

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

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|---------------------------------------|---|-------------------------|
| APOTEX, INC., | : | CIVIL ACTION |
| | : | |
| Plaintiff, | : | |
| | : | |
| v. | : | No. 2:06-cv-2768 |
| | : | |
| CEPHALON, INC., <u>et al.</u>, | : | |
| | : | |
| Defendants. | : | |

Goldberg, J.

May 18, 2017

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 Apotex, Inc., a generic competitor, and other Plaintiffs claim that these settlement agreements were created and signed with the purpose of delaying the market entry of generic versions of the brand-name pharmaceutical, Provigil. Defendants maintain that the agreements were legitimate settlements of Hatch-Waxman patent litigation and contained procompetitive terms.

A liability trial is currently scheduled for June 5, 2017. As a result of various settlements and the procedural postures of the other related cases, the only plaintiffs in that trial are Apotex

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

and a group of owners and operators of retail pharmacies who filed their own separate actions. Over the course of this litigation, these plaintiffs have been referred to as “Individual Plaintiffs,” “Retailer Plaintiffs,” “Opt-Out Plaintiffs” and “Merchant Plaintiffs.” The only defendants in the June trial are Mylan and Ranbaxy.

This Opinion addresses Mylan and Ranbaxy’s motion challenging the damages analysis set forth by Apotex’s expert, Dr. Hal Singer, under Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).² For the reasons that follow, Defendants’ motion will be granted in part and denied in part.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Hatch-Waxman Administrative Framework

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, commonly known as the Hatch-Waxman Act, is designed to encourage the development and marketing of generic versions of approved drugs. It allows generic manufacturers to file an Abbreviated New Drug Application (“ANDA”) when seeking approval from the Food and Drug Administration (“FDA”) to market a generic version of an approved drug. See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1282 (Fed. Cir. 2008).

ANDA filers must submit one of four certifications addressing any and all patents covering the brand-name drug, certifying either: (1) that the relevant patent information has not been filed with the FDA; (2) that such patent has expired; (3) the date that such patent will expire; or (4) “that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” Id. at 1282-83 (quoting 21 U.S.C.

² The Daubert motion challenging Dr. Singer’s damages analysis was filed by all Defendants. However, Cephalon, Teva and Barr have since settled with Apotex and the Retailer Plaintiffs. (See Dkt. 06-1797, Doc. No. 503; Dkt. 06-2768, Doc. No. 1057.)

§ 355(j)(2)(A)(vii)). “If a generic drug company seeks to market a generic version of a listed drug before the expiration of the Orange-Book-listed patents³ covering that drug, it must file a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), i.e. a ‘Paragraph IV certification.’” Id. at 1283 (citing Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990)).

Filing a Paragraph IV ANDA constitutes an act of patent infringement, often prompting the patent holder to file a lawsuit. However, as an incentive to generic companies to challenge weak patents, the first applicant to file an ANDA with a Paragraph IV certification is entitled to a 180-day period of exclusivity for its generic drug beginning on the first day it markets its drug commercially. Federal Trade Commission v. Actavis, Inc., 133 S. Ct. 2223, 2228-29 (2013).

When a patent holder files an infringement lawsuit within forty-five days of a Paragraph IV ANDA filing, the FDA is barred from approving the generic company’s ANDA for a period of 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). If the case is resolved during the 30-month stay, the FDA will take action on the ANDA consistent with the court’s judgment. Actavis, 133 S. Ct. at 2228. If the case is still ongoing at the end of the 30-month period, the FDA may grant final approval on the ANDA, at which point the generic company will have to decide whether to sell its drug “at risk” of incurring damages should the Paragraph IV litigation result in a judgment favorable to the patent holder. Id.

B. Factual History

In 1997, Cephalon was issued U.S. Patent No. 5,618,845, covering specific formulations of modafinil, the active pharmaceutical ingredient (“API”) in Provigil. Cephalon was granted a

³ The FDA publishes a list of all patents covering a drug under which a claim of patent infringement could reasonably be asserted in the “Approved Drug Products with Therapeutic Equivalence Evaluations” publication, also known as the Orange Book. Caraco Pharm. Labs., Ltd., 527 F.3d at 1282.

reissue patent on modafinil, U.S. Patent No. RE 37,516 (“the RE ‘516 patent”), in 2002, which was scheduled to expire October 6, 2014.⁴

Modafinil is a wakefulness-promoting agent used to treat narcolepsy and other sleep disorders. On December 24, 2002, the Generic Defendants each filed an ANDA seeking to market generic versions of Provigil, and each filed a Paragraph IV certification with the FDA indicating that Cephalon’s RE ‘516 patent was either invalid or the generic products did not infringe the patent. Because each of the Generic Defendants filed ANDAs on the first possible day, all were eligible to share the 180-day first filer exclusivity. On March 28, 2003, Cephalon sued the Generic Defendants for patent infringement, (the “Paragraph IV litigation”), triggering an automatic thirty-month stay on the approval of their ANDAs.

The Paragraph IV litigation between Cephalon and the Generic Defendants settled between December 2005 and February 2006, while the Generic Defendants’ motions for summary judgment were pending. All of the settlement agreements included a provision by which Cephalon granted the Generic Defendants a license to market their generic modafinil products on a “date certain”—April 6, 2012. Also, all of the settlement agreements provided that the Generic Defendants could enter the market earlier than the date certain if: (1) Cephalon licensed any other generic manufacturer to market generic modafinil prior to the date certain; (2) another generic decided to launch “at risk”; or (3) if a judgment declared that generic modafinil may be sold without infringing the RE ‘516 patent (“the Contingent Launch Provisions”). Through a series of contemporaneous agreements reached at or around the time of settlement, Cephalon paid the Generic Defendants a total of approximately \$300 million.

⁴ As a result of studying Provigil’s effects on children, Cephalon also received an additional six months of pediatric exclusivity on Provigil, extending Cephalon’s exclusivity period through April 6, 2015.

