**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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

**INDIVIDUAL PLAINTIFFS' MEMORANDUM IN SUPPORT OF**
**MOTION FOR NEW TRIAL**

# TABLE OF CONTENTS

# TABLE OF AUTHORITIES

## Cases



## Statutes



## Other Authorities

The Individual Plaintiffs[1] submit this memorandum in support of their motion for a new trial. We join in Class Plaintiffs' similar motion, but make this separate submission to emphasize that the Court's fundamental misunderstanding of Plaintiffs' legal theory requires a new trial. Throughout most of Plaintiffs' case, the Court incorrectly maintained that a reverse payment to Ranbaxy could not delay the entry of Teva's generic Nexium. The Court recognized its error shortly before Plaintiffs rested, but all of its instructions, evidentiary rulings, and case management decisions to that point were infected by this error, and Plaintiffs were unable to put on the parts of their case that the Court excluded in the few remaining trial days. This record creates a definite and firm conviction that a mistake has been made.

## INTRODUCTION

At the final pretrial conference before trial began, the Court made a fundamental legal error. It held that its summary judgment ruling that Plaintiffs had insufficient evidence to prove that Ranbaxy could have introduced its own generic Nexium product prior to May 27, 2014 precluded Plaintiffs from proving that AstraZeneca's payment to Ranbaxy delayed Teva from entering before that date. While the Court eventually recognized its error, it did not do so until two days before Plaintiffs rested, and it did not permit Plaintiffs to put on evidence previously excluded or to supplement the record in rebuttal. In particular, the Court did not permit Plaintiffs to present any economic testimony explaining the net present value of the no-authorized-generic agreement or how it would have been in the interest of both AstraZeneca and Ranbaxy to agree to an earlier generic entry date (rather than continue to litigate) had AstraZeneca not agreed to terms worth hundreds of millions of dollars to Ranbaxy. The excluded evidence included

[1] The Individual Plaintiffs are the retailer plaintiffs in the *Walgreen* (No. 13-cv-10337-WGY), *Giant Eagle* (No. 13-cv-11305-WGY), *Rite Aid* (No. 13-cv-12074-WGY), and *CVS* (14-cv-11788) actions.

opinions from Dr. Thomas McGuire, originally retained by Class Plaintiffs, whose testimony the Court drastically limited based on its misconception of Plaintiffs' legal theory, as well as Individual Plaintiffs' expert economist Dr. Keith Leffler, who was prepared to opine on rebuttal as to an entry date that would have been in the economic interests of both AstraZeneca and Ranbaxy had AstraZeneca not paid Ranbaxy to accept the May 27, 2014 entry date.

In making this motion, Individual Plaintiffs recognize that the Court invited Plaintiffs to join Defendants' motions for a mistrial filed on November 19 and 20, 2014. However, at that time, Plaintiffs hoped that the errors could be corrected and that it would not be necessary to waste the huge investment in time and money in what was then already a month long trial. As it turned out, there were only three trial days after argument of those motions, and the Court did not permit Plaintiffs to put on the kind of evidence that would have been necessary to correct the record. For more than a month of trial, the Court's instructions and evidentiary rulings were based on what the Court recognized to be a "fairly fundamental misconception" (11/18/14 Tr. at 4:20-5:4) that AstraZeneca's huge reverse payment to Ranbaxy was irrelevant to when Teva would have entered the market. The prejudice to Plaintiffs was multiplied by the Court's refusal to permit Plaintiffs to call either Dr. McGuire or Dr. Leffler in rebuttal to explain how economic principles could be used to determine a competitive entry date in the absence of a reverse payment. As a result, in closing, Defendants were able to argue that there was no evidence of an alternate entry date in the record. And, the jury's "No" answer to Interrogatory 4 suggests that this is precisely the point at which the jury decided that Plaintiffs' case had failed. A "Yes" answer to Interrogatory 4 would have required the jury to provide a specific date in response to Interrogatory 5 ("If so, what would be the effective date of such a license?"). By responding "No" to Interrogatory 4, the jury avoided having to provide such a date, but its answer that

AstraZeneca and Ranbaxy would not have agreed to an earlier launch date for generic Nexium was in clear conflict with its answer to Interrogatory 3 that there was a delay of generic entry (because that delay was the anticompetitive effect that outweighed any pro-competitive justifications).

