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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE MERCK & CO., INC., SECURITIES,
DERIVATIVE AND "ERISA" LITIGATION

MDL No. 1658 (SRC)

THIS DOCUMENT RELATES TO:

Case No. 2:05-CV-01151-SRC-CLW

Case No. 2:05-CV-02367-SRC-CLW

THE CONSOLIDATED SECURITIES ACTION

ORAL ARGUMENT REQUESTED

Return Date: April 21, 2014

(Document Electronically Filed)

**REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT
DR. EDWARD M. SCOLNICK'S MOTION FOR SUMMARY JUDGMENT**

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CITATION CONVENTIONS

Parties and Entities

“Merck”: Defendant Merck & Co., Inc.

“Dr. Reicin”: Individual Defendant Dr. Alise S. Reicin, M.D.

“Dr. Scolnick”: Individual Defendant Dr. Edward M. Scolnick, M.D.

Pleadings, Orders, and Court Submissions

“In re Merck”: *In re Merck & Co., Inc. Sec., Derivative, & ERISA Litig.*, MDL 1658 SRC, 2011 WL 3444199 (D.N.J. Aug. 8, 2011), ECF. No. 287

“Ex. ___”: Exhibit to the Certification of Sheila A. Sadighi, Esq. in Further Support of Defendant Dr. Edward M. Scolnick’s Motion for Summary Judgment, dated April 11, 2014

“Merck Reply”: Reply Memorandum of Law in Further Support of Defendants’ Motion for Summary Judgment, dated April 11, 2014, filed by counsel for Defendants Merck & Co., Inc. and Alise Reicin

“Merck Memorandum” or “Merck Mem.”: Memorandum of Law in Support of Defendants’ Motion for Summary Judgment, filed by counsel for Defendants Merck & Co., Inc. and Alise Reicin, filed January 17, 2014

“Merck Memoranda”: “Merck Reply” and “Merck Memorandum”

“Opening Brief” or “Op. Br.”: Memorandum of Law in Support of Defendant Dr. Edward M. Scolnick’s Motion for Summary Judgment, filed January 17, 2014

“Opposition” or “Opp.”: Lead Plaintiffs’ Memorandum of Law in Opposition to Defendants’ Motions for Summary Judgment, filed March 14, 2014

“P. Ex. ___”: Exhibit to the Declaration of Salvatore J. Graziano in Support of Lead Plaintiffs’ Opposition to Defendants’ Motions for Summary Judgment, filed March 14, 2014

“S. Ex. ___”: Exhibit to the Certification of Sheila A. Sadighi, Esq. in Support of Defendant Dr. Edward M. Scolnick’s Motion for Summary Judgment, filed January 17, 2014

Frequently Used Abbreviations in Dr. Scolnick’s Memorandum of Law

“Class Period”: May 21, 1999 through September 29, 2004

“CV”: cardiovascular

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“FDA”: United States Food & Drug Administration

“VIGOR”: Vioxx Gastrointestinal Outcomes Research study

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Defendant Dr. Scolnick respectfully submits this reply memorandum of law in support of his motion for summary judgment. Dr. Scolnick also hereby joins in, adopts, and incorporates as though fully set forth herein and made on his behalf, the arguments in the Merck Reply.

PRELIMINARY STATEMENT

Plaintiffs' Opposition clearly demonstrates that which *defeats* Plaintiffs' claims: there was—and still is—a legitimate scientific debate regarding the naproxen hypothesis. Plaintiffs describe an array of evidence reflecting that numerous scientists disagreed with that hypothesis. In so doing, however, Plaintiffs argue a point that Dr. Scolnick does not dispute—that there were questions in the scientific community about whether the VIGOR CV results were best explained by the naproxen hypothesis or by, for example, Dr. FitzGerald's theory.

The crux of Dr. Scolnick's motion is that Plaintiffs cannot—and, in their Opposition, have not—set forth adequate admissible evidence that he *lied* when he publicly articulated his *belief* that the naproxen hypothesis explained the VIGOR CV results. That there were opinions at odds with Dr. Scolnick's merely establishes what Dr. Scolnick *publicly acknowledged*—that he could not state with certainty that he was correct. **REDACTED**

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REDACTED Plaintiffs have utterly failed to put forward adequate admissible evidence **REDACTED** that Dr.