Apotex alleges that had the Paragraph IV litigation continued, the RE '516 patent would have been declared invalid, not infringed by the Generic Defendants' products, and unenforceable due to Cephalon's fraud in the procurement of the patent. Apotex explains that due to the Generic Defendants maintaining the 180-day first filer exclusivity while agreeing to stay off of the market through 2012, a "bottleneck" was created, preventing Apotex and other generic drug companies from entering the market. Apotex has challenged the settlements and Cephalon's enforcement of the RE '516 patent as violations of Sections 1 and 2 of the Sherman Act.

C. Procedural History

In addition to the antitrust challenges to the enforcement of Cephalon's patent and the settlements, Apotex also sought declaratory judgments that the RE '516 patent was invalid, that Cephalon had procured the patent by fraud, and that the patent was not infringed by Apotex's generic Provigil product. After holding two bench trials, I entered judgment in favor of Apotex on the patent claims, finding: (1) that the RE '516 patent was invalid pursuant to the on-sale bar, and also for derivation, obviousness and lack of written description; (2) that the RE '516 patent was unenforceable due to Cephalon's fraud on the PTO; and (3) that Apotex's generic product did not infringe Cephalon's patent. See Apotex, Inc. v. Cephalon, Inc., 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011) affirmed Apotex Inc. v. Cephalon, Inc., 500 Fed. Appx. 959 (Fed. Cir. 2013) (unpublished); Apotex, Inc. v. Cephalon, Inc., 2012 WL 1080148 (E.D. Pa. Mar. 28, 2012).

After several rulings on the parties' motions for summary judgment and various settlements, Apotex's remaining antitrust claims relating to the reverse-payment settlement agreements are as follows: (1) illegal agreements in restraint of trade against all Defendants in

violation of Section 1 of the Sherman Act, and (2) conspiracy to monopolize against all Defendants in violation of Section 2 of the Sherman Act.⁵

D. The Damages Opinions of Apotex's Expert, Dr. Hal Singer

Dr. Singer has provided three alternate damages calculations in support of Apotex's damages claims.

1. Calculation 1

Damages Calculation 1 measures the lost profits Apotex allegedly suffered as a result of being unlawfully barred from the market by Defendants' conduct. (Singer Rep., Apr. 26, 2011, ¶¶ 87-88.) It assumes that in the but-for world, absent any settlement agreement with Cephalon, the Generic Defendants would have launched their generic Provigil products in either June or December 2006. Due to the 180-day exclusivity granted to the Generic Defendants as first filers, Dr. Singer then assumes that Apotex would have entered the market with its generic product 180 days later—on either December 21, 2006 or June 22, 2007. (Singer Rep. ¶¶ 70, 73; Singer Supp. Rep., Dec. 20, 2013, ¶ 35.) Dr. Singer opines that Apotex would have entered the market as the fifth generic entrant. (Singer Rep. ¶ 79.) He further relies upon contemporaneous projections maintained by Apotex in the normal course of business, to determine that Apotex would have captured 20 percent of the market for generic Provigil during this initial damages period. (Id. at ¶¶ 85-86, 88.)

Dr. Singer's opinion also factors in the September 2009 FDA Import Alert against two of Apotex's manufacturing sites, which prohibited Apotex from selling pharmaceuticals

⁵ As a result of the settlement with Cephalon, the following claims brought by Apotex are no longer part of the case: 1) Walker Process fraud against Cephalon in violation of Section 2 of the Sherman Act; (2) sham litigation against Cephalon in violation of Section 2 of the Sherman Act; and (3) tortious interference with prospective business relations against Cephalon.

manufactured at those facilities. The Import Alert ban was lifted on July 1, 2011, at which time Apotex was permitted to resume producing pharmaceuticals for sale from those manufacturing locations. Acknowledging that Apotex could not have marketed generic Provigil during this time in the but-for world, Dr. Singer excludes any lost profits that may have otherwise occurred during the period in which the Import Alert was in effect. (Singer Supp. Rep. ¶ 22; Fahner Rep., Exs. A, B.)

Relying upon the testimony of an Apotex executive, Mr. Gordon Fahner, Dr. Singer assumes that sales of generic Provigil would have resumed in September 2011, two months after the Import Alert was lifted. Further acknowledging that the Import Alert would have affected Apotex's relationships with its customer base, Dr. Singer opines that Apotex would have maintained a 7.5 percent market share upon re-launch. (Singer Supp. Rep. ¶ 33.)

Calculating the estimated sales and profits that Apotex would have earned in the but-for world during the initial damages period (December 2006 through September 2009) and the re-entry damages period (September 2011 through November 2013), Dr. Singer determines that Apotex suffered a total of \$113.2 million in lost profits.⁶ (Id. at ¶¶ 38-39.)

2. Calculation 2

In addition to the lost profits assessment set forth above, Dr. Singer provides a second damages calculation that was created at the request of counsel for Apotex. This second calculation modifies Calculation 1 to “assume[] that (a) first filers will be held to their contractual agreement with Cephalon not to enter until April 2012, and (b) Apotex would have entered the market and captured its anticipated profits as the fifth entrant plus the but-for profits

⁶ Dr. Singer also provides an alternate calculation in which the initial damages period extends from June 2007 through September 2009, in the event that the jury finds that Apotex would not have entered the market until June 2007. (See Singer Supp. Rep., Appx. 3, ¶ 11.)

of the first four generic entrants.” (Singer Exp. Rep. ¶ 89 (emphasis in original).) According to Dr. Singer, “[s]uch a theory of damages prevents defendants from keeping the overwhelming majority of their illegally obtained profits.” (Id.) Notably, Dr. Singer provides very little explanation regarding how Apotex would be entitled to the profits of the Generic Defendants. Using these parameters, Dr. Singer opines that Apotex suffered lost profits in the amount of \$455.8 million in Calculation 2. (Singer Supp. Rep. ¶¶ 38-39.)

