

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

IN RE MERCK & CO., INC. SECURITIES,  
DERIVATIVE & “ERISA” LITIGATION

THIS DOCUMENT RELATES TO: THE  
CONSOLIDATED SECURITIES ACTION

MDL No. 1658 (SRC)

Civil Action No. 05-1151 (SRC)

Civil Action No. 05-2367 (SRC)

**JOINT DECLARATION OF CO-LEAD COUNSEL IN SUPPORT OF  
(A) LEAD PLAINTIFFS’ MOTION FOR FINAL APPROVAL OF THE  
PROPOSED SETTLEMENT AND APPROVAL OF PLAN OF ALLOCATION  
AND (B) CO-LEAD COUNSEL’S MOTION FOR AWARD OF  
ATTORNEYS’ FEES AND REIMBURSEMENT OF LITIGATION EXPENSES**

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SALVATORE J. GRAZIANO, DAVID A.P. BROWER, MATTHEW A. KUPILLAS,  
and MARK LEVINE declare as follows:

**I. INTRODUCTION**

1. I, Salvatore J. Graziano, am a member of the bars of the State of New York, the U.S. District Courts for the Southern and Eastern Districts of New York, and the U.S. Courts of Appeals for the First, Second, Third, Ninth, and Eleventh Circuits. I have been admitted to appear *pro hac vice* before this Court in the above-captioned action (the “Action”). I am a Partner of the law firm of Bernstein Litowitz Berger & Grossmann LLP (“BLB&G”). I have personal knowledge of the matters set forth herein based on my active participation in the prosecution and settlement of the claims asserted on behalf of the class in this Action from the time I became involved in this Action in 2007 and based on available records and my conversations with counsel regarding events before my involvement in this Action.

2. I, David A.P. Brower, am a member of the bars of the State of New York, the U.S. Supreme Court, the U.S. Courts of Appeals for the First, Second, Third, Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Tenth and Eleventh Circuits, and the U.S. District Courts for the Southern and Eastern Districts of New York. I have been admitted to appear *pro hac vice* before this Court in this Action. I am a Managing Director of the law firm of Brower Piven, A Professional Corporation (“Brower Piven”). I have personal knowledge of the matters set forth herein based on my active participation in the prosecution and settlement of the claims asserted on behalf of the class in this Action.

3. I, Matthew A. Kupillas, am a member of the bars of the State of New York, the U.S. Supreme Court, the U.S. Courts of Appeals for the Second and Tenth Circuits, and numerous federal trial courts. I have been admitted to appear *pro hac vice* before this Court in this Action. I am a partner of the law firm of Milberg LLP (“Milberg”). I have personal knowledge of the

matters set forth herein based on my active participation in the prosecution and settlement of the claims asserted on behalf of the class in this Action.

4. I, Mark Levine, am a member of the bars of the State of New York, the U.S. District Courts for the Southern, Western and Eastern Districts of New York and the Northern District of Illinois, and the U.S. Courts of Appeals for the Second, Fourth, Sixth, Ninth, Tenth and Eleventh Circuits. I am an attorney at the law firm of Stull, Stull & Brody (“SSB”). I have personal knowledge of the matters set forth herein based on my active participation in the prosecution and settlement of the claims asserted on behalf of the class in this Action.

5. BLB&G, Brower Piven, Milberg, and SSB are Court-appointed co-lead counsel (“Co-Lead Counsel”) for the Court-appointed lead plaintiffs The Public Employees’ Retirement System of Mississippi (“Miss. PERS”), Richard Reynolds, Steven LeVan and Jerome Haber (collectively, “Lead Plaintiffs”) and the Settlement Class.<sup>1</sup>

