement with a license date before May 27, 2014. Nor did counsel know, when examining witnesses and presenting evidence, that the Court would ask the jury whether AstraZeneca would have wanted to do a deal with an earlier date; the last-minute inclusion of Question 4 was a significant, substantive departure from the previously discussed verdict forms – all of which contemplated asking a more general question consistent with antitrust causation law – that asked about a competitively derived date (*i.e.*, the month and year Nexium would have otherwise been available).

Confusion regarding the Court's intentions regarding the final jury verdict slip is also shown by the Court's equivocation on Question 6. During the charge conference, the Court said that "even if they answer 'no' to Question 4, I'm going to tell them I want an answer to Question 6, 'Had it not been for the unreasonably anticompetitive settlement, would Ranbaxy have agreed with Teva to launch a generic version of Nexium before May 27th, 2014?'"[38] The Court

[37] *See* Exhibit D to the Sobol Declaration.

[38] 12/02/14 Charge Conf. Tr. (ECF No. 1437) at 6:7-12.

acknowledged that in order to have "an adequate record upon which to be reviewed . . . if they answer 'no' to 4, they don't have to answer 5. But I also want them to answer 6. If they answer 'yes' to 6, I want to know when."[39] Despite this ruling, the Court did not follow its own guidance. In charging the jury, the Court chose not to charge the jury to answer Question 6 regardless of its answer to Question 4, and when a slip came back without an answer to question 6, the Court simply indicated that the verdict slip was in order. The equivocation simply presents another example of lack of clarity and direction for the parties and the jury as to how to address the issue of antitrust injury in these circumstances.

A new trial is appropriate given the jury's internally contradictory verdict illustrative of the jury's confusion. That confusion resulted from the confusing (and late-disclosed) jury verdict sheet and from the cumulative effect of fundamental evidentiary errors.[40]

4. Question 4's instructions confusingly blended subjective and objective considerations.

During questioning of their own witnesses, Defendants repeatedly elicited testimony that AstraZeneca and Ranbaxy each believed it would not have agreed to any date earlier than May 27, 2014. During AstraZeneca's questioning of its very first fact witness, AstraZeneca's General Counsel Jeffrey Pott,[41] AstraZeneca elicited testimony from Mr. Pott that: (a) AstraZeneca had

[39] *Id.* at 14:8-10.

[40] *See Ruiz-Troche v. Pepsi Cola Bottling of Puerto Rico*, 161 F.3d 77, 88 (1st Cir. 1998) (reversing the trial court and remanding for a new trial where "improper exclusion of the dosage testimony, coupled with the errors regarding the court's consideration of the impairment testimony, can be said to have materially curtailed the Defendants' opportunity to present their theory of the case to the jury" and "worked a substantial and injurious effect on the jury's ability to evaluate liability").

[41] Defendants' questioning of Mr. Pott (and of Mr. Hester, AstraZeneca's outside counsel) occurred out of order as a result of the Court's ruling that required Defendants to bring witnesses live in plaintiffs' case-in-chief that Defendants also planned to call live in their case-in-chief. *See* 10/15/14 Charge Conf. Tr. (ECF No. 1100) at 41:19-22 ("If they want them, you bring them, and they'll come one time, I'll let you examine and I'll explain it to the jury. I won't prejudice anyone. But if they want them, you bring them, if you're going to use them."); *see also* 10/18/14 email from John Schmidtlein, counsel for AstraZeneca, to Thomas M. Sobol, counsel for plaintiffs (representing to plaintiffs that AstraZeneca intended to call live in its case-in-chief Jeffrey Pott, Timothy Hester, and Linda Palczuk), attached as Exhibit H to the Sobol Declaration.

determined by the first settlement conference in July 2007 that it would be willing to offer a license date of May 27, 2014;[42] and (b) subsequent to that conference, AstraZeneca never "wavered or negotiated" the May 27, 2014 date with Ranbaxy, Teva or any other generic company.[43] Similarly, during AstraZeneca's questioning of Timothy C. Hester, the outside AstraZeneca attorney who negotiated the agreements with Ranbaxy, Teva and other subsequent generics, AstraZeneca elicited testimony that it had never offered a license date before May 27, 2014.[44] During closing argument, counsel for AstraZeneca repeated this very testimony – which it had elicited in its case-in-chief – in support of its argument that May 27, 2014 was "the only day AstraZeneca would ever have agreed to."[45]

Ranbaxy elicited similar testimony from Ranbaxy witness Venkatachalam Krishnan during the last day of Defendants' case-in-chief on December 1, 2014 (which, because the Court prevented Plaintiffs from offering any rebuttal evidence, turned out to be the last day of trial testimony). Upon Mr. Baldridge's questioning, Mr. Krishnan testified that AstraZeneca had never "express[ed] any willingness to agree to any" date other than May 27, 2014, and that the May 27, 2014 date coincided with the expiration of AstraZeneca's compound patents.[46]

Defendants similarly elicited testimony from their witnesses that entry in May 27, 2014 was "early." Mr. Hester, for example, testified that entry in May 27, 2014 was "early" multiple times in response to questioning by defense counsel.[47] In addition, the Court permitted, over

[42] 10/28/14 Trial Tr. (ECF No. 1394) at 143:8-15 (questioning by Mr. Butswinkas).

[43] *Id*. at 143:16-144:1; *see also id*. at 127:19-25 (questioning by Mr. Butswinkas).

[44] 11/04/14 Trial Tr. (ECF No. 1403) at 136:11-137:4 (questioning by Mr. Butswinkas).

[45] 12/03/14 Trial Tr. (ECF No. 1440) at 100:25-101:24.

[46] 12/01/14 Trial Tr. (ECF No. 1436) at 127:23-128:24.

[47] *See, e.g.*, 11/04/14 Trial Tr. (ECF No. 1403) at 156:11-18 (settlements provided for entry "four years early on the patents"); *id*. at 158:22-159:10 (AstraZeneca told Ranbaxy it would be "willing to use as the settlement allowing early entry on our patents, but respecting the expiration of those key medicine patents"); *id*. at 158:22-159:10 (the first key term of the settlement was "that there would be early entry, four years early under the AstraZeneca

Plaintiffs' objection, testimony from Mr. Krishnan as to whether "in any way the settlement agreement between AstraZeneca and Ranbaxy delayed entry of generic Nexium reaching the market?"[48] Mr. Krishnan's answer – "not at all"[49] – was based upon the fact that AstraZeneca's latest-expiring patent did not expire until 2019[50] and was designed to support Defendants' position that AstraZeneca's massive reverse payment to Ranbaxy did not delay the license date the parties would have agreed to in the absence of the payment.

The Plaintiffs' view of this evidence is that, as a matter of antitrust law, a company that violates the antitrust laws subjective claim that it never would have behaved differently is not dispositive. Defendants here chose to settle their patent dispute; the only thing the law asks is how reasonable companies would have achieved a competitive settlement with a competitive entry date, not whether the brand would have preferred to extend its monopoly for even longer.

The Court's jury charge mentioned, in passing, that the standard should be "objective,"[51] but never explained that the jury should be evaluating what two reasonable companies in AstraZeneca and Ranbaxy's respective positions would have done.[52] To the contrary, the Court's charge left the impression that the jury *should* consider AstraZeneca's and Ranbaxy's

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patents"); 11/05/14 Trial Tr. (ECF No. 1404) at 12:18-13:4 ("the way the license was structured [Ranbaxy] could come in early under AstraZeneca's patents").

[48] 12/01/14 Trial Tr. (ECF No. 1435) at 20:24-21:3.

[49] *Id*. at 21:4.

[50] *Id*. at 21:4-24.

[51] 12/03/14 Trial Tr. (ECF No. 1439) at 49:11-50:5 ("Now, the test here is an objective test. In other words I use the names 'AstraZeneca' and 'Ranbaxy' because those are the folks we're talking about here, but the test is not what they did, we know what they did, we know what agreement they entered into, you would have found that agreement is unreasonably anticompetitive. So then you're asked the question, 'Well, suppose they didn't enter into such an agreement, suppose they were settling straight up without any anticompetitive effects, would that settlement license entry date have been earlier than the date they agreed to, May 27th, 2014?' Now, look, if it wouldn't have been, that question is answered 'no' and the case is over. If it would have been, by a fair preponderance of the evidence, not guessing, not speculating, if it would be sometime earlier, you answer -- and don't take anything from where I draw these lines, they're just to illustrate the concept, but if it would have been earlier, you can answer that question 'yes.'")

[52] The Ranbaxy defendants objected to this charge. *See* 12/03/14 Trial Tr. (ECF No. 1439) at 67:21-68:1.

subjective, self-serving testimony.[53] The Court instructed the jury: "Well, suppose *they* [*i.e.*, AstraZeneca and Ranbaxy] didn't enter into such an agreement, suppose *they* were settling straight up without any anticompetitive effects, would *that* settlement license entry date have been earlier than the date *they* agreed to, May 27th, 2014."[54] Without a more thorough explanation of what the "objective test" is and how it applies in this case, the jury understandably could have been confused about whether to answer Question 4 based on AstraZeneca and Ranbaxy's self-serving statements or, as it should have, based on its assessment of what reasonable companies would have done in similar circumstances.

The Court compounded the problem by concluding its charge with, "Be very clear, the antitrust law does not require anyone to agree to anything."[55] That is confusing, if not wrong. Again, having chosen to settle the patent dispute, the only thing the law asks is how reasonable companies would have achieved a competitive settlement with a competitive entry date; it is not a matter of making anyone agree to anything, it is simple imposing compliance with the law on the choice the company already made (to settle).

The Court's somewhat jumbled instruction to the jury no doubt contributed to the jury's contradictory answers on Questions 3 and 4. Such circumstances compel a new trial.

B. The Court improperly excluded all competent economic and other objective evidence as to how a competitive market would have reached a competitively-derived, agreed generic Nexium entry date.

Critical to trial of this first reverse payment case in the wake of *Actavis* was for the jury to hear competent economic and other objective evidence about how a competitively-derived resolution of the AstraZeneca-Ranbaxy settlement would have been achieved. The Plaintiffs

[53] Plaintiffs explain that they have not waived their rights to object to this or any other errors raised in this brief in Section E below.