3. Calculation 3

Finally, Dr. Singer presents a third damages model, which was also prepared at the request of counsel, “under a legal theory in which Apotex would have been the first firm to enter at-risk.” (Id. at ¶ 35.) This damages model is described as including, in addition to the lost profits described in Calculation 1, the lost profits that Apotex would have experienced if Apotex was not “subject to the 180-day exclusivity ‘bottleneck,’ but instead . . . entered as the sole generic competitor in December 2006.” (Id. at ¶ 36.) Using data from Teva’s real-world launch as the sole first filer in 2012, Dr. Singer projects lost profits in the amount of \$155.9 million in Calculation 3. (Id.)

E. Defendants’ Motion to Exclude Damages Testimony of Dr. Singer

Defendants raise a number of challenges to Dr. Singer’s damages opinions under Federal Rule of Evidence 702 and Daubert. Defendants challenge Dr. Singer’s first damages calculation, arguing that: (1) Dr. Singer’s assumption about Apotex’s initial market entry date is speculative and contrary to the evidence; (2) his assumption about Apotex’s re-launch date is unreasonable; (3) his market share assumption for the initial damages period is unreasonable; and (4) his market share assumption for the re-entry period is unreasonable. Defendants further challenge

Dr. Singer's Calculations 2 and 3, arguing that they lack factual support and that they measure damages in excess of lost profits, and thus, are contrary to the law.

For the reasons that follow, I find that Dr. Singer's Damages Calculation 1 meets the requirements of Daubert and Rule 702, and therefore will be permitted at trial. However, I agree with Defendants that Calculations 2 and 3 do not fit the facts of the case and are contrary to the law on antitrust damages, and thus, will be excluded.

II. LEGAL STANDARD

Rule 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 is 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

“An antitrust plaintiff who is excluded from the relevant market by anticompetitive activity is entitled to recover his lost profits.” Dolphin Tours, Inc. v. Pacifico Creative Svc., Inc., 773 F.2d 1506, 1511 (9th Cir. 1985). In antitrust cases, “the jury may not render a [damages] verdict based on speculation or guesswork” but “may make a just and reasonable estimate of the damage based on relevant data.” Bigelow v. RKO Radio Pictures, 327 U.S. 251, 264 (1946). An antitrust plaintiff’s proof of damages need not be exact because “[t]he most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created.” Id. (citing Package Closure Corp. v. Seal-Right Co., 141 F.2d 972, 979 (2d Cir. 1944)).

However, “the burden is placed upon the plaintiff to show that the damage claimed was in fact caused by the unlawful acts of the defendant and did not result from some other factor, such as . . . lawful competition by the defendant.” R.S.E., Inc. v. Pennsy Supply, Inc., 523 F. Supp. 954, 964 (M.D. Pa. 1981) (citing Van Dyk Research Corp. v. Xerox Corp., 631 F.2d 251 (3d Cir. 1980)). The United States Court of Appeals for the Third Circuit has held that a failure to consider the probable effects of lawful competition and changed economic conditions will lead to a damages award that is based on speculation and guesswork. See Coleman Motor Co. v. Chrysler Corp., 525 F.2d 1338, 1353 (3d Cir. 1975).

A. Defendants’ Challenges to Calculation 1

Defendants challenge Dr. Singer’s first damages calculation for two primary reasons: (1) the market entry dates for both the initial damages period and the re-entry damages period are

unreliable and unreasonable; and (2) the market share projections are speculative and not supported by the record. Apotex responds that the generic entry dates and market projections used in Dr. Singer's damages analysis are well-supported by contemporaneous documents, expert and lay witness testimony, and real world experience with the launch of generic Provigil.

1. The Initial Market Entry Date

As described above, Dr. Singer assumes that in the but-for world, the Generic Defendants would have launched their generic Provigil products in either June 2006 or December 2006. He then assumes that Apotex would have launched immediately after the 180-day period of exclusivity that is granted to first filers expired—that is, either December 21, 2006 or June 22, 2007. Apotex defends these opinions urging that experts are permitted to “make the assumptions of fact necessary to render a sound opinion, so long as such assumptions have a reasonable basis in the available record and are disclosed to the finder of fact.” Brill v. Marandola, 540 F. Supp. 2d 563, 568 (E.D. Pa. 2008); see also Elcock v. Kmart Corp., 233 F.3d 734, 754-55 (3d Cir. 2000) (assumptions used to support damages calculations must be based on a proper factual foundation).

Defendants' position is that Dr. Singer's assumptions regarding the initial entry dates by the Generic Defendants are not supported by the record, and that Dr. Singer provides no independent explanation for why at-risk entry was likely in the but-for world. According to Defendants, Dr. Singer's failure to provide an independent analysis as to the likelihood of at-risk entry renders his opinions unreliable and inadmissible.

Regarding the initial entry dates, Apotex explains that the Generic Defendants “would launch in June 2006 under two well-supported scenarios: (1) the invalid ‘516 patent was never issued, listed in the Orange Book, and/or enforced against the Generic Defendants; or

(2) Cephalon had still sued the Generic Defendants based on the ‘516 patent, but one or more of the Generic Defendants’ pending motions for summary judgment had been granted before June 2006.” (Apotex Resp., p. 7.) Both Apotex and Dr. Singer cite the report of another Plaintiffs’ expert, John R. Thomas, for support. Mr. Thomas opines that, as a regulatory matter, the Generic Defendants would have been eligible for final FDA approval on their generic Provigil products in June 2006 in the absence of the RE ‘516 patent, or if summary judgment had been granted prior to June 2006. (See Thomas Rep. ¶¶ 117-18.)⁷

In its initial response, Apotex argued that the first scenario—a world in which the ‘516 patent never issued—was supported by its Walker Process and sham litigation claims. However, as noted above, Apotex has since settled with Cephalon and, therefore, the Walker Process and sham litigation claims are no longer at issue. Consistent with this reality, Apotex recently conceded that there is no factual basis for Dr. Singer’s assumption that the Generic Defendants would have entered the market in June 2006 if the ‘516 patent never issued. (See Tr. May 12, 2017.) As such, I need only resolve Defendants’ challenge to the second scenario which is based on an assumption that one or more Generic Defendants would have obtained a favorable summary judgment ruling prior to June 2006. Generic Defendants primarily argue that there is no factual basis in the record to support this assumption.

