

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

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ABBVIE INC. et al.,

Defendants.

CIVIL ACTION

Case No. 14-cv-5151

PUBLIC VERSION

**MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION IN LIMINE TO
PRECLUDE CERTAIN TESTIMONY OF FTC'S EXPERT CARL SHAPIRO**

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I. INTRODUCTION

One of FTC’s expert witnesses is antitrust economist Dr. Carl Shapiro. In opining [REDACTED]

[REDACTED] Dr. Shapiro uses various scenarios, each based on a factual “assumption”¹ regarding the particular dates on which Perrigo and/or Teva would have begun marketing its respective testosterone product in a world in which the allegedly sham litigation was never filed (the “but-for world”). Ex. 1, Shapiro Report at 2. The current motion does **not** seek to preclude Dr. Shapiro from testifying to his assumptions with respect to each scenario, or to his financial gain calculation for each scenario. What the current motion **does** seek to exclude is Dr. Shapiro’s commentary on why his assumptions are supposedly reasonable—commentary that is beyond Dr. Shapiro’s expertise, not based on rigorous economic analysis or application of reliable economic principles, and merely summarizing and putting an argumentative gloss on documents cherry-picked by FTC personnel.

Dr. Shapiro agrees that the question of whether the evidence supports any of the assumptions on which he bases his economic analysis is a factual issue for the Court to determine.² Nonetheless, Dr. Shapiro spends portions of his reports explicitly or implicitly commenting on why he thinks the assumptions underlying his scenarios are “reasonable.” Defendants hereby move in limine to preclude this commentary by Dr. Shapiro. This subjective commentary is outside the scope of Dr. Shapiro expertise. None of it is either an expert opinion

1 [REDACTED]

2 [REDACTED]

or a statement of the basis for such an opinion.³ None of it purports to be supported by rigorous economic analysis or reliable economic principles—or indeed by rigorous analysis or principles of any sort. Most of it is no more than Dr. Shapiro’s interpretation of, and gloss on, the non-expert evidence—that is, the documents and fact witness testimony that will be offered in evidence. As Dr. Shapiro recognizes, it is the Court’s province to evaluate that evidence, not Dr. Shapiro’s.

II. BACKGROUND

Dr. Shapiro is an antitrust economist. Ex. 1, Shapiro Report at 1. While he has extensive experience in economics, Dr. Shapiro is by his own admission not an expert in many other fields relevant to this litigation—such as pharmacology, medicine, testosterone replacement therapy for hypogonadism, pharmaceutical manufacturing, FDA regulations and procedures relating to new drug applications, citizen petitions to the FDA, and the FDA’s process and standards for awarding or evaluating whether to award therapeutic equivalence ratings to drugs (*e.g.*, AB ratings or BX ratings). Ex. 3, Shapiro Dep. at 22:20-25:10.

Dr. Shapiro’s expert report contains multiple disgorgement or “financial gain” scenarios about which Dr. Shapiro intends to testify. Each of Dr. Shapiro’s scenarios is based on a different set of assumptions about if and when, in the but-for world, Teva and/or Perrigo would have begun marketing its respective testosterone product. Dr. Shapiro’s first two scenarios involve the assumption that Teva entered the market with a non-AB-rated product in June 2012 and the assumption that Perrigo obtained an AB rating for its product and entered the market with that AB-rated product in June 2013. Dr. Shapiro’s next scenarios are based on the

³ Defendants’ antitrust economist Dr. Cremieux has of necessity responded to Dr. Shapiro’s commentary. To the extent that the Court precludes Dr. Shapiro, Defendants agree that the same rule would apply with respect to Dr. Cremieux’s testimony.

assumption that Perrigo entered the market with its AB rated product in July 2013 instead of in June 2013, as in the prior scenarios. Dr. Shapiro’s final scenarios are based on the assumption that Teva never entered the market—just as Teva did not enter the market in the actual world.

At his deposition, Dr. Shapiro explained the role of his assumptions as just what the word “assumption” suggests they are: assumed facts that need to be independently proved. As Dr. Shapiro explained:



Ex. 3, Shapiro Dep, at 45:15-46:9.