It is impossible to look at the record of this case without arriving at the definite and firm conviction that a mistake has been made on the fundamental issue of whether the reverse payment to Ranbaxy delayed Teva's introduction of generic Nexium. Plaintiffs spent more than a month seeking to satisfy the legal construct announced by the Court at the pretrial conference. As a result, most of the trial focused on whether AstraZeneca's reduction of its damage claim against Teva for infringement of the Prilosec patents was a large and unjustified payment when the principal large and unjustified payment in this case was the hundreds of millions of dollars in value that AstraZeneca transferred to Ranbaxy to agree to the May 27, 2014 entry date. Accordingly, before this record goes to the Court of Appeals, we respectfully ask the Court to consider this motion for a new trial to allow the important issues that this case raises about competition in the pharmaceutical market to be addressed on a proper record.

## ARGUMENT

### I. THE COURT SHOULD GRANT A NEW TRIAL WHEN A FUNDAMENTAL ERROR OF LAW THREATENS A MISCARRIAGE OF JUSTICE.

A trial court may grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). The court's power to grant a new trial under Rule 59 "is much broader than its power to grant a JMOL." *Jennings v. Jones*, 587 F.3d 430, 436 (1st Cir. 2009); *Fine v. Sovereign Bank*, 671 F. Supp. 2d 219, 224 (D. Mass. 2009) (noting that the standard for granting a new trial is "less stringent than the standard for a Rule 50 motion"); *see also* 9B ARTHUR R. MILLER, FED. PRAC. & PROC.

§ 2531 (3d ed. 2008).

A district court "has the power and duty to order a new trial whenever, in its judgment, the action is required in order to prevent injustice." *Jennings*, 587 F.3d at 436 (quoting *Kearns v. Keystone Shipping Co.*, 863 F.2d 177, 181 (1st Cir. 1988)). On such a motion, the court need not consider the evidence in the light most favorable to the verdict winner. *Id*. at 436, 438. To the contrary, "a trial judge may order a new trial 'even where the verdict is supported by substantial evidence.'" *Id*. at 439 (quoting *Lama v. Borras*, 16 F.3d 473, 477 (1st Cir. 1994)); *see also* 11 CHARLES A. WRIGHT, ARTHUR R. MILLER, & MARY KAY KANE, FED. PRAC. & PROC. § 2806 (2d ed. 1995 ). "While the court, of course, should give due respect to 'the collective wisdom of the jury,' if after reviewing all of the evidence the court 'is left with the definite and firm conviction that a mistake has been committed,' it should grant a request for a new trial." *Fine*, 671 F. Supp. 2d at 224 (citing 11 CHARLES A. WRIGHT, ARTHUR R. MILLER, & MARY KAY KANE, FED. PRAC. & PROC. § 2806 (2d ed. 1995)).

A prejudicial error of law is grounds for a new trial. *See Kennedy v. Town of Billerica*, 617 F.3d 520, 527 (1st Cir. 2010) (quoting 11 CHARLES A. WRIGHT, ARTHUR R. MILLER, & MARY KAY KANE, FED. PRAC. & PROC. § 2805 (2d ed. 1995)) ("Any error of law, if prejudicial, is a good ground for a new trial. . . .'"). Legal errors that affect substantial rights of the parties and threaten a "miscarriage of justice" warrant review regardless of any failures to object during trial. *See, e.g.*, *Chestnut v. City of Lowell*, 305 F.3d 18, 20 (1st Cir. 2002). In considering whether a particular error potentially represents such a miscarriage of justice, a court should consider "'whether the failure to raise the claim below deprived the reviewing court of helpful fact finding; whether the issue is one of constitutional magnitude; whether the omitted argument is highly persuasive; whether the opponent would suffer any special prejudice; whether the

omission was inadvertent or deliberate; and, perhaps most importantly, whether the issue is of great important to the public." *Suboh v. Borgioli*, 298 F. Supp. 2d 192, 203 (D. Mass. 2004) (Young, J.) (*citing Play Time, Inc. v. LDDS Metromedia Commc'ns., Inc.*, 123 F.3d 23, 30 n.8 (1st Cir. 1997)).

