IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| KING DRUG COMPANY OF FLORENCE, INC., et al., Plaintiffs, | : | CIVIL ACTION |
| v. | : | No. 2:06-cv-1797 |
| CEPHALON, INC., et al., Defendants. | : | |
| VISTA HEALTHPLAN, INC., et al., Plaintiffs, | : | CIVIL ACTION |
| v. | : | No. 2:06-cv-1833 |
| CEPHALON, INC., et al., Defendants. | : | |
| APOTEX, INC., Plaintiff, | : | CIVIL ACTION |
| v. | : | No. 2:06-cv-2768 |
| CEPHALON, INC., et al., Defendants. | : | |

**Goldberg, J.** **October 5, 2015**

**MEMORANDUM OPINION**

This antitrust case involves allegations that four reverse-payment settlement agreements entered into by a brand-name drug manufacturer and four generic drug companies constitute antitrust violations under the Sherman Act.[1] A variety of Plaintiffs[2] claim that these agreements,

[1] These agreements were entered into by Defendant, Cephalon, Inc. ("Cephalon"), the brand-name manufacturer of Provigil, and the following Defendant generic drug manufacturers: Barr Pharmaceuticals, Inc. ("Barr"); Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"); Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA,

whereby the brand-name manufacturer paid the alleged generic infringers approximately $300 million, were created and signed with the purpose of delaying the market entry of generic versions of the brand-name pharmaceutical, Provigil. Defendants, both the generics and the brand-name manufacturer, respond that the agreements were legitimate settlements of Hatch-Waxman patent litigation and contained procompetitive terms. A more thorough recitation of the background of this case can be found in several previously issued Opinions. See, e.g., King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2015 WL 356913 (E.D. Pa. Jan. 28, 2015).

This Opinion addresses several motions filed pursuant to Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). In the first motion, "Plaintiffs' Daubert Motion to Exclude the Opinions of Gregory K. Bell," both the Direct Purchaser and End Payor Class Plaintiffs argue that the testimony of defense expert, Gregory Bell, should be excluded.[3] A second motion, filed by the Direct Purchaser Class Plaintiffs only,[4] also seeks the exclusion of defense experts and is styled "Direct Purchaser Class Plaintiffs' Daubert Motion to Exclude Certain Opinions and Proposed Trial Testimony of Defendants' Experts Jerry Hausman and Edward A. Snyder." Both of these motions raise a multitude of reasons as to why the proposed expert testimony should be excluded.

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Inc. (collectively "Teva"); and Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy") (collectively referred to as the "Generic Defendants").

[2] These Plaintiffs include: Direct Purchasers of the brand-name pharmaceutical Provigil ("Direct Purchasers"), End Payors of Provigil ("End Payors") and Apotex, Inc. ("Apotex"). The Federal Trade Commission ("FTC") also brought claims against Cephalon arising out of the reverse-payment settlement agreements, but those parties have recently settled.

[3] This motion has also been joined by Apotex.

[4] This motion is joined by the End Payors and Apotex.

Plaintiffs' motions primarily challenge the experts' failure to consider the subjective intent of the persons that executed the settlement agreements in question. Plaintiffs assert that Defendants are attempting to convince the jury through the objective economic analyses performed by Bell, Hausman and Snyder that the settlements were motivated by certain economic factors, despite the fact that these experts never reviewed evidence on Defendants' subjective intent. According to Plaintiffs, this omission is particularly troubling because Defendants have resisted any discovery regarding the decision makers' subjective intent through the assertion of the attorney-client privilege. (DP Hausman Snyder Br., p. 2 ("Indeed, the defendants' actual ex ante views of the strength of the RE '516 patent and the merits of the patent litigation have been withheld by the defendants based on the attorney-client privilege").) Plaintiffs also challenge these experts' opinions regarding potential procompetitive justifications for the settlements, including opinions relating to "litigation uncertainty." Plaintiffs further question Bell's training and experience.

For the reasons detailed below, Plaintiffs' motion will be denied in most respects. I do conclude, however, that opinions offered on behalf of a patent holder that a reverse-payment settlement was procompetitive because it resolved its litigation uncertainty is not admissible.