As shown below, Dr. Shapiro does not limit his report to the economic opinions he offers on the amount of “financial gain” under the various assumptions set forth above (or on the other issues on which he offers economic opinions, market definition and monopoly power), and the bases for those opinions. Rather, Dr. Shapiro offers improper commentary on what he considers to be the reasonableness—based on his reading of the evidentiary record or what he was told by FTC lawyers—of the assumptions about if and when Teva and Perrigo would have entered the market in the but-for world. That commentary is outside of Dr. Shapiro’s area of expertise, is not based on economic analysis, and is more in the nature of improper case “narration” than legitimate expert testimony.

A. Dr. Shapiro's Non-Expert Commentary Relating to His Assumptions on the Timing of Entry by Teva in the But-For World

Some of Dr. Shapiro's commentary relates to assumption for some of his scenarios that in the but-for world Teva would have begun marketing its testosterone product in June 2012, without an AB rating from FDA. Dr. Shapiro's commentary on this subject includes wholly unsupported assertions regarding the date of Teva's "operational readiness" to launch its product and regarding the levels of sales that Teva would have obtained if it had launched with a non-AB rated product in June 2012.

- ***Commentary regarding date of Teva's "operational readiness."*** [REDACTED]
[REDACTED] Ex. 1, Shapiro Report at 18. At his deposition, Dr. Shapiro admitted that he did not conduct an economic analysis to support that commentary. [REDACTED]
[REDACTED]
[REDACTED] At his deposition, Dr. Shapiro admitted that the documents he reviewed were selected for him by FTC's economists and lawyers. *Id.* at 18:11-19:14. Dr. Shapiro also admitted that he had no familiarity with the basic facts that would be relevant to evaluating the reliability of these documents, such as what steps Teva would have needed to take to achieve operational readiness. *Id.* at 140:19-145:17. [REDACTED]
[REDACTED] *Id.* at 145:11-12. Dr. Shapiro therefore is unqualified to provide an expert opinion on how long it would take Teva to achieve operational readiness (even if he had gone through any sort of rigorous analysis, which he did not).
- ***Commentary regarding Teva's hypothetical sales.*** [REDACTED]
[REDACTED] Dr. Shapiro also comments that these are reasonable assumptions. Ex. 1, Shapiro Report at 18-20; Ex. 2, Shapiro Rebuttal Report at 18-19. [REDACTED]
[REDACTED] Dr. Shapiro admitted at

deposition that he did not do anything more than give the documents the proverbial once-over: Dr. Shapiro did not do any economic analysis that would be necessary to purport to offer an expert opinion on this subject. For example, Dr. Shapiro did not review any industry studies relating to competition from a non-AB rated drug product. *Id.* at 74:23-76:15. [REDACTED]

[REDACTED] *Id.* at 88:9-17. Dr. Shapiro also did not do a quantitative economic analysis of the profitability to Teva of launching in mid-2012 (or at any other time). *Id.* at 51:13-22.

B. Dr. Shapiro's Non-Expert Commentary Relating to His Assumptions on the Timing of Entry by Perrigo in the But-For World

In his reports, Dr. Shapiro also gratuitously comments about the assumptions relevant to two of his scenarios that, in the but-for world, Perrigo would have received an AB rating from FDA and entered the market in June or July 2013, about a year before FDA in the actual world awarded Perrigo an AB rating. Dr. Shapiro's assumption in this regard is based on two subsidiary assumptions, which are:

- (1) that Perrigo would have sued FDA for unreasonable delay in deciding whether to give it an AB rating just 2 months after FDA's January 2013 approval of Perrigo's product, rather than wait the 14 months that in the actual world elapsed before Perrigo sued for unreasonable delay; and
- (2) that if Perrigo had sued FDA earlier, FDA would have voluntarily granted Perrigo an AB rating a year earlier as well.

See Ex. 2, Shapiro Rebuttal Report at 26 (asserting that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]).