Legal errors that impact substantive rights are likely to warrant a new trial. Thus, in *Suboh*, 298 F. Supp. 2d 192, this Court granted a new trial where it concluded that it had "botched the instructions to the jury" by improperly instructing the jury on plaintiffs' burden of proof on a procedural due process claim. Even though none of the parties objected to the instruction, the Court ordered a new trial to correct this legal error because it threatened a miscarriage of justice. *Id.* at 205. Similarly, this Court ordered a new trial in *DiFiore v. American Airlines, Inc.*, 561 F. Supp. 2d 131, 134 (D. Mass. 2008) (Young, J.), where it changed its interpretation of the relevant statutory language applicable to plaintiffs' claims "upon further reflection and analysis" after the jury returned its verdict. And, in *Blake v. Pellegrino*, 329 F.3d 43 (1st Cir. 2003), the Court of Appeals held that this Court's mid-trial redaction of the cause of death from a death certificate offered into evidence by the plaintiffs was erroneous. Because the removal of the evidence 17 days into trial after plaintiffs had made it the "centerpiece" of their case was very likely "devastating" to plaintiffs' case, the Court ordered a new trial on remand. *Id.* at 50. It held that it was "difficult to imagine a more prejudicial turn of events" than that caused when the court "abruptly reversed direction and sawed the limb off at the eleventh hour, bringing the plaintiffs' case down with it." *Id.* at 49.

In this case, the Court did not abruptly exclude Plaintiffs' evidence. Instead, for 15 of the 22 days on which evidence was taken, it refused to permit Plaintiffs to offer evidence of the amount of AstraZeneca's payment to Ranbaxy and its effect on Teva's ability to introduce

generic Nexium. Then, on the 16th day of evidence, the Court abruptly recognized its legal error and announced that it understood why the evidence was relevant. But, as we explain next, this change in understanding did not ameliorate the effects of the error because the Court did not provide Plaintiffs with the leeway necessary to put on additional economic evidence of the effect of the Ranbaxy payment on economically rational actors.

## II. THE COURT'S FUNDAMENTAL LEGAL ERROR AFFECTED VIRTUALLY EVERY PART OF THE TRIAL AND REQUIRES A NEW TRIAL TO AVOID A MISCARRIAGE OF JUSTICE.

The Court's legal error concerning the relevance of AstraZeneca's payment to Ranbaxy infected the entire trial and severely prejudiced Plaintiffs. Given that the Court has already recognized this error, it should grant a new trial to create a proper record on this important issue and cure the prejudice to Plaintiffs.

### A. The Legal Error

In its summary judgment opinion, the Court held that, in light of the regulatory issues that Ranbaxy faced in getting FDA approval of its generic Nexium, a reasonable jury could not find that Ranbaxy would have been able to introduce generic Nexium before the May 27, 2014 date to which it agreed with AstraZeneca. *In re Nexium (Esomeprazole) Antitrust Litig.*, 2014 WL 4370333 at *40 (D. Mass. Sept. 4, 2014).[2] Plaintiffs did not understand this ruling to preclude them from proving that: (1) AstraZeneca paid Ranbaxy through the no-authorized generic agreement and side deals to accept the May 27, 2014 entry date; and (2) that purchased entry date also delayed Teva from entering any earlier because Ranbaxy, as the first-to-file an ANDA for generic Nexium, was a bottleneck to subsequent generic manufacturers. However, at the September 20, 2014 pretrial conference, the Court went much further and held that Plaintiffs

[2] While Individual Plaintiffs do not agree with this holding and reserve all of their rights with respect to it, it is not the basis for this motion for a new trial.

could pursue only one theory at trial:

> The plaintiffs [have] one theory, only one theory, and here it is. That AstraZeneca, desirous of extending its monopoly premium due to its patent rights, which perhaps are questioned, . . . entered into an agreement with Ranbaxy to keep Ranbaxy off the market, but that agreement has no antitrust impact because Ranbaxy could never get on the market. And we're not going back at the trial to redo things done by summary judgment.

9/20/14 Tr. at 4:8-18. That theory did not include proving that AstraZeneca's payment to Ranbaxy delayed Teva's ability to introduce its own generic Nexium:

> This business that the AstraZeneca-Ranbaxy agreement itself caused delay on the market, there's insufficient evidence of that, I'm not going for that, I think and rule, I guess, if I have to put it in some sort of formal ruling, that Teva had ample remedies open to it under the law.