Scolnick espoused the naproxen theory despite actually believing that Vioxx was prothrombotic.

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merely to rely on the naproxen hypothesis while quashing efforts to challenge it—a *sine qua non* of Plaintiffs’ case. That Dr. Scolnick pressed for more scientific data and greater certainty as to the naproxen hypothesis is antithetical to the proposition that he acted with scienter.

Accordingly, Plaintiffs cannot survive summary judgment.

ARGUMENT

I. THERE REMAIN ONLY FOUR STATEMENTS PURPORTEDLY ACTIONABLE AGAINST DR. SCOLNICK UNDER SECTION 10(b)

There are just four statements remaining in the case alleged to be actionable against Dr.

Scolnick. (Op. Br. 12-14.) **REDACTED**

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Plaintiffs also cannot seek to support or expand liability against Dr. Scolnick by vaguely grouping him within the label of “Defendants.” This Court has already ruled that “group pleading” is impermissible in light of the PSLRA. *In re Merck*, at *19. The equivalent of group

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pleading is no more permissible on summary judgment. *In re Phillips Petroleum Sec. Litig.*, 738 F. Supp. 825, 837 (D. Del. 1990) (on summary judgment, a plaintiff must establish each element of a Rule 10b–5 violation as to each particular defendant).

II. PLAINTIFFS HAVE NOT SET FORTH EVIDENCE TO ESTABLISH THAT DR. SCOLNICK’S OPINION CONCERNING VIOXX’S SAFETY WAS WITHOUT A REASONABLE BASIS AND THEREFORE OBJECTIVELY FALSE

This Court previously held that the “gravamen” and “core” of Plaintiffs’ complaint is “the allegedly fraudulent presentation by Merck of the naproxen hypothesis as its opinion concerning adverse CV event data.” *In re Merck*, at *4. Thus, Plaintiffs must satisfy the exacting standards established in *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1095-96 (1991) for §10(b) liability predicated on opinions.² The opinion—here, that the cause of VIGOR’s CV results could not be determined with certainty, but was most likely attributable to the naproxen hypothesis—must be false, both objectively and subjectively. Plaintiffs must set forth sufficient admissible evidence demonstrating that: (a) the naproxen hypothesis was false, because it had no reasonable basis (objective falsity); and (b) Dr. Scolnick actually did not believe the naproxen hypothesis, and believed instead that Vioxx was causing heart attacks and killing people (subjective falsity).³ As subjective falsity and scienter are inextricably intertwined under *Virginia Bankshares*, subjective falsity is addressed below in the section of this memorandum devoted to scienter, while objective falsity is addressed in this section.

² The Merck Reply addresses Plaintiffs’ assertion that their case also rests on misstatements of fact and allegedly misleading material omissions from such statements. (Merck Reply 3-4.)

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Plaintiffs cannot survive summary judgment because they have not adduced admissible evidence establishing that the naproxen hypothesis was false and had no reasonable basis. Instead, the Opposition details a fact that is not in dispute: that there was considerable *debate* as to whether the naproxen hypothesis was valid, with many qualified scientists believing that it was not. Proving that this *debate* existed, however, and proving that there was *no reasonable basis* for the naproxen hypothesis are two different things. And as recently as *this year*, an FDA advisory panel considered whether naproxen carries a lower CV risk than other NSAIDs. (See Merck Reply.) In that process, the FDA’s invited guest speaker, Dr. FitzGerald, concluded that naproxen is safer than other NSAIDs from a CV perspective, and that in “some patients naproxen will be cardioprotective like aspirin.” (Merck Reply at 1, 6.) Furthermore, as set forth in the Opening Brief and Merck Memoranda, considerable evidence supported the naproxen hypothesis, and even Drs. REDACTED Oates, and Fitzgerald testified that the scientific debate over the naproxen hypothesis was legitimate. Accordingly, Plaintiffs have not demonstrated, and cannot demonstrate, the requisite objective falsity. As such, Dr. Scolnick is entitled to summary judgment as to all four of the statements allegedly actionable against him—all of which hinge on Dr. Scolnick’s opinion that Vioxx was safe despite the VIGOR CV results.