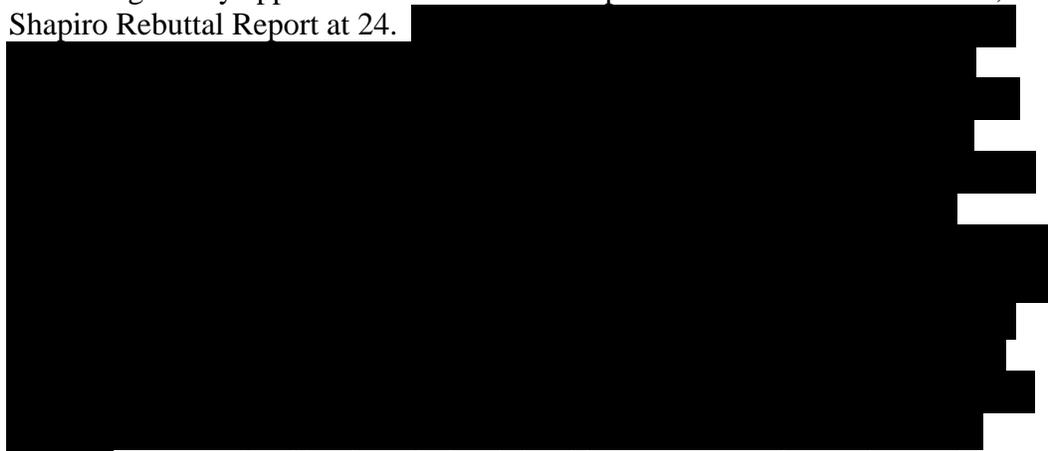
Like the commentary that Dr. Shapiro offers on his assumptions regarding Teva, the commentary that Dr. Shapiro offers on these assumptions regarding Perrigo is not presented as expert opinion and is not based on rigorous economic analysis or reliable economic principles by

Dr. Shapiro—as Dr. Shapiro himself admits. It therefore is not appropriate for Dr. Shapiro to present this commentary in his trial testimony.

1. Dr. Shapiro’s Non-Expert Commentary on His Assumption (1) Regarding When Perrigo Would Have Sued FDA for Unreasonable Delay

In an attempt to demonstrate the reasonableness of his assumption that absent the allegedly sham litigation Perrigo would have sued FDA, a mere two months after the agency approved Perrigo’s product, for unreasonable delay in awarding a therapeutic equivalence rating, Dr. Shapiro made a number of unsupported guesses and assertions. Dr. Shapiro commented, without analysis, that Perrigo had economic incentives to sue quickly—disregarding that such a suit would have not been viable at that time because of the absence of delay by FDA, and disregarding that Perrigo likewise had incentives to prod FDA to act more quickly when Perrigo’s date for market entry was still far away. None of that commentary represents permissible expert testimony on economic issues.

- ***Commentary regarding Perrigo’s economic incentives to sue FDA.*** Dr. Shapiro comments in his report that his assumption that Perrigo would have sued FDA to act on Perrigo’s request for an AB rating almost immediately after receiving FDA’s regulatory approval for its testosterone product is “reasonable.” Ex. 2, Shapiro Rebuttal Report at 24.



In sum, Dr. Shapiro admitted that his commentary is not the product of economic or other rigorous analysis; it is just an incomplete and off-handed mention of one factor among many that might have contributed to Perrigo’s decision-making.

- ***Unevaluated assumption that earlier suit for unreasonable delay would have been viable before most of that delay occurred.*** [REDACTED]

[REDACTED] Ex. 2, Shapiro Rebuttal Report at 25. This, too, is casual commentary that is completely speculative and lacking in evidentiary foundation, and does not represent a rigorously derived expert opinion. At his deposition, Dr. Shapiro was not able to identify basic relevant facts such as the nature of the substantive claim that Perrigo asserted against FDA—which was in fact a claim for unreasonable delay. *See* Ex. 3, Shapiro Dep. at 60:15-18 [REDACTED]

[REDACTED]. Dr. Shapiro was unable to provide any information on the nature of Perrigo’s argument that the FDA engaged in unreasonable delay with respect to the potential award of an AB rating. *Id.* at 60:19-24. Dr. Shapiro’s report does not indicate he reviewed a single pleading or other filing in the *Perrigo v. FDA* litigation, and at deposition Dr. Shapiro did not recall having done so. *Id.* at 63:2-8. Lacking such basic knowledge, Dr. Shapiro could not have a basis to conclude that a claim of unreasonable delay could have been brought so much earlier—before any time that could legitimately be regarded as an FDA “delay” had transpired.

