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 MEMORANDUM IN SUPPORT OF DIRECTED VERDICT MOTION ON THRESHOLD ISSUE OF A LARGE AND UNEXPLAINED PAYMENT

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INTRODUCTION

Teva moves for directed verdict based on the lack of legally sufficient evidence that AstraZeneca made a large and unexplained payment to Teva. Although the Court instructed plaintiffs to present their evidence on this issue at the beginning of the trial,[1] they waited nearly three weeks before finally putting their payment expert, Dr. W. Shannon McCool, on the stand. And we now know why: Dr. McCool turned out to be the classic *ipse dixit* opinion witness. His reasonable royalty opinion had no foundation and was not a product of "reliable principles and methods applied in a reliable manner." *McGovern v. Brigham & Women's Hosp.*, 584 F.Supp.2d 418, 423 (D. Mass. 2008) (citing *Daubert v.Merrell Dow Pharms., Inc.*, 509 U.S. 590-91). Dr. McCool did not identify any sales or profit base against which to apply his assumed royalty rate and, at the last minute, plaintiffs decided ***not*** to have him express any opinion on the main issue they had hired him to address: whether Teva received a reverse payment from AstraZeneca and, if so, the amount of any such payment. Nor did he (or any other expert) offer any opinion that the $9 million Teva paid AstraZeneca to settle the Prilosec litigation was not a reasonable royalty, was not a reasonable settlement, or was outside the range of reasonable settlements or the range of reasonable royalties.

On the threshold issue of payment, there has been a complete failure of proof. Despite the extensive pretrial proceedings devoted to this subject, the do-overs the Court afforded plaintiffs, and all the promises plaintiffs made about their expected evidence, plaintiffs have not delivered. There is no legally sufficient evidence from which the jury could conclude that there

[1] *See* 9/30/14 Pretrial Conf. Hr'g Tr. at 6 ("And when you're done [with the Plaintiffs' presentation of evidence on the alleged large and unexplained payment], I want to know it because the rule provides that when we have all of the evidence on an issue -- and we'll have all the plaintiff's evidence on an issue -- defendants can move for [a directed verdict]. And absent that, if that fails, if there isn't a substantial unjustified payment, case over…."); Oct. 15, 2014 Charge Conf. Hr'g Tr. at 10 ("Once you've put in all your evidence on that point, then you're to notify the Court. That's the pretrial order…. [I]f I resolve it against the plaintiffs, I will be satisfied that I have created a sufficient record and … that the case is teed up for appeal.").

was a payment from AstraZeneca to Teva, that any such payment was "large," or that the $9 million Teva paid AstraZeneca was not within a reasonable royalty or settlement range. And that is true even if the Court does not grant defendants' separately filed motion to exclude the testimony of Dr. McCool. Dr. McCool's central premise, repeated throughout his testimony, was that there are ***no*** transactions that are "truly" comparable to the hypothetical Prilosec license negotiation, which involved a non-exclusive bare patent license for a fifth entrant in a shrinking generic market:

> Q. Now, you mentioned on direct that there weren't any good hypothetical negotiation comparables out there. Do you recall that testimony?
>
> A. None that I'm aware of.

11/6/14 Tr. at 143; *see also id*. at 118 ("There are no true comparable deals, I don't think.") and 124 ("There just aren't comparables to these kinds of deals."); 11/5/14 Tr. at 99-102 ("…they're about as rare as hen's teeth. I mean, you just don't see them. There are no true comparables.").

