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

TEVA'S SUPPLEMENTAL SUBMISSION IN SUPPORT OF
MOTIONS TO EXCLUDE DR. MCCOOL AND FOR DIRECTED VERDICT

Teva respectfully submits this Memorandum in response to the points made by Mr. Sobol during oral argument before we had to break for the day on Monday:

1. Plaintiffs' counsel again failed to identify any foundation or reliable methodology sufficient to satisfy Rule 702 explaining how Dr. McCool arrived at his royalty rate of 55% of net sales plus $10m. They point to no licensing deals, patent litigation settlements or litigation outcomes which support that royalty rate in the circumstances of the Teva Prilosec litigation. Dr. McCool's numbers are plucked out of thin air, which is exactly what the Federal Circuit has said is not permitted in this context. *Laser Dynamics Inc. v. Quanta Computer USA, Inc.*, 694 F.3d 51, 69, 76-77, 79-81 (Fed. Cir. 2012) (ordering new trial and ruling that trial court erred in admitting *Georgia-Pacific* opinion to a royalty rate "that appears to have been plucked out of thin air based on vague qualitative notions" and that was "arbitrary and speculative" and "finds no support in the facts in the record").

2. Dr. McCool waited until trial to admit that he did not have any comparables to anchor his analysis. 11/6/14 Tr. 118, 143. In his report, Dr. McCool never said that no comparables existed, and cited a number of purported "data points" as "support" for his rate.

But as set out in defendants' brief, none of those data points can possibly explain how he arrived at 55% plus $10m:

• In his report, the "market analysis" of the twelve deals purportedly all showing rates in excess of 50% of net sales was the basis for Dr. McCool's 55% of net sales number. But plaintiffs now admit that: (a) this analysis was not based on a reliable methodology since he purposefully ignored "low rate" deals; (b) none of the 12 deals are even remotely comparable; and (c) the majority fell were well below 55% of net sales in any event.

• Mr. Sobol conceded that Dr. McCool did rely on *Apotex* as a data point. *Apotex* involved the same Prilosec patents, the same court, and a hypothetical negotiation less than one year prior to the Teva hypothetical negotiation making it a direct comparable. But again, Dr. McCool could not explain how his rate is "based" on that case, given that: (a) AstraZeneca claimed a royalty equal to 45% of net sales with no upfront payment; (b) the Court awarded a royalty of 50% of profits, which is equivalent to 38% of net sales with no upfront payment; and (c) Dr. McCool could not identify any *Georgia-Pacific* factor that would support a higher royalty rate for Teva. 11/6/14 Tr. 102-107.[1]

• The *Andrx* settlement offer was 50% of profits, and therefore a much lower percentage of net sales, with zero upfront payment on the relevant 10 mg and 20 mg dosages. Accordingly, it does not explain Dr. McCool's 55% of net sales plus $10 million either. 11/6/14 Tr. 73, 77-78, 106.

[1] In their opposition, plaintiffs note that the *Apotex* royalty rate was not available at the time of the parties' 2004 hypothetical negotiation, but that did not prevent Dr. McCool from using it as a data point, just as, in the *Apotex* case, Judge Cote considered post-infringement events under the book of wisdom doctrine. *See* Ex. AUY at 64-79; Ex. AVB at 34 (in binder of stipulated documents plaintiffs submitted for admission on Monday). Further, if post-2004 data points are somehow out, then the Ranbaxy distribution agreement and powerpoint document also may not be considered, as those documents (Exs. 31, 32, 103) did not exist as of 2004 either.

• The supposed industry standard for authorized generic distribution agreements, of which Dr. McCool had no personal knowledge, is of no relevance given that Dr. McCool concedes that the Teva hypothetical negotiation did not concern a distribution agreement or an authorized generic at all, and that there are numerous differences between such an agreement and a bare patent license with no supply. While Mr. Sobol made arguments why he believes such agreements are comparable, Dr. McCool failed to provide any such economic reasoning on the stand, and therefore provided no foundation at all for basing a royalty rate on them. *ResQNet.Com, Inv. v. Lansa, Inc.*, 594 F.3d 860, 872 (Fed. Cir. 2010) (expert must provide foundation that licenses relied on are "commensurate with what the defendant has appropriated"; otherwise plaintiff "would be free to inflate the reasonable royalty analysis with conveniently selected licenses without an economic or other link" to the hypothetical license in question). Further, Dr. McCool provided no methodology which explains how he went from the 80% of actual profits with zero upfront payment in the Ranbaxy distribution agreement to his royalty rate of 55% of net sales plus $10 million, which amounts to 127% of the Teva/Impax actual profits. *See* Ex. CAK (in binder of stipulated exhibits plaintiffs offered for admission on Monday).