- ***Commentary based on untrue fact regarding Perrigo’s actual interactions with the FDA.*** [REDACTED]

[REDACTED] Ex. 1, Shapiro Report at 22. His commentary on the purported reason for Perrigo’s actions is not appropriate expert testimony. Dr. Shapiro conducted no analysis to justify the commentary—as evidenced by the fact that the commentary is demonstrably false, as he ultimately admitted in his deposition testimony. Ex. 3, Shapiro Dep. at 127:9-128:8; *accord id.* at 137:18-21. [REDACTED]

2. Dr. Shapiro’s Non-Expert Commentary on His Assumption (2) Regarding When FDA Would Have Granted Perrigo an AB Rating

Dr. Shapiro’s effort to show that it is reasonable for him to assume that if Perrigo had sued FDA a year earlier then FDA would have granted Perrigo an AB rating a year earlier is similarly not permissible expert testimony. Dr. Shapiro asserted, without any support, that FDA would have issued an AB rating to Perrigo after the filing of an earlier suit for unreasonable

delay just as quickly as it issued an AB rating to Perrigo after the (much later) suit that Perrigo filed in the real world. He also asserted that if Perrigo had filed suit earlier, then FDA would have decided a then-pending citizen petition—resolution of which was a prerequisite to the grant of an AB rating to Perrigo—significantly earlier than FDA actually did. Dr. Shapiro performed no analysis of these matters, instead simply assuming that they were causally related, and his expertise does not extend to them.

- ***Commentary regarding when the FDA would have acted.*** Dr. Shapiro comments in his rebuttal report that his assumption regarding when Perrigo would have received an AB rating, if Perrigo had sued a year earlier, is “reasonable.” Ex. 2, Shapiro Rebuttal Report at 26. Dr. Shapiro’s Rebuttal Report states his only basis for this comment: [REDACTED]

[REDACTED] *Id.*
In his deposition, Dr. Shapiro did not even attempt to defend this statement as expert analysis rather than just a naked assumption. [REDACTED]

[REDACTED] hat is the sum total of Dr. Shapiro’s “analysis” of this point.

- ***Commentary about when FDA would have decided a citizen petition that had to be resolved in conjunction with any determination of whether to issue an AB rating.*** In the real world, FDA decided Perrigo’s request for an AB rating only in conjunction with deciding a related citizen petition that Abbott had filed (which FTC does not contend was improper). The reasonableness of Dr. Shapiro’s assumption that in the but-for world FDA would have awarded Perrigo its AB rating earlier than it did if only Perrigo had sued earlier also requires as a factual predicate that FDA would have decided Abbott’s citizen petition earlier than FDA decided it in the actual world. Dr. Shapiro does not and could not legitimately opine that FDA would have done that; as noted, Dr. Shapiro has admitted that he is not an expert in FDA procedures.

Dr. Shapiro nonetheless comments as follows in his Rebuttal Report: [REDACTED]

[REDACTED] *Id.*

at 26-27. Dr. Shapiro does not provide any further specificity or set forth any methodology, let alone rigorous scientific or economic methodology, that supports his commentary on how the citizen petition would have played out in the but-for world.

* * *

As shown below, the Court should exclude all of this commentary by Dr. Shapiro because none of it is legitimate expert testimony.

III. ARGUMENT

Rule 702 of the Federal Rules of Evidence provides:

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.

The proponent of expert testimony has the burden of proving admissibility pursuant to Rule 702 by a preponderance of the evidence. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 n.10 (1993).