## I. FACTUAL AND PROCEDURAL BACKGROUND

### A. Proffered Opinions of Gregory Bell

Bell's opinions are set forth in three separate reports, which total in excess of 150 pages, excluding exhibits. On March 27, 2015, I ordered Defendants to submit an offer of proof summarizing the opinions of a number of their experts, including Bell. Bell's opinions can be boiled down to the following points:[5]

[5] This summary does not include Bell's opinions on damages.

- The settlement agreements at issue did not delay generic entry onto the relevant market, largely because shared exclusivity among the Generic Defendants granted by the FDA decreased the economic incentives of an at-risk launch;

- The settlement agreements resolved litigation uncertainty for both Cephalon and the Generic Defendants;

- It was unlikely that an at-risk entry would occur;

- The settlement agreements did not foreclose other generic drug manufacturers from challenging the RE '516 patent and entering the market, e.g., the agreements did not cause a "bottleneck";

- The payments made under the settlement agreements were not "large and unexplained," but rather commercially reasonable and procompetitive;

- The settlement agreements reflected "traditional settlement considerations";

- The available economic evidence does not support an objective inference that the RE '516 patent was known to be invalid or "perceived to be weak"; and

- Cephalon did not possess monopoly power within this larger product market.

**B. <u>Proffered Opinions of Jerry Hausman and Edward A. Snyder</u>**

Hausman's opinions are set forth in several voluminous reports. As a result of my March 27, 2015 Order, Hausman's opinions were summarized as follows:

- The settlements at issue were procompetitive because they removed litigation uncertainty;

- An at-risk launch by the Generic Defendants was unlikely due to reduced economic incentives;

- The settlement payments were small and included an analysis of litigation risk;

- Plaintiffs' experts' analyses of the settlement agreements are deficient;

- The settlement agreements did not create a bottleneck preventing other generic companies from coming to market; and

- The procompetitive aspects of the settlement agreements outweighed any adverse effects on competition.

Snyder's expert reports are in excess of one hundred pages. Although framed and drafted slightly differently, Snyder's summary proffer and expert reports are similar in nature to those of Hausman in many respects. Snyder performs an objective economic analysis of the competitive effects of the reverse-payment settlements and the contemporaneous business transactions, taking into account, among other things, the resolution of the parties' litigation uncertainty. He also argues that the record does not support Plaintiffs' experts' conclusions that Defendants believed the RE '516 patent to be weak. Snyder opines that any analysis regarding whether the settlement agreements were procompetitive, whether the business agreements were for fair value, or whether the parties believed the RE '516 patent was strong must be viewed from the time that the settlement agreements were signed.[6]

**C. Summary of Arguments Raised**

Although Plaintiffs raise a variety of reasons under Daubert as to why some of the opinions of Bell, Hausman and Snyder should be stricken, Plaintiffs primary concern seems to be that these experts do not opine on or consider the subjective beliefs of the actual decision makers who signed the settlement agreements. Plaintiffs assert that in order for these opinions to be

[6] Snyder's original report, written in 2011, discussed the "Scope of the Patent Framework," a standard that was rejected by the Supreme Court in Federal Trade Commission v. Actavis, Inc., 133 S. Ct. 2223 (2013). However, Snyder's supplemental expert report, which was completed after Actavis, acknowledges that the rule of reason framework is appropriate for reviewing the effects that reverse-payment settlements may have on competition.

Plaintiffs seek to exclude Snyder's first expert report in its entirety due to his application of the scope of the patent test in reviewing the reverse-payment settlements. However, Defendants acknowledge that the scope of the patent test is not the appropriate standard in a reverse-payment settlement case, and state that Snyder "will of course not be offering opinions about the application of the scope of the patent framework." (Defs.' Hausman & Snyder Resp., p. 18.) Defendants' concession on this point puts this issue to rest. The mere fact that Snyder discussed the scope of the patent test in his initial report does not render the entire report unreliable or inadmissible. While the scope of the patent test is mentioned throughout Snyder's reports, that framework does not impact or influence a significant number of his opinions.

reliable or fit the facts of the case, Defendants' subjective intent in entering into the agreements must be considered.

In conjunction with this argument, Plaintiffs continue to raise a concern that Defendants have long asserted the attorney-client privilege, preventing discovery on Defendants' decision makers' state of mind when entering into the settlement agreements. Plaintiffs argue that Defendants cannot side-step harmful evidence on the subjective intent of their decision makers by asserting the attorney-client privilege and then have an expert witness testify as to the reasonableness of those transactions. (Pls.' Bell Br., pp. 5-6; Pls.' Hausman Snyder Br., pp. 6-13.)