While defendants disagree with that premise, it has an important and binding corollary for purposes of directed verdict: at the time AstraZeneca and Teva negotiated their Prilosec settlement, there were ***no*** transactions that provided an objective benchmark that defined the range of reasonable royalties. Beyond rendering his opinion baseless, Dr. McCool's insistence that comparable transactions do not exist also means that different experts could reach materially different conclusions about what a reasonable royalty might be and, because there are no comparables, there is no way to conclude that one royalty is right or wrong or that the royalty paid by Teva was too low. Indeed, Dr. McCool admitted that as of 2004 (the time of his hypothetical negotiation) as well as as of the settlement negotiation in 2009, the prevailing "rule of thumb" in licensing negotiations was that a reasonable royalty was ***25%*** of profits, which is less than half of what Teva actually paid AstraZeneca. 11/6/14 Tr. at 85-87. Dr. McCool never

testified that such a royalty, while different from his preferred rate, was outside the range of reasonableness, and he took no position on what that range might be or, in the absence of ***any*** comparables or an established royalty range, how any royalty estimate could be deemed to fall outside the range of reasonableness.

Plaintiffs bear the burden of proof. Despite clear warning of the importance of the payment issue, they have squandered the repeated opportunities the Court gave them to demonstrate that they have legally sufficient evidence of a reverse payment. They do not. For the reasons explained more fully below, the Court should direct a verdict in favor of defendants on the threshold payment question.

The Prilosec Patents

From September 2004 until mid-2007 Teva sold a generic formulation of Prilosec supplied by Impax. Teva was the fifth company to enter the generic Prilosec market. The first company was Schwarz-KUDCO, which began selling its product in December 2002 *after* its formulation was found not to infringe AstraZeneca's patents. Ex. 1 ¶¶ 101-03. The second and third generic entrants, Mylan and Novartis (Lek) entered at risk in 2003, and ultimately were found not to infringe AstraZeneca's Prilsoec patents. *Id.* ¶ 101. The fourth generic entrant, Apotex, entered at risk in November 2003, and was still litigating with AstraZeneca at the time of the Teva settlement in January 2010. *Id.* Accordingly, at the time of that settlement there was no established range of reasonable royalty rates for the Prilosec patents. All of the prior generic entrants had either been found not to infringe, or were still litigating with AstraZeneca.

As plaintiffs' payment expert, Dr. McCool acknowledged, prior to Teva entering the Prilosec market in September 2004, AstraZeneca had already lost 95% of its sales to the four prior generic entrants, and the omeprazole (Prilosec) market as a whole (brand and generic

combined) was shrinking. 11/6/14 Tr. at 93, 95, 99. As a result, Teva entered to a smaller market opportunity than Apotex and, according to Dr. McCool, Apotex ended up with a "much bigger" share of the generic market for Prilosec than Teva did. *Id.* at 100-101.

Litigation relating to the Impax product began in May 2000, when AstraZeneca sued Impax alleging that Impax's generic Prilosec infringed AstraZeneca's Prilosec patents. Ex. 1 ¶ 100. Teva was not a party to the Impax suit, but AstraZeneca brought a separate infringement suit against Teva on January 18, 2005. *Id*. ¶¶ 100, 102. The Impax case and a case AstraZeneca had brought against Apotex, the fourth entrant, were tried together, and on May 31, 2007, the district court found that two of AstraZeneca's Prilosec patents were valid and infringed by both the Apotex and Impax products. *Id*. ¶ 103. The Federal Circuit affirmed this finding in August 2008, and the litigation returned to the district court for further proceedings. *Id.*

AstraZeneca's lawsuit against Teva included a claim for damages. On April 15, 2009, in response to a motion Teva had filed to compel the production of various financial documents, AstraZeneca disclosed that it was not seeking damages based on a lost profits theory, but only a reasonable royalty. Ex. 85 at 2. In May and June 2009, Teva, in response to pending discovery requests, produced to AstraZeneca the quarterly reports that Teva provided to its supplier, Impax, in the ordinary course of business regarding Teva's generic Prilosec net sales and profits. Exs. 50, 51, and 57. According to the reports contained in Exhibit 57, Teva's net sales of generic Prilosec totaled $38.4 million, the gross profits shared by Teva and Impax totaled $22.7 million and Teva's profits, after deducting its payments to Impax, totaled $16.4 million.[2]

[2] Exhibit 57 is the only primary evidence in the record regarding Teva's net sales and profits on generic Prilosec. Teva has also produced in the litigation a summary of the data reflected in its audited financial statements, which shows net sales of $41.1 million and profits of $19.7 million, but plaintiffs have not introduced that data in evidence. Ex. BZW. The audited data shows slightly higher net sales and profits due to differences in the definition of net sales and profits in the contract with Impax as opposed to the definition used for financial reporting purposes. There is no evidence that AstraZeneca had access to the audited numbers, as opposed to the Impax report numbers in Ex.