[54] *See* 12/03/14 Trial Tr. (ECF No. 1439) at 49:17-22 (emphasis added).

[55] 12/03/2014 Trial Tr. (ECF No. 1439) at 48:1-2.

came loaded for bear – two accomplished economists submitted a series of reports elucidating how AstraZeneca's massive payment to Ranbaxy in fact delayed the generic entry date, and further elucidating what earlier agreed entry dates would be reached by reasonable parties obeying the law. The Defendants, too, had three opinion witnesses lined up to speak on objective economic conditions.[56]

But the jury heard none of it. This Court improperly excluded all efforts by Plaintiffs to adduce objective economic evidence as to how a competitively-derived settlement of the AstraZeneca-Ranbaxy Nexium litigation would have resulted in an earlier agreed entry date. And in the wake of those rulings against Plaintiffs, the Defendants withdrew all of their own experts on the subject (apparently fearing that cross-examination of their witnesses would yield "but-for" agreed entry date testimony helpful to the Plaintiffs).[57] The problem was then exacerbated by Defendants' highlighting, during closing arguments, the absence of this economic testimony (improperly suggesting that either Plaintiffs' chose not to adduce it or simply had no such evidence; in either case, the suggestion was false).

The exclusion of this evidence plainly resulted in "substantial and injurious effect or influence in determining the jury's verdict" and warrants a new trial.

[56] *See, e.g.*, Defendants' Tentative Order of Proof provided to plaintiffs on November 14, 2014, attached to the Sobol Declaration as Exhibit J (listing Mr. Gordon Johnston, and Dr. Gregory Bellas witnesses that Defendants would call, and listing Mr. Peter Ludwig as a "may call" witness).

[57] After the Court again stated on November 25, 2014 that "McGuire is out. He's not coming back," 11/25/14 Trial Tr. (ECF No. 1434) at 63:14-15, Defendants removed both Dr. Bell and Mr. Ludwig from their order of proof. *Compare* Sobol Declaration, Exhibit K (Defendants' Tentative Order of Proof (November 23, 2014) listing Dr. Bell as testifying and Mr. Ludwig as "may call") *with* Sobol Declaration, Exhibit L (e-mails dated November 28 and 29, 2014 from Benjamin Greenblum and John Schmidtlein, counsel for AstraZeneca, confirming Defendants did not intend to call any additional witnesses other than Mr. Krishnan, Mr. Pott, and Mr. Johnston.)

1. During the Plaintiffs' case-in-chief, the Court improperly excluded opinion testimony of Dr. McGuire that the payments to Ranbaxy resulted in a delayed entry date.

Plaintiffs sought in their case-in-chief to have Dr. McGuire testify that the large and unjustified payments from AstraZeneca to Ranbaxy resulted in a substantially delayed entry date. The proffered testimony had two principal sources and forms.

First, Dr. McGuire's August 23, 2013 Report[58] and October 25, 2013 Report[59] detailed the historical use of No-AG clauses to delay generic entry, described the value here of the No-AG clause to Ranbaxy, described the cost to AstraZeneca of agreeing to the clause, and unequivocally concluded that the payments to Ranbaxy *substantially delayed the generic entry date*: "[e]conomic analysis of the terms of the settlement clearly imply that the settlement implemented a delay in generic entry beyond what could have been expected if the parties had continued with litigation."[60] When the Court first changed course and allowed testimony regarding AstraZeneca's payments to Ranbaxy, the Court announced that Plaintiffs could recall Dr. McGuire to provide this testimony to the jury.[61] But two days later the Court abruptly ruled that Dr. McGuire could *not* give this testimony.[62]

[58] Report of Richard G. Frank and Thomas G. McGuire, Economic Analysis of the Nexium Settlement Agreements, Aug. 23, 2013 ("August 23, 2013 Report"), attached as Exhibit A to Plaintiffs' Evidentiary Proffer as to Dr. Thomas G. McGuire (ECF No. 1282).

[59] Report of Thomas G. McGuire, Response to Defendants' Reports As They Relate to the Economic Analysis of the Nexium Settlement Agreements, Oct. 25, 2013 ("October 25, 2013 Report"), attached as Exhibit I to the Sobol Declaration.

[60] August 23, 2013 Report, at ¶ 178; *see also id*. at ¶¶ 2, 3.

[61] 11/18/14 Trial Tr. (ECF No. 1421) at 167:13-17.

[62] 11/20/14 Trial Tr. (ECF No. 1424) at 83:7-85:4; *id*. at 85:18. The Court stated without elaboration that to let Dr. McGuire testify to "the enormous value of the AstraZeneca-Ranbaxy settlement" would be "unfair and not contemplated by the Court's management orders." *Id.* at 84:16-19. *See also* 11/25/14 Trial Tr. (ECF No. 1434) at 63:14-15 ("McGuire is out. He's not coming back.").

Second, Dr. McGuire's October 8, 2014 Report[63] used a traditional "event study" to calculate a *specific* competitive entry date to which reasonable manufacturers would have agreed in the absence of unlawful payments.[64] The Court acknowledged that event studies are a reliable economic tool.[65] And the Court repeatedly held Dr. McGuire to be eminently qualified to give expert economic testimony.[66] But the Court excluded the event study because it purportedly lacked "fit" to the facts of this case.[67]

Altogether, the Court excluded all but a sliver of Dr. McGuire's opinions on the large and unjustified payment by AstraZeneca to Ranbaxy. And the Court did so despite recognizing (on the last day or so of the Plaintiffs' case) that the large payment to Ranbaxy formed the crux of Plaintiffs' claims and potentially impacted Nexium purchasers.[68] The Court then compounded these errors by prohibiting Dr. McGuire from testifying to any of these opinions in rebuttal, even after Defendants created the need for such rebuttal by testifying that they would not have agreed to any entry date earlier than May 27, 2014.[69]

a. Dr. McGuire would have given relevant testimony that AstraZeneca's large payments delayed the entry date.

The Court summarily precluded Dr. McGuire from testifying to the Ranbaxy-related opinions in his August 23, 2013 and October 25, 2013 Reports. The Court thereby precluded a

[63] Supplemental Declaration of Thomas G. McGuire, Oct. 8, 2013 ("October 8, 2014 Report"), as Exhibit B to Plaintiffs' Evidentiary Proffer as to Dr. Thomas G. McGuire (ECF No. 1282).

[64] *Id*. at ¶ 16.

[65] 11/20/14 Trial Tr. (ECF No. 1424) at 83:11-12.

[66] *See, e.g.*, Electronic Clerk's Notes for proceedings held on 1/21/14 (ECF No. 846) ("The Court finds that McGuire is qualified"); 11/20/14 Trial Tr. (ECF No. 1424) at 83:11 (Dr. McGuire is "qualified").

[67] 11/20/14 Trial Tr. (ECF No. 1424) at 83:13-17.

[68] 11/18/14 Trial Tr. (ECF No. 1420) at 5:11-6:4.

[69] *See* 12/01/14 Trial Tr. (ECF No. 1436) at 161:15-19.

massive amount of compelling testimony that went to the heart of what turned out to be Question 4 on the verdict slip.

Dr. McGuire would have testified unequivocally that the payments to Ranbaxy substantially delayed the generic entry date: "[e]conomic analysis of the terms of the [Ranbaxy] settlement *clearly imply that the settlement implemented a delay* in generic entry beyond what could have been expected if the parties had continued with litigation."[70] The massive payment to Ranbaxy "vastly exceeds expected litigation costs …. AstraZeneca was willing to make a payment of this magnitude because *it is buying more exclusivity* and profits than it expected in the competitive (litigation) outcome."[71] And again: "*Only when … the delay is very long* would Ranbaxy require such a massive financial transfer to agree to the delay in entry."[72]

The jury heard none of this critical testimony that demonstrates that, indeed, but for the reverse payment there *would* have been a settlement with an earlier entry date. AstraZeneca, a rational profit maximizing entity concluded that it was in its economic self-interest to pay Ranbaxy consideration worth hundreds of millions of dollars to settle their patent suits with an entry date of May 27, 2014, rather than litigate the patents and subject itself to the risk that it could lose the patent suits and suffer greater economic harm than it was in paying Ranbaxy if Ranbaxy, or another entity in a venture with Ranbaxy, came to market "at risk." The jury's answer of "no" to Question 4 (putting aside, *arguendo*, the contradiction with the jury's "yes"

[70] August 23, 2013 Report, at ¶ 178 (emphasis added); *see also id*. at ¶¶ 2, 3; October 25, 2013 Report, at ¶ 2. Other than Dr. McGuire's testimony about the economic framework generally applicable to whether payments from brand pharmaceutical companies to generic pharmaceutical companies delay generic entry, *see generally* 11/07/14 Trial Tr. (ECF No. 1409 and 1410) at 57:20-92:3, the only aspect of the AstraZeneca-Ranbaxy payment the Court permitted Dr. McGuire to testify about was AstraZeneca's and Ranbaxy's incentives to enter into the no-authorized generic agreement.

[71] August 23, 2013 Report, at ¶ 179 (emphasis added).

[72] *Id*. at ¶ 180 (emphasis added). A more complete recitation of the AstraZeneca-Ranbaxy payment evidence the Court precluded Dr. McGuire from explaining to the jury can be found in Plaintiffs' Evidentiary Proffer as to Dr. Thomas G. McGuire (ECF No. 1282).

answer to Question 3 and the improper framing of Question 4) suggests that the jury believed that AstraZeneca would have decided to continue its patent litigation against Ranbaxy rather than agree to *any* entry date before May 27, 2014. The testimony of Dr. McGuire which the Court improperly excluded would have helped the jury understand that any such belief on its part would contravene basic economic logic. No rational, profit-maximizing brand company pays a generic competitor many multiples of the brand's expected litigation costs *unless* it is buying more delay than the brand expects it could achieve without the payment. Eliminating the payment does not eliminate the risk, which was AstraZeneca's management's goal in entering into the settlement in the first place. The settlement is proof that AstraZeneca's management had already made the decision to eliminate the risk of the patent case by transferring to Ranbaxy consideration worth hundreds of millions of dollars. If AstraZeneca could not use the No AG and side deals as consideration, it would have been left with negotiating an earlier entry date to achieve its goal of eliminating the risk of losing the patent suit. In sum, Dr. McGuire's excluded testimony would have enabled the jury to understand that (1) AstraZeneca's large payment moved the entry date back, later than AstraZeneca expected it could have achieved without the payment; (2) without making the large payment, AstraZeneca as a rational profit-maximizing company would have agreed to an earlier entry date; and (3) that date by definition would have been *before* May 27, 2014.