This motion does not seek to exclude the financial gain analysis that is a centerpiece of Dr. Shapiro’s report. Nor does this motion challenge the factual sufficiency of the assumptions on which Dr. Shapiro bases his financial gain analysis.⁴ Instead, this motion challenges only Dr. Shapiro’s repeated straying from economic analysis to offer commentary on the evidence that—

⁴ Defendants reserve all trial objections to any aspect of Dr. Shapiro’s testimony and will provide their own expert evidence to demonstrate the flaws in Dr. Shapiro’s financial analysis.

by Dr. Shapiro's own admission—does not constitute expert opinion, is outside the scope of Dr. Shapiro's expertise, is not determined by the methods of economic analysis, and is not shown to have been derived by any sort of rigorous analysis or reliable methods.

It is irrelevant that Dr. Shapiro's commentary concerns the assumptions of fact, or premises, on which Dr. Shapiro bases his financial gain analysis. FTC must prove by competent evidence that Dr. Shapiro's assumed facts are indeed facts. Dr. Shapiro's commentary is not competent evidence. As Dr. Shapiro testified, [REDACTED] Ex. 3, Shapiro Dep. at 42:14-15. FTC cannot evade its burden of proof by having Dr. Shapiro baldly assert that he believes his assumptions to be reasonable, and then present cursory and broad-brush support for those assumptions.

A. Dr. Shapiro's Commentary Regarding His Assumptions Should Be Excluded as Outside the Scope of Dr. Shapiro's Expertise

“[A] court should ‘exclude proffered expert testimony if the subject of the testimony lies outside the witness’s area of expertise.’” *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 962545, at *3 (E.D. Pa. June 28, 2000) (quoting 4 Weinstein’s Federal Evidence § 702.06[1], at 702-52 (2000)). Here, all of Dr. Shapiro’s commentary about the reasonableness of the assumptions underlying his financial gain scenarios—as opposed to the economic analysis he conducted to develop those scenarios—is outside the scope of Dr. Shapiro’s expertise in economics. The Court should therefore preclude Dr. Shapiro from presenting any of that commentary as part of his expert testimony.

It is no answer to state that Dr. Shapiro indisputably has expertise in his field. No one is an expert in everything. Under *Daubert*, “[a]n expert may be generally qualified but may lack qualifications to testify outside his area of expertise.” *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 322 (3d Cir. 2003). Thus, if an individual has been found qualified to present

expert opinions under Rule 702 and then testifies beyond the scope of his expertise, courts strike the extraneous testimony, for “[a] layman, which is what an expert witness is when testifying outside his area of expertise, ought not to be anointed with ersatz authority as a court-approved expert witness for what is essentially a lay opinion.” *Apple, Inc. v. Samsung Elecs. Co.*, 2013 WL 5955666, at *2 (N.D. Cal. Nov. 6, 2013) (quoting *White v. Ford Motor Co.*, 312 F.3d 998, 1008-09 (9th Cir. 2002)); *see, e.g., In re Jacoby Airplane Crash Litig.*, 2007 WL 5037683, at *34 (D.N.J. Aug. 27, 2007); *Advanced Med. Optics, Inc. v. Alcon, Inc.*, 2005 WL 782809, at *9 (D. Del. Apr. 7, 2005); *523 IP LLC v. CureMD.Com*, 48 F. Supp. 3d 600, 647 (S.D.N.Y. 2014) (“[A]ll portions of [the expert’s] report touching on areas outside his field of expertise are stricken; the Court will not rely on those portions in coming to a decision on any summary judgment motion and [the expert] will *not be permitted to offer such testimony at trial.*” (emphasis added)); *Davis v. Carroll*, 937 F. Supp. 2d 390, 413 (S.D.N.Y. 2013); *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d 966, 994-95 (C.D. Cal. 2012).

