UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to All Actions	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

RANBAXY'S MOTION FOR A MISTRIAL

Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc., and Ranbaxy Laboratories, Ltd. respectfully move this Court for a mistrial. Based on the Court's ruling of November 18, 2014, Ranbaxy has and will suffer substantial unfairness and prejudice that cannot be cured.

Legal Standards

A trial court should grant a motion for mistrial where the trial proceedings have resulted in serious prejudice to a party. *See Ramirez v. Debs-Elias*, 407 F.3d 444, 447-48 (1st Cir. 2005) (citing *United States v. Sepulveda*, 15 F.3d 1161, 1184 (1st Cir. 1993)). Under such circumstances, a mistrial should only be utilized where a curative instruction cannot eradicate the harm. *Id.*; *see also Hatfield-Bermudez v. Aldanondo-Rivera*, 496 F.3d 51, 64 (1st Cir. 2007); *Ramirez*, 407 F.3d at 447-48; *Doty v. Sewall*, 908 F.2d 1053, 1057, n.4 (1st Cir. 1990).

Argument and Factual Overview

On November 18, 2014, five weeks into trial of this case, the Court announced its ruling on the pending motions for Rule 50 directed verdict. In doing so, the Court revealed that it had a "fundamental misconception" regarding certain facts and arguments in its prior rulings:

> 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.

* * *

[T]he conspiracy that Ranbaxy – that the plaintiffs are proving as to Ranbaxy is the AstraZeneca-Ranbaxy settlement. 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.

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 on the market earlier? If so, when?" If they did, would there be a" – "would there be an authorized generic?"

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What's fundamentally different is that I structured the original verdict slip so that if the jury answered "no" to any one question, the rest of it all fell away. I don't see that now. If the jury answers "yes," monopoly power, "yes," large and unjustified payment to Ranbaxy, which is anticompetitive, they could answer "no" as to Teva, Teva drops out, but we have a case of – well, so long as they answer "yes" as to Teva would have – but for that agreement Teva would have partnered with Ranbaxy and gotten to market, then I've got two conspirators, AstraZeneca and Ranbaxy.

(Ex. 8, 11/18/14 Trial Tr. Vol. 1 at 4:20-5:15, 5:18-6:20, 7:7-17.)

This week-five correction of the Court's misconception by adding the so-called "Ranbaxy payment issue" back into this trial is in direct conflict with the legal framework upon which Ranbaxy has relied in preparing for this trial and trying this case; namely, the Court's September 4, 2014 summary judgment opinion holding that "the net effect of these rulings is that the Ranbaxy Settlement is not a basis for imposing antitrust liability." (ECF No. 977 at 101.) Based on the Court's summary judgment opinion, and the guidance provided by the Court in its 155-page summary judgment opinion, Ranbaxy assembled and constructed its entire case in direct reliance on the Court's ruling that its "settlement [was indeed] not a basis for imposing antitrust liability." (*Id.*) At every juncture in these proceedings, both leading up to and at trial, Ranbaxy relied on the legal construct of the Court's summary judgment opinion in making every important decision regarding trial presentation and strategy. And, at every juncture, Ranbaxy was encouraged by the Court to do so:

- **Motion for Reconsideration of the Summary Judgment Ruling:** On February 28, 2014, Plaintiffs moved for reconsideration of the Court's February 12, 2014 Summary Judgment Order arguing that "absent the 'large, unexplained payment' in the AstraZeneca-Ranbaxy agreement, those parties would have entered into a payment-free agreement with a markedly earlier licensed entry date (around May 2012)," and generic entry would have occurred then, by among other things Ranbaxy "relinquish[ing] its 180 day exclusivity." (ECF No. 871 at 1, 17.) The Court summarily denied the Plaintiffs' motion for reconsideration "out of hand." (ECF No. 874 at 1.)
- **September 4, 2014 Summary Judgment Opinion:** The Court issues its Summary Judgment Opinion and concludes that "the net effect of these rulings is that the

Ranbaxy Settlement is not a basis for imposing antitrust liability." (ECF No. 977 at 101.)

- **September 30, 2014 Pre-Trial Conference**:

> THE COURT: … The plaintiffs has [sic] one theory, only one theory, and here it is … but that the 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 … [t]he business that the AstraZeneca-Ranbaxy agreement itself caused a delay on the market, there's insufficient evidence of that, I'm not going for that….

(Ex. 1, 9/30/14 Final Pretrial Hearing Tr. at 4:8-5:17.)

The Court emphasizes that "absent" sufficient proof of a "substantial and unjustified payment arising out of Teva, um, AstraZeneca agreements…case over, because that's the overt act of the conspiracy, that's the beginning of the, um, antitrust impact." (*Id*. At 6:4-17.)

- **October 21, 2014 Argument Regarding Opening Statement Demonstrative Exhibits**:

> MR. BALDRIDGE: Your Honor, I just wanted to follow up just to be clear on our position. **Based on your summary judgment rulings and the way we prepared this case, any amount of money paid to Ranbaxy is not relevant.** And I just want to be clear that I think these slides had put enormous dollar values on any agreement or relationship—
>
> THE COURT: I thought I cut them all out?