Teva and AstraZeneca witnesses both testified that they used data from the documents found in Exhibit 57 when negotiating the Prilosec settlement in August 2009. On August 19, 2009, David Stark of Teva sent a calendar invitation to arrange a preparation session for a settlement call that Richard Egosi of Teva was to have with Jeffrey Pott of AstraZeneca. Ex. 76. The invitation asked that, during that session, Kai Lyman "have the data handy for the royalty discussion." *Id.* In negotiating the Prilosec settlement with AstraZeneca, Teva used a summary of the sales and profit information in Exhibit 57. *See* 10/31/14 Tr. at 52, 55; 10/28/14 Tr. at 112-120. Even if the jury were to disbelieve defendants' testimony, the plaintiffs have offered no other evidence showing any other data for Teva's net sales and profits for the relevant time period.

Teva and AstraZeneca subsequently agreed to settle the Prilosec litigation. Ex. 1 ¶ 104. In that settlement, Teva agreed to pay AstraZeneca $9 million, *id*., which corresponds to 23.4% of its net sales of generic Prilosec, 39.6% of the gross profits shared by Teva/Impax on those sales, and 54.7% of Teva's retained profits after its payments to Impax. *See* Ex. 57.

LEGAL STANDARD

"A district court may grant a Rule 50 motion before the case is submitted to the jury if, after the party 'has been fully heard on an issue,' the court 'finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue.'" *Cham v. Station Operators, Inc.*, 685 F.3d 87, 93 (1st Cir. 2012) (quoting Fed. R. Civ. P. 50(a)(1)). The First Circuit has repeatedly held that a party seeking to overcome a directed verdict must adduce "evidence which consists of 'more than fragmentary tendrils: a mere scintilla of evidence is not enough to forestall a directed verdict.'" *Newharbor Partners, Inc. v. F.D. Rich Co.*, 961 F.2d

57, at the time of the settlement negotiation, but the differences between the two data sets are not of the magnitude that they would have any material impact on a reasonable royalty determination in any event.

294, 298 (1st Cir. 1992) (quoting *Fashion House, Inc. v. K Mart Corp.*, 892 F.2d 1076, 1088 (1st Cir. 1989)). In opposing a directed verdict motion, "the plaintiff is not entitled to inferences based on speculation and conjecture.'" *Malone v. Lockheed Martin Corp.*, 610 F.3d 16, 20 (1st Cir. 2010) (quoting *Vazquez-Valentin v. Santiago-Diaz*, 385 F.3d 23, 30 (1st Cir. 2004));

"[T]he partial denial of summary judgment does not preclude a motion for directed verdict following the close of evidence because facts presented in trial may enable the trial court to reach a determination as a matter of law." *Newharbor*, 961 F.2d at 297. Although "the standard for granting summary judgment 'mirrors' the standard for judgment as a matter of law," "[w]here differences between these two standards occur, the standard for granting summary judgment is more exacting than the standard for granting judgment as a matter of law. After all, judgment as a matter of law comes after a trial allowing the impeachment of evidence while nonmoving parties do not have the full ability to impeach testimony before the summary judgment stage." *SEC v. EagleEye Asset Mgmt., LLC*, 975 F.Supp.2d 151, 157 (D. Mass. 2013) (Young, J.) "Although the law does not change during the course of a trial, the clarification of issues and working out of the body of relevant evidence can result in a situation in which the jury's work ultimately is not needed … although initially it may have appeared that a jury trial was required." *MacNeill Eng'g Co. v. Trisport, Ltd.*, 126 F.Supp.2d 51, 69 (D. Mass.) (Young, J.) *dismissed*, 15 F. App'x 835 (Fed. Cir. 2001). Such is the case here.