These opinions were buttressed by mounds of other summarily precluded testimony, including:

- Testimony, supported by FTC studies, that manufacturers have historically used No-AG clauses to delay generic entry;[73]

[73] *Id*. at ¶¶ 54-62; *see also id*. at ¶ 122.

- Testimony, supported by Defendants' documents and a detailed, elaborate economic analysis, that the value of the No-AG clause to Ranbaxy was $750 million ($499 million in real, *i.e.*, present-day-discounted dollars);[74]

- Testimony, supported by Defendants' own documents, that the value of the side deals to Ranbaxy was $37.6 million to $57.5 million;[75]

- Testimony, again supported by detailed economic analysis and Defendants' own documents, that the payments to Ranbaxy were more than Ranbaxy could have earned if it had won the patent litigation;[76]

- Testimony that the purpose of the side deals was to give Ranbaxy an income stream during the period of time that it had agreed to delay entry;[77]

- Testimony, supported by Defendants' own documents and a detailed, elaborate economic analysis, that the cost to AstraZeneca of foregoing an authorized generic was some $600 million;[78] and

- Testimony analyzing these enormous payments under Dr. McGuire's general economic framework (to which he had previously testified) for determining whether a payment is "strong economic evidence that there *has been a delay*."[79]

All of this testimony – some 75 paragraphs in Dr. McGuire's opening and rebuttal reports – bears directly on what would later turn out to be Question 4 of the verdict slip. The evidence was more than relevant – it was critical to Plaintiffs' case-in-chief on an issue that the Court subsequently made into a specific question on the verdict slip.

The Court stated that it excluded this testimony on the belief that it went "simply [to] … the enormous value of the AstraZeneca-Ranbaxy settlement to AstraZeneca."[80] That belief was

[74] *Id*. at ¶¶ 158-168; *see also id*. at ¶¶ 120-129; October 25, 2013 Report, at ¶¶ 71-76.

[75] August 23, 2013 Report, at ¶¶ 169-177; *see also id*. at ¶ 70.

[76] *Id*. at ¶ 166. *See Actvais*, 133 S. Ct. at 2235 (discussing a payment of this size as being especially suspect).

[77] *Id*. at ¶¶ 169-170.

[78] *Id*. at ¶ 131; *see also id*. at ¶¶ 136 – 137, 139 – 157. The Court prohibited all detailed testimony about the cost to AstraZeneca of foregoing an authorized generic. *See, e.g.*, 11/13/14 Tr. 37:4-7, 61:19, 62:24-63:4, 63:21-22; 64:3-4, 64:11-12, 69:17-22, 70:14-16, 72:16-22, 75:19-25. Plaintiffs were limited to posing the question to Dr. McGuire "what observations, if any, did you make regarding the economic incentives of AstraZeneca to erect and strength the bottleneck." *Id*. at 71:3-6.

[79] 11/07/14 Trial Tr. (ECF No. 1410) at 86:8-10 (emphasis added); *see also id*. at 86:14-20, 86:25-87:15, 88:12-22. Dr. McGuire's August 23, 2013 Report applied the value of these payments to his general economic pay-for-delay economic framework. *See* August 23, 2013 Report, at ¶¶ 73, 120.

mistaken. As is plain from the summary above, this evidence went to the fundamental point that a large payment by the brand to the generic *moves back the generic entry date*. That, of course, is the very subject of what would later become Question 4.

The Court's erroneous exclusion of this vital evidence warrants a new trial.

b. Dr. McGuire would have given relevant testimony about a *specific* competitive entry date.

The Court also precluded Dr. McGuire from opining regarding the specific entry date to which reasonable manufacturers would have agreed in the absence of unlawful payments. Had he been permitted to do so, Dr. McGuire would have testified that if such manufacturers had resolved the Nexium patent litigation without a large reverse payment, then the agreed launch date would have been on or about January 17, 2011.[81] This evidence went directly to both Question 4 and what later became Question 5.

Dr. McGuire would have explained that investors' collective expectations may be used as a proxy for what a rational actor who had a financial stake in the agreement would have agreed to regarding a generic entry date in a settlement without a large reverse payment.[82] The movement in AstraZeneca's market capitalization when it announced its unlawful settlement with Ranbaxy reflected investors' changed expectations about the profits that would flow to AstraZeneca as a result of Defendants' settlement, and those market movements can be used to estimate the expected date of generic entry in settlement without a large reverse payment (as he described that concept during his November 7, 2014 testimony).[83]

[80] 11/20/14 Trial Tr. (ECF No. 1424) at 84:15-17.

[81] October 8, 2014 Report, at ¶¶ 16, 22.

[82] *Id*. at ¶ 3.

[83] *Id*. at ¶ 6.

Dr. McGuire would have testified that a rational actor in the position of AstraZeneca would have agreed to an entry date on or about January 17, 2011 as part of an agreement with no large payment.[84] Investors have a direct financial interest in AstraZeneca's business prospects, and their collective, objective judgment about when generic competition is expected is an economically sound basis for estimating the "expected date of generic entry" in the absence of a reverse payment settlement.[85] AstraZeneca earned approximately $1 billion per year on Nexium, so an increase of $3 billion upon the news of the settlement indicates that the market—before learning of the AstraZeneca-Ranbaxy settlement containing a massive reverse payment to Ranbaxy—had expected generic Nexium to be available approximately three years earlier than the agreed entry date of May 2014, or early 2011 (May 27, 2014 less 1226 days, *i.e.*, January 17, 2011).[86]

Dr. McGuire also would have testified that a rational actor in Ranbaxy's position would also have agreed to that earlier entry date without requiring a payment from AstraZeneca because the value to Ranbaxy of knowing for a certainty (i) it would keep its 180-day exclusivity and (ii) when it would come to market outweigh the cost to Ranbaxy of delaying market entry.[87] On April 15, 2008, investors bid up the stock of Ranbaxy by $356 million and of AstraZeneca by

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[84] *Id*. at ¶¶ 16, 22.

[85] *Id*. at ¶ 14.

[86] *Id*. at ¶¶ 13-14. Dr. McGuire described his calculation as follows:

> In 2008, AstraZeneca forecasted that it would make gross margins of $1.119 billion per year on Nexium. AstraZeneca would make some sales of Nexium even after loss of exclusivity. One forecast estimated that AstraZeneca would make $0.067 billion per year from brand Nexium sales post-generic entry. Thus, the additional profit per year associated with exclusivity was $1.052 billion. The extra time that would account for the $3.534 billion in value can be found by solving for the variable T in the following equation (where dollars are expressed in billions): T * $1.052 = $3.534, or, T = 3.4 years or 1,226 days. The elevation in market capitalization of almost $3 billion at the announcement of the AstraZeneca-Ranbaxy agreement containing a major payment to Ranbaxy implies that investors' expected date of generic entry was May 27, 2014 less 1,226 days, i.e., January 17, 2011.

[87] *Id*. at ¶¶ 17-20, 22.

almost $3 billion, in anticipation of the additional profits each would get as the result of the settlement *with* large reverse payments – the only explanation for this market reaction is that investors recognized that AstraZeneca would make billions of dollars in extra expected profits from higher prices paid by consumers and had agreed to share some of these profits with Ranbaxy, and these higher prices and profits had not been expected by the market.[88]

The jury, however, heard none of this testimony.[89] The jury was thus deprived of evidence that went directly to the specific entry date to which rational actors in AstraZeneca and Ranbaxy's positions would have agreed in the absence of a large payment.

The problem with Dr. McGuire's testimony, according to the Court, was a purported lack of "fit" between "the event study and this culmination of the case, when, um, Ranbaxy and Teva would have cut a deal but for the arguably anticompetitive agreements."[90] But Plaintiffs did *not* offer Dr. McGuire's testimony on the issue of when "Ranbaxy and Teva would have cut a deal," but on what entry date would have emerged from an AstraZeneca-Ranbaxy settlement *without* a large reverse payment. Plaintiffs offered *other* evidence as to when Ranbaxy and Teva would

[88] *Id*. at ¶ 23. A more complete recitation of the competitive entry date evidence the Court precluded Dr. McGuire from explaining to the jury can be found in Plaintiffs' Evidentiary Proffer as to Dr. Thomas G. McGuire (ECF No. 1282).

[89] Because the Court severely restricted Dr. McGuire's testimony, he was also prevented from rebutting any of the purported procompetitive justifications offered by Defendants in connection with the jury's consideration of Question 3. For example, he was specifically precluded from offering, *inter alia*, the following opinions: (a) risk aversion by AstraZeneca managers could not account for the size of the reverse payment to Ranbaxy (or the settlement generally) (August 23, 2013 Report, at ¶¶ 142-157); (b) the May 27, 2014 license date did not provide for "early entry" since reasonable actors in AstraZeneca's and Ranbaxy's shoes would have entered a competitive settlement with licensed entry in January 2011 (October 8, 2014 Report, at ¶¶ 4, 13-14); (c) AstraZeneca's theoretical ability to offer price discounts on branded Nexium to compete with generic Nexium after generic entry would not outweigh the anticompetitive effects of the no-authorized generic agreement because, *inter alia*, price competition between an authorized generic and ANDA generics is much more swift and effective than price competition between branded and generic products (October 25, 2013 Report, at ¶¶ 42-44); (d) even assuming some level of cannibalization of Nexium profits from Nexium OTC entry, the no-authorized generic clause cost AstraZeneca much more than its saved litigation expenses (*id*. at ¶¶ 11-16); and (e) the conceptually correct basis for assessing the value of the agreements is the participants' expectation at the time, *i.e.*, if AstraZeneca believed it was paying more than saved litigation costs then that is an indication that the agreed-upon delay was increasing AstraZeneca's profits in relation to the date of generic entry expected with litigation (*id*. at ¶ 45).