(Ex. 2, 10/21/14 Trial Tr. Vol. 1 at 46:23-47:5 (emphasis added).)

- **October 21, 2014:** The Court issues its Verdict Form, which includes five questions only one of which (Question 4) pertains to Ranbaxy. That same day, the Court instructs the jury "[s]o that's Question 1 … So the way I've set up this jury

verdict, if at the end you're not satisfied, that's the only question you have to answer, the rest of them are out." (*Id.* at 39:18, 39:23-25.)

- **October 21, 2014:** Opening Statements are made to the jury in reliance on the Court's summary judgment opinion and specifically referencing the Court-approved and issued Verdict Form. (See below.)

- **October 27, 2014 Sidebar:**

> THE COURT: I'm going to allow him to explore the AstraZeneca-Ranbaxy connection, not going back on any summary judgment. They [Plaintiffs] do seem somehow to continue to hope that maybe things will play out differently, but they won't.

(Ex. 4, 10/27/14 Trial Tr. Vol. 2 at 96:17-20.)

- **October 27, 2014 Sidebar:**

> MR. BALDRIDGE: At this time is it possible just to avoid juror confusion to instruct the jury that the Ranbaxy agreement has been ruled to not be –
>
> THE COURT: I have. I have.

(*Id.* at 97:5-8.)

- **November 12, 2014 Sidebar**:

> THE COURT: … [I]'m not letting McGuire get into payments from Ranbaxy. The question – the only question as to Ranbaxy is whether they knew that, um, from the deal with AstraZeneca, AstraZeneca was going to pay for delay as to everyone else? ... I'm not interested in payments.

(Ex. 5, 11/12/14 Trial Tr. Vol. 1 at 10:13-17, 10:21-22.)

- **November 12, 2014 Sidebar:**

> THE COURT: But having said that, **I've ruled that Ranbaxy caused no antitrust damages**.… **But I'm not interested, as a matter of law, in whether there was any**

> **payment from AstraZeneca to Ranbaxy. I'm not interested in had there not been a payment, Ranbaxy would have done this, that or the other thing**….

(*Id.* at 35:20-21, 36:2-6 (emphasis added).)

- **November 12, 2014 Sidebar:**

> THE COURT: 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….

(*Id.* at 39:2-7.)

- **November 13, 2014 Sidebar:**

> MR. SCHOEN: My concern, your Honor, is that I just heard you say, at least at the last sidebar, that this theory that the Ranbaxy settlement caused harm and delayed Teva was out?
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> THE COURT: It is out.

(Ex. 6, 11/13/14 Trial Tr. Vol. 1 at 36:5-9.)

- **November 13, 2014 Sidebar:**

> THE COURT: I'm sticking to my rulings. I don't see the 700 million [alleged payment to Ranbaxy] being relevant.

(Ex. 7, 11/13/14 Trial Tr. Vol. 2 at 64:3-4.)

- **November 13, 2014 Sidebar:**

> MR. SOBOL: And so if we're permitted, therefore, to now go into what the payment was to Ranbaxy –
>
> THE COURT: We're not. You're not.

(*Id.* at 75:23-25.)

- **November 18, 2014 Ruling:** The Court advises the parties that it will re-work the Verdict Form, adding among other things a specific question regarding "[t]he large and unjustified payment to Ranbaxy…." (Ex. 8, 11/18/14 Trial Tr. Vol. 1 at

4:22-23, 7:11-12.) In doing so, the Court acknowledges a "fairly fundamental misconception" and a "fundamentally different … verdict slip." (*Id.* at 5:4, 7:7-8.)

The Court's consistent and invariable ruling has permeated these proceedings and every decision Ranbaxy has made regarding trial of this case.[1] As a result, Ranbaxy has suffered and will suffer serious prejudice that cannot be cured. Without limiting the extent of the unfair impact the current situation will have on Ranbaxy's rights, the following decisions were made by Ranbaxy in direct reliance on the Court's initial summary judgment opinion and its repeated confirmation that it would stick by that opinion:

- **Ranbaxy's Opening Statement**: The representations made by Ranbaxy's counsel in his opening statement relied directly on the legal framework established by the Court's summary judgment opinion and the Verdict Form which was formed in accordance with that opinion and was presented to the jury in opening statements. Based on the Court's rulings, Ranbaxy's counsel framed his opening statement from the outset around Question 4 from the Verdict Form. The jury was advised that only one of the five questions on the Verdict Form even pertained to Ranbaxy. (Ex. 3, 10/21/14 Trial Tr. Vol. 2 at 120:11-14) ("There's five questions. Only one pertains to my client at all and that's question 4. You have to get through 1 through 3 before you even get to us.") The jury was promised that "Ranbaxy remains in this case for a single reason, and that's question 4 in the verdict form," followed by reading question 4 to the jury. (*Id.* at 120:18-21.) The jury was assured that

[1] Ranbaxy believes the Court was correct in its initial Summary Judgment Opinion to the extent of its ruling regarding the Ranbaxy payment issue.

answering "no" to question 4 in the Verdict Form "should be the end of the case as to Ranbaxy." (*Id.* at 122:22-24.) The jury was told that the issue of "large and unjustified payment" has "nothing to do with Ranbaxy…" (*Id.* at 125:9-13.) And, Ranbaxy's opening statement concluded with the comment that "if there is no agreement between Ranbaxy and both of the other defendants to delay the entry of generic Nexium on the market," the jury has to return a verdict for Ranbaxy. (*Id.* at 129:3-8.)