Defendants readily agree that these expert opinions do not include the subjective views of those persons who entered into the settlement agreements, as Bell, Hausman and Snyder perform an objective economic analysis of the settlement agreements. They further respond that all of the opinions are properly offered, do not offend the standards set forth in Daubert, and do not discuss or consider the subjective intent of Defendants' decision makers, which is consistent with Defendants' assertion of the attorney-client privilege.

As noted above, Plaintiffs also raise concerns regarding expert opinions that litigation uncertainty was a procompetitive justification for the agreements, arguing that such a justification would run afoul of Actavis. Defendants respond that litigation uncertainty constitutes a traditional settlement consideration that the Supreme Court determined could justify a reverse-payment settlement.[7]

[7] Plaintiffs also raise concerns as to certain expert opinions that necessarily assume the validity of the RE '516 patent in light of the fact that this patent was subsequently determined to be invalid. This issue will be addressed in a separate opinion concerning the relevance and reliability of proposed testimony provided by Defendants' patent experts.

## II. LEGAL STANDARD

Federal Rule of Evidence 702 governs the admissibility of expert testimony, and states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702 "embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-43 (3d Cir. 1997)). In evaluating whether an expert opinion is admissible, the district court acts as a gatekeeper, excluding opinion testimony that does not meet these requirements. Id. The burden is on the party offering the evidence to establish admissibility by a preponderance of the evidence. Padillas v. Stork-Gamco, Inc., 186 F.3d 412, 418 (3d Cir. 1999).

An expert is qualified if he or she has specialized knowledge "greater than the average layman." Waldorf v. Shuta, 142 F.3d 601, 625 (3d Cir. 1998) (quoting Aloe Coal Co. v. Clark Equip. Co., 816 F.2d 110, 114 (3d Cir. 1987)). This requirement is interpreted liberally, as "a broad range of knowledge, skills, and training qualify an expert." Schneider, 320 F.3d at 404.

Reliability requires that an expert's opinion be based upon "'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'" In re Paoli, 35 F.3d at 742 (quoting Daubert, 509 U.S. at 590). In considering whether an expert's method is reliable, courts should consider: (1) whether it is based upon testable hypotheses; (2) whether the method has been subject to peer review; (3) the known or potential error rate; (4) "the existence and maintenance of standards controlling the technique's operation"; (5) whether it is generally

accepted; (6) the relationship of the technique to other methods that have been deemed reliable; (7) the expert's experience or qualification with the technique or method; (8) non-judicial uses the method has been put to; and (9) all other relevant factors. Id. at 742 n.8.

The reliability requirement is not to be applied "too strictly" and is satisfied as long as the expert has "good grounds" for his or her opinion. Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 784 (3d Cir. 1996). "Proponents of expert testimony do not have to 'prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of the evidence that their opinions are reliable.'" In re DVI, Inc. Sec. Litig., 2014 WL 4634301, at *5 (E.D. Pa. Sept. 15, 2014) (quoting In re Paoli, 35 F.3d at 744) (emphasis in original).

There also must be a "valid scientific connection" or "fit," between the facts of the case and the expert's opinion. Daubert, 509 U.S. at 591-92; see also Holbrook, 80 F.3d at 777. This requirement ensures that the opinion is relevant and will "assist the trier of fact to understand the evidence or to determine a fact in issue." Daubert, 509 U.S. at 591. Finally, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Id. at 596 (citing Rock v. Arkansas, 483 U.S. 44, 61 (1987)).