[90] 11/20/14 Trial Tr. (ECF No. 1424) at 83:13-17.

have reached an agreement.[91] For all the reasons identified in their Motion to Permit Dr. McGuire to Testify Concerning Entry Date and Request for Oral Argument,[92] which Plaintiffs incorporate by reference herein, there is a perfect "fit" between Dr. McGuire's opinion as to "what a rational actor who had a financial stake in the transaction would have expected in terms of the date of anticipated generic entry and agreed to in terms of settlement"[93] in the absence of a payment, and a fact in issue[94] in the case – when reasonable pharmaceutical companies would have agreed generic entry could occur in the absence of a massive payment from the brand to the generic company.

c. The Court prevented Dr. McGuire from rebutting Defendants' evidence.

Although Defendants presented evidence in their case-in-chief that they purportedly would never have agreed to a date earlier than May 27, 2014, and that May 27, 2014 entry was "early," not delayed,[95] the Court prohibited Plaintiffs from offering evidence to counteract this testimony. And despite the Court's stated concern that it did not "see the evidence that will support a month and year"[96] for an earlier agreed license date in a no-payment settlement – "a

[91] *See, e.g.*, testimony about analogous Lipitor agreement: 10/30/14 Trial Tr. (ECF No. 1396) at 112:24-122:3 (Staci Julie); 11/10/14 Trial Tr. (ECF No. 1412) at 145:16-155:10 (Venkat Krishnan); 11/18/14 Trial Tr. (ECF No. 1420) at 68:19-78:19 (Cheryl Blume); 11/18/14 Trial Tr. (ECF No. 1421) at 87:6-90:14, 91:20-95:1; 12/01/14 Trial Tr. (ECF No. 1436) at 92:19-102:16, 118:7-120:6.

[92] ECF No. 1325. Plaintiffs also incorporate by reference herein the following briefs related to the admissibility and reliability of Dr. McGuire's testimony: Plaintiffs' Opposition to Defendants' Motion to Exclude the Supplemental Declaration of Thomas McGuire (ECF No. 1207); Plaintiffs' Opposition to Defendants' Motion to Exclude Dr. McGuire's Event Study (ECF No. 1246); and Plaintiffs' Supplemental Trial Brief in Support of Dr. McGuire's Event Study (ECF No. 1254).

[93] October 8, 2014 Report, at ¶ 3.

[94] *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993) ("Rule 702 further requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.' This condition goes primarily to relevance….The consideration has been aptly described by Judge Becker as one of 'fit.'").

[95] *See supra*, Section III. A. 4.

[96] 11/24/14 Trial Tr. (ECF No. 1431) at 6:18-19.

concern that the plaintiffs can counter"[97] – the Court did not permit Plaintiffs to put on any rebuttal evidence after that point to address the Court's concern.

After the Court ruled that Dr. McGuire could offer no more testimony in Plaintiffs' case-in-chief, Plaintiffs sought permission from the Court for Dr. McGuire to testify concerning the competitive entry date during Plaintiffs' rebuttal case.[98] Plaintiffs explained in detail, *inter alia*, how Dr. McGuire's opinion "fit" the purpose for which it was being offered. The Court denied Plaintiffs' request without providing any reasoning for its ruling.[99] In so doing, the Court precluded Dr. McGuire from testifying—in Plaintiffs' case-in-chief or on rebuttal—about matters at the heart of what became Questions 4 and 5, *i.e.*, a competitive entry date in a no-payment settlement.

2. The Court improperly excluded competitive entry date opinion testimony of Dr. Leffler.

Plaintiffs also sought to introduce, in their rebuttal case, the testimony of another economist, Dr. Keith Leffler, Ph.D., as an alternative to the rebuttal testimony of Dr. McGuire, to "show the jury that reasonable actors in AstraZeneca's and Ranbaxy's positions would have agreed to an earlier date in a no-payment settlement scenario."[100] As with Dr. McGuire, Plaintiffs offered the testimony of Dr. Leffler on matters directly relevant to Questions 4 and 5, *i.e.*, a competitive entry date in a no-payment settlement, in order to rebut testimony elicited from AstraZeneca and Ranbaxy in Defendants' case-in-chief (including by Defendants' last

[97] *Id*. at 7:9-10.

[98] Plaintiffs' Motion to Permit Dr. McGuire to Testify Concerning Entry Date and Request for Oral Argument (ECF No. 1325).

[99] *See* 12/01/14 Trial Tr. (ECF No. 1436) at 161:15-19 ("So document ECF No. 1325, Plaintiffs' motions to permit Dr. McGuire to testify concerning entry date, denied.... Defendants' amended motion to exclude purported rebuttal testimony of McGuire, Leffler and Barker, allowed.").

[100] *See* Plaintiffs' Opposition to Defendants' Amended Motion to Exclude the Rebuttal Testimony of Dr. Keith Leffler (ECF No. 1334), at 1-2.

witness) that those specific (bad) actors would never have agreed to any entry date other than May 27, 2014.[101] Plaintiffs emphasized that the critical issue was not whether AstraZeneca and Ranbaxy would have agreed to an earlier date, but whether "two reasonable companies in the same position, acting in their own economic self-interest, would have had an economic interest in agreeing to an earlier date."[102]

Dr. Leffler was prepared to testify that an entry date for an alternative settlement with no reverse payments that would have been acceptable to reasonable actors in AstraZeneca's and Ranbaxy's positions can readily be determined based upon well-recognized principles of expected value, *i.e.*, whether the expected value of settling is greater than the expected value of continued litigation.[103]

Dr. Leffler would have testified that had AstraZeneca and Ranbaxy each had an equal chance of winning the Nexium patent case, *i.e.*, the patent case was a coin flip, AstraZeneca would accept a settlement without payment to Ranbaxy with an entry date of February 2012 rather than pursue the litigation.[104] Dr. Leffler would have opined that Ranbaxy also would accept the February 2012 alternative entry date -- but with competition from AstraZeneca's authorized generic -- as long as Ranbaxy's expectation of winning were less than 82% – substantially higher than the expectations viewed in the market at the time of settlement.[105]

[101] 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 115:18-116:17.

[102] *Id.* at 116:17-20.

[103] Supplemental Expert Report of Keith Leffler, Ph.D., Oct. 6, 2014 ("Leffler Rpt."), at ¶ 3. This report is attached as Exhibit C to Plaintiffs' Evidentiary Proffer As To Dr. Keith Leffler (ECF No. 1351).

[104] *Id.* at ¶ 4.

[105] *Id.* at ¶ 4, nn.4, 6. A more complete recitation of the competitive entry date evidence the Court precluded Dr. Leffler from explaining to the jury can be found in Plaintiffs' Evidentiary Proffer As To Dr. Keith Leffler (ECF No. 1351).

The Court ruled, however, that Dr. Leffler's testimony was not proper rebuttal and excluded his testimony entirely.[106] Plaintiffs thus filed another evidentiary proffer, this time regarding the evidence Dr. Leffler would have presented to the jury as to what a competitive, no-payment settlement between reasonable companies would have looked like.[107]

3. The Court improperly excluded competitive entry date evidence from an FTC study.

Plaintiffs also sought to introduce in their rebuttal case a government study conducted by the Federal Trade Commission, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions."[108] The FTC study concluded that settlements with payments from the brand to the generic on average prohibit generic entry seventeen months longer than settlements without payments.[109] Seventeen months before May 2014 is December 2012.

The study was relevant to a competitive entry date that would have been reached by reasonable actors in a settlement without payments, and it rebutted Defendants' evidence that AstraZeneca and Ranbaxy would never have agreed to any entry date before May 27, 2014 even if AstraZeneca had not made a large payment to Ranbaxy.[110] Although the Court found the FTC study to be admissible,[111] the Court improperly excluded the FTC study as rebuttal evidence because it was "central to the case."[112]

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[106] 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 117:5-6.

[107] Plaintiffs' Evidentiary Proffer As To Dr. Keith Leffler (ECF No. 1351).

[108] Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study (Jan. 2010), available at http://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff. This study (the "FTC study") was on plaintiffs' exhibit list and marked for identification as FAX.

[109] 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 112:13-18; FAX, FTC Report at pp. 2, 4.

[110] *See* 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 112:13-113:3.

[111] *Id*. at 115:11-13.

[112] *Id*. at 115:11-16.

4. The erroneous exclusion of Plaintiffs' objective, economic evidence influenced the verdict.

a. Erroneous evidentiary rulings warrant a new trial.

"An erroneous evidentiary ruling requires vacation of a jury verdict if the ruling excludes evidence and the exclusion results in actual prejudice because it had a substantial and injurious effect or influence in determining the jury's verdict."[113] A new trial must be granted unless the Court can "say with a fair degree of assurance that the erroneous ruling did not substantially sway the jury."[114] All that must be shown is a reasonable likelihood that the error influenced the jury's verdict.[115] Plaintiffs can easily satisfy this burden. The erroneous exclusion of expert testimony substantially influences the jury's verdict where a party is prevented from challenging arguments that are vital to the case,[116] and where the cumulative effect of the court's rulings can be said to have swayed the jury.[117] This is precisely the situation presented here.

From the start, the Court severely handicapped Plaintiffs' ability to present their evidence regarding the large and unjustified payment to Ranbaxy and how, and by how much, that large payment affected the entry date that reasonable pharmaceutical companies would have agreed to in a no-payment settlement. Then, in an abrupt about-face, the Court ruled it would permit Plaintiffs to put on this evidence in their case-in-chief. But then, just as abruptly, the Court reversed course again. The result was that the Court precluded Plaintiffs from offering this

[113] *Ruiz-Troche* , 161 F.3d at 87(internal quotation omitted).

[114] *Id*.

[115] *Blake v. Pellegrino*, 329 F.3d 43, 49 (1st Cir. 2003) (new trial is warranted where there is a reasonable likelihood that error influenced the eventual verdict).