In response, Apotex notes (1) Cephalon did not oppose the Generic Defendants’ statements of fact submitted in support of their motions for summary judgment; (2) the summary judgment motions were pending and fully briefed shortly before the Paragraph IV litigation settled; and (3) internal corporate documents indicate that the Generic Defendants expected to

⁷ Mr. Thomas opined that Cephalon’s various FDA exclusivities would have lapsed on June 24, 2006. (See Thomas Rep. ¶ 117.)

launch their generic Provigil products in June 2006. Based upon this evidence, particularly the timing of the events, Apotex argues that a reasonable jury could infer that the impetus behind the settlement agreements was a reasonable expectation that summary judgment would be granted in the Generic Defendants' favor.

In light of the foregoing, I conclude that Apotex has proffered evidence which could support its contention that the Generic Defendants' motions for summary judgment would have been granted before June 2006. While the evidence Apotex identifies certainly does not compel such a finding, it would be inappropriate to resolve the parties' disputes about what the evidence proves at this juncture. If a damages trial does occur, Defendants are free to explore the foundation for the June 2006 entry date through cross-examination and may present argument to the jury. Additionally, if necessary, Defendants may reassert their objection to the June 2006 entry date at trial, at which time I will be better suited to address the objection with a developed trial record. As it is premature to make such a fact-intensive determination, Defendants' challenge to Calculation 1 to the extent that it assumes that the Generic Defendants would have launched in June 2006 will be denied.

As noted above, Calculation 1 is based on two different dates on which the Generic Defendants would have launched—June 2006 and December 2006. Regarding the second launch date—December 2006, I also conclude that facts in the record, if accepted, could provide a reasonable basis for Dr. Singer's assumption that, absent the settlement agreements, the Generic Defendants would have entered the market at-risk in December 2006. Mr. Thomas's opinion that the 30-month stay would have expired in December 2006 and that the Generic Defendants would have been eligible, as a regulatory matter, to enter the market at-risk at that time are not challenged by Defendants.

Indeed, Apotex has pointed to a number of facts that would support a finding that the Generic Defendants would have launched at-risk at the conclusion of the 30-month stay. (See Pls.' Comb. Stat. of Uncontested Facts ¶¶ 97-136; Apotex Resp., Exs. H-K); see also King Drug Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402, 421-22 (E.D. Pa. 2015) (denying Ranbaxy's motion for summary judgment on causation due to genuine dispute of material fact on likelihood of at-risk launch). Any facts indicating otherwise would be appropriate grounds for cross-examination. Accordingly, I also disagree with Defendants' assertion that Calculation 1 should be excluded to the extent that it assumes that the Generic Defendants would have entered the market in December 2006.

In addition to the foregoing challenges, Defendants also object to Dr. Singer's assumption that Apotex would have launched 181 days after the initial entry by the Generic Defendants. Defendants argue that Cephalon would have sued Apotex for patent infringement in the but-for world when Apotex converted its ANDA to include a Paragraph IV certification, which was a necessary step for Apotex to enter the market. If that occurred, Apotex would be subject to its own 30-month stay on the approval of its ANDA, which would largely negate Apotex's damages during this initial entry period. (See Singer Dep., July 27, 2011, p. 131.)

Defendants argue that failing to account for this 30-month stay is unreasonable, as antitrust law requires Dr. Singer to presume, for purposes of his damages analysis, that Defendants would have responded rationally to Apotex's attempt to enter the market. (Defs.' Br., p. 8 (citing Dolphin Tours, 773 F.2d at 1511).) In support of its assertion that Cephalon would have unquestionably sued Apotex for patent infringement in the but-for world had it tried to enter the market 181 days after the Generic Defendants, Defendants point out that Cephalon actually did sue two other non-first filers that sought generic entry in the real world—Carlsbad

and Sandoz. See Complaint, Cephalon, Inc. v. Sandoz, Inc., No. 04-cv-2458 (D.N.J. May 26, 2004); Complaint, Cephalon, Inc. v. Carlsbad Tech., Inc., No. 05-cv-1089 (D.N.J. Feb. 24, 2005).

Apotex responds that there exists a sufficient factual basis for the assumption that Cephalon would not have sued Apotex for patent infringement in the but-for world. I agree.

If the jury finds antitrust liability based on the reverse-payment settlement agreements, there is sufficient evidence in the record to support Dr. Singer's assumption that Cephalon would not have sued Apotex for patent infringement when it attempted to enter the market.⁸ Indeed, Cephalon had the opportunity to sue Apotex in the real world when Apotex filed its Paragraph IV certification, but it declined to do so. (Thomas Rep. ¶ 123.) Further, Dr. Singer stated at deposition that economically speaking, he was "fairly confident . . . that the cost benefit calculus does not work in favor of suing." (Singer Dep., July 27, 2011, p. 132.) This is because "[a]ccording to Cephalon's own plans they thought they would accede about 90 percent of the market in a very short period of time, and the notion that they would then get any benefit out of suing Apotex to slow down the fifth entrant by 180 days seems to fail on a cost benefit calculus." (Id. at p. 123.) Because there is a rational factual basis underlying Dr. Singer's assumptions regarding the initial entry dates, I find that his opinions on these matters are admissible. Cross-examination is the appropriate means of challenging this expert testimony.