## III. LEGAL ANALYSIS

My January 28, 2015 Memorandum Opinion generally sets out the framework for reverse-payment settlement antitrust claims under Federal Trade Commission v. Actavis, Inc., 133 S. Ct. 2223 (2013). There, I concluded that the following burden-shifting rule of reason analysis should apply:

> [U]nder a standard rule of reason analysis, the plaintiff bears the initial burden of demonstrating that "the alleged combination or agreement produced adverse, anti-

> competitive effects within the relevant product and geographic markets." Brown Univ., 5 F.3d at 668. The plaintiff can meet this burden by demonstrating actual anticompetitive effects or by establishing that the defendant possesses market power. Id. Actavis notes that both the likelihood of anticompetitive harm and the probability that the patent holder possesses market power increase as the size of the reverse payment increases. Actavis 133 S. Ct. at 2235-36. For example, the Court remarks that a large payment can provide strong evidence of the relevant anticompetitive harm—"that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." Id. at 2235. Importantly, Actavis instructs that "the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of [market] power." Id. at 2236 (citation omitted) (emphasis added). These statements indicate that evidence of a large payment is required for a plaintiff to satisfy its initial burden of demonstrating anticompetitive effects under the Actavis rule of reason analysis. See also id. at 2237 ("the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size . . .").
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> Under a standard rule of reason analysis, after a plaintiff establishes that an agreement has brought about anticompetitive effects, the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently procompetitive objective—in other words, to justify the conduct. Brown Univ., 5 F.3d at 669; 7 Areeda & Hovenkamp ¶ 1504a, pp. 401-02 (under rule of reason "we look to the defendant, with its knowledge of its own situation, to identify the possible justifications for its conduct"). Synthesizing this precedent with the Court's statements in Actavis, I find that whether or not the reverse payment is unjustified or unexplained is examined under the standard rule of reason burden-shifting framework, with the defendant bearing the burden of providing evidence that the reverse payment is justified by procompetitive considerations.

King Drug Co. of Florence, Inc., 2015 WL 356913, at *10-11. Given this backdrop, I conclude that as proffered in their reports, and further refined through Defendants' joint offers of proof on experts, most of Bell, Hausman and Snyders' opinions are admissible. I reach this conclusion for several reasons.

First, the majority of the challenged expert testimony fits within the framework I set out regarding the burdens of proof in an Actavis trial. Opinions pertaining to the agreements' procompetitive objectives and the value obtained from certain contemporaneous business transactions fall within the rule of reason analysis endorsed in Actavis. Other opinions regarding

why the payments are not "large and unexplained" and Cephalon's market power are also relevant to the rule of reason analysis outlined above. See Actavis, 133 S. Ct. at 2236-37.

Second, despite Plaintiffs' insistence that several of these opinions should be excluded for failing to consider Defendants' subjective intent, expert testimony on Defendants' subjective reasons for entering into the settlement agreements will not be offered, and in any event, is inadmissible. Throughout their memoranda of law, Plaintiffs press inconsistent arguments. On one hand, they continually urge that certain opinions should be excluded because the opinions impermissibly speculate on Defendants' state of mind. At the same time, Plaintiffs also complain that Defendants' experts did not speak with decision makers to learn of Defendants' subjective intent prior to forming their expert opinions. Plaintiffs posit that the relevant ex ante inquiry is what was actually on the minds of Defendants' decision makers at the time of settlement.

The admissibility of evidence relating to a party's state of mind was recently explored in the antitrust case of In re Flonase Antitrust Litigation, 884 F. Supp. 2d. 184 (E.D. Pa. 2012), where a brand-name drug manufacturer was alleged to have impermissibly delayed generic market entry. The plaintiffs alleged that this delay was caused by the filing of a sham citizen petition with the FDA. The defendant's Daubert motion challenged testimony from one of the plaintiffs' experts regarding the defendant's knowledge of "whether a final guidance from FDA needed to be issued prior to approval of an Abbreviated New Drug Application (ANDA)[.]" Id. at 190. The defendant argued that an expert could not testify regarding its state of mind. Id. at 191. In resolving this dispute, the district court allowed the expert to opine as to what information would normally be available to the brand regarding "FDA practice and policy." Id.

at 192. However, the court emphasized that any expert testimony regarding the brand's "state of mind" as to why it filed a citizen petition would be "impermissible." Id. at 193.