ARGUMENT

Some procedural history is in order. At the summary judgment stage, this Court found that the primary evidence that plaintiffs offered to support their claim that the Prilosec settlement included a large reverse payment was legally insufficient and that plaintiffs required reliable expert support for such a claim. 2/12/14 Order (ECF No. 857) at 3 (granting summary judgment "primarily on the basis that the Plaintiffs fail to demonstrate the existence of a 'large, unjustified

reverse payment' under Actavis, and have not taken the additional opportunity provided by this Court for their expert, Dr. Thomas McGuire, to prepare a proper reasonable royalty damages calculation under accepted methodologies.") After giving plaintiffs some additional bites at the apple, the Court, in denying Teva's renewed motion for summary judgment, again made clear that the issue of whether the Prilosec settlement included a large reverse payment required reliable expert support. 9/4/14 Summ. J. Op. (ECF No. 977) at 103-117. The Court even noted that if this case had gone to trial as originally scheduled, plaintiffs' case would have failed because of the flawed methodology of their original reverse-payment expert, Dr. McGuire. *Id*. at 112, note 12 ("the Plaintiffs would have been caught short and their carefully constructed theory would have collapsed, as McGuire's originally flawed methodology was (and is) unacceptable to the Court. It is only the unavoidable continuance of the case to the October running trial list that has permitted the Plaintiffs to cobble together this theoretically acceptable analysis.")

Three weeks of trial have now passed and, despite the Court's explicit warnings about the type of evidence required to meet their burden of proof, plaintiffs have not presented any new primary evidence or any opinion evidence that would support a finding the Prilosec settlement included a reverse payment, let alone one that was "large" and "unjustified." Plaintiffs' case rests entirely on speculation and conjecture and the testimony of a reverse-payment expert who (1) offered no opinion on whether the $9 million Prilosec settlement included a reverse-payment or was outside the range of reasonable royalties; (2) offered no opinion on whether the Prilosec settlement was outside the range of reasonable settlements; and (3) could not identify a single licensing agreement, settlement, or court award involving a non-exclusive bare patent license to a late generic market entrant where the royalty was materially different from the royalty Teva paid AstraZeneca to settle the Prilosec case, let alone the 55% of net sales and an upfront payment of $10 million conjured by Dr. McCool. 11/6/14 Tr. at 145-46. Indeed, Dr. McCool repeatedly insisted that there are no

transactions comparable to the one at issue here. The Court should direct a verdict because the trial record does not contain any legally sufficient evidence that the Prilosec settlement included a large reverse payment.

I. THERE IS NO LEGALLY SUFFICIENT EVIDENCE OF A REVERSE PAYMENT.

The issue of whether a reverse payment is "large" and "unjustified" does not arise unless there is first sufficient evidence of a reverse payment. There is no such evidence here. Neither the primary evidence nor the opinion evidence provides a legally sufficient basis for a finding of a reverse payment.

A. The Primary Evidence Does Not Support A Finding Of A Reverse Payment.

As this Court recognized, "[t]rial experts are not the source of primary evidence. They merely provide the jury with a potential means for analyzing that evidence." 9/4/14 Summ. J. Op. (ECF No. 977) at 111. The Court already ruled at the summary judgment stage that plaintiffs' primary evidence was insufficient to support their reverse-payment claim and, therefore, plaintiffs required reliable expert support to prove such a payment. The situation has not changed: plaintiffs have not presented to the jury any primary evidence that would support a finding of a reverse payment.

First and foremost, plaintiffs have not put before the jury a single patent licensing agreement involving a non-exclusive license to a late market entrant in a shrinking market where the royalty was outside the range that Teva paid AstraZeneca. Not one. Nor have they introduced any evidence that in any comparable circumstances AstraZeneca or Teva ever negotiated or was ordered to pay a royalty that was materially higher than that they agreed to here (23.4% of net sales or 54.7% of profit). Quite the opposite, Dr. McCool testified that, apart

from the Prilosec settlement, he is not aware of any instance in which Teva agreed to pay a royalty rate that exceeds 10% of its net sales. 11/6/14 Tr. at 90-91.