⁸ Plaintiffs filed a motion in limine seeking to preclude Defendants from presenting evidence or arguing that Cephalon would have sued Apotex in the but-for world. I denied this motion without prejudice because I could not resolve the issues raised therein without considering actual pieces of evidence or argument and the context in which they were presented. (See Doc. No. 1050, Or. Jan 20, 2016.) In denying the motion, I noted that Plaintiffs are free to renew their objections at the trial as the record develops. That said, if Plaintiffs elicit from Dr. Singer testimony that Cephalon would not have sued Apotex in the but-for world, Defendants' evidence and argument to the contrary are certainly relevant. In the event that Defendants do seek to present such evidence and argument, Plaintiffs may renew their other objections at the appropriate time.

2. The Re-Entry Date

Next, Defendants challenge Dr. Singer's assumption that, after the FDA lifted the Import Alert on July 1, 2011, Apotex would have re-launched generic Provigil only two months later in September 2011. Dr. Singer bases this assumption on the lay opinion of Gordon Fahner, Apotex's Vice President of Business Operations and Finance. Citing In re TMI Litigation, 193 F.3d 613 (3d Cir. 1999), Defendants argue that Dr. Singer's reliance on Mr. Fahner is impermissible because Dr. Singer did not assess the reliability of Mr. Fahner's opinion.

Pursuant to Federal Rule of Evidence 701, Mr. Fahner opines that in the but-for world generic Provigil would have been a top priority for re-launch and likely would have been launched in August 2011. Defendants filed a motion challenging Mr. Fahner's lay opinions, arguing he lacked personal knowledge and that his opinions were not helpful to the jury. I considered Defendants' challenges to Mr. Fahner's testimony and determined that his opinion as to generic Provigil's re-launch date in the but-for world is admissible.⁹ (See Doc. No. 896.) In resolving the motion to exclude Mr. Fahner's testimony, I found that "Apotex adequately demonstrated that Mr. Fahner possessed the requisite experience and personal knowledge under Rule 701 to offer an opinion as to the likely date that generic modafinil would have been re-launched in the but-for world." (Id. at ¶ 15.) As I have already considered the admissibility and reliability of Mr. Fahner's opinion and because Mr. Fahner will be subject to cross-examination, I do not find that Dr. Singer's reliance on Mr. Fahner's opinions is unreasonable.

⁹ The motion was originally referred to Magistrate Judge David R. Strawbridge for disposition. Judge Strawbridge initially granted Defendants' motion to exclude Mr. Fahner's opinions. However, Apotex objected to the ruling, and I partially reversed Judge Strawbridge's order, finding that Mr. Fahner's opinion as to generic Provigil's re-launch date in the but-for world was admissible.

Further, I find that Dr. Singer's assumption is distinguishable from the cases cited by Defendants. For example, in In re TMI Litigation, a personal injury action arising out of the nuclear meltdown at Three Mile Island, one expert had reviewed the testimony of an entire team of experts, then on the basis of that review, "offered an opinion as to the radiation dose to which Three Mile Island area residents were exposed as a result of the reactor accident." 193 F.3d at 714. The expert assumed that the effects that other dose experts had described were actually caused by radiation, and he assumed that those other experts' estimates as to how much radiation was required to produce those effects were correct. Id.

Nonetheless, the testifying expert had also acknowledged significant flaws in the methodologies of some of the experts he had relied upon and had testified at deposition that an appropriate analysis on his part would include an "assessment of the strengths and weaknesses of the available evidence." Id. at 715. In light of all of the above, the court found that the expert's "failure to assess the validity of the opinions of the experts he relied upon together with his unblinking reliance on those experts' opinions, demonstrates that the methodology he used to formulate his opinion was flawed under Daubert as it was not calculated to produce reliable results." Id. at 716.

Here, Dr. Singer relied upon Mr. Fahner for part of his damages assessment model—the start date of the re-launch period. Mr. Fahner's opinions do not have any other effect on Dr. Singer's opinions, and certainly do not make up the building blocks of Dr. Singer's economic analysis, unlike the expert described in In re TMI Litigation. In light of my determination that Mr. Fahner's opinion meets the standard for admissibility set forth in Rule 701, there is no concern that Dr. Singer has assumed the correctness of a completely unreliable opinion. The jury will be able to assess Mr. Fahner's credibility and the reliability of his opinion when he testifies.

Therefore, I disagree with Defendants' position that Dr. Singer's opinions should be excluded for assuming a re-launch date of September 2011.

3. The Initial Market Share Projection

Defendants further challenge Dr. Singer's reliance upon Apotex's internal business projections in determining that Apotex would have captured 20 percent of the modafinil market during the initial damages period. Because Dr. Singer projects that Apotex would have been the fifth entrant in the market following a 180-day period of exclusivity for the Generic Defendants, Defendants argue that a 20 percent market share is unreasonable on its face, as it "assumes away the well-recognized first mover advantage that first filers enjoy." (Defs.' Br., p. 9.) Defendants point out that in the actual world, the fifth generic entrant only received 2.9 percent of the modafinil market share. (Stangle Rebuttal Rep., Jan. 29, 2014, ¶ 98.) Further, Defendants assert that Apotex's Chairman, Bernard Sherman, testified at deposition that the forecasts were "worthless" and "of no value." (Sherman Dep., pp. 110, 300.) According to Defendants, because Dr. Singer conducted no independent economic assessment of Apotex's projected but-for market share, his reliance on the business projections renders his damages opinions inadmissible.

Defendants rely upon ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254 (3d Cir. 2012) in support of this argument. There, an expert assessed the plaintiff's lost profits by considering the revenues that the plaintiff would have earned in the but-for world. However, the expert's analysis of the plaintiff's but-for revenues were derived entirely from a one-page set of profit and volume projections maintained by the plaintiff, and the expert did not know "the circumstances under which such projections were created or the assumptions on which they were based." Id. at 291-92. The Third Circuit recognized that "internal projections for future growth often serve as legitimate bases for expert opinions" because "businesses are generally well-informed about the

industries in which they operate and have incentives to develop accurate projections.” Id. at 292 (internal quotation marks and citations omitted).