III. PLAINTIFFS HAVE NOT SET FORTH EVIDENCE ESTABLISHING THAT DR. SCOLNICK’S OPINION CONCERNING THE SAFETY OF VIOXX WAS RENDERED WITH SCIENTER AND THEREFORE SUBJECTIVELY FALSE

A. Plaintiffs Have Not Set Forth Evidence Establishing That Dr. Scolnick Did Not Genuinely Believe His Opinion

Plaintiffs argue they need not demonstrate that Dr. Scolnick actually disbelieved his statements of opinion.⁴ (Opp. 30.) Plaintiffs are wrong. To establish §10(b) liability based on

⁴ According to Plaintiffs, the Court already held that “actual belief” is not required to prove scienter. (Opp. 30-31.) This is wrong. Rather, the Court stated that factual allegations “sufficient to permit a strong inference that a defendant acted with a reckless state of mind may

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an opinion after *Virginia Bankshares*, a plaintiff must establish, in addition to objective falsity, *subjective* falsity, *i.e.*, that the speaker has knowingly misstated his truly held opinion:

It is not sufficient for these purposes to allege that an opinion was unreasonable, irrational, excessively optimistic, not borne out by subsequent events, or any other characterization that relies on hindsight or falls short of an identifiable gap between the opinion publicly expressed and the opinion truly held. . . . Although in the typical case falsity and scienter are different elements, in a false statement of opinion case the two requirements are essentially identical. For example, in a case where a material misstatement of fact is alleged, the statement may be both objectively false *and* believed in good faith by the speaker to be true. However, in contrast, a material misstatement of opinion is by its nature a false statement, not about the objective world, but about the defendant's own belief. Adequately alleging the falsity of a statement like "I believe AWE will grow" is the same as adequately alleging scienter on the part of the speaker, since the statement (unlike a statement of fact) cannot be false at all ***unless the speaker is knowingly misstating his truly held opinion.***

In re Salomon Analyst AT&T Litig., 350 F. Supp. 2d 455, 466 (S.D.N.Y. 2004) (regular emphasis in original; bold emphasis added).

In seeking to avoid this burden, Plaintiffs rely on the Third Circuit's observation in *In re Merck & Co., Inc.*, 543 F.3d 150, 166 (3d Cir. 2008) "that for misrepresentations in an opinion or belief to be actionable, plaintiffs must show that the statement was issued without a genuine belief or reasonable basis," (quoting *Herskowitz v. Nutri/System, Inc.*, 857 F.2d 179, 185 (3d Cir. 1988) (quoting *Eisenberg v. Gagnon*, 766 F.2d 770, 776 (3d Cir. 1985))) (internal quotation marks and ellipses omitted). The Third Circuit simply observed that opinions issued with *neither* a genuine belief *nor* a reasonable basis are not actionable under *Virginia Bankshares*. It does not follow—and cannot follow, under *Virginia Bankshares*—that an opinion issued *with* a genuine belief in its truth is actionable, even if Plaintiffs are able to establish that it is *objectively* false.

There can be no doubt, after *Virginia Bankshares*, that an opinion can be actionable under §10(b)

also suffice ***at the pleading stage*** to set forth through circumstantial evidence. . . . that a defendant knowingly made misrepresentations of fact and/or opinion." *In re Merck*, at *21 (emphasis added). On summary judgment, Plaintiffs must adduce admissible evidence proving the "gravamen" of their case—that Dr. Scolnick did not believe in the naproxen hypothesis.

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only if it is *both* objectively *and subjectively* false.⁵ Plaintiffs' effort to collapse these two requirements would render *Virginia Bankshares* meaningless, and §10(b) actions predicated on opinions indistinguishable from those predicated on statements of fact.⁶

Even under Plaintiffs' characterization of the test, however, Dr. Scolnick would still be entitled to summary judgment. First, for the reasons set forth above, Plaintiffs are unable to adduce adequate evidence establishing that the naproxen hypothesis was issued without a reasonable basis. Second, Plaintiffs cannot establish that Dr. Scolnick *knew* that the naproxen hypothesis was objectively false. This, indeed, would require a showing that Dr. Scolnick persisted in perpetuating the naproxen hypothesis, resulting in Merck keeping Vioxx on the market, despite *disbelieving* it, while believing that it was killing people. Plaintiffs cannot establish this preposterous proposition.