6. We respectfully submit this Declaration in support of Lead Plaintiffs’ motion (a) for final certification, pursuant to Fed. R. Civ. P. 23(a) and (b)(3), of the settlement class consisting of all persons and entities who, from May 21, 1999 through October 29, 2004, inclusive (the “Settlement Class Period”), purchased or otherwise acquired Merck & Co., Inc. common stock or Merck Call Options, or sold Merck Put Options (the “Settlement Class”)<sup>2</sup>, (b) final approval,

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<sup>1</sup> Unless otherwise noted, capitalized terms shall have the meanings ascribed to them in the Stipulation and Agreement of Settlement, dated as of February 8, 2016 (the “Stipulation”), entered into by and among Lead Plaintiffs and Defendants. ECF No. 949-2. (All references to ECF numbers herein are to the Securities Action Docket, No. 05-cv-2367.)

<sup>2</sup> Excluded from the Settlement Class are: Defendants; the officers and directors of Merck at all relevant times; members of the Immediate Family of any excluded person; the legal representatives, heirs, successors, and assigns of any excluded person or entity; any entity in which any excluded person or entity has or had a controlling interest; the Merck & Co., Inc. Employee Savings & Security Plan (now known as the Merck U.S. Savings Plan), the Merck and Co., Inc. Employee Stock Purchase & Savings Plan (now known as the MSD Employee Stock Purchase & Savings Plan), the Merck Puerto Rico Employee Savings & Security Plan (now known as the MSD

pursuant to Fed. R. Civ. P. 23(e), of the proposed Settlement of the above-entitled consolidated securities action (the “Action”), which will resolve the claims asserted in the Action on behalf of the class that was certified by the Court (the “Certified Class”), plus the claims of additional Settlement Class Members; and (c) final approval of the proposed plan of allocation of the proceeds of the Settlement (the “Plan of Allocation”).

7. The Court preliminarily approved the Settlement by its Order entered on February 11, 2016 (ECF No. 951) (the “Preliminary Approval Order”).

8. We believe the proposed Settlement achieved in this case is exceptional. The Settlement is the product of arduous and protracted litigation, spanning more than 12 years, which ended less than three months before trial was set to begin. This Declaration sets forth in detail how Lead Plaintiffs were able to overcome extraordinary hurdles and great risk to achieve this outstanding result on behalf of the Class.

9. We also respectfully submit this Declaration in support of Co-Lead Counsel’s request for an award of attorneys’ fees and reimbursement of litigation expenses in connection with Co-Lead Counsel’s motion for an award of attorneys’ fees from the combined \$1,062,000,000.00 (including funds for attorney’s fees and expenses, plus interest earned thereon) recovered in the Action on behalf of the Settlement Class (the “Settlement Funds”), and reimbursement of plaintiffs’ counsel’s litigation expenses in the amount of \$9,473,356.02 (collectively, the “Fee and Expense Applications”).

10. For the reasons set forth below and in the accompanying memoranda and individual

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Puerto Rico Employee Savings & Security Plan), and the Merck-Medco Managed Care, LLC 401(k) Savings Plan (and any successor or successors thereto). Also excluded from the Settlement Class are: (i) any New Opt Outs; or (ii) any Person listed in Appendix 1 to the Stipulation who does not opt back into the Settlement Class.



plaintiffs' firms declarations, Lead Plaintiffs and Co-Lead Counsel respectfully submit that (i) the Settlement Class meets all of the requirements of Fed. R. Civ. P. 23(a) and (b)(3), and final certification should be granted; (ii) the terms of the Settlement are fair, reasonable, and adequate in all respects and the Settlement should be finally approved by the Court; (iii) the proposed Plan of Allocation of the Net Settlement Fund is fair and reasonable and should be approved; and (iii) the Fee and Expense Application is fair and reasonable, supported by the facts and the law and should be granted in all respects.