[116] *Blake*, 329 F.3d at 49 (new trial warranted where improperly excluded evidence was the "centerpiece" of plaintiffs' theory); *U.S. v. Shay*, 57 F.3d 126, 134 (1st Cir. 1995), *citing U.S. v. Versiant*, 849 F.2d 827, 832 (3d Cir. 1988) (error not harmless where improperly excluded evidence went to heart of the defense); *U.S. v. Oimette*, 753 F.2d 188, 193 (1st Cir. 1985) (error not harmless because excluded testimony was "the core of the defendant's case")).

[117] *See Ruiz-Troche*, 161 F.3d at 87 (vacating the judgment and ordering a new trial where the district court's exclusion of expert testimony "in cumulation, had a substantial and injurious influence upon the jury's determinations").

critical evidence at all in their case-in-chief. The Court then precluded Plaintiffs from introducing this evidence in rebuttal because it purportedly should have been introduced in Plaintiffs' case-in-chief. In closing, Defendants highlighted the hole the Court's exclusion of this evidence left in Plaintiffs' case on matters directly related to Questions 4 and 5 of the special verdict form. And then, without hearing Plaintiffs' evidence of a competitive entry date, the jury returned a "no" answer to Question 4 even though it had found (in answering Question 3) that the *anticompetitive effects* of the AstraZeneca-Ranbaxy agreement *outweighed* any procompetitive benefits.

On this record, there is clearly a reasonable, indeed a very high, likelihood that the Court's errors influenced the eventual verdict.[118] The Court should grant Plaintiffs' motion for a new trial.

b. Rebuttal evidence properly counteracts evidence presented by the opposing party.

The Court was apparently of the view that Plaintiffs were precluded from offering in their rebuttal case any evidence that may conceivably have been introduced during their case-in-chief.[119] But Plaintiffs *did* offer the Dr. McGuire testimony in Plaintiffs' case-in-chief: Plaintiffs offered it *again* in rebuttal. And once the Court refused to permit further economic testimony from Dr. McGuire in Plaintiffs' case-in-chief, Plaintiffs reasonably concluded that the ruling applied to calling Dr. Leffler in our case-in-chief as well.

As to the FTC study, the Court has the law wrong. "The fact that testimony would have been more appropriately offered during the proponent's case-in-chief does not preclude its

[118] *Blake*, 329 F.3d at 49 (new trial warranted because exclusion of key evidence mid-trial was not harmless).

[119] *See* 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 115:11-16 (excluding FTC Study because it went to an issue that was "central to the case"). The Court did not give any reason as to why the testimony of Dr. McGuire or Dr. Leffler did not constitute proper rebuttal evidence.

admission as rebuttal evidence."[120] Thus, even if Plaintiffs could have offered the FTC study in our case-in-chief, that does not justify its exclusion in rebuttal – particularly since, in the Court's own view,[121] such evidence was "vital" to Plaintiffs' case.[122] The fact that Plaintiffs' competitive entry date evidence was "central to the case" supports *permitting* rebuttal testimony, it does not preclude it. "A court's discretion should be tempered greatly where the probative value of proffered evidence is potentially high and where such evidence, though admissible on the case in chief, was unnecessary for the Plaintiff to establish in its *prima facie* case."[123] Here, *the Court did not permit Plaintiffs to put on, during their case-in-chief, evidence regarding the size of the payment from AstraZeneca to Ranbaxy or how much delay that huge payment bought*.[124]

The "function of rebuttal is to explain, repel, counteract or disprove the evidence of the adverse party."[125] That is precisely the function that Plaintiffs offered the FTC study to perform. As explained above, Plaintiffs offered this evidence of a competitive entry date in a no-payment settlement to "explain, repel, counteract or disprove" Defendants' evidence that AstraZeneca and Ranbaxy purportedly would never have agreed to an entry date before May 27, 2014, and that the

[120] *U.S. v. LiCausi*, 167 F.3d 36, 52 (1st Cir. 1999); *Luschen*, 614 F.2d at 1170-71.

[121] *See supra* at Section III. B. 1. c.

[122] *Kaczmarek v. Allied Chemical Corp.*, 836 F.2d 1055, 1061-62 (7th Cir. 1988) (trial judge abused its discretion in excluding the rebuttal testimony of a witness that could have been called in plaintiff's case-in-chief where rebuttal testimony was "vital" to plaintiff's case). *See also U.S. v. Grintjes*, 237 F.3d 876, 879 (7th Cir. 2001) (upholding the district court's allowance of introduction of rebuttal evidence where the government "had no way to know whether Grintjes would testify at all, much less what he would say[.]").

[123] *Weiss v. Chrysler Motors Corp.*, 515 F.2d 449, 457–58 (2d Cir.1975) (holding that district court abused its discretion by precluding rebuttal testimony).

[124] *See supra* at Section III. B. 1.

[125] *U.S. v. Clotida*, 892 F.2d 1098, 1107 (1st Cir. 1989) (quoting *U.S. v. Luschen*, 614 F.2d 1164, 1170 (8th Cir. 1980)); *see also* Black's Law Dictionary (9th ed. 2009) (defining "rebuttal evidence" as "[e]vidence offered to disprove or contradict the evidence presented by an opposing party. Rebuttal evidence is introduced in the rebutting party's answering case; it is not adduced, *e.g.*, through cross-examination during the case-in-chief of the party to be rebutted.").

delayed May 27, 2014 generic entry was somehow "early."[126] It was particularly egregious for the Court to refuse to permit Plaintiffs to counteract in their rebuttal case Defendants' "early" entry evidence because such evidence was offered by Defendants in their case-in-chief as a procompetitive justification for the settlement *and* a reason that AstraZeneca would not have agreed, in the absence of being able to make a large payment, to an earlier entry date. The rule of reason applicable to Plaintiffs' antitrust claims requires that Plaintiffs be afforded the opportunity to rebut any asserted procompetitive justifications.[127] Yet the Court denied Plaintiffs that opportunity at trial.

Plaintiffs also asked the Court to instruct the jury on less restrictive alternatives, in accordance with *Sullivan v. NFL*, an instruction that would have helped the jury to understand that an alternative settlement without a payment was plausible (and did not depend on whether AstraZeneca, subjectively, would have wanted to accept an earlier entry date);[128] the Court declined to give Plaintiffs proposed instruction.[129]

c. Defendants compounded the problem by arguing in closing that Plaintiffs offered no rebuttal testimony.

Compounding the problem, during closing arguments the Defendants highlighted the fact that Dr. McGuire had not given an opinion on a competitive entry date to rebut Defendants'

[126] *See supra* at Section III. A. 4. As explained herein at Section III. C. 1., it also constituted meaningful error for the Court to permit Defendants to defend the settlement on the grounds that it provided for generic entry before the expiration of the patents. Such a defense simply amounts to the discredited "scope of the patent" test that was overruled by *Actavis*.

[127] *See, e.g., Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 422 (D. Del. 2006) ("[I]f such a [procompetitive] justification were offered, the plaintiff could rebut it or, alternatively, establish antitrust liability by demonstrating that 'the anticompetitive harm of the conduct outweighs the procompetitive benefit.' That balancing approach embodies the familiar 'rule of reason' test . . . articulated by the Supreme Court[.]") (citations omitted).

[128] 12/04/14 Trial Tr. (ECF No. 1443) at 5:18-22, 10:13-22; see also 12/02/14 Charge Conf. Tr. (ECF No. 1437) at 17:24-19:11; Plaintiffs' Submission Regarding Objective Standard on Jury Verdict Form (ECF No. 1358), at 1.

[129] 12/04/14 Trial Tr. (ECF No. 1443) at 5:18-22, 10:24-25.

evidence that May 27, 2014 was the only date AstraZeneca and Ranbaxy purportedly would have agreed to. Counsel for Ranbaxy argued:

> In fact, the only evidence is that the only date AstraZeneca would accept is May 27, 2014. You know that from Venkat, Deshmukh, Pott, Stacie Julie. Dr. McGuire tried to tell you that, well, whenever there's a payment there might be delay…. If the great Dr. McGuire - - and I mean that sincerely, brilliant man - - could not tell you a date, there is no evidence in the record and no one else is going to be able to guess the date.[130]

Dr. McGuire and Dr. Leffler's opinions would have undermined the credibility of AstraZeneca and Ranbaxy's witnesses who testified they believed AstraZeneca and Ranbaxy would have been unwilling to agree to any other entry date. Instead, Ranbaxy's counsel was left free to suggest (falsely) in closing that Dr. McGuire had been unable -- in the (here false) sense of lacking the expert ability to provide -- to offer the jury a "but for" date. Plaintiffs should not have been punished for failing to put on evidence in their case-in-chief that the Court prevented Plaintiffs from putting on in their case-in-chief.

C. The Court's inconsistent patent instructions and its Hobson's choice on "at risk launch" contributed to the jury's contradictory response to Question 4.

1. On liability, settling for a date before patent expiration cannot immunize Defendants from antitrust scrutiny.

The Court's instructions and off-hand remarks to the jury about the presumed validity of AstraZeneca's patents suggested that an entry date before patent expiry may immunize AstraZeneca from antitrust liability. The Court's instructions were in error and warrant a new trial.

Two observations about *Actavis* on patents:

[130] *See* 12/03/14 Trial Tr. (ECF No. 1440) at 112:21-113:10.

First, *Actavis* held that the "scope of the patent" test was wrong as a matter of law; settling for a date prior to patent expiry does not avoid antitrust scrutiny.[131]

Second, *Actavis* held, explicitly, that Plaintiffs need not prove that the patents at issue are invalid in order to prove an antitrust violation.[132] *Actavis* held that a large payment is strong economic evidence that the settlement pushed out the generic entry date that otherwise would have been agreed to by the parties.[133] And "[a] large, unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the patent's validity."[134]

In light of these observations, Plaintiffs proposed jury instructions that told the jury, concretely, that (1) "[t]he mere fact that AstraZeneca has patents relating to Nexium – whether

[131] *Actavis*, 133 S. Ct. at 2230 ("Solvay's patent, if valid and infringed, might have permitted it to charge drug prices sufficient to recoup the reverse settlement payments it agreed to make to its potential generic competitors. And we are willing to take this fact as evidence that the agreement's 'anticompetitive effects fall within the scope of the exclusionary potential of the patent.' But we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack.") (citation omitted). *See also id.* at 2231 ("contrary to the Circuit's view that the only pertinent question is whether 'the settlement agreement ... fall[s] within' the legitimate 'scope' of the patent's 'exclusionary potential,' 677 F.3d, at 1309, 1312, this Court has indicated that patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent."); *id.* at 2231-232 ("whether a particular restraint lies 'beyond the limits of the patent monopoly' is a *conclusion* that flows from that analysis and not, as THE CHIEF JUSTICE suggest, its starting point.") (emphasis in original).