• Dr. McCool testified that his "primary" focus was to come to the right number necessary to "make AstraZeneca whole," but then admitted that he performed no analysis of the actual or expected financial impact on AstraZeneca of Teva's market entry as a fifth entrant into a shrinking market in which AstraZeneca had already lost 95% of its sales to the other generics. Plaintiffs offer no explanation as to how Dr. McCool could

reliably determine the rate necessary to make AstraZeneca "whole" without performing any analysis of how AstraZeneca would be affected, if at all, by Teva's entry.

3. It is only because cross-examination has revealed that none of Dr. McCool's "data points" can possibly explain how he arrived at his royalty rate that plaintiffs have now pivoted to the argument that it is "not their fault" because "there are no comparables." Plaintiffs suggest that any "uncertainty" should be held against defendants. ECF No. 1192 at 4-5. In so arguing, plaintiffs defeat their own claims. If what plaintiffs now argue is correct, and there were no relevant comparables at the time of the Prilosec settlement, then their entire theory of the case evaporates. If the Prilosec patent case was unchartered territory in terms of what a reasonable royalty would be, then there is no possible way that both AstraZeneca and Teva could have known that Teva was getting a "sweetheart deal" as plaintiffs allege. According to plaintiffs' own expert, there were no objective benchmarks for a reasonable royalty that the parties could have looked to at the time of their settlement in assessing whether one side or the other was coming out "ahead."

4. It is for this reason that defendants are entitled to a directed verdict even if plaintiffs prevail on their argument (they should not) that Dr. McCool's testimony is "shaky but admissible." ECF No. 1192 at 17. At best, Dr. McCool's testimony could allow a jury to find that a different royalty rate than what the parties agreed to could be reasonable. But Dr. McCool did not testify that his rate was the only rate that would be reasonable under the circumstances. Given that he concedes there were no objective benchmarks at the time, it follows that there is a wide range of royalty rates that would be reasonable under the circumstances, particularly in the context of the settlement in this climate of admitted uncertainty. Dr. McCool did not testify to the range of reasonable royalty rates, and most importantly, did not offer any opinion that the

rate Teva and AstraZeneca actually agreed to in their settlement fell outside of that range such that it amounted to an effective payment. In its summary judgment opinion, this Court made clear that it was the plaintiffs' burden to prove not just that other royalty rates might be possible outcomes, but rather that the rate the parties agreed on in their settlement was "so far below what [Teva] would have been required to pay had damages been assessed in litigation" that it amounts to a reverse payment. ECF No. 977 at 107. On this core issue, plaintiffs have offered zero evidence, even if Dr. McCool's "shaky" and foundation-less testimony is permitted to stand.

5. During argument, the Court made reference to Justice Breyer's statement in *Actavis* that it is "normally not necessary" to relitigate the patent case to "answer the antitrust question." *FTC v. Actavis*, 133 S. Ct. 2223, 2236 (2013). But Justice Breyer did not make that statement in the context of a case in which the alleged payment is the supposedly discounted settlement of another patent case. That is, Justice Breyer was suggesting it may not be necessary to relitigate all aspects of the Nexium case, because the presence of a "large unexplained payment" might say something about what the parties thought about the patent merits in that Nexium case.[2] The Supreme Court did not suggest that if, as here, the settlement of another unrelated patent case (Prilosec) is the supposed basis for a payment, that there is no need to get into the merits of that case to determine whether a reverse payment was made at all.

6. Given that this is not the underlying Prilosec case, but an antitrust case in which the basis for plaintiffs' claim is that the settlement of the Prilosec case is outside the range of reasonable settlement outcomes, if anything Dr. McCool should be held to a more rigorous standard, not a more lenient one. That is, plaintiffs here are seeking to use Dr. McCool's royalty rate as a benchmark against which the "reasonableness" of the Prilosec settlement is to be

[2] With regard to the Nexium patent case, the patent merits are still, however, relevant to causation, as discussed in prior briefing.

evaluated. To permit the jury to do so with the testimony of a royalty expert whose testimony is so speculative and lacking in foundation that it would not even be admissible in the underlying Prilosec case would defy all logic and hold the defendants' settlement against an unfair standard.