## **II. THE OUTSTANDING RECOVERY ACHIEVED**

11. Lead Plaintiffs have succeeded in obtaining a combined cash recovery of \$1,062,000,000.00. If approved, the Settlement would rank among the fifteen largest securities class action settlements since the passage of the PSLRA in 1995, according to the latest report of Securities Class Action Services. *See* Exhibit 1 hereto. The Settlement is also the largest securities fraud class action settlement ever obtained from a pharmaceutical company, and the second largest settlement ever within the Third Circuit. *See id.* As set forth in the Stipulation, in exchange for this payment, the proposed Settlement would dismiss with prejudice all claims asserted by Lead Plaintiffs and the Settlement Class against defendants Merck, Dr. Edward Scolnick ("Scolnick") and Dr. Alise Reicin ("Reicin") (collectively, "Defendants") and conclude the Action.

12. As discussed further below, Lead Plaintiffs obtained this substantial recovery for the Settlement Class despite the significant risks inherent in complex securities class actions generally, and the specific risks they faced in prosecuting the Action. The parties were less than three months from trial when they reached a settlement in principle. The outcome of the parties' pre-trial motions and a jury trial, especially in a highly complex case such as this, can never be predicted with reasonable certainty. Even if Lead Plaintiffs prevailed on the pre-trial motions and at trial, there is no assurance that they would have recovered an amount equal to, much less greater

than, the Settlement Funds. Moreover, even a positive outcome at trial is not a guarantee of an ultimate positive result for the class. There are several recent instances where plaintiffs' verdicts in securities fraud cases have been reversed by the trial court or on appeal.

13. Lead Plaintiffs not only had a clear understanding of the practical considerations confronting them, but at the time the Settlement was reached, also understood the strengths and weaknesses of the case through Co-Lead Counsel's extensive investigation, prosecution of the case and preparation for trial. Over a span of more than twelve years of extensive and hard-fought litigation, Co-Lead Counsel engaged in thorough and vigorous litigation in which they, among other things: (i) conducted a thorough investigation into the class's claims; (ii) drafted detailed consolidated class action complaints; (iii) successfully appealed the District Court's initial dismissal of the Action to the U.S. Court of Appeals for the Third Circuit; (iv) withstood Defendants' appeal of that decision to the U.S. Supreme Court and achieved a unanimous 9-0 victory at the Supreme Court; (v) successfully opposed, in substantial part, Defendants' subsequent motions to dismiss the complaint and motion for judgment on the pleadings; (vi) defended the depositions by Defendants of each of the Lead Plaintiffs and successfully achieved certification of the Certified Class; (vii) engaged in an extensive and exhaustive discovery effort, including reviewing more than 35.8 million pages of documents, taking or defending fifty-nine (59) depositions, several of which were conducted not just in Merck's home state of New Jersey but in many cases throughout the United States or overseas, and preparing detailed responses to Defendants' contention interrogatories; (viii) successfully opposed Defendants' motions for summary judgment; and (ix) completed virtually all pre-trial preparations, including the briefing of *Daubert* motions, as well as completing a comprehensive joint Pretrial Order. Co-Lead Counsel also engaged in a multi-day mock trial session, which provided them with extensive insight into

the risks they faced at trial.

14. The Settlement was ultimately accomplished through arm's-length settlement discussions facilitated by the Court, as well as the Court-appointed mediator, former United States District Judge, the Honorable Layn R. Phillips. The settlement discussions included numerous in-person settlement conferences and mediation sessions over the span of several years with attorneys representing each side, and telephonic follow-up and in-person sessions. The parties reached an agreement in principle to settle the Action on December 17, 2015, less than three months before trial, which was scheduled to begin on March 1, 2016. Even after reaching the agreement in principle, the parties continued to negotiate for an additional two months over the specific terms of the Stipulation.

15. As evidenced by the enormous effort and zealous advocacy summarized above and described in greater detail herein, by the time the Settlement was reached, Co-Lead Counsel had a detailed and thorough understanding of the strengths and weaknesses of the case. We unequivocally believe, based on our knowledge and understanding of the claims and defenses asserted in this Action, that the Settlement is an outstanding result for the Settlement Class, particularly when considered against the very substantial risks that would have still confronted Lead Plaintiffs' ultimate class-wide recovery in the Action and the likely multi-year additional delay that would result from the inevitable post-trial motions and lengthy appeals that would follow any success at trial.