Exclusion of the testimony that goes beyond the individual’s expertise is appropriate even where, as here, the issues on which the expert is qualified are related to the other issues he addresses. In *Redman v. John D. Brush & Co.*, 111 F.3d 1174 (4th Cir. 1997), for example, the court of appeals held that a metallurgic expert could testify about properties and characteristics of metal safes, but would not be permitted to testify about industry standards for design of safes because “he had never before analyzed a safe, engaged in the manufacture or design of safes, or received any training regarding safes,” and, “[e]ven more importantly, he was not personally familiar with the standards . . . used in the safe industry.” *Id.* at 1179. So too here. That Dr. Shapiro has expertise in economics does not make him qualified to comment on such issues as how quickly FDA would have acted on a request for an AB rating in particular circumstances

and whether Perrigo's lawsuit against FDA based on alleged unreasonable delay would have been viable to file only two months after FDA approved Perrigo's NDA. *See, e.g., Barrett v. Atlantic Richfield Co.*, 95 F.3d 375, 382 (5th Cir. 1996) (ecologist with expertise in behavior patterns of rats was not qualified to opine on source of chromosomal damage exhibited by rats); *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d at 994-95 (economist was qualified to testify on certain market definition issues relating to concerts but not on subsidiary issue of whether particular performers were "rock artists"). In words equally applicable here, the district court in *Live Concert* excluded certain commentary by an economist because "the Court [could not] discern any meaningful application of [the expert's] expertise as an economist to the[] determinations" that were at issue. *Id.*; *see* George J. Stigler, *What Does an Economist Know*, 33 J. Legal Educ. 311, 311 (1983) (observing that an "economist has no special skill in reading documents and relating them to actual behavior").

B. Dr. Shapiro's Commentary Regarding His Assumptions Should Be Excluded as Not Based on Rigorous Economic Analysis

An expert must apply appropriate reasoning in a reliable manner to reach the conclusions he offers. *Daubert*, 509 U.S. at 592-93. "Under *Daubert* and Rule 702, expert testimony should be excluded if the witness is not actually applying [his] expert methodology." *United States v. Dukagjini*, 326 F.3d 45, 54 (2d Cir. 2003). That is the situation here with respect to all of the commentary by Dr. Shapiro that is at issue. Dr. Shapiro does not purport to apply economic analysis in making any of that commentary. The rule prohibiting expert testimony not sufficiently grounded in a sound methodology applies to expert testimony about assumptions supporting an expert analysis, just as much as it applies to the expert analysis itself. As the Third Circuit has held, an expert's "supporting assumption must be sufficiently grounded in sound methodology[] and reasoning to allow the conclusion it supports to clear the reliability hurdle."

In re TMI Litig., 193 F.3d 613, 677 (3d Cir. 1999), *amended on other grounds*, 199 F.3d 158 (3d Cir. 2000).

C. Dr. Shapiro’s Commentary Regarding His Assumptions Should Be Excluded As Improper Mere Interpretation Of Lay Evidence And As Improper “Case Narration”

Much of Dr. Shapiro’s commentary at issue consists of a factual narrative of select portions of documents—and occasionally excerpts of witness testimony—together with the purported expert’s personal interpretation and speculation regarding that evidence. That commentary purports to tell the Court how it should interpret the evidence in question. For example, Dr. Shapiro’s commentary on how quickly Teva could have achieved “operational readiness” to launch its non-AB-rated product, as well as his commentary on the sales that Teva allegedly would have achieved if it had launched its non-AB rated product, is all no more than Dr. Shapiro’s lay reading and interpretation of a handful of company documents that were—as Dr. Shapiro admitted in deposition testimony cited above (Ex. 3, Shapiro Dep. at 18:11-19:14) – chosen for him by FTC’s economists and lawyers in this case.

Such a narrative inherently addresses lay matters that the factfinder can assess for itself. Under Rule 702, “an expert may not offer testimony that simply ‘regurgitates what a party has told him’ or constructs ‘a factual narrative based on record evidence.’” *In re Longtop Fin. Techs. Ltd. Sec. Litig.*, 32 F. Supp. 3d 453, 460 (S.D.N.Y. 2014) (footnotes omitted); *see, e.g., Ridge Clearing & Outsourcing Solutions, Inc. v. Khashoggi*, 2011 WL 3586468, at *2 (S.D.N.Y. Aug. 12, 2011) (excluding part of expert report because “[s]imply rehashing evidence about which an expert has no personal knowledge is impermissible under Rule 702”); *Karavitis v. Makita U.S.A., Inc.*, 243 F. Supp. 3d 235, 241 (D. Conn. 2017); *Tchatat v. City of New York*, 315 F.R.D. 441, 444-45 (S.D.N.Y. 2016); *In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 192

(S.D.N.Y. 2009); *Highland Capital Mgmt. L.P. v. Scheider*, 379 F. Supp. 2d 461, 468-69 (S.D.N.Y. 2005).