However, in order to rely upon the estimates of others in creating a hypothetical reality, the Third Circuit held that “the expert must explain why he relied on such estimates and must demonstrate why he believed the estimates were reliable.” Id. (citations omitted). Because the expert was generally not familiar with who created the projections or how they were created, the defendant was prevented from effectively cross-examining the expert. Id. at 293. Thus, the exclusion of the expert’s testimony was affirmed. Id. at 293.

I am not persuaded that Dr. Singer’s reliance on Apotex’s market share projections is comparable to the expert’s reliance in ZF Meritor. Dr. Singer’s expert reports and deposition testimony demonstrates that he considered the reliability of the market projections, that he understood how they were created, and that he will be able to provide detailed explanations as to why he found their use appropriate. Dr. Singer reviewed a series of Apotex’s internal projections for modafinil market share created between December 2002 and February 2008. (Defs.’ Br., Ex. 1.) Over time, the projected market share increased from an initial low of 5 percent to a maximum of 25 percent. Dr. Singer understood that the increase in market share was due to pharmaceutical supply agreements executed between Apotex and two large customers: McKesson, a major drug wholesaler, and ExpressScripts, a major mail-order pharmacy. (Apotex Resp., Exs. L-M; Singer Rep. ¶ 86; Singer Supp. Rep., Appx. 3, ¶ 6.) According to Dr. Singer, “by at least one estimate, McKesson alone enjoyed a 34 percent share of the wholesale distributor industry in 2004.” (Singer Rep. ¶ 86.) Indeed, even Defendants’ expert, Dr. Ordover, recognized that McKesson and ExpressScripts ordered substantial amounts of Provigil during the initial damages period. (Ordover Rep., June 10, 2011, Ex. 3.)

Dr. Singer's report also demonstrates that he considered the deposition testimony of Tammy McIntire Stefanovic, Apotex's former President, regarding the use of the market share projections. (Id. at ¶ 86 n. 123-25.) Ms. Stefanovic reviewed and signed off on the market share forecasts relied upon by Dr. Singer, and generally explained how they were created. (Stefanovic Dep., pp. 62-63, 77, 261-62.) In short, Dr. Singer was clearly more informed about how the market share projections were created than the expert in ZF Meritor. (See Singer Dep., July 27, 2011, p. 212 (in speaking with Ms. Stefanovic, Dr. Singer concluded that Apotex "had a reasonable grasp on – on calculating market shares").)

While Defendants make much of the statements by Apotex's Chairman, Bernard Sherman, that the forecasts were "worthless" and "of no value," Defendants take these statements out of context. Mr. Sherman's statements that aspects of the projection were "worthless" were in reference to the potential cost and profit margins, not market share. (See Sherman Dep., pp. 108, 110.) The only issues Mr. Sherman raised as to the market share portion of Apotex's projections is that they may be too low, which would undervalue, not overvalue, Apotex's damages. (Id. at pp. 111, 114-15, 235; see also Singer Dep., July 27, 2011, pp. 209-10 (demonstrating that Dr. Singer considered Mr. Sherman's deposition, and concluded that Sherman believed a 20 or 25 percent market share was too conservative).)

Whether Dr. Singer relied on the best data in forming his opinions is a question for the jury. See Manpower, Inc. v. Ins. Co. of Pa., 732 F.3d 796, 809 (7th Cir. 2013). "Assuming a rational connection between the data and the opinion—as there [is] here—an expert's reliance on [allegedly] faulty information is a matter to be explored on cross-examination; it does not go to admissibility." Id. (citing Walker v. Soo Line R.R. Co., 208 F.3d 581, 589 (7th Cir. 2000)).

Therefore, I find that Dr. Singer's reliance on the initial market share projections created by Apotex is not unreasonable.

4. The Re-Entry Market Share Projection

Dr. Singer also relied upon Apotex's internal projections in determining that Apotex would have maintained a 7.5 percent market share during the re-launch period (i.e. the period of time after the Import Alert was lifted.) In making this assumption, Dr. Singer reviewed contemporaneous market share projections prepared by Apotex, and averaged¹⁰ a 2011 forecast showing a 5 percent market share projection and a 2013 forecast showing a 10 percent market share projection. His report explains that he "adjust[ed] [his] estimates of Apotex's market share to 7.5 percent during this re-entry period (from 20 percent during the initial damages period) due to uncertainty whether the supply agreements comparable to those pertaining to the initial damages period would have remained in effect during the FDA import alert and the extent to which pre-import alert market share could be recaptured." (Singer Supp. Rep. ¶ 33, n.83.)

Defendants raise many of the same challenges to this re-launch market share assumption as those raised with respect to the initial market share projections—namely that Dr. Singer did not conduct an independent economic assessment of Apotex's projected but-for market share, which renders his opinions inadmissible under ZF Meritor. Additionally, Defendants argue that Dr. Singer did not appropriately take into account the challenges that Apotex would face in capturing market share following the Import Alert when assessing the re-entry market share.

¹⁰ Dr. Singer explained during deposition that averaging market share assumptions in this manner is "a fairly common thing to do, and because each month is being treated the same, [he is] fairly confident that had [he] done a step function, five five five and then ten ten ten, [he is] pretty confident it wouldn't have made a difference." (Singer Dep., Feb. 28, 2014, pp. 198-99.) Defendants provide no evidence indicating that averaging market shares in this manner is uncommon for economists or otherwise improper.