[132] *Actavis*, 133 S. Ct. at 2237 ("These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases. *To say this is not to require the courts to insist*, contrary to what we have said, *that the Commission need litigate the patent's validity*… As a leading antitrust scholar has pointed out, '[t]here is always something of a sliding scale in appraising reasonableness,' and as such 'the quality of proof required should vary with the circumstances.'" (emphases added) (citing *California Dental Assn. v. FTC*, 526 U.S. 756, 786–787 (1999) and 7 Areeda ¶ 1507, at 402 (1986)).

[133] 133 S. Ct. at 2236("An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness. 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.") (emphasis added).

[134] *Actavis*, 133 S. Ct. at 2229; *see also* 10/21/14 Trial Tr. (ECF No. 1385) at 37:18-22 (instructing the jury that, "In a word, 'The size of the unexplained reverse payment,' that is from the patent holder, AstraZeneca, to Teva, the challenger, 'can provide a workable surrogate for a patent's weakness.'").

they expired before or after May 27, 2014 – is not a defense;"[135] (2) "AstraZeneca and Ranbaxy are not immune from antitrust liability just because their agreement permitted generic entry before AstraZeneca's last Nexium patent expired;"[136] and (3) "Plaintiffs do not have to prove that any of AstraZeneca's Nexium patents is invalid or would not have been infringed in order to prove that Defendants violated the antitrust laws."[137]

But the Court ignored *Actavis* and Plaintiffs' proposed instructions and repeatedly suggested to the jury that AstraZeneca's patents gave it a lawful monopoly and, therefore, that settling for an "earlier" entry date was a legitimate procompetitive justification:

- "[I]f you get a patent from the Patent Office, that gives you the legal right to, um, practice your invention, license your invention and make money from licensing it, and to exclude other people from practicing your invention, imitating your invention."[138]
- "a patent gives you – and we're going to talk about monopoly here and monopoly power, a patent is a lawful monopoly, it gives you that lawful monopoly for a period of years."[139]
- "Remember, AstraZeneca had a lawful patent monopoly as to its branded drug Nexium and any imitator that was the same that actually infringed Nexium, whatever you called it, and that's the patent laws."[140]
- "It's not a violation of the antitrust laws -- it's not a violation of the antitrust laws that AstraZeneca have market power from its patent monopoly…"[141]
- "one [procompetitive justification] that you may consider is where, with respect to the expiration of patents that you think make a difference, was the agreed-upon date?"[142]

[135] Plaintiffs' Proposed Jury Instructions (ECF No. 1333-3), at Proposed Jury Instruction 18, p. 35.

[136] *Id.* at Proposed Jury Instruction 19, p. 36.

[137] *Id.* at Proposed Jury Instruction 18, p. 35.

[138] 12/03/14 Trial Tr. (ECF No. 1438) at 21:24-22:4.

[139] *Id.* at 22:6-9.

[140] *Id.* at 32:15-18.

[141] *Id.* at 33:18-20.

[142] *Id.* at 38:10-12.

The Court also made remarks to the jury midtrial that suggested that the mere existence of the patents could serve as a barrier to antitrust liability. During the testimony of Dr. McGuire, the Court told the jury:

> [K]eep in mind that they had patents for this item. So earning this money, unless the antitrust laws have been abused, the issues that will be before you, they had patents. No one's declared those patents invalid. And that is one of the returns, in order to give companies an incentive to do the research and develop worthwhile medicines and things, we have this patent law. So if you believe that's true and they were earning them, well, they had patents.[143]

The Court's instructions were confusing, wrong as a matter of fact and law, and had a genuine potential for creating contradictory responses to Questions 3 and 4. Given the incorrect framing of Question 4 and the erroneous instructions on patent law, the jury may have mistakenly thought "Why would AstraZeneca have agreed to an earlier entry date if it had a lawful monopoly based on presumptively valid patents that extended out until 2018?" But, as discussed above, this is the wrong question and is premised on an incorrect articulation of antitrust law (as announced in *Actavis*).

The Court's instructions and off-hand remarks to the jury about the presumed validity of AstraZeneca's patents suggested that an early entry date before patent expiry may immunize AstraZeneca from liability. The Court's instructions were in error and warrant a new trial.

2. On causation, whether the Plaintiffs showed that AstraZeneca's patents were invalid is irrelevant.

There are three ways that the patent merits may be relevant to causation.

[143] 11/13/14 Trial Tr. (ECF No. 1419) at 74:25-75:8. *See also* 12/03/14 Trial Tr. (ECF No. 1440) at 160:22-161:4 ("Let's just be clear about one thing. On the record that's before you, we don't know how some other Court and other jury, if they ever got to the merits of any of these patents, would have come out. It's not inappropriate to argue to you risks and the like, but on this record there is no evidence that any of these patents at the end of the day would have been held invalid. I'll say that.")

First, Plaintiffs could try to show that it was more likely than not that the generic would have won the patent infringement litigation. The Court ruled out this theory in its ruling on summary judgment,[144] and Plaintiffs did not try to show this at trial. Despite the fact that the Court prevented Plaintiffs from pursuing the argument, the Court simultaneously seemed to suggest to the jury that Plaintiffs had failed to present evidence that the patents would have been found invalid (*see supra* Section C. 1.).

Second, Plaintiffs could try to show that a generic thought so little of the merits of AstraZeneca's patents that it would have launched "at risk," before the merits of the patents were finally resolved by the courts. Given the Hobson's choice presented by the Court, Plaintiffs did not argue at risk launch in their closing argument.

Finally, Plaintiffs could address the role that the parties' evaluations of the patent merits played in their actual settlement negotiations, and let those views inform the jury about what would have happened in the absence of a payment-laden settlement. But the evidence actually adduced at trial – through the selective waiver of the attorney-client privilege on topics where Plaintiffs had previously been prevented from discovering the Defendants' views – showed that the Defendants did not form views of the patent merits at the time, and in any event the patent merits played no role in their settlement negotiations at any stage. It is simply not possible to resurrect the negotiations between the Defendants at the point in time before the payment entered

[144] Memorandum and Order on Summary Judgment, ECF No. 977, pp. 126-127 (Sept. 4, 2014) ("The Plaintiffs also posit an alternative scenario, arguing that a reasonable jury could find that if Teva had decided not to settle with AstraZeneca, Teva would ultimately have prevailed in its litigation and obtained final, non-appealable judgments that AstraZeneca's Nexium patents were invalid or not infringed…. This second scenario, however, is sheer speculation, and the Court pays it no mind. It is too speculative as matter of law to assume that Teva would have prevailed in all its actions and seen those rulings affirmed by the Federal Circuit."). We reserve all appellate rights as to this and other aspects of the Court's ruling on summary judgment.

into the equation based on their perceptions of the patent merits; those conditions never existed.[145]

Against this backdrop, for the Court to offer up the strength of the patents as a bar to causation is wrong as both a matter of fact and law. It is wrong as a matter of fact because, on this record, the patent merits did not enter into the Defendants' negotiations. And it is wrong as a matter of law because *Actavis* acknowledges the risks associated with Paragraph IV Hatch Waxman litigation and rejects the position that patents are a bar to antitrust liability.[146]

[145] Given the parties' total disregard for the patent merits, Plaintiffs thus tried to prove what the competitive conditions would have resulted in in other ways. Plaintiffs tried to present evidence, well grounded in econometrics, about what the competitive conditions would have been in the absence of a payment through Dr. McGuire. Plaintiffs tried to present evidence related to handicapping the litigation through Dr. Leffler (*e.g.*, if the parties believed the patent merits were a coin flip, what date would they have agreed to?). Plaintiffs also tried to present statistical evidence, based on the FTC's analysis that showed payment-free settlements on average result in generic entry 17 months earlier. As discussed above, the Court prevented Plaintiffs from introducing any of this evidence.

[146] The Court, on no less than half a dozen occasions, precluded Defendants from introducing evidence of events occurring on or after May 27, 2014. *See, e.g.*, 10/30/14 Trial Tr. (ECF No. 1399) at 140:4-7; s*ee generally* Appendix A at A16-A18; Appendix D. But the Court's application of this ruling was inconsistent and confusing, sometimes permitting witnesses to speak about events that occurred after May 27, 2014. *See, e.g.*, 11/24/14 Trial Tr. (ECF No. 1431) at 44:5-11. Defendants AstraZeneca and Ranbaxy repeatedly argued in closing post-May 27, 2014 evidence, *i.e.*, as of today, generic Nexium had not received FDA approval and was not on the market). *See* Appendix A. The Court denied Plaintiffs' request for a curative instruction regarding Defendants' many post-May 27, 2014 arguments during the closing arguments. 12/3/14 Trial Tr. (ECF No. 1440) at 160:17-20. As a result, the jury may have (incorrectly) concluded that if a generic had not come to market to date, it could not have come to market earlier than May 27, 2014.

3. On "at risk launch," Plaintiffs should not have faced a Hobson's choice.[147]

Question 4 further compounded jury confusion because it conveyed to the jury that the only way generic Nexium could have come to market before May 27, 2014 was if AstraZeneca would have agreed to an earlier entry date in the absence of a large and unjustified payment. But Plaintiffs should have been permitted to present the alternate possibility of an "at risk" launch without facing additional jury instructions on patents that were incorrect as a matter of law.