*Id.* at 5:14-19.

**B. Effects of the Error**

In light of its ruling on the relevance of the Ranbaxy payment, the Court required Plaintiffs to put on all of their evidence of the "substantial and unjustified payment" to Teva first so that Defendants could move for a directed verdict before Plaintiffs completed putting on their case. *Id.* at 6:3-7:2 The Court's preliminary charge also focused on the payment to Teva. 10/21/14 Tr. at 36:5-9. The Court emphasized that it had determined that "Ranbaxy in fact never had the capacity to bring its generic to market," did not mention the potential impact on Teva of a payment to Ranbaxy to accept a later entry date, and instructed the jury that the first question that it had to answer was whether there was "a large and unjustified payment by AstraZeneca to Teva." *Id.* at 35:14-15, 36:5-9.

In light of the Court's ruling, Plaintiffs put on almost four weeks of evidence focused on whether AstraZeneca paid Teva to delay its generic entry. At times, there were references to the Ranbaxy settlement, but they were limited to context. On the 13th day of trial, however, the

Court ruled that AstraZeneca's questioning of its outside antitrust counsel Tim Hester had waived its attorney-client privilege over certain documents that it had withheld. 11/10/14 Motion Tr. at 10:10-25. One of the subsequently produced documents was a memo written by Mr. Hester and admitted into evidence as Exhibit 140. That document showed that Mr. Hester had advised AstraZeneca to follow the precise strategy that Plaintiffs sought to prove, but which the Court had excluded – that AstraZeneca paid Ranbaxy to delay both Ranbaxy and other generics. The Hester memo explained that Ranbaxy "may be willing to agree to a relatively late entry date in a settlement that provides it with sole exclusivity," meaning "exclusivity against authorized generic competition." Ex. 140. It recognized that Teva "may have limited incentives to continue the litigation if Ranbaxy has settled with a period of exclusivity and has preserved its 180-day rights." *Id.*

But the Court still did not let Plaintiffs show that AstraZeneca had paid off Ranbaxy. On November 12, Plaintiffs called Jay Deshmukh, Ranbaxy's outside counsel responsible for the Nexium patent litigation against AstraZeneca. Plaintiffs sought to examine Mr. Deshmukh with respect to Ranbaxy's settlement with AstraZeneca, but the Court cut off the examination, telling counsel at side bar: "Now, the business about whether [Ranbaxy's] date would have been moved up to me is immaterial in light of my rulings because [Ranbaxy] could never bring that thing to market." 11/12/14 Tr. at 35:8-41:16.

The issue came to a head on November 13, when Plaintiffs recalled Professor McGuire to testify about how the payment to Ranbaxy caused it to accept a later date than would have otherwise been in its economic interest.[3] Based on its prior rulings, the Court hardly permitted

[3] Professor McGuire had earlier testified generally about the anticompetitive effects of reverse payments and specifically about certain aspects of AstraZeneca's settlement with Teva. 11/07/14 Trial Tr. at 57-97.

Dr. McGuire to say anything. Before Dr. McGuire testified, the Court told counsel that it didn't "buy this theory that they bought off Ranbaxy and had they not bought off Ranbaxy, Ranbaxy would have been able to enter in 2011, and if Ranbaxy entered in 2011, obviously Teva could have entered in 2011." 11/13/14 Tr. at 30:4-8. As a result, the Court announced that it would not let Dr. McGuire "testify to that" because it "settled that on summary judgment." *Id.* at 30:8-10. Later in the examination, the Court explained that it would not allow "anything from pay-for-delay with respect to Ranbaxy . . . given [its] earlier rulings." *Id.* at 37:4-7. When Dr. McGuire testified that Ranbaxy's receipt of the no-authorized generic clause provided an incentive to Teva to join the conspiracy, the Court struck that answer. *Id.* at 52:17-54:2. And when Plaintiffs asked Dr. McGuire about the value of the no-AG provisions to Ranbaxy, the Court cut off the examination saying:

> Mr. Shadowen, the more we horse around here, the more I think that an instruction might be appropriate. We're not -- what is the logic, what is the relevance of getting into the dollar amounts that the settlement would have benefitted Ranbaxy? The live issue is, and I'm letting you have everything I can think of that goes to it, the incentive to Ranbaxy to conspire with AstraZeneca to keep other people out of the market for that period. How does this go to that?