Second, plaintiffs have not put before the jury any primary evidence that would allow a jury to conclude that the $9 million payment Teva made to AstraZeneca falls outside the range of reasonable royalties that are negotiated or awarded in analogous circumstances or the range of reasonable settlements.

The only primary evidence they have offered would require the jury to speculate about matters that require expert analysis and opinion that plaintiffs chose not to provide. For example, plaintiffs introduced evidence that in the Prilosec case, AstraZeneca asserted claims for willful infringement and attorney fees, which they apparently will argue means that even though Teva's Prilosec sales and profits were small, Teva still faced a risk of substantial damages. But plaintiffs offered no evidence on the likelihood that such claims would have succeeded. They presented no evidence that AstraZeneca had ever recovered such damages or that they had ***ever*** been awarded against Teva. The evidence is entirely to the contrary. *See* 10/31/14 Tr. at 84 (Teva has "never been found to willfully infringe"); 10/28/2014 Tr. at 140 (AstraZeneca's counsel had "no recollection of ever winning a willful infringement claim."). Nor did plaintiffs provide any expert opinion that would allow the jury to assess the strength of these claims or the likelihood that AstraZeneca would have prevailed. Neither Dr. McCool nor Dr. McGuire made any mention of these claims or attempted to assign any value to them. The jury cannot speculate on these types of legal matters, and the mere assertion of such claims is not legally sufficient evidence that such claims materially increased Teva's financial risk. *See* 9/4/14 Summ. J. Op. (ECF No. 977) at 127 ("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. *Cf. FTC v.*

Watson Pharm, Inc., 677 F.3d 1298 1313 (11th Cir. 2012)("A chance is only a chance, not a certainty.")."); 10/31/14 Tr. at 83 ("THE COURT: I remind the jury that Mr. Sobol's numbers are not evidence of anything. The evidence came from the witness.").

Plaintiffs also introduced evidence relating to the supply and distribution agreements between Ranbaxy and AstraZeneca and a Ranbaxy Powerpoint slide presentation (Ex. 103) that states that a 90% profit share is the "industry standard" for *authorized generic* distribution agreements, *i.e.*, an agreement in which a generic company distributes for the brand a brand-produced generic product at the same time as and during the 180-day exclusivity of the first-generic filer. But no expert testified that these types of agreements are at all analogous to the non-exclusive bare patent license at issue here, where the "licensee" is a late entrant to a shrinking generic market and there is no supply relationship. To the contrary, rather than provide an opinion that they are analogous, Dr. McCool said there are *no* comparable agreements. *See. e.g.*, 11/6/14 Tr. at 123-124 ("A nonexclusive bare patent license. Again, it falls under the category of not being a comparable. There just aren't comparables to these kinds of deals.") The jury cannot, on its own, reach a different conclusion and find that the Ranbaxy supply and distribution agreements or agreements involving the distribution of a brand company's authorized generic has anything to do with the type of bare patent license at issue here. In the absence of expert support, such a finding would rest entirely on confusion and speculation.[3]

[3] Of course, Teva does not agree with Dr.McCool's assertion that there are no comparable transactions. He just decided not to use them. For example, Apotex was the fourth company to enter the generic Prilosec market and, was found to have infringed the Prilosec patents in the same trial as Impax. AstraZeneca offered to settle its claim against Apotex for a royalty rate of 37% of Apotex's net profits, 10/29/14 Tr. at 32 and 34, and, as Dr. McCool noted, the court eventually awarded AstraZeneca a royalty of 50% of Apotex's profits (equivalent to 38% of Apotex's net sales, with zero upfront payment) The profit percentage Teva paid AstraZeneca to settle the Prilosec case exceeded both the settlement offer and award in the Apotex dispute, even though Teva entered the market after Apotex. In addition, the evidence showed that in another matter where, as here, AstraZeneca and Teva agreed to