The mere fact that an expert adds a gloss or filter to the evidence does not thereby transform what is essentially no more than improper advocacy of the party's position from the witness stand into proper expert testimony. See *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004). In *In re Lyondell Chemical Co.*, for example, the court excluded sections of an expert report that consisted of "cherry-picked examples from the discovery record, including . . . e-mails and presentations, external press releases, and board minutes[,] . . . along with [the expert's] own characterizations of the record." 558 B.R. 661, 668 (Bankr. S.D.N.Y. 2016). The court reasoned that "[t]his selection, organization, and characterization of excerpts from the discovery record is 'no more than counsel . . . will do in argument'" and "is exactly the type of 'factual narrative' that courts routinely exclude." *Id.* (citation omitted); see, e.g., *Louis Vuitton Malletier S.A. v. Sunny Merch. Corp.*, 97 F. Supp. 3d 485, 507-08 (S.D.N.Y. 2015) (excluding part of an expert report that did "little more than summarize evidence in the record in order to construct a narrative").

That rule is all the more significant here because Dr. Shapiro has expressly agreed that his commentary cannot be characterized as a fair summary of the relevant evidence on the points he is addressing. As Dr. Shapiro testified, [REDACTED]

[REDACTED]

[REDACTED] Ex. 3, Shapiro Dep. at 38:16-20; see also *id.* at 36:13-39:15.

D. Dr. Shapiro's Commentary Regarding His Assumptions Should Be Excluded as Improper Expert Testimony on the Knowledge or Motivation of Others

A fair amount of Dr. Shapiro's commentary is improper for the additional reason that expert witnesses are not permitted to testify as to the "knowledge, motivations, intent, state of

mind, or purposes” of others. *Fosamax*, 645 F. Supp. 2d at 192; *Rezulin*, 309 F. Supp. 2d at 546 (“[T]he opinions of these witnesses on the intent, motives, or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise.”); *Taylor v. Evans*, 1997 WL 154010, at *2 (S.D.N.Y.1997) (“[M]usings as to defendants’ motivations would not be admissible if given by any witness—lay or expert.”). In commenting that, in the but-for world, Perrigo supposedly would have had an incentive to sue the FDA in 2013 and likely would have done so, Dr. Shapiro is improperly opining on Perrigo’s intent, state of mind, and purpose—as is evident from the simple fact that the only concrete input on which he relies for his commentary is the testimony of a Perrigo lay witness (which itself notes that predicting that Perrigo would have sued would be inherently speculative). Similarly, in commenting on when FDA would have acted on such a suit in the but-for world, Dr. Shapiro would be improperly testifying about FDA’s motivations and purposes.

Such testimony is impermissible. In *Fleischman v. Albany Medical Center*, for instance, the Court held that an antitrust economist was precluded from testifying about how the defendants used certain information exchanges that were challenged in that case. 728 F. Supp. 2d 130, 167-68 (N.D.N.Y. 2010). The economist’s expertise, the court observed, “does not give him any specialized knowledge to discern the thought processes of” others, and the testimony was therefore improper. *Id.* at 168; *see Fosamax*, 645 F. Supp. 2d at 192 (“[The challenged expert] conceded at the hearing that her regulatory expertise does not give her the ability to read minds. Nevertheless, her report is replete with such conjecture. This is not a proper subject for expert or even lay testimony.”). The same conclusion applies in this case.

IV. CONCLUSION

The Court should preclude Dr. Shapiro from testifying to the commentary in their reports that is discussed in this motion.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on January 10, 2018, the foregoing document was filed with the United States District Court for the Eastern District of Pennsylvania using the ECF system. The document is available for viewing and downloading.

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