*Id*. at 62:10-63:5. The Court then told Plaintiffs that the only thing that kept their case against Ranbaxy alive was the "contingent launch provision" and that it was "sticking to [its] rulings" that the $700 million in value transferred to Ranbaxy as a result of the no-AG agreement was not relevant. *Id.* at 63:20-64:4.

When Plaintiffs asked Dr. McGuire to explain the lost profit opportunities to AstraZeneca of agreeing to the no-authorized-generic provision with Ranbaxy, the Court instructed the jury that it had already "been through pounds of evidence" and that there was no evidence that "Ranbaxy ever could have gotten to market with a generic Nexium." *Id.* at 71:2-72:7. After Dr.

McGuire provided his explanation of the significant revenues that AstraZeneca would preserve for itself by selling an authorized generic, the Court suggested to the jury that it did not matter because AstraZeneca held patents:

> Also keep 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 return, 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.
>
> The question is, the questions that I'm – we're going to put to you, did they keep Teva out of the market by making a large and unjustified payment. Did they, AstraZeneca, conspire with both Teva and Ranbaxy to extend this delay period up to the date. Those are the questions.

*Id.* at 74:25-75:13. When Plaintiffs' counsel asked for a sidebar to object to the instruction on patent law, the Court told counsel that Plaintiffs would not be permitted to go into the payment to Ranbaxy and overruled the objection to telling the jury that it had to consider patent law to resolve the reverse payment issue. *Id.* at 75:19-76:16. Shortly thereafter, Plaintiffs concluded their examination of Dr. McGuire "within the confines of the sidebars." *Id.* at 82:15-16.

**C. Recognition of the Error**

Following this examination, the trial recessed for four days during which the Court considered Defendants' motion for a directed verdict. When trial resumed on November 18, the Court announced that it had realized that it had a "fundamental misconception" about the relevance of the Ranbaxy payment. As it explained:

> It's been very helpful for the Court to take these four days and, among other things, ruminate about this case and the first thing I've decided is that I've got to "jimmy" the verdict slip, should we get that far, and we'll put "monopoly power" first, that will be the first question, as traditionally it is, but then I got puzzling, because I know that we are close to the end of the plaintiffs' case, on what it is that Ranbaxy is supposed to have

> done as a conspirator, and on that issue *I confess to a fairly fundamental misconception*.
>
> Ranbaxy, quite appropriately, as well as the other defendants, keeps howling about, "Don't go back on your summary judgment rulings," with some success and they have -- and their cross-examinations show sort of a traditional view of a three-party conspiracy, and they point out in their cross-examinations that they're not part of any AstraZeneca-Teva negotiations. And while puzzling about that I came to realize that Ranbaxy is in this case in a, um, more direct way than I had conceived as the case has been presented, and it's really very simple.
>
> . . .The large and unjustified payment to Ranbaxy, which keeps Ranbaxy, given its blocking position, off the market until May 27th, 2014, has an effect on all the later ANDA filers, such that if it were to be proved that but for that agreement -- and we'll see what the evidence is going to be, Teva could have partnered with Ranbaxy and come to market prior to that date, then that's the antitrust damages, they entered -- or the antitrust impact, the actual loss to people, and that will, in the Court's view, require some tinkering with the verdict slip unless this whole thing collapses on the directed verdict at the close of the plaintiffs' evidence because there isn't enough evidence now of causation, and I'm not sure there is.

11/18/14 Tr. at 4:20-6:9 (emphasis added).

The reason for the limited evidence of causation, however, was the Court's exclusion of virtually all of Dr. McGuire's testimony about the effect of the Ranbaxy payment on the immediately preceding trial day. Dr. McGuire had been prepared to testify that the no-AG agreement had a net present value to Ranbaxy at the time that it entered the agreement with AstraZeneca of $499 million, that such a large payment together with the lucrative side deals that AstraZeneca made to Ranbaxy induced it to agree to honor the expiration date of AstraZeneca's so-called medicine patents, and that it is possible to use econometric analysis of the stock market's reaction to the actual settlement reached by AstraZeneca and Ranbaxy to estimate an objective entry date without such a payment. *See* McGuire Proffer at ¶¶ 29-33, 41-43 (Dkt. No.