I conclude that the basic evidentiary principle articulated in Flonase—that any witness, including an expert, cannot offer testimony regarding someone else's state of mind—squarely applies here. See also In re Rosuvastatin Calcium Patent Litig., 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) ("Generally, expert witnesses are not permitted to testify regarding 'intent, motive, or state of mind, or evidence by which such state of mind may be inferred.'") (quoting Oxford Gene Tech., Ltd. v. Mergen Ltd., 345 F. Supp. 2d 431, 443 (D. Del. 2004)); In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony"). Indeed, Defendants recognize this basic evidentiary rule and clearly acknowledge that they will not ask Bell, Hausman or Snyder to opine about the state of mind of persons who entered into the settlement agreements at issue. (Defs.' Bell Resp., p. 7 ("Dr. Bell did not conduct these subjective analyses because such assessments are improper for an expert economist. Instead, Dr. Bell performed a proper objective economic analysis").)[8] Should Plaintiffs believe that any question posed to

[8] Dr. Bell described his analysis as follows:

> [M]y ex-ante analysis is based on the information that . . . somebody in my position would have had at the time. . . . I'm not making any representation of what a generic defendant would have believed or thought or necessarily expected, per se, other than what might be expressed in deposition testimony or other available documents. But, rather, my analysis is done using the information available at the time.

(Bell Dep., Feb. 11, 2014, pp. 55-58.)

defense experts at trial goes beyond permissible inquiries, they are, of course, free to object at that time.[9]

The challenged experts' analyses are largely derived from the economic information available to Defendants at the time of the settlement agreements, and these experts opine on what a rational, objective actor would have considered in light of that information. While Plaintiffs assert that this type of objective analysis is not relevant to the issues a jury would need to consider in conducting an Actavis inquiry, they provide no support for this assertion. Other courts have permitted this type of objective economic analysis in reverse-payment settlement cases. (See Bell CV, Dec. 20, 2013, pp. 4, 7, 10 (listing several reverse-payment Hatch-Waxman antitrust cases where Bell has provided expert economic testimony).) Therefore, I find that objective economic analysis of the settlement agreements and the various business deals executed alongside these agreements fit the rule of reason framework applicable in this case and do not offend the standards set forth in Daubert.

Plaintiffs have also continually pressed the point that the expert opinions of Bell, Hausman and Snyder impermissibly allow Defendants' assertion of the attorney-client privilege to be used as both a shield and a sword. I disagree. These experts have made clear that they did not consider any privileged information in forming their opinions, and they will not be permitted to opine as to Defendants' subjective intent. Thus, no privileged information has been utilized, or put "at issue." Nor have Defendants relied upon the advice of counsel as a defense. See

[9] One exception to my general conclusion that Bell, Hausman and Snyder perform appropriate, objective economic analyses is an opinion from Snyder, opining that "Generic manufacturers also realized the importance of potential generic entry, and considered necessary contingency plans." (Snyder Reply Exp. Rep., ¶ 21(ii).) Opining upon what the Generic Defendants "realized" and "considered," as opposed to what would have been considered by a rational economic actor, crosses the line into impermissibly stating the subjective thoughts and intentions of Defendants. This aspect of the motion will be granted, as Defendants themselves acknowledge that expert opinions regarding a party's subjective intent is not admissible.

Rhone-Poulenc Rorer Inc. v. Home Indem. Co., 32 F.3d 851, 863 (3d Cir. 1994) (attorney-client privilege waived where "the client has made the decision and taken the affirmative step in the litigation to place the advice of the attorney in issue"). Accordingly, Plaintiffs' assertion that Defendants have used the attorney-client privilege as both "a shield and a sword" is simply inaccurate.

Plaintiffs also assert that opinions regarding at-risk launch should be excluded because they do not fit the facts of this case. Returning to the same theme, Plaintiffs urge that this testimony is inadmissible because "Dr. Bell did not attempt to recreate what was actually on the minds of the Generic Defendant decision-makers ex ante." (Pls.' Bell Br., p. 13.) Plaintiffs raise similar complaints regarding Hausman. Again, Defendants have not offered these experts to speculate regarding the state of mind of those persons who entered into the settlement agreements, and in any event, such testimony would be inadmissible.