B. The Opinion Evidence Does Not Support A Finding Of A Reverse Payment.

Since June, when they submitted the report of Dr. McCool, plaintiffs had made clear that they planned to use his testimony to meet their burden of proving that the Prilosec settlement included a reverse payment. But between the time Dr. McCool took the stand last Wednesday and stepped down on Friday, they had a change of heart. Although his original assignment, repeated in each of his reports, explicitly included offering an opinion on whether the $9 million Prilosec settlement included a "net payment" from AstraZeneca to Teva, plaintiffs decided not to have him address this subject. Instead, all he did was offer a bare and conclusory opinion giving his preferred royalty rate (55% of net sales and an upfront payment of $10 million). He did not identify any sales or profit base against which to apply this royalty rate; he did not opine that other, lower royalty rates would be unreasonable; he did not express any opinion on whether Teva received a reverse payment from AstraZeneca and, if so, the amount of any such payment (much less that it was "large" and "unjustified"); and he did not express an opinion that the $9 million Teva paid falls outside the range of possible reasonable royalties or the range of reasonable settlement outcomes. In fact, Dr. McCool did not even express an opinion as to what that range might be. His opinion left the jury without any legally sufficient basis to conclude that the $9 million Teva paid to settle the AstraZeneca case was so far below the amount of reasonable royalty damages that it included a reverse payment.

Dr. McCool's testimony should be stricken for the reasons set out in defendants' separately filed motion to strike. But even if the Court did not grant that motion, Dr. McCool's repeated assertion that he could not find any relevant comparable transactions means that there is no basis for the jury to favor any royalty rate over any other. Dr. McCool did not, for example,

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settle their dispute, they did so for a royalty rate of 2.3% of Teva's net sales when "there were five generics in the market." 10/31/14 Tr. at 68, 71. In contrast, Teva paid AstraZeneca 23.4% of Teva's net sales of generic Prilosec.

point to other non-exclusive bare patent licenses, litigation settlements, or judgments involving late generic entry and show how the amount Teva agreed to pay was far below the royalties owed or paid in directly analogous circumstances. He said, instead, that there are no comparable transactions. In the absence of any comparable transactions, there is no evidentiary basis on which to find that the royalty paid by Teva fell outside of the range of royalties within which the Prilosec settlement "should have" fallen.

Dr. McCool never testified that his royalty "best estimate" should or could be given any more weight than any other estimate. He even conceded that, as of 2004, when the hypothetical negotiation between AstraZeneca and Teva was assumed to have occurred, and continuing up through 2010, when the case actually settled, the prevailing "rule of thumb" was that a licensor "ought to be entitled to 25% of the fruits of the license, if you will" and "that's usually interpreted as 25 percent of the profits after expenses have been paid." 11/6/14 Tr. at 85-87. Teva's $9 million payment exceeded this "rule of thumb" two-fold. And Dr. McCool provided no opinion that a payment that met this "rule of thumb" was any less reasonable then his proposed royalty of 55% plus a $10 million upfront payment. Nor did he testify that the royalty rate Teva paid AstraZeneca was itself unreasonable. In the absence of any comparables, the range of reasonable royalties is necessarily far larger than the single speculative rate hypothesized by Dr. McCool.[4] Dr. McCool did not suggest otherwise -- and said nothing to suggest that -- Teva's $9 million payment fell outside the range of a reasonable royalty.

II. THERE IS NO LEGALLY SUFFICIENT EVIDENCE OF A "LARGE" AND "UNEXPLAINED" REVERSE PAYMENT.

Even assuming that plaintiffs had presented legally sufficient evidence that the Prilosec settlement included a reverse payment, which they did not, under *Actavis* they would still have to

[4] Moreover, it cannot possibly be the case that a single rate is the only rate that can be negotiated by parties to a settlement. There would, by definition, be a range -- and Dr. McCool gave no such range.

prove that any such payment was "large" (as well as unexplained). There is no legally sufficient evidence to support such a finding.