1282).

**D. Plaintiffs' Attempts to Supplement the Record**

After the Court recognized its legal error, the Court initially suggested that it would permit additional testimony from Dr. McGuire (11/18/14 Tr. at 167:10-21), but later changed its mind and refused to let Dr. McGuire resume the stand to explain the effect of the payment to Ranbaxy. The Court recognized Dr. McGuire to be a qualified expert and held that the event study on which he based his opinion was a "recognized and perhaps reliable" methodology accepted by courts in other contexts. 11/20/14 Tr. at 83:7-20. However, it excluded Dr. McGuire's event study in this case because there was "just no fit" between the event study and the issue of when "Ranbaxy and Teva would have cut a deal but for the arguably anticompetitive agreements." *Id.* But that was not the issue on which Dr. McGuire opined. Dr. McGuire's opinion was that the stock market's reaction to the deal between *AstraZeneca* and Ranbaxy to accept a May 27, 2014 entry date demonstrated that the reverse payment to Ranbaxy resulted in a settlement that was more advantageous to AstraZeneca than the one that the market was expecting. Dr. McGuire used the increase in AstraZeneca's market valuation to estimate the competitive date that objective market participants were expecting in the absence of a payment. *See* McGuire Proffer at ¶¶ 35-40 (Dkt. No. 1282).

Although the Court recognized that it had precluded Dr. McGuire from testifying to other matters based on its "fairly fundamental misconception" of Plaintiffs' case and that those matters were made relevant by the Court's changed view of the case, the Court nevertheless concluded that it would be unfair to *Defendants* to allow Dr. McGuire to testify a third time to explain the "enormous value of the AstraZeneca-Ranbaxy settlement." *Id.* at 84:10-19.

**E. Excluded Rebuttal Case**

When they chose not to join in Defendants' motion for a mistrial, Plaintiffs hoped that the

Court would give them leeway to salvage a month of trial time and prove the case that the Court's misunderstanding had precluded them from proving. But, after the Court's recognition of its error, the Court permitted little opportunity for Plaintiffs to supplement the record to support the legal theory that the Court belatedly recognized. During Defendants' case in chief, Ranbaxy's former Regional Director for North America, Venkatachalam Krishnan, testified that AstraZeneca never "express[ed] any willingness to agree to any" date other than May 27, 2014. 12/1/14 Tr. at 127:23-128:3. When Plaintiffs sought to put on evidence to support their theory and rebut this claim by showing that it would have made economic sense for AstraZeneca and Ranbaxy to agree to an earlier date rather than going to trial, the Court precluded Plaintiffs from putting on any rebuttal evidence.

In addition to Dr. McGuire's event-study testimony, which Plaintiffs offered once again in rebuttal (Dkt. No. 1325), Plaintiffs also sought to offer testimony from Individual Plaintiffs' expert Dr. Keith Leffler regarding the entry date that would have been in the economic interests of AstraZeneca and Ranbaxy in the absence of a reverse payment. Dr. Leffler's analysis was different from Dr. McGuire's. It used well known and accepted expected value analysis to demonstrate that, based on reasonable assumptions about the two companies' expectations concerning the outcome and duration of the patent litigation, AstraZeneca and Ranbaxy would have preferred settling for an entry date in February 2012 rather than continuing to litigate. *See* Leffler Proffer at ¶¶ 3-4 (Dkt. No. 1351). Plaintiffs also offered a study by the FTC titled *Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Ex. FAX ) that concluded that settlements with payments from the brand to the generic on average prohibit generic entry 17 months longer than settlements without payments. *See* 12/2/14 Tr. at 111:22-113:5.