An opening statement is a promise to the jury about the case and what the evidence will show. Indeed, "…little is more damaging than to fail to produce important evidence that has been promised in an opening." *Anderson v. Butler*, 858 F.2d 16, 17 (1st Cir. 1988); *see also Plummer v. Jackson*, 491 Fed. Appx. 671, 679 (6th Cir. 2012) ("Promises to the jury … [in] and opening statement create expectations that, when broken, can lead a reasonable jury to draw negative inferences about the strength and integrity of the defendant's case.") The Court's November 18, 2014 ruling leaves Ranbaxy in the untenable position that it cannot keep its promises to the jury. Ranbaxy cannot possibly explain why the statements properly made in its opening statement are no longer relevant or perhaps, even worse, no longer accurate. And, there is no way to cure the substantial prejudice flowing from this situation through a jury instruction or otherwise.

- **Cross Examination of Witnesses**: Ranbaxy's counsel has made decisions with respect to every single one of the twelve witnesses who have testified live in direct reliance on the legal framework established by the Court's summary judgment opinion, the Verdict Form that was presented to the jury, and the guidance provided by the Court in the various sidebar conferences. Questions were foregone, some witnesses were not questioned at all, topics of inquiry were avoided altogether – all

in reliance upon the Court's rulings. The Court openly acknowledged that its "fundamental misconception" has had a direct impact on Ranbaxy's cross-examination approach. (Ex. 8, 11/18/14 Trial Tr. Vol. 1 at 5:5-11.) There is no possible way to cure the prejudice caused by Ranbaxy's decisions as to what extent and how to cross examine these live witnesses.

- **Deposition Designations**: Ranbaxy made strategic decisions regarding the specific testimony to designate and the objections to press in direct reliance on the legal framework established by the Court's summary judgment opinion, the Verdict Form that was presented to the jury, and the guidance provided by the Court in the various sidebar conferences.

- **Witness Selection and Retention**: Ranbaxy's witness list and order of proof were developed in direct reliance on the legal framework established by the Court's summary judgment opinion. Witnesses have been included and excluded in reliance on this Court's prior rulings. More importantly, a number of critical Ranbaxy employees who have information potentially relevant, if not critical, to the so-called "Ranbaxy payment issue" (now back in the case) are no longer employed with Ranbaxy and cannot be controlled by Ranbaxy in terms of securing their appearance at trial. One example of a former employee who is no longer under Ranbaxy's control is P.P. Nath, former Ranbaxy Vice President of Regional Supply Chain. Had Ranbaxy known the "Ranbaxy payment issue" would be in this case at the time these employees left the company, it could have taken steps to secure by agreement their appearance at trial and their contribution to defense of the claims

related to this issue. There is no way to cure the prejudice flowing from this situation.

- **Selection of Exhibits**: Ranbaxy's selection of exhibits was made in direct reliance on the legal framework established by the Court's summary judgment opinion. While possibly curable, the enormous effort required to comb through the existing exhibit list and potentially have to search the approximate 4,000,000 pages of documents produced in an attempt to find the best documentary evidence to address the "Ranbaxy payment issue" would be formidable, to say the least, especially in the middle of this trial.
- **Supplemental Expert Reports**: Plaintiffs have filed numerous expert reports, supplementing and outright changing their experts' opinions as rulings were made by this Court. Ranbaxy made specific decisions regarding whether and to what extent to supplement its own experts' opinions in direct reliance on the legal framework established by the Court's summary judgment opinion. It has foregone supplementation to address the numerous times Plaintiffs have altered their course with experts. Without limitation, Defendants' expert Dr. Greg Bell would no doubt have prepared supplemental opinions had Defendants known the "Ranbaxy payment issue" was coming back into the case mid-trial.

CONCLUSION

As this Court is well aware, the stakes in this trial are very high, with potentially billions of dollars on the line. The prejudice flowing from the Court's November 18, 2014 ruling poses a substantial risk that this case will be decided improperly and that Ranbaxy will suffer serious prejudice. Given Ranbaxy's justifiable reliance on the legal framework established by the Court's

summary judgment opinion, the Verdict Form, and the various sidebar conferences, a mistrial must be declared. There is simply no possible way five weeks into this complicated trial to cure the current decision through a jury instruction or otherwise.

Dated: November 19, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, J. Douglas Baldridge, hereby certify that this document was electronically filed and served using the Court's ECF system on November 19, 2014.

/s/J. Douglas Baldridge
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