16. For all of the reasons set forth herein, including the excellent result obtained, we respectfully submit that the Settlement is "fair, reasonable and adequate" in all respects, and that the Court should approve it pursuant to Federal Rule of Civil Procedure Rule 23(e). Lead Plaintiffs also respectfully request that the Court affirm its determination to certify the Settlement Class

pursuant to Rules 23(a) and (b)(3). We also submit that the proposed Plan of Allocation is fair and reasonable and should be approved. For similar reasons, and for the additional reasons set forth below, we respectfully submit that Co-Lead Counsel's request for attorneys' fees and reimbursement of litigation expenses is fair and reasonable, and should be approved.

### **III. PROSECUTION OF THE ACTION**

#### **A. Factual Background of the Action**

17. This securities fraud class action arises out of alleged public misrepresentations and omissions concerning the Merck painkiller rofecoxib, brand named Vioxx® ("Vioxx"), which Merck began selling in May 1999 and removed from the market on September 30, 2004. Plaintiffs' claims in this case at the time of the Settlement were as follows: (i) violation of Section 10(b) of the Securities Exchange Act of 1934 ("the Exchange Act") against Defendants Merck and former Merck senior executives Drs. Reicin and Scolnick; (ii) violation of Section 20(a) of the Exchange Act against Defendants Reicin and Scolnick based on their control over Merck; and (iii) violation of Section 20A of the Exchange Act against Defendant Scolnick arising out of his alleged insider trading in Merck common stock based on material undisclosed adverse information.

18. Vioxx belonged to a class of pain relievers known as non-steroidal anti-inflammatory drugs ("NSAIDs").<sup>3</sup> NSAIDs are commonly used to treat the symptoms of arthritis. Vioxx was developed by Merck in the 1990s with the aim of creating an NSAID that would relieve pain while causing fewer adverse gastrointestinal ("GI") complications than traditional NSAIDs, such as aspirin and ibuprofen.

19. In general, NSAIDs work by inhibiting the cyclooxygenase ("Cox") enzyme, which

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<sup>3</sup> The facts set forth in the Factual Background of the Action section are based on our review of the record and the Court's Opinion denying the Defendants' motions for summary judgment.

is involved in the production of chemicals in the body called prostaglandins. Prostaglandins promote pain and inflammation, but they also protect the stomach lining and have an anti-coagulation effect on platelets. In the early 1990s, scientists discovered that the Cox enzyme exists in two isoforms, Cox-1 and Cox-2. Cox-1 is responsible for prostaglandin synthesis, a function that protects the GI tract, whereas Cox-2 is responsible for the production of prostaglandins. Traditional NSAIDs inhibit both isoforms, thereby reducing inflammation but also increasing the risk of adverse GI effects. In contrast, Vioxx was believed to selectively inhibit only Cox-2, thus suppressing prostaglandin production and reducing pain and inflammation without inhibiting the protective GI function of Cox-1.

20. Prior to the FDA's approval of Vioxx, Merck conducted Protocol 023, a study of the effects of Vioxx on the kidneys, led by outside Merck consultant Dr. Garret FitzGerald, a Professor of Medicine and Pharmacology at the University of Pennsylvania and a world-renowned expert in prostaglandins. Protocol 023 measured the excretion of various urinary metabolites in older adults with a focus on sodium excretion, but also measured urinary excretion of prostacyclin metabolites and thromboxane metabolites. Prostacyclin is a prostaglandin which inhibits platelet aggregation (blood clotting) and dilates blood vessels, whereas thromboxane is a substance that promotes platelet aggregation. The final results of the two-week Protocol 023 trial revealed that the patients receiving Vioxx showed decreased levels of anti-clotting prostacyclin metabolites but not pro-clotting thromboxane metabolites.