A fraud claim may not be premised "upon a mere disagreement with how defendants chose to interpret the results of [a] clinical trial." *In re MELA Sciences, Inc., Sec. Litig.*, NO. 10 CV 8774, 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012). Here, Dr. Scolnick publicly disclosed that one could not be sure whether the VIGOR CV results were attributable to a prothrombotic effect of Vioxx or a cardioprotective effect of naproxen. Plaintiffs themselves maintain that Dr. Scolnick told the *New York Times* that "none of the findings to date are enough to prove that the issue is fully resolved." Nothing in Plaintiffs' opposition overcomes the diametric inconsistency between these statements and an intent to deceive: according to

⁵ Statements of opinion or belief must be both objectively and subjectively false for liability to attach to them. *See e.g., Fait v. Regions Fin. Corp.*, 655 F.3d 105, 110-12 (2d Cir. 2011); *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 566 (S.D.N.Y. 2011).

⁶ If a purported statement of fact is genuinely believed by the speaker but is false and made recklessly without any reasonable basis, it would satisfy the falsity and scienter elements. If the same were true as to statements of opinion, the *Virginia Bankshares* distinction for opinions would be a nullity.

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Plaintiffs' own allegations, Dr. Scolnick expressly disclosed to the world that Vioxx might raise the heart attack rate. *See In re Keryx Biopharmaceuticals, Inc. Sec. Litig.*, NO. 13 Civ. 1307, 2014 WL 585658, at *8 (S.D.N.Y. Feb. 14, 2014) (courts examine statements "collectively" and do not ask "whether any individualized statement . . . scrutinized in isolation" meets the §10(b) scienter standard) (internal quotation marks omitted).

Even evidence mischaracterized by Plaintiffs illustrates Dr. Scolnick's rigorous assessment of Vioxx's safety—candid and consistent with his public disclosures. For example, Dr. Scolnick's "unambiguously" comments at an Annual Business Briefing on December 12, 2000 (the "ABB") echo his internal views and public disclosures regarding Vioxx. Plaintiffs selectively quote his remarks. In response to a question from the audience, Dr. Scolnick stated: "the cardiovascular issues in VIGOR, *even at this point, compared to where we were when we first got the data*, are unambiguously related to a decrease in the events in the naproxen arm, and not an increase in the Vioxx arm of the study." (Opp. 34; P. Ex. 323 at 2:1-5.) Plaintiffs omit the critical bolded language, which makes clear that Dr. Scolnick is not stating that the naproxen hypothesis is a certainty—merely that it is more certain than when he first received the VIGOR data on March 9, 2000. Additional emails mischaracterized by Plaintiffs are addressed in the Merck Reply. Plaintiffs also ignore the significance of the many contemporaneous emails in which Dr. Scolnick affirmatively expressed his belief in Vioxx's CV safety during the Class Period. (Op. Br. 8-9.)

Similarly, other undisputed evidence, including evidence highlighted by Plaintiffs, shows the *opposite* of scienter: for example, suggesting and pursuing additional scientific research with respect to the CV safety issues and circulating an email expressing an initial reaction to the VIGOR results that Vioxx *was* prothrombotic. (S. Ex. S.) Pursuing additional research—

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“agonizing” about it—is exactly what a scientist seeking the truth would do, and is exactly what a defendant seeking to deceive the public into thinking that a drug was safe, without adequate evidence, would *not* do.⁷ Plaintiffs cannot evade this fatal flaw in their Opposition.