For many of the reasons recited above, I disagree with Defendants' position. Both market share projections were created by Apotex in the normal course of business,¹¹ and economists often rely upon such contemporaneous business documents in assessing damages. See ZF Meritor, 696 F.3d at 292.¹² Just as Dr. Singer considered the reliability of the initial entry market share projections and made a determination that their use was appropriate in calculating Apotex's damages, he also considered the reliability of the re-entry market share projections. During deposition, Dr. Singer explained that he and/or his staff communicated with Apotex regarding the re-entry projections, and sought to understand why the market share during the re-entry period differed from the prior projections. They also discussed how the Import Alert

¹¹ Defendants attempt to argue that Dr. Singer's review of the 2011 and 2013 market share projections was deficient because he did not independently verify with Apotex that the projections were prepared for the same purpose and used in the same manner as the initial entry market share projections described above. Dr. Singer explained that after reviewing various depositions and speaking with Apotex employees, he understood that the initial market share projections were created in Apotex's day-to-day business operations, and were used to make various decisions about market entry and opportunities. (Singer Dep., Feb. 28, 2014, pp. 183-84.) He explained that he understood the 2011 and 2013 market share projections to be used in the same fashion, but could not recall independently verifying that understanding with Apotex employees. (Id. at pp. 184-86.) However, there is no indication in the record that the creation or purpose of the 2011 and 2013 market share projections somehow differed from the projections created by Apotex between 2002 and 2008. Therefore, I do not find that exclusion on this ground is appropriate.

¹² Defendants also cite to Legendary Art, LLC v. Godard, 2012 WL 3550040 (E.D. Pa. Aug. 17, 2012). Unlike Dr. Singer, the expert in Legendary Art performed absolutely no independent assessment as to the reliability of a business projection. Id. at *1. Further, the business projection in that case provided the backbone for the expert's entire damages assessment, including expected profits and losses, in a market with which the expert had no familiarity. Id. at *1, 4. Here, Dr. Singer has testified as an expert in several antitrust cases involving the pharmaceutical industry, and he is relying upon Apotex's assessment for one piece of his overall analysis. Indeed, the majority of his economic analysis has not been challenged as unreliable by Defendants. Finally, the court in Legendary Art had numerous reasons to question the accuracy of the business records that the expert relied upon. Id. at *2, 4. Therefore, I find Dr. Singer's analysis to be distinguishable.

affected Apotex's relationship with its customers. (Singer Dep., Feb. 28, 2014, pp. 187-88, 199-200.) The fact that the market share projections are considerably lower following the Import Alert demonstrates that Apotex considered the impact of that event on business relationships. (See *id.* at pp. 199-201.)

As with the initial market share projections, Defendants may have reason to believe that Dr. Singer could have based his re-entry market share assumption on "better" evidence. That, however, is not grounds for exclusion. "Again, to the extent that there are facts in dispute which [Dr. Singer] should or should not have relied upon . . . a jury will be given the opportunity to sort through these facts and apply their conclusions in assessing each of the parties' respective expert damages witnesses." *Aetna Inc. v. Express Scripts, Inc.*, 261 F.R.D. 72, 81-82 (E.D. Pa. 2009).

B. Defendants' Challenges to Calculations 2 and 3

Calculation 2 adopts the assumptions made by Dr. Singer in Calculation 3, and builds upon them, providing for even greater damages. Therefore, if the assumptions that underlie Calculation 3 render it inadmissible, Calculation 2 would also be inadmissible. Therefore, I will address the challenges to Calculation 3 first.

Dr. Singer's third damages calculation, prepared at the request of counsel, modifies Calculation 1 to assume that Apotex would have entered the market as a first filer "in order to capture market share during the exclusivity period." (Singer Supp. Rep. ¶ 36.) "In this scenario, Apotex would not have been subject to the 180-day exclusivity 'bottleneck,' but instead would have entered as the sole generic competitor in December 2006." (*Id.*) Dr. Singer explains that "[p]art of what makes the [] challenged conduct offensive is the . . . bottleneck that's created, not just the settlement itself but the generic defendants agreeing to get out of the market and maintaining their exclusivity rights." (Singer Dep., Feb. 28, 2014, p. 265.) Therefore, Calculation

3 models a but-for world in which the Generic Defendants settled with Cephalon, but agreed to waive their 180-day period of exclusivity, opening the door for other generic companies, such as Apotex, to enter the market. For this scenario, Dr. Singer models Apotex's lost profits on the real-world launch of Teva's generic Provigil product in 2012. (Singer Supp. Rep. ¶ 36.)

Defendants argue that Calculation 3 does not fit the facts of the case and is contrary to the law. First, they note that Dr. Singer provides no factual basis to support Apotex's theory that the Generic Defendants would have agreed to settle in the but-for world, while also surrendering their exclusivity rights. (Singer Dep., Feb. 28, 2014, p. 265 (“Q: Are you opining on a rationale of why the generic defendants might surrender their exclusivity rights in the but-for world? A: No.”).) Defendants note that antitrust damages models “must presume the existence of rational economic behavior in the hypothetical free market.” Dolphin Tours, Inc., 773 F.2d at 1511. Further, Defendants assert that Calculation 3 measures damages in excess of those attributable to allegedly illegal conduct.

Apotex responds that the bottleneck caused by the Generic Defendants maintenance of their 180-day exclusivity period during settlement of the Paragraph IV litigation is a critical aspect of their theory of liability that has been argued since the inception of this case. According to Apotex, Calculation 3 does nothing more than model “a scenario in which Generic Defendants waived these periods when they settled the patent case,” alleviating the anticompetitive bottleneck, and allowing Apotex to enter the market in December 2006. (Apotex Resp., p. 18.)