21. On October 20, 1997, Dr. Briggs Morrison, the Executive Director of Worldwide Clinical Data Management at Merck during the Class Period, sent a memo to various Merck employees, informing them of the results from Protocol 023. He highlighted the observed effect of Vioxx on the imbalance in prostaglandin metabolites, calling it the "most surprising result from

this study” and noting that it would be discussed with prostaglandin experts.

22. Among those commenting on the Protocol 023 results was Dr. FitzGerald himself. His interpretation of the data came to be known as the “FitzGerald Hypothesis.” He posited that the mechanism of selective Cox-2 inhibitors, such as Vioxx, which suppresses prostacyclin (anti-clotting function) without suppressing thromboxane (pro-clotting function) “might mediate a risk of thrombosis from Cox-2 inhibitors in predisposed individuals.” The concern was that thrombosis could lead to adverse cardiovascular (“CV”) events, such as myocardial infarction (heart attack, or “MI”).

23. On May 20, 1999, the FDA approved Vioxx for “relief of the signs and symptoms of osteoarthritis, management of acute pain [in adults] and treatment of primary dysmenorrhea.”

24. Prior to FDA approval of Vioxx, Merck began a large-scale, double-blind clinical trial to study GI outcomes in patients with rheumatoid arthritis (“RA”) who took Vioxx. This study, known as VIGOR (Vioxx Gastrointestinal Outcomes Research), sought to examine whether Vioxx significantly reduced the risk of serious GI complications (*i.e.*, stomach perforations, ulcers and bleeds, or “PUBs”) as compared to the traditional NSAID Naproxen. The study enrolled 8,076 RA patients, randomly assigning roughly half of them to receive a 50 mg daily dose of Vioxx and the other half to receive 500 mg of Naproxen twice daily.

25. On March 9, 2000, the results of the VIGOR study were formally unblinded to a group of Merck scientists, including Defendants Reicin and Scolnick. While Merck used VIGOR to confirm Vioxx’s GI benefit versus Naproxen, the data also showed a statistically significant difference in CV events in the Vioxx arm versus the Naproxen arm. In particular, the Vioxx group experienced a five-fold greater number of MIs than the Naproxen group.

26. Internally, Merck’s initial assessment of the VIGOR CV data was that the greater

number of CV events in the Vioxx arm was attributable to a prothrombotic effect of Vioxx. As Defendant Scolnick admitted, his first reaction to the VIGOR results was that Vioxx had elevated the CV event rate as opposed to Naproxen lowering the rate, and his connection was to the FitzGerald Hypothesis. Defendant Reicin similarly testified in this Action that her “first impression was that what we saw was a result of Vioxx and not naproxen acting as a cardioprotective agent.”

27. Nevertheless, because VIGOR involved two active comparators (as opposed to Vioxx and placebo), Merck scientists, including Defendant Reicin, began to advance an alternative hypothesis to explain the study’s CV data: that Naproxen administered at 500 mg twice daily could have a cardio-protective effect and thus be responsible for the lower incidence of CV events in VIGOR’s Naproxen arm (rather than Vioxx causing any CV harm). This Merck explanation for the VIGOR results was later dubbed by Defendants the “Naproxen Hypothesis.”

28. Plaintiffs alleged that Merck searched for evidence to reasonably support the Naproxen Hypothesis, but Defendants were unable to find such evidence. Nevertheless, starting on March 27, 2000, Merck publicly advanced the Naproxen Hypothesis to investors and patients as the likeliest explanation for the VIGOR CV results, and Merck continued to make statements throughout the Class Period touting the safety of Vioxx and attributing the higher level of CV events for Vioxx users in the VIGOR trial to Naproxen’s purported cardio-protective qualities.