B. Plaintiffs Have Not Set Forth Evidence Establishing That Dr. Scolnick’s Stock Trading Reflects Scienter

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Plaintiffs base this fantastic theory on a portion of a sentence in an email that has nothing to do with his stock trading and which, when read in full, demonstrates Dr. Scolnick’s belief in the naproxen hypothesis. In the email, Dr. Scolnick wrote: “we would be better off, in fact, not having a public meeting where Cv events would be discussed for as long as possible *as we gather more information in other controlled trials.*” (P. Ex. 552) (emphasis added.) Plaintiffs do not quote the bolded portion of the statement. With the bolded portion included, it is clear that Dr. Scolnick preferred to have the FDA advisory committee meeting held at a time when additional data were available—indicating that he believed that additional data would be supportive of Vioxx’s CV safety and the naproxen hypothesis. Plaintiffs’ suggestion that this email supports scienter for securities fraud is baseless and at best purely speculative.⁸

Plaintiffs also argue that the scope of Dr. Scolnick’s sale was unusual, contending, without legal support, that “Scolnick’s \$25 million profit, alone, is enough to support a finding of

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⁸ Nor is scienter supported by the fact that months after the August 7, 2000 email and his stock sale, Dr. Scolnick emailed Messrs. Gilmartin and Anstice stating that adverse publicity could result from the meeting. (P. Ex. 324.) **REDACTED**
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unusual scope.” (Opp. 64.) Plaintiffs are wrong. Courts have recognized that “large dollar amounts, standing alone, typically do not suffice to establish motive.” *In re KeySpan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 382 (E.D.N.Y.2003); *Bldg. Trades United Pension Trust Fund v. Kenexa Corp.*, NO. CIV. A. 09-2642, 2010 WL 3749459, at *9-*12 (E.D. Pa. Sept. 27, 2010).

Further, Plaintiffs ignore the fact that during the Class Period, Dr. Scolnick did not sell *any* of the substantial amount of Merck stock—more than \$20 million worth as of October 25, 2000—he held outright and, in fact, owned more Merck shares at the end of the Class Period than he did at the beginning. (Op. Br. 23.)⁹ Dr. Scolnick simply continued his usual practice of holding the Merck shares he held outright and selling shares acquired through options. Indeed, the total amount of Merck stock Dr. Scolnick sold in a comparable time period preceding the Class Period was almost the same as the total amount Dr. Scolnick sold during the Class Period (\$30.9 million v. \$32.4 million)—another fact ignored by Plaintiffs. (Op. Br. 22.)

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REDACTED Plaintiffs must adduce *admissible evidence* to refute Dr. Scolnick’s explanation for his stock sales, especially in light of the highly personal reasons that formed part of his rationale. This they have not done. The record demonstrates that Dr. Scolnick had several reasons for his stock sale, including (i) to diversify his assets in accordance with past practice, **REDACTED**

⁹ At the time of the sale, Dr. Scolnick held at least 250,118 shares of Merck stock and 985,000 stock options. (S. Ex. TT; S. Ex. SS.) *In re Astea Int’l. Inc. Sec. Litig.*, NO. CIV. A. 06-1467, 2007 WL 2306586, at *14 (E.D. Pa. Aug. 9, 2007) (unvested options considered as part of total holdings). Even including his wife’s shares and excluding his unvested options, the October 25, 2000 stock sale disposed of just 60% of his Merck stock holdings. This does not render the sale suspicious. *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000) (trades not suspicious even where individual defendants sold 90.71% and 88.75% of their shares). That he *retained* 40% of his stock reflects the *opposite* of scienter, a fact that Plaintiffs conveniently elide.

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(S. Ex. B at REDACTED 243:21-

244:18, REDACTED

As to diversification, Plaintiffs argue that Dr. Scolnick “was diversifying *away from* Merck stock.” (Opp. 66) (emphasis in original.) Obviously, however, given Dr. Scolnick’s large holdings in Merck stock, diversification of his investments, *by definition*, would mean liquidation of some portion of his Merck shares. (S. Ex. TT.) What Plaintiffs ignore is that Dr. Scolnick’s exercise and sale of Merck stock options was consistent with his practice over a decade.¹⁰ Plaintiffs offer no evidence to refute this.

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¹⁰ Plaintiffs also absurdly suggest that the fact that Dr. Scolnick did not sell any additional Merck stock for many years after the October 2000 sale rebuts his diversification explanation. (Opp. 66.) What Dr. Scolnick did years later—after his retirement and including after the Vioxx litigation was commenced—is simply not relevant. REDACTED

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IV. OTHER REASONS THAT CERTAIN STATEMENTS ARE NOT ACTIONABLE AGAINST DR. SCOLNICK

A. The 1999 Form 10-K Statement Should Be Dismissed

As set forth in the Opening Brief, Plaintiffs’ claim based on the 1999 Form 10-K should also be dismissed because it has already been dismissed from this case. (Op. Br. 18-19.)