The Court denied Plaintiffs' request to call Dr. McGuire in rebuttal without any

explanation. *See* 12/01/14 Tr. at 161:15-19. And, it also excluded Dr. Leffler and the FTC study as improper rebuttal testimony. 12/02/14 Tr. at 115:11-117:6. However, all of this evidence would have tended to disprove the suggestion that AstraZeneca and Ranbaxy would not have agreed to an earlier entry date had AstraZeneca not made any reverse payments to Ranbaxy, which was raised in Defendants' case in chief. *See* 12/1/14 Tr. at 127:23-128:3. In this respect, it was proper rebuttal. As the First Circuit has held, "'[r]ebuttal evidence may be introduced to explain, repel, contradict or disprove an adversary's proof." *U.S. v. LiCausi,* 167 F.3d 36, 52 (1st Cir. 1999) (quoting *U.S. v. Laboy*, 909 F.2d 581, 588 (1st Cir. 1990)). That the testimony would have been more appropriately offered during the proponent's case-in-chief does not preclude its admission as rebuttal evidence. *Id*. (citing *U.S. v. Clotida,* 892 F.2d 1098, 1007 (1st Cir. 1989)).

While a court may have discretion to limit evidence on rebuttal that could have been offered in a party's case in chief, Individual Plaintiffs believe that it was an abuse of discretion to exclude Plaintiffs' rebuttal evidence here. The Court's legal error precluded Plaintiffs from offering evidence of the effect of the Ranbaxy payment during most of their case in chief. When the Court reassessed its view of Plaintiffs' case, it concluded that it would be unduly prejudicial to *Defendants* to hear more from Dr. McGuire. But given the dramatic change in the Court's view of the case, the Court's error precluded Plaintiffs from putting on concrete evidence that the jury could have used to estimate the date that AstraZeneca and Ranbaxy would have agreed to in the absence of the reverse payment that it found. Dr. McGuire's analysis based on the reaction of the market suggested that the market expected that date in the absence of a payment to be in January 2011 (Dkt. No. 1325 at 1); Dr. Leffler's expected value analysis showed that it would have made economic sense for AstraZeneca and Ranbaxy to agree on an entry date in February

2012 in the absence of the reverse payments (Dkt. No. 1351 at ¶¶ 3-4); and the FTC study suggested that if the average delay caused by reverse payments were used, entry in the absence of the reverse payment may have been December 2012, seventeen months before May 27, 2014 (12/2/14 Tr. at 112:10-18).

**F. Prejudice to Plaintiffs**

Plaintiffs suffered clear prejudice from the Court's legal error. The Court precluded Plaintiffs from putting on the case that they sought to put on – that AstraZeneca paid Ranbaxy to accept the May 27, 2014 entry date; that in the absence of that payment, the entry date would have been significantly earlier; and that that earlier date would have compelled Ranbaxy and Teva to reach a separate deal to bring generic Nexium to market to avoid Ranbaxy's loss of its first-to-file exclusivity. After the Court recognized its error, it permitted Plaintiffs to recall Mr. Deshmukh (11/18/14 Tr. at 167:10-21)[4] and Mr. Pott to testify about Exhibit 140 (11/25/14 Tr. at 63:1-3). However, the jury did not hear at all about the value of the no-authorized generic term to Ranbaxy as of the date of the agreement. That present value was unaffected by whether or not Ranbaxy actually introduced a generic product. *Cf.* 12/3/14 Tr. at 120:24-121:4 (closing argument suggesting that no-authorized generic agreement had no value if Ranbaxy never came to market). Nor did the jury learn that economic principles can be used to estimate an objectively reasonable entry date in the absence of a reverse payment.

The jury's task was further complicated by the way that the Court made Plaintiffs try the case and the radical and last minute changes to the verdict form and jury instructions. Throughout most of the case, the Court compelled Plaintiffs to focus on the payment to Teva

[4] At this time, the Court initially suggested that it would permit Plaintiffs to recall Dr. McGuire, but it reversed that decision a couple of days later in response to a motion filed by Defendants. *See* 11/20/14 Tr. at 83:7-20.

rather than the more significant and much larger reverse payment to Ranbaxy. The Court's preliminary instructions and verdict form focused entirely on the Teva payment and said nothing about the Ranbaxy payment. However, the final instructions and verdict form focused on the Ranbaxy payment and asked the jury to determine an alternate date to which AstraZeneca would have agreed in the absence of the payment. Because the Court changed its view of the case just two days before the end of Plaintiffs' case, and refused to permit any additional economic testimony to address the theory that it had belatedly recognized, the jury was deprived of critical evidence to answer the fourth and fifth jury interrogatories concerning the date to which AstraZeneca and Ranbaxy would have agreed in the absence of the reverse payment.