A. No Evidence Payment Was Large

Importantly, plaintiffs did not present any testimony on the amount of the alleged reverse payment. Although Dr. McCool had addressed this issue in his report (as did Dr. McGuire in his original report), at trial plaintiffs chose not to ask him what conclusion he had reached. In the absence of any expert opinion quantifying the alleged reverse payment, a jury could not reasonably find that any such payment was large. *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410, *21 (D.N.J. Oct. 6, 2014) ("Plaintiffs' calculation of the monetary value of the [claimed payment] is vague and amorphous…. Plaintiffs must provide some reliable foundation to show that a reverse payment agreement was actually entered and present specific facts showing how the alleged non-monetary payment was calculated.").

In an apparent attempt to get around this problem and lower their burden of proof, plaintiffs had Dr. McGuire testify that the test for whether the alleged reverse payment is large is whether it exceeds avoided litigation costs. 11/7/14 Tr. at 90. One problem with this effort is that it ignores the applicable legal test, which focuses on the profit opportunities of the brand drug and the generic drug. *FTC v. Actavis*, 133 S. Ct. 2223 2235 (2013); *Effexor*, 2014 WL 4988410 at *23 (D.N.J. Oct. 6, 2014) ("[T]o determine if [a payment] is large, [a plaintiff must demonstrate] whether the value of the non-monetary payment was a substantial amount of annual sales of the brand product …, as it must be a payment that appears to be large from the perspective of the brand company making the payment."); *In re Lipitor Antitrust Litig.*, 2014 WL 4543502, *21 (D.N.J. Sept. 12, 2014) ("One [possible] way to measure the 'largeness' of a reverse payment is to assess whether the amount is larger than what the generic would gain in profits if it won the Paragraph IV litigation and entered the market."). Here, the Court already

has ruled that plaintiffs' sole surviving causation theory is that "Ranbaxy could have voluntarily relinquished its exclusivity rights and entered into a strategic partnership with Teva in jointly launching generic Nexium…. [in order to] 'share in exclusivity'" 9/4/14 Summ. J. Op. (ECF No. 977) at 125-26. That opportunity, because it would have involved six months of de facto exclusivity, would have amounted to billions in lost profits for AstraZeneca and hundreds of millions of dollars in foregone economic opportunity for Teva in the first six months alone, with continued profits for years. 10/29/14 Tr. at 107 ("Q: I want to make one other point. This is the economics for the brand. He goes from making $3 billion a year to making $300 million, right? A: Yes."); 10/31/14 Tr. at 64-66 (opportunity for first generic filer is approximately $600 million during the first *six months*; opportunity for second filer is $200 million over the next six months); 10/29/14 Tr. at 109 ("Q: The economics are a lot different if you're the first filer, right? A: Yes, it is…. Q: And that's because during that 180-day exclusivity period, if the manufacturer is the only manufacturer on the market, this price erosion isn't anywhere near down to 5 percent, right? A: That's correct."). Those comparators are so much larger than any claimed reverse payment here that plaintiffs have failed to lay a reliable foundation and failed to adduce legally sufficient evidence of a "large" payment under governing law. Plaintiffs' payment theory is the very definition of vague.

But even assuming that Dr. McGuire was correct and the standard was only whether a payment exceeded avoided litigation costs, his assertions about the litigation costs avoided in the Prilosec and Nexium litigation have no foundation. As this Court found prior to trial, "Dr. McGuire's explanation of saved litigation costs is so lacking in analysis that it cannot be useful to any jury." 9/4/14 Summ. J. Op. (ECF No. 977) at 115. Nothing has changed since then. Dr. McGuire testified that he had simply read a survey about the costs of patent infringement litigation with claimed damages of $25 million and up and simply picked the "median" of that