The jury heard evidence pertaining to at-risk launch, but was denied the opportunity to deliberate on that evidence.[148] Plaintiffs produced compelling evidence that AstraZeneca was afraid of, and preparing for, an at-risk launch well before May 27, 2014.[149] Rick Fante, Chief Operating Officer for U.S. Business at AstraZeneca, testified that one of the main reasons AstraZeneca considered making an authorized generic was that the company faced the threat of an at-risk launch.[150] Mr. Fante acknowledged that "Project Genesis" (AstraZeneca's internal name for its preparations to manufacture and launch an authorized generic version of Nexium)[151] continued to exist after the AstraZeneca-Ranbaxy settlement in April 2008 in the event Teva got

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[147] A "Hobson's choice" describes a situation in which your options are either to take what is offered (even when undesirable), or else take nothing at all. Thomas Hobson, immortalized by the poet John Milton, ran a stable near Cambridge University in the 17th century. Mr. Hobson had a stable of about 40 horses that he rented to students. He kept the most recently ridden horses at the rear of the stable and the more rested ones up front. When students came to rent a horse, Hobson gave them the first one in line –even if it was an old, sick, or otherwise undesirable horse – or no horse at all. *See*, *e.g.*, Milton, J., The Poetic Works of John Milton 199-200 (vol. 3 1874) (available at https://books.google.com/books?id=2nhAAAAAYAAJ&lpg=PA200&ots=9lsnb5yu0T&dq=milton%20hobson's%20choice&pg=PA200#v=onepage&q=milton%20hobson's%20choice&f=false). *See also I.N.S. v. Chadha*, 462 U.S. 919, 968 (1983) ("Without the legislative veto, Congress is faced with a Hobson's choice: either to refrain from delegating the necessary authority, leaving itself with a hopeless task of writing laws with the requisite specificity to cover endless special circumstances across the entire policy landscape, or in the alternative, to abdicate its law-making function to the executive branch and independent agencies."); *Oregon v. Kennedy*, 456 U.S. 667, 670 (1982) ("This personal attack left respondent with a Hobson's choice - either to accept a necessarily prejudiced jury, or to move for a mistrial and face the process of being retried at a later time.") (internal citation omitted).

[148] 11/24/14 Trial Tr. (ECF No. 1432) at 107:4-108:13.

[149] *Id*. at 103:7-9.

[150] *Id*. at 98:8-15, 102:23-103:6, 105:11-25.

[151] 11/07/14 Trial Tr. (ECF No. 1410) at 153:4-9, 155:6-11 (Rothwein); 11/13/14 Trial Tr. (ECF No. 1419) at 102:7-9 (Barker).

into the market and launched generic Nexium at-risk.[152] In fact, the evidence demonstrated that on July 29, 2008, after the settlement agreements between AstraZeneca and Ranbaxy were executed, AstraZeneca was letting its executives know that the authorized generic "[p]roduct is ready according to schedule and on hold."[153] Indeed, there was substantial testimony from AstraZeneca's witnesses that Project Genesis was initiated and that AstraZeneca had manufactured 110 million capsules of an authorized generic version of Nexium, all ready to be sold if a generic competitor launched a generic Nexium at-risk.[154] Only after the settlement agreements with Ranbaxy and Teva were executed, and any threat of "at risk" launch was extinguished, were those capsules then destroyed.[155]

Plaintiffs also established through several witnesses that Teva was a regular at-risk launcher.[156]

Despite the substantial evidence submitted to the jury concerning an at-risk launch, Plaintiffs were offered a Hobson's choice.[157] Plaintiffs could choose to have at-risk launch

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[152] 11/24/14 Trial Tr. (ECF No. 1432) at 108:5-13.

[153] *Id*. at 109:3-110:15.

[154] 10/27/14 Trial Tr. (ECF No. 1392) at 131:23-132:6, 132:19-133:8; 11/07/14 Trial Tr. (ECF No. 1410) at 153:4-9, 155:6-11; 11/13/14 Trial Tr. (ECF No. 1419) at 102: 7-12; 11/24/14 Trial Tr. (ECF No. 1432) at 103:10-17, 106:1-12.

[155] 11/24/14 Trial Tr. (ECF No. 1432) at 106:18-25.

[156] 10/30/14 Trial Tr. (ECF No. 1399) at 110:22-111:4; 11/21/14 Trial Tr. (ECF No. 1428) at 145:6-147:14, 147:24-148:2.

[157] 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 94:5-19:

> MR. GAFFNEY: So that the second-to-last paragraph of that deals with the lawfulness of the generic drug that would be on the market prior to the May 27th date. So some version of that will instruct the jury that if they're going to consider causation as a result of an unlicensed sale by Teva --
>
> THE COURT: I see your point. At least the first -- as you look at the paragraph there cannot be causation when the allegedly suppressed competition – I don't know as I like your language, but the idea if it was lawful, i.e., with the patents --
>
> MR. GAFFNEY: It's more important to me that you like the idea than the language, obviously.
>
> THE COURT: I like the idea. And if we're going to have at-risk launch, I'm going to give that.

See also id. at 95:13-97:9:

addressed on the jury slip and erroneous jury instructions conveying that companies cannot or do not launch at risk against putatively valid patents (which is both factually and legally inaccurate). Or, Plaintiffs could have no at-risk launch at all.

The Court made clear that if Plaintiffs were going to press forward with an at risk launch theory, then the Court would give jury instructions like the following:

> [I]f I give you at risk, I'm at least giving the charge that Mr. Gaffney has mentioned out of 31, and because I conceive that to be the law. And I think evenhanded I have to do this. I might want to reflect on whether you want me to do that, and I will hear you at

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THE COURT: What we are concerned about here is what people thought their risks were, then coming, if I give you at-risk launch, you seem to want that so much, if you want at-risk launch and, you know, I'm then going to say, In an at-risk launch, if it were to be held that the patent infringed, that the idea infringed, the competition infringed, then that's lawful, that's not antitrust harm. It just isn't if it's an infringing device. You don't cut down the patent monopoly by launching at risk against patents that are putatively valid.

MR. SOBOL: They are not putatively valid, your Honor, with all due respect.

THE COURT: Of course they are.

MR. SOBOL: No, this --

THE COURT: They're putatively at risk.

MR. SOBOL: These patents, with all due -- if I may be heard on this, your Honor, because it occurred more than once during this trial. Okay. These patents were being challenged by more than a dozen generic companies across the United States and they are not, therefore, putatively valid. They were very much in dispute. And to the extent that you -- and you -- let me put this -- I'm going to take a step back. During the trial at some point Dr. McGuire was testifying and he talked about how the consequences of something would be hundreds of millions of dollars, and you interrupted him and said but that's the situation, we've got putatively valid patents here. Okay. That's just scope of the patent, your Honor. That's just assuming that the patents are valid, assuming that they're infringed, and assuming giving defendants complete carte blanche to do what they want to do. The at-risk launch that would have occurred here would have been in the face of patents that were, in fact, in question and for which there was a risk. And whether or not they would have been held valid or invalid neither side has done any evidence.

THE COURT: I'll give you this. There's no sufficient evidence that they would have been held invalid. You bear the burden. I ruled that way at the end of the direct case. None of this comes in unless you want at risk. You seem desperately to want at risk. I'm going to – I think I'm going to give you at risk, as a theory, but a patent, without a Court doing anything, once the Patent Office, to which the law gives that power, issues a patent, it is putatively valid. It can be challenged but the burden is on the challenger, and not just by a fair preponderance but by clear and convincing evidence.

id. at 97:20-98:2:

THE COURT: Well, I had thought we were not going to get into this but, again, if I give you at risk, I'm at least giving the charge that Mr. Gaffney has mentioned out of 31, and because I conceive that to be the law. And I think evenhanded I have to do this. I might want to reflect on whether you want me to do that, and I will hear you at any -- hear you. You can communicate to the Court anytime today.

> any -- hear you. You can communicate to the Court anytime today.[158]
>
> In an at-risk launch, if it were to be held that the patent infringed, that the idea infringed, the competition infringed, then that's lawful, that's not antitrust harm. It just isn't if it's an infringing device. You don't cut down the patent monopoly by launching at risk against patents that are putatively valid.[159]
>
> . . . .
>
> ***Excerpt from Defendants Proposed Instruction #31:*** In addition, a generic drug manufacturer cannot lawfully sell a generic drug if the sale of the generic drug infringes a valid patent. Thus, Plaintiffs must prove that the sale of generic Nexium by Teva prior to May 27, 2014 would not have infringed any valid Nexium patent owned by AstraZeneca. Because I have instructed you that Teva could not have won its patent case in New Jersey, the only way Plaintiffs can meet its burden on this point is to prove that AstraZeneca would have licensed the Nexium patents to Teva starting on an earlier date.[160]

The Court's proposed jury instruction, had it been given, would have been erroneous. By definition, "at risk" means launching before a court has issued a final order determining the patent's validity and whether the generic infringes. Generic companies do, in fact, launch "at risk" on a regular basis – as they are permitted to under Hatch-Waxman[161] and patent law,[162] and which the evidence adduced at trial (particularly about Teva) confirmed.

The Court's proposed erroneous instruction would have further confused the jury, and so Plaintiffs did not proceed with at-risk launch on the verdict slip. This "choice" resulted in the jury not getting the benefit of deliberation on evidence that was presented to them, causing

[158] 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 97:20-98:2.

[159] 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 95:13-22.

[160] Defendants' Proposed Jury Instructions (ECF No. 1338) at Instruction 31.

[161] The 30-month stay provision of Hatch-Waxman by definition expires after 30 months, and so the generic can obtain final FDA approval and launch regardless of the continued pendency of the patent suit.

[162] *See* ECF No. 1308 at 6-7 (citing patent cases demonstrating that where, as here, patent validity is challenged, the patent holder would bear burden of establishing likelihood of success on defeating the invalidity challenge to obtain a preliminary injunction).

Plaintiffs severe prejudice and adding to jury confusion over Question 4. This prejudice can only be cured by a new trial.