In reaching his opinions as to whether a rational economic actor in the position of the Generic Defendants was objectively likely or unlikely to launch at risk, Bell considered: (1) that the Generic Defendants' shared a 180-day exclusivity period and the impact that arrangement had on the economic incentives to launch at risk; (2) the potential liability associated with launching at risk; and (3) the costs of litigation. (Bell Exp. Rep. ¶¶ 8, 41-53; Bell Supp. Exp. Rep. ¶¶ 7, 41-47.) Similarly, Hausman conducted an ex ante analysis of the net present value of profits from an at-risk launch and compared those prospective profits to the potential liability the Generic Defendants would face if they were to lose the patent litigation. (Hausman Exp. Rep. ¶¶ 67-74.) To the extent that evidence in the record contradicts Bell and Hausman's conclusions or indicates that the Generic Defendants intended to launch at risk, such evidence would provide grounds for cross-examination. See Tormenia v. First Inv. Realty Co., Inc., 251 F.3d 128, 135

(3d Cir. 2000) ("Whether through contrary expert testimony or cross-examination, appellants possessed ample available means to challenge perceived weaknesses in assumptions underlying [expert's] testimony"); Boucher v. U.S. Suzuki Motor Corp., 73 F.3d 18, 21 (2d Cir. 1996) (unless expert testimony is speculative or so unrealistic that it suggests bad faith, "other contentions that the assumptions are unfounded go to the weight, not the admissibility, of the testimony") (citations and quotation marks omitted).

Plaintiffs also attack Bell's qualifications and ability to offer opinions regarding the fair value of the business transactions entered into at the time of settlement. Bell's extensive experience in economics and the pharmaceutical industry is detailed in Defendants' response, as well as Bell's CV, and does not need to be repeated here. (Defs.' Bell Resp., pp. 15-16; Bell CV.) Despite this experience, Plaintiffs press that Bell does not have expertise in particular aspects of the business agreements—for example, the value of active pharmaceutical ingredient supply agreements.

Bell supplemented his own understanding of supply and demand and other economic factors with that of other experts to provide a detailed, objective economic analysis. (See Bell Supp. Exp. Rep. ¶¶ 6, 17-27.) An expert's qualifications are interpreted liberally under Daubert and Bell clearly has extensive experience in conducting economic analyses in the pharmaceutical context. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596 (citing Rock, 483 U.S. at 61).[10]

[10] Plaintiffs raise additional concerns that Bell's opinions regarding the fair value of the business agreements "run[ ] counter to substantial and clear evidence to the contrary" and thus do not fit the facts of the case. (Pls.' Bell Br., pp. 13-16.) As previously stated, evidence within the record that is contrary to any of Bell's opinions can be addressed on cross-examination and will go to the weight the jury will give to Bell's testimony. See Walker v. Gordon, 46 Fed. Appx. 691,

Plaintiffs further assert that any opinions offered by Bell, Hausman and/or Snyder that the reverse payments were made to avoid litigation uncertainty are contrary to the holding of Actavis, and thus, do not fit the facts of the case. Defendants respond that avoidance of litigation uncertainty constitutes a relevant, procompetitive justification for reverse-payment settlements under the rule of reason.

After closely reviewing Actavis, I find that opinions that the reverse payments were made to avoid Cephalon's "litigation uncertainty"—that is, the risk of Cephalon losing the infringement litigation against the Generic Defendants and the RE '516 patent being declared invalid or not infringed—is not relevant for the purposes of explaining or justifying the reverse payments. Therefore, for the following reasons, I conclude that opinions regarding the patent holder's litigation uncertainty do not meet Daubert's fit requirement and are excluded.

First, while Actavis provides many observations regarding Hatch-Waxman reverse-payment settlements, one prevailing theme is that they are "unusual." Actavis, 133 S. Ct. at 2231. In typical patent litigation settlements, the alleged infringer, who has been accused of entering the market and infringing on the patent, pays the patent holder money damages. However, in reverse-payment settlements, the opposite occurs—the brand name patent holder pays money to the alleged generic infringer, even though the generic does "not have any claim that the [patentee] was liable to [it] for damages." Id.

Certainly, in typical litigation settlements, a plaintiff with a claim for a specific sum of damages must consider the "risk" or "uncertainty" that the litigation could result in an outcome that is less than favorable, thus explaining a settlement for less than the claim. This logic does not apply to the unusual terms of a Hatch-Waxman reverse-payment settlement where the patent

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695-96 (3d Cir. 2002) ("An expert is . . . permitted to base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion is for the jury.")

holder—i.e. the plaintiff—is making the payment to the generic defendant, the challenges to the patent are dropped, and the generic agrees to stay off of the market for a specified period of time. As the Actavis court stressed, these circumstances may lead a jury to conclude that the party with no damages claims "walks away with money simply so it will stay away from the patentee's market. That, we think, is something quite different." Id. at 2233.