survey ($5 million to $6 million) to present to the jury (after cutting it in half). 11/7/14 Tr. at 131-135. Dr. McGuire admitted that he performed no analysis of the Prilosec and Nexium cases to assess their complexity, determine where they fell within the types of cases included in the survey data, analyze the litigation costs actually expended in those cases compared to the cases in that survey, or even identify what issues remained to be litigated in the Prilosec and Nexium cases. 11/7/14 Tr. at 126, 124, 129-30. Nor could Dr. McGuire explain how he arrived at his number, even based on the survey data, given that three separate patent cases were covered by the settlements. The primary evidence in this case is that by settling the Prilosec and two Nexium cases AstraZeneca avoided $14 million in future litigation costs. Ex. 107 ¶¶ 4, 6. Plaintiffs have adduced no legally sufficient evidence that the Prilosec settlement included a reverse payment of $14 million.

B. No Evidence Payment Was Unexplained or Unjustified

As the Court explained in the opening charge to the jury, under *Actavis* a payment reflecting "traditional settlement considerations" is not one that is "unexplained" under the law. Oct. 21, 2014 Trial Tr. at 37-38; *see also Actavis,* 133 S. Ct. at 2233, 2236. Such "traditional settlement considerations" necessarily include "the traditional example[] [where] a party with a claim (or counterclaim) for damages receives a sum equal to ***or less than*** the value of its claim." *Actavis*, 133 S. Ct. at 2233, 2236 (emphasis added).

No evidence has been presented that the Prilosec settlement (whether or not the reasonable royalty that would have been awarded at trial) was not a reasonable *compromise* of that litigation based on its procedural context and the Teva sales and profit numbers at the time of settlement, the very traditional settlement considerations envisioned and approved of by the Supreme Court. The actual primary evidence adduced on this point is uniform and dispositive:

- At the time of the Prilosec settlement, Teva was still asserting its ability to contest liability anew (10/31/14 Tr. at 36);
- Litigation risks and uncertainty remained for both parties (10/31/14 Tr. at 36, 62);
- Any damages phase of the Prilosec litigation had yet to begin and would take substantial time and litigation expense to complete (10/29/14 Tr. at 134-136);
- The parties had just exchanged Teva sales and profit information that formed the basis of the parties' royalty rate assessment (10/31/14 Tr. at 61).

In the face of this evidence, even if the Prilosec settlement were at a level below what AstraZeneca would have obtained had it litigated the case against Teva to conclusion (of which there is no evidence), there is no evidence it was something other than a traditionally discounted negotiated settlement amount reflecting litigation uncertainty, saved legal expenses, the time value of money, and the parties' desire for certainty and resolution. Allowing a jury to second-guess the compromise (without any legally sufficient evidence to do so) would have a chilling effect on patent settlements.[5]

After all, patentees who settle rarely obtain the *full* damages they could recover at trial. If they did, the accused infringer would have little incentive to settle. That is why it is a ***compromise***. While plaintiffs contend AstraZeneca might have recovered more at trial, they offer no evidence that Teva's $9 million settlement was not reasonable as a compromise of a disputed claim.

Even if plaintiffs had put forward a proper reasonable royalty analysis (which they did not), the mere existence of a differential or discount between a possible reasonable royalty award and the amount for which Teva and AstraZeneca settled their dispute does not establish and "unexplained" payment. Plaintiffs point to no evidence that the ***compromise*** reached, *i.e.*, the

[5] It would be irrational to settle a patent damages case when, by doing so, a party would have to effectively re-litigate the issues years later to prove its settlement was "reasonable." *See e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188, 251-52 (E.D.N.Y. 2003).

alleged discount off a possible Prilosec judgment, was so unreasonable that it constituted an unexplained or unjustified reverse payment to Teva.

CONCLUSION

For the foregoing reasons, a directed verdict should be entered in favor of Teva on all claims, based on the plaintiffs' failure of proof on the threshold issue of whether AstraZeneca made a large and unexplained payment to Teva.

Dated: November 10, 2014

Respectfully submitted,

/s/ Laurence A. Schoen

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th 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
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