D. The cumulative result of these errors is a contradictory answer to Question 4.

The jury answered "yes" to Question 2, "Did the settlement of the AstraZeneca-Ranbaxy patent litigation include a large and unjustified payment by Ranbaxy to Ranbaxy?" The jury also answered "Yes" to Question 3, "Was AstraZeneca's Nexium settlement with Ranbaxy unreasonably anticompetitive, i.e. did the anticompetitive effects of that settlement outweigh any pro-competitive justifications?" In other words, the jury found that there were anticompetitive *effects* stemming from the AstraZeneca-Ranbaxy agreement, *effects* that outweighed any pro-competitive justifications. This jury finding of anticompetitive effects necessarily means that the jury found that the AstraZeneca-Ranbaxy agreement caused delay of the agreed entry date for generic Nexium.[163]

The Court instructed the jury with respect to Question 3 that they could answer "yes" only if "the plaintiffs have proven *the challenged restraint has harmed competition*."[164] The instruction made perfectly clear that only a restraint that *in fact caused harm* could properly elicit the jury's affirmative response. Similarly, when the jury asked for additional instruction on Question 3, the Court specifically instructed that "conduct that moves the license date of the

[163] In charging the jury on Question 3, the Court explained: "So the comparison that you're asked to make here, 'Did the anticompetitive *effect* of the settlement outweigh any procompetitive justifications?'" 12/03/14 Trial Tr. (ECF No. 1439) at 46:2-4 (emphasis added). Significantly, the Court instructed the jury that Question 3 related to the actual delay of generic Nexium: "You must determine whether the restraints challenged here, the alleged payment and the *delay of entry of generic [...] esomeprazole magnesium into the market* are unreasonable." *Id.* at 46:10-16 (emphasis added). The Court further instructed the jury: "In making this determination you must determine whether the plaintiffs have *proven the challenged restraint has harmed competition*." *Id.* at 46:16-48 (emphasis added). Finally, in response to a jury question about the meaning of Question 3, the Court explained that: "conduct that *moves the license date* of the AstraZeneca-Ranbaxy license further into the future is an anticompetitive *effect*, because of course it prevents or has the practical effect of preventing a Ranbaxy, and perhaps people backing up Ranbaxy, backing up in the sense of standing later in line, from entering the market." 12/04/14 Trial Tr. (ECF No. 1443) at 8:5-11 (emphasis added).

[164] 12/03/14 Trial Tr. (ECF No. 1439) at 46:17-18 (emphasis added).

AstraZeneca-Ranbaxy license further into the future is an anticompetitive effect."[165] The Court emphasized that Question 3 required the jury to "look to see what anticompetitive effects there are of the settlement,"[166] explaining that "Here we're asking 'What actually happened, did the anticompetitive effects outweigh the procompetitive justifications?'"[167]

Answering "yes" to Question 3, and deciding that the anticompetitive effects outweighed any procompetitive justification, logically entailed that the jury believed that the large and unjustified payment caused the agreed upon entry date to be later than it otherwise would have been. Given the Court's earlier rulings, Plaintiffs did not try to prove at trial that the generics would have won the patent infringement litigation.[168] Nor (given the Hobson's choice posed by the Court, discussed above), did Plaintiffs argue that a generic would have launched at risk. The only theory, then, that the jury had available to consider in evaluating Question 3 was an alternative settlement agreement with an earlier agreed upon entry date.

As initially conceived by both Plaintiffs and the Court, Question 4 was framed to pose the objective, competitive antitrust injury question: "Had there been no violation of the antitrust laws, a generic version of Nexium would first have come to market on __ [Month], 20__ [Year]." But as ultimately presented to the jury, Question 4 asked: "Had it not been for the unreasonably anticompetitive settlement, *would AstraZeneca have agreed* with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?"

To the extent that Question 4 was intended to ask whether the jury believed the entry date would have been earlier in the absence of a large and unjustified payment, it was redundant; the

[165] 12/04/14 Trial Tr. (ECF No. 1443) at 8:5-7.

[166] *Id*. at 9:1-2.

[167] *Id*. at 9:9-12.

[168] Memorandum and Order on Summary Judgment, ECF No. 977, p. 126-127 (Sept. 4, 2014).

jury already provided that information in answering Question 3. And the jury's "no" answer to Question 4 is inconsistent with its "yes" answer to Question 3.

The jury's inconsistent verdict did not occur in a vacuum. Throughout the trial, Plaintiffs consistently objected to the Court's rulings: excluding critical relevant testimony from Dr. McGuire[169] and Dr. Leffler;[170] using a verdict slip that improperly split the causation question and framed it as a subjective (as opposed to objective) inquiry;[171] and forcing Plaintiffs into a Hobson's choice of abandoning an "at risk" launch scenario or be saddled with a harmful and erroneous jury instruction.[172] These evidentiary and other errors unfolded during the course of the trial and contributed to the jury's confusion and this nonsensical result.

E. Plaintiffs did not forfeit their objections to these issues by opposing Defendants' Motion for Mistrial.[173]

Plaintiffs did *not* need to join Defendants' mistrial motions to preserve Plaintiffs' rights to move for a new trial; instead, Plaintiffs' numerous objections are sufficient to preserve Plaintiffs' rights. "A party need not object to an offensive argument *and* move for a mistrial in order to preserve the right to bring a motion for a new trial."[174] "This rule is implied by the First Circuit's decision in *Computer Systems Engineering*[.] Indeed, the general rule appears to be that a proper objection to known misconduct at trial is sufficient to preserve the right to later

[169] 11/20/14 Trial Tr. (ECF No. 1424) at 83:8-10.

[170] 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 115:18-117:6.

[171] 12/02/14 Charge Conf. Tr. (ECF No. 1437) at 9:2-20.

[172] 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 96:7-10, 110:21-111:3; 12/03/14 Trial Tr. (ECF No. 1440) at 161:1-4.

[173] Plaintiffs do not address, here, the case law on whether any of the objections raised in this brief have been waived by purportedly inadequate earlier objections. If Defendants raise this issue in their anticipated opposition, Plaintiffs will respond to their specific objections.

[174] *Harrison v. Purdy Bros. Trucking Co.*, 312 F.3d 346, 353 (8th Cir. 2002).

move for a mistrial under *Rule 59*."[175] Numerous opinions across multiple circuits "focus[] on the failure to make *either* an objection *or* a motion for a mistrial, suggesting that either would be sufficient to preserve the right to a new trial on a motion for a new trial under *Rule 59*."[176]

Mistrial motions generally seek to remove the taint of wrongly admitted prejudicial evidence that, according to the movants, cannot be cured in other ways. Here, Plaintiffs were faced with the inverse: wrongly excluded relevant evidence (not improperly admitted prejudicial evidence).

In this scenario, the cure – admission of such relevant evidence – is readily available, and can be accomplished at any time until the end of trial. Thus, there was no need for Plaintiffs to seek a mistrial when Defendants did so, and in fact no way that Plaintiffs could argue that the Court's exclusion of relevant evidence could not be "cured by less drastic means,"[177] a remedy that Plaintiffs sought repeatedly throughout the trial.[178] And so Plaintiffs opposed the mistrial motion, presuming that Plaintiffs would be afforded an opportunity to introduce relevant evidence either in their case in chief or – depending on the Defendants' case in chief and the verdict slip – in rebuttal. Even former-Defendant Teva declined to join AstraZeneca's and Ranbaxy's mistrial motions for similar reasons, noting that "[w]e reserve the right to reevaluate

[175] *Park W. Galleries, Inc. v. Hochman*, 692 F.3d 539, 547 (6th Cir. 2012) (citing *Computer Systems Engineering, Inc. v. Qantel Corp*., 740 F.2d 59, 69 (1st Cir. 1984) ("Qantel's failure to object to the argument at trial *or* to move for a mistrial bars it from urging the improper argument as grounds for a new trial after the jury had returned its verdict.") (emphasis added)). *Accord Wildman v. Lerner Stores Corp*., 771 F.2d 605, 609 (1st Cir. 1985) ("This issue [that plaintiff's counsel misled the jury on the burden of proof and distorted the testimony] is foreclosed, however, by defense counsel's failure to object at the time the allegedly improper statements were made *or* move for a mistrial before the verdict was returned.") (emphasis added).

[176] *Park W. Galleries*, 692 F.3d at 547.

[177] *Rodriguez-Torres*, 399 F.3d at 63.

[178] *See* 12/01/14 Trial Tr. (ECF No. 1436) at 161:8-19; 12/02/14 Charge Conf. Tr. (ECF No. 1438) at 115:18-117:6, 117:20-24.

that once [the jury verdict slip] is finalized because your Honor has not clearly indicated what the new scope of the trial would be."[179]

As discussed above, here the Court reversed its decision to allow Dr. McGuire's testimony[180] and did not later cure that error by allowing Dr. McGuire or Dr. Leffler to testify. The Court then compounded that error by improperly splitting the causation question into multiple questions and then refusing to hear specific objections to those questions that were only finalized and shown to the parties an hour before they were given to the jury. The Court recognized Plaintiffs' objections to the jury charge and verdict slip, noting that "I'll save your rights."[181]

Plaintiffs' decision not to seek a mistrial when less extreme measures were then still available to remedy the harm in no way forfeits Plaintiffs' rights to contest the Court's failure to take that corrective action through curative jury instructions and admission of relevant evidence and cannot excuse the improper verdict form.

IV. CONCLUSION

For these reasons, Class Plaintiffs' Motion for New Trial should be granted. A Proposed Order is filed herewith. Plaintiffs request oral argument on this motion.

Dated: December 31, 2014

/s/ Thomas M. Sobol
Thomas M. Sobol, BBO No. 471770
David S. Nalven, BBO No. 547220
Donna M. Evans, BBO No. 554613
Kristen A. Johnson, BBO No. 667261

[179] 11/20/14 Afternoon Hrg. Tr. (ECF No. 1426) at 4:15-23.

[180] *See* 11/20/14 Trial Tr. (ECF No. 1424) at 83:7-85:18.

[181] 12/03/14 Trial Tr. (ECF No. 1439) at 53:25. As described in the Declaration of David F. Sorensen, attached as Exhibit M to the Sobol Declaration, Plaintiffs also tried to object to Question 4 in the morning before the jury charge. The clerk informed Plaintiffs that the charge was final and that the Court would not hear any more objections.

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: December 31, 2014

/s/ Thomas M. Sobol
Thomas M. Sobol