Plaintiffs insist that the dismissed statement “simply recites Merck’s past earnings,” whereas the statement here “specifically concerns Vioxx’s safety profile.” (Opp. 68.) This is false. The statement dismissed in the Consolidated Direct-Action cases included the *identical words* as the product-safety language from the Form 10-K allegedly actionable against Dr. Scolnick. The only additional language alleged to be actionable against Dr. Scolnick is one sentence: “VIOXX

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is also enjoying success in the 47 other countries in which it has been launched.” But Plaintiffs do not allege that statement to have been false or misleading. Plaintiffs fail to explain why this language can survive here but not the Consolidated Direct-Action cases.

B. The *Bloomberg* Statement Should Be Dismissed

The *Bloomberg* Statement is not actionable because it is true: Merck did conduct a large CV outcomes study as Dr. Scolnick announced. (Op. Br. 17-18.) Furthermore, Plaintiffs cannot show that Dr. Scolnick did not believe *at the time he made the statement* that Merck would conduct more research so it could be sure of Vioxx’s safety.

V. MPERS HAS NOT SET FORTH EVIDENCE ESTABLISHING THAT IT CAN SUSTAIN ITS SECTION 20A CLAIM AGAINST DR. SCOLNICK¹²

Where, as here, the record establishes that a §20A plaintiff *could not possibly* have been the counterparty to a trade with the defendant, the plaintiff does not have standing to maintain the §20A claim. (Op. Br. 24-28.) MPERS complains that the law does not require it to prove it was a counterparty with Dr. Scolnick. (Opp. 74-75.) This argument misconstrues the point. MPERS need not *prove* trading privity with Dr. Scolnick, but it must at least demonstrate that it was a *potential* counterparty to Dr. Scolnick’s trades. (Op. Br. 26.) That it cannot do.¹³

MPERS also wrongly argues that “because the Class’s total remedy is limited ‘to the insider’s profit gained,’” MPERS need not show that it was harmed by the “contemporaneous” trade to have standing. (Opp. 76-77.) MPERS confuses recoverable damages with standing.

¹² MPERS incorrectly suggests that the Court has already ruled on Dr. Scolnick’s §20A argument. It has done no such thing, having expressly ruled that the issue was more appropriately considered on summary judgment. (See Op. Br. 24, n. 19.)

¹³ MPERS and Dr. Scolnick traded at different prices and in different transaction sizes, and MPERS previously conceded that they traded at different times of the day and were not counterparties. (S. Ex. XX.) MPERS now speculates that perhaps it is theoretically possible that MPERS and Dr. Scolnick could have been counterparties if a “market maker” were involved in the trade. (Opp. 76, n. 97.) Speculation cannot defeat summary judgment.

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The measure of damages does not eliminate the standing requirement that “harm to the [§20A] plaintiff is a necessary factor” for the plaintiff to maintain suit. *Buban v. O’Brien*, NO. C 94-0331, 1994 WL 324093, at *3 (N.D. Cal. June 22, 1994).¹⁴

VI. PLAINTIFFS HAVE NOT SET FORTH EVIDENCE ESTABLISHING DR. SCOLNICK IS LIABLE AS A CONTROL PERSON UNDER SECTION 20(a)

Because Plaintiffs cannot establish scienter, Plaintiffs also cannot establish that Dr. Scolnick was a “culpable participant” in the alleged fraud. Accordingly for this reason and because Plaintiffs cannot establish a predicate violation of the Exchange Act, Plaintiffs’ §20(a) claim against Dr. Scolnick fails. (*See Op. Br. 28-29.*)

CONCLUSION

For the reasons set forth above, in the Opening Brief, and the Merck Memoranda, the Court should grant Dr. Scolnick’s Motion for Summary Judgment and dismiss all claims.

Dated: April 11, 2014
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¹⁴ Plaintiffs do not dispute that under LIFO all of the 15,600 shares of Merck stock MPERS purchased on October 25, 2000 were sold before the end of the Class Period (Opp. 77); nor do they dispute the propriety of using LIFO to determine whether a plaintiff was harmed. (*Id.*)