The Actavis opinion supports the determination that a patent holder's litigation uncertainty cannot justify a reverse payment. The Court explained:

> [t]he owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And . . . that consequence constitutes the relevant anticompetitive harm.

Id. at 2236. Consequently, any expert opinion offered by Cephalon regarding its own litigation uncertainty is precluded.

Although I conclude that evidence of Cephalon's litigation uncertainty cannot be offered to explain or justify the terms of the settlement agreements and the associated payments, this does not mean that other procompetitive justifications for the reverse payment, such as "avoided litigation costs or fair value for services" are inadmissible. Actavis approves of these potential justifications because, unlike a patent-holder's avoidance of litigation risk, they do not raise the same "concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." Actavis, 133 S. Ct. at 2236 (emphasis added).

My conclusion regarding Cephalon's litigation uncertainty does not, however, extend to the Generic Defendants. Unlike Cephalon, the litigation uncertainty that the Generic Defendants faced in the underlying infringement litigation was the potential of the RE '516 patent being upheld as valid and infringed. Thus, the "risk" to be avoided for the Generic Defendants was

being kept off of the market for the duration of the RE '516 patent or owing money damages for an at-risk launch. As these considerations do not implicate anticompetitive motivations, they may be introduced by the Generic Defendants. Indeed, when denouncing the avoidance of patent invalidation as a procompetitive justification, the Actavis Court focused its comments towards the patent owner, not the generic/alleged infringer. See id. ("the owner of a particularly valuable patent" cannot justify the payment with the risk of patent invalidation). Therefore, the Generic Defendants may present expert testimony regarding their own litigation uncertainty in providing procompetitive justifications for the reverse-payment settlements. (See e.g., Hausman Exp. Rep., June 10, 2011, ¶¶ 25-29 (opining on how the average generic defendant will have "substantial uncertainty about whether it will succeed in its patent challenge").)[11]

Finally, Plaintiffs argue that the experts in question should be precluded from opining that generally, settlement is procompetitive. Plaintiffs urge that this testimony does not fit the facts of the case under Actavis because what is relevant here is whether the challenged payments are procompetitive. It is true that some of the opinions presented by these experts relate more to the procompetitive merits of settlement in general as opposed to the reverse payments specifically at issue. That does not mean, however, that this evidence is irrelevant under the broad rule of reason balancing test that will be applied.

Ultimately, the jury will have to determine why each Defendant entered into its respective settlement agreement—whether it was to avoid invalidation of the RE '516 patent and

[11] This testimony may include Bell's opinions that the settlements were procompetitive because they eliminated the Generic Defendants' risk of infringing any later issuing patents for Provigil. While Plaintiffs insist that Defendants have already stipulated that the only later-issuing patent—the '346 patent—would not have been an obstacle to generic market entry, this fact requires the benefit of hindsight. As Bell is performing an ex ante analysis, it would have been unclear to the parties at the time of settlement whether any additional patents would be forthcoming. Therefore, the resolution of the Generic Defendants' uncertainty regarding the possibility of future patents may constitute a relevant procompetitive justification. Plaintiffs may, of course, cross examine Bell regarding the absence of any post-settlement patents.

share in monopoly profits, or if it was for some other, procompetitive reason. General background on patent litigation, the Hatch-Waxman framework, and the adverse effects that litigation may have on businesses can provide the jury with context for answering these questions. Accordingly, I decline to exclude this evidence on the procompetitive merits of settlement, so long as it is not offered to establish that the reverse payment was in any way connected with avoiding the risk of patent invalidation or a finding of noninfringement.

## IV. CONCLUSION

Defendants have no stated intention of introducing expert testimony regarding the subjective state of mind of persons who entered into the settlement agreements, and such testimony would be inadmissible. Therefore, challenges to Bell, Hausman and Snyder's opinions for failing to consider or opine upon the decision makers' subjective intent will be denied. I further find that the vast majority of Plaintiffs' additional challenges to Bell, Hausman and Snyder regarding qualifications, and the reliability and fit of these experts' opinions do not warrant exclusion under Daubert, and are more appropriately addressed through cross-examination or competing expert testimony. Plaintiffs' motion to preclude expert opinions regarding Cephalon's litigation uncertainty is granted.

An appropriate Order follows.