I agree with Defendants that the record does not support Dr. Singer's assertion that the Generic Defendants would have agreed to stay off of the market through 2012, while simultaneously forfeiting their first filer rights of 180 days of exclusivity. As I found in granting Defendants' motions for summary judgment on Plaintiffs' claims for overall conspiracy, the

record demonstrates that it was in each Generic Defendants' independent economic self-interest to maintain its period of exclusivity and enter into the contingent launch provisions, such that if any competitor entered the market, each Generic Defendants' economic interests would be protected. King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2014 WL 2813312, *13-14 (E.D. Pa. June 23, 2014). Dr. Singer essentially admits that he is unaware of any factual basis to support a scenario where the Generic Defendants would agree to forfeit their 180 days of exclusivity. (See Singer Dep., Feb. 28, 2014, pp. 265-68.) As antitrust lost profits damages scenarios must presume the existence of rational economic behavior in the hypothetical free market, this lack of factual basis renders Calculation 3 inadmissible.

Even more troubling is that Dr. Singer's Calculation 3 measures lost profits in excess of those stemming from the alleged anticompetitive activity. "In economic terms, the amount of damages is the difference between what the plaintiff could have made in a hypothetical free economic market and what the plaintiff actually made in spite of the anticompetitive practices." Id. (citing Bigelow, 327 U.S. at 264). "It is a requirement that an antitrust plaintiff must prove that his damages were caused by the unlawful acts of the defendant." MCI Commc'n Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081, 1161 (7th Cir. 1983) (citing 15 U.S.C. § 15) (emphasis in original). When recreating a but-for world to establish antitrust damages, a plaintiff must create a world "characterized by the absence of the . . . challenged practices." Allied Orthopedic Appliances, Inc. v. Tyco Healthcare Grp., L.P., 247 F.R.D. 156, 165 (C.D. Cal. 2007).

While Apotex is correct that it has consistently alleged that the bottleneck created by the settlement agreements had a significant anticompetitive effect, it was not just the statutorily-granted 180-day period of exclusivity that created that bottleneck. The bottleneck was instead allegedly created by the Generic Defendants maintaining 180-day exclusivity while

simultaneously agreeing to stay off of the market through 2012. This combination of allegedly illegal delay and first filer exclusivity is what prevented Apotex from challenging the RE '516 patent and entering the market on an earlier date. See King Drug Co. of Florence, Inc., 2014 WL 2813312, at *7-8 (first filer exclusivity combined with agreement to stay off of the market and Apotex's inability to seek declaratory judgment under the law at the time created the bottleneck).

Simply put, standing on its own there is nothing inherently anticompetitive about first filer exclusivity. Indeed, first filer exclusivity is provided for under the Hatch-Waxman Act in order to “encourage generic entry and challenges to drug patents.” In re K-Dur Antitrust Litig., 686 F.3d 197, 204 (3d Cir. 2012) vacated on other grounds, Upsher-Smith Labs., Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013). Market entry by the Generic Defendants in 2006, as Dr. Singer's Calculation 1 models, would promote consumer choice and would constitute lawful competition. Therefore, assigning lost profits to Apotex stemming from the initial 180 days under which the Generic Defendants were first eligible to market generic Provigil would require assessing damages against Defendants for lawful competition. This the law does not allow. MCI Commc'n Corp. v. Am. Tel. & Tel. Co., 708 F.2d at 1161 (“If a plaintiff has suffered financial loss from the lawful activities of a competitor, then no damages may be recovered under the antitrust laws”); Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 487-89 (1977) (“The antitrust laws . . . were enacted for the protection of competition not competitors” and damages must flow “from that which makes defendants' acts unlawful”) (citations omitted).

As Dr. Singer explained with respect to Calculation 1, if the reverse-payment settlement agreements are found to be unlawful, the but-for world would assume the absence of the unlawful activity (i.e. the settlement agreements), leading to market entry by the Generic

Defendants in December 2006—the first day on which the Generic Defendants would have been eligible to enter under the Hatch-Waxman Act. Evidence in the record demonstrates that Apotex would then be eligible to enter the market 180 days later.

For all of these reasons, I find that Dr. Singer’s Calculation 3 is both contrary to the record and measures damages in excess of lost profits attributable to the alleged anticompetitive actions of the Defendants, which is contrary to the law. Accordingly, Calculation 3 will be excluded.

Dr. Singer’s second damages calculation builds on Calculation 3 and includes the “assumption that the other generic manufacturers forfeited their exclusivity because of their misconduct and should not be permitted to use their possible entry in the market to reduce their liability.” (Singer Exp. Rep. ¶ 89.) It further “assumes that (a) first filers will be held to their contractual agreement with Cephalon not to enter until April 2012, and (b) Apotex would have entered the market and captured its anticipated profits as the fifth entrant plus the but-for profits of the first four generic entrants.” (Id. (emphasis in original).) According to Dr. Singer, “[s]uch a theory of damages prevents defendants from keeping the overwhelming majority of their illegally obtained profits.” (Id.)

For all of the reasons described above as to Calculation 3, there is no factual support for Dr. Singer’s assumption that the Generic Defendants would have entered into the settlement agreements with Cephalon that required them to stay off of the market until April 2012, while simultaneously surrendering their first filer exclusivity. Similarly, there is no factual support for the Generic Defendants signing the settlement agreements absent the contingent launch provisions.

Finally, Calculation 2 would model damages far in excess of Apotex's lost profits. Assuming away the 180-day period of exclusivity would provide Apotex with lost profits stemming from lawful competition. Most importantly, there is no rational or legal basis for assigning profits that the Generic Defendants would have made in the but-for world to Apotex as "lost profits."

Accordingly, because Dr. Singer's Calculation 2 assumes a but-for world for which there is no factual support, which requires assuming away rational economic behavior by competitors, and measures damages in excess of Apotex's lost profits, Calculation 2 will be excluded.

IV. CONCLUSION

For all of the reasons recited above, I find that Dr. Singer's first damages calculation is sufficiently reliable and fits the facts of the case, such that it may be presented to a jury. While Defendants may have legitimate factual disputes with some of the inputs Dr. Singer considered, those disputes can be aired through the presentation of contrary evidence and cross-examination. Because I find that Dr. Singer's second and third damages calculations are unreliable and do not fit the facts of the case, they will be excluded.

An appropriate Order follows.