The Court's refusal to permit Plaintiffs an opportunity to call Dr. McGuire or Dr. Leffler to explain the effect of the reverse payment was devastating. It permitted counsel for Ranbaxy to argue in closing that because Dr. McGuire had not presented a date, it was impossible for the jury to determine such a date without speculating:

> You're not allowed to guess, you're not allowed to speculate, and you're not allowed to add, as Judge Young said. 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 that date.

12/3/14 Tr. at 113:5-10.

The Court's legal error precluding Plaintiffs from proving that the Ranbaxy payment delayed Teva's generic will be reviewable *de novo* on appeal. *U.S. v. Pires*, 642 F.3d 1, 10 (1st Cir. 2011); *U.S. v. Snyder*, 136 F.3d 65, 67 (1st Cir. 1998). Given that the Court has already recognized its error, we believe that the Court should take action now to correct it by allowing this case to be tried on a proper record with proper instructions and a proper verdict form.

The Court's error was so fundamental that it could not be waived. The Court's ruling that the Ranbaxy payment was irrelevant was a plain and obvious error that affected the

substantive rights of the parties, and threatens a "miscarriage of justice." *Cf. Suboh*, 298 F. Supp. 2d at 200-01. Almost all of the criteria that the Court of Appeals has identified as hallmarks of a miscarriage of justice are present. *Id.* at 203; *Play Time*, 123 F.3d at 30 n.8.

First, Plaintiffs' failure to join in Defendants' motion for a mistrial did not deprive the Court of any helpful fact finding. The question of the proper role of the Ranbaxy payment was a legal question squarely addressed by the Court at the beginning of the trial and reconsidered shortly before Plaintiffs rested. Far from depriving the Court of any helpful fact-finding, Plaintiffs failure to join the motion for a mistrial allowed the Court to see the effects of its rulings. Indeed, in considering Defendants' motion for a mistrial, the Court recognized that the issue might benefit from letting the case go to verdict.[5]

Second, while the issue in this case is not constitutional in magnitude, it implicates important policy issues under the antitrust and pharmaceutical laws of this country – policy issues that the Supreme Court recognized and attempted to resolve in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

Third, the relevance of the Ranbaxy payment is highly persuasive. Although the Court disagreed with Plaintiffs through most of the trial, it ultimately agreed with Plaintiffs that the Ranbaxy payment could have delayed Teva's entry.

Fourth, there would be no special prejudice to Defendants from a new trial. Defendants themselves requested a new trial, and Plaintiffs declined to join that request just four days before the close of evidence. Defendants' participation in four additional trial days at the end of a

[5] At the argument on a mistrial, the Court gave the parties the option of holding Defendants' motion for a mistrial in abeyance until the jury returned its verdict. 11/20/14 Motion Tr. at 3:22-4:10. However, the Court said that it would only do so if all parties agreed. Plaintiffs did not join in the request, but none of the Defendants agreed to the Court's proposal either making Plaintiffs' failure to join moot.

month-long trial is not special prejudice. Nor is it prejudice for Defendants to retry this case after a jury verdict when that verdict was the likely result of fundamental legal error.

Finally, the issues in this case are of great importance to the public. They involve the competitive pricing of pharmaceutical drugs, and this is the first case involving reverse payments to go to trial post-*Actavis*. The magnitude of the issues deserves a complete and fair record.

Accordingly, it would be a miscarriage of justice not to order a new trial in this case at which all of the issues could be fully and fairly explored with a jury that is properly instructed from the beginning, evidence that is presented in a logical manner without any artificial restrictions, and full and complete economic testimony explaining how the jury can estimate a competitive entry date in the absence of reverse payments.

## CONCLUSION

For the foregoing reasons, and those in Class Plaintiffs' motion for a new trial, Individual Plaintiffs respectfully request that the Court order a new trial.

Dated: December 31, 2014

Respectfully submitted,

/s Barry L. Refsin
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**CERTIFICATE OF SERVICE**

I, Barry L. Refsin, 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 Barry L. Refsin
Barry L. Refsin