7. If Dr. McCool is excluded, this case is over. Nothing has changed since the Court recognized this in its summary judgment ruling. ECF No. 977 at 112 n.12, 154. While plaintiffs point to evidence they believe establishes that the Nexium and Prilosec settlements were a "package deal," that evidence does not establish the existence or amount of any payment; indeed, that merely explains why the Prilosec settlement is being subjected to a second-look to determine whether it was, as plaintiffs claim, a sweetheart deal. Plaintiffs still need to prove that the Prilosec settlement was "so far" below what was reasonable that it constituted a reverse payment, and they have adduced no evidence sufficient to prove this, with or without Dr. McCool.

8. Nor is there any merit to plaintiffs' argument that they can prove a payment merely by showing that AstraZeneca was claiming treble damages and attorney fees in the Prilosec case, so that Teva theoretically faced exposure well above the $9 million for which they settled. Every case settles for less than the plaintiff has a Rule 11 basis to claim. As this Court held at summary judgment, the standard is not how the settlement compares to the maximum theoretical exposure, but to the damages the defendant "would have been required to pay." ECF No. 977 at 107. There is absolutely no primary or expert evidence in the record from which a reasonable jury could conclude that Teva would have been required to pay treble damages or attorney fees in the Prilosec case.[3]

9. One need look no further than this very case to highlight the absurdity of plaintiffs' last-ditch payment argument. Plaintiffs asserted claims in this case against DRL for

[3] The only evidence is to the contrary. *See* Exhibit AUW, at 12-13 (in binder of stipulated exhibits submitted for admission on Monday).

billions of dollars in damages, prior to trebling, but then settled with DRL for zero in exchange for DRL's cooperation. By plaintiffs' logic, this would mean that plaintiffs effectively "paid" DRL billions of dollars for its cooperation. Of course they did not, because the plaintiffs properly recognized that even though they had a Rule 11 basis to make claims against DRL, they had virtually no chance of prevailing on them, making their zero dollar settlement reasonable under the circumstances. If this Court were to allow plaintiffs to continue this case based on a "payment" theory that turns not on evidence of what reasonably could have been recovered in the Prilosec case, but on how the settlement compares to what was claimed, then literally no settlement would be immune from antitrust scrutiny. This plainly was not what the Supreme Court contemplated in *Actavis*, or what this Court had in mind when it denied summary judgment based on the assumption that the plaintiffs had a competent expert who could provide a valid foundation for the existence of a payment using a reliable methodology. Plaintiffs were given two do-overs on their Prilosec royalty analysis prior to trial (first with Dr. McGuire and then with Dr. McCool) and nonetheless failed to come forward at trial with any competent evidence that the Prilosec settlement constituted an "effective payment" to Teva. Accordingly, it is time for the Court to finally pull the plug on the plaintiffs' sole remaining theory of liability.

CONCLUSION

The expert testimony of W. Shannon McCool should be stricken in its entirety. But with or without Dr. McCool's testimony, Teva is entitled to a directed verdict, as plaintiffs have failed to come forward with any evidence sufficient to prove a large and unjustified payment to Teva.

Dated: November 12, 2014

Respectfully submitted,

/s/ Laurence A. Schoen

Laurence A. Schoen, BBO # 633002
Adam L. Sisitsky, BBO # 637532
MINTZ, LEVIN, COHN, FERRIS,
GLOVSKYAND POPEO, P.C.
One Financial Center
Boston, MA 02111
Telephone: (617) 542-6000
Facsimile: (617) 542-2241
LASchoen@mintz.com
ALSisitsky@mintz.com

KIRKLAND & ELLIS LLP
Jay P. Lefkowitz, P.C. (*pro hac vice*)
Karen N. Walker, P.C. (*pro hac vice*)
Kevin T. Van Wart (*pro hac vice)*
Jonathan D. Janow (*pro hac vice*)
655 Fifteenth Street, N.W., Suite 1200
Washington, D.C. 20005
Telephone: (202) 879-5000
Facsimile: (202) 879-5200
karen.walker@kirkland.com
jonathan.janow@kirkland.com

CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of November 2014, I filed and served the foregoing via the Court's CM/ECF system, which will serve notification of such filing by email to all counsel of record.

/s/ Laurence A. Schoen
Laurence A. Schoen