29. Merck also claimed repeatedly that a comprehensive review of all of its Vioxx safety data showed “no difference” in CV risk between Vioxx and comparator drugs. Over the course of fact and expert discovery, Lead Plaintiffs amassed evidence demonstrating that Merck’s purported Vioxx safety data (including from its studies of Vioxx in Alzheimer’s disease patients) in fact lacked statistical power, which rendered Merck’s claim materially misleading.

30. Merck conducted other studies of Vioxx, including studies of Alzheimer's patients (which showed undisclosed increases in mortality and CV mortality in patients taking Vioxx), and the APPROVe trial.

31. The APPROVe trial (as later amended) compared Vioxx at a 25 mg dose to placebo, and its purpose was to study Vioxx's ability to prevent the recurrence of colon polyps. On September 17, 2004, the APPROVe study's External Safety Monitoring Board ("ESMB") met to review the ongoing trial's cumulative safety data. It observed significant differences between the Vioxx group and placebo group in many categories of adverse events, specifically, a disparity in confirmed thromboembolic events, some of which were fatal. Upon reviewing this data, the ESMB unanimously recommended that Merck's Executive Committee be unblinded to APPROVe's safety data and that the study be discontinued.

32. On September 30, 2004, Merck announced Vioxx's immediate withdrawal from the worldwide market. The press release issued that day quoted Merck's CEO at the time, Raymond Gilmartin, who explained that Merck was voluntarily taking such action in light of the availability of "alternative therapies," and the "questions raised by the [APPROVe study] data." It also quoted Peter Kim, then head of Merck Research Laboratories, as stating that "the cause of these results is uncertain at this time." On that day, in response to this disclosure, Merck's stock price fell by more than \$12.00 per share.

33. Lead Plaintiffs alleged that Defendants' series of materially false and misleading public statements concerning Vioxx's purported CV safety and reasons for the results of the VIGOR study violated Section 10(b) of the Exchange Act. Lead Plaintiffs alleged that Defendants' material misstatements and omissions artificially inflated the prices of Merck common stock (and distorted the prices of Merck options) during the Class Period. Lead Plaintiffs also alleged that



Defendant Scolnick sold \$32.4 million worth of Merck common stock on October 25, 2000 based on material undisclosed adverse information about the safety of Vioxx.

34. Defendants have denied all of Lead Plaintiffs' allegations of wrongdoing and do not admit, as part of this Settlement, to any wrongdoing.

**B. The Initial Complaint**

35. On November 6, 2003, an individual plaintiff, Frank Pringle, filed the first securities class action complaint against Merck related to Vioxx, which was filed in the Eastern District of Louisiana, captioned *Pringle v. Merck & Co., Inc., et al.*, No. 03-cv-3125 (E.D. La.).

36. On November 20, 2003, Mr. Pringle amended his complaint to include the unidentified names of Merck's insurance companies based on the Louisiana statute permitting direct actions against insurers. Mr. Pringle also attached an affidavit and his trades in Merck securities to this First Amended Complaint, which also added SSB as counsel for Mr. Pringle.

**C. The Appointment of the Initial Lead Plaintiffs and Lead Counsel**

37. On January 26, 2004, a group of investors that included Richard Reynolds ("Reynolds") and Steven LeVan ("LeVan") filed a motion seeking to be appointed as Lead Plaintiffs in the Action pursuant to the PSLRA. At that time, Messrs. Reynolds and LeVan were represented by the firm then known as Milberg Weiss Bershad Hynes & Lerach LLP, now known as Milberg LLP ("Milberg").

38. On January 27, 2004, a group of individual investors that included Jerome Haber ("Haber") and Marc Nathanson ("Nathanson") filed a motion seeking to be appointed as Lead Plaintiffs.

39. On February 23, 2004, after the Court set a hearing date for Lead Plaintiffs' motions, Reynolds, LeVan, Nathanson, and Haber submitted to the Court a Stipulation and Proposed Order agreeing to: (i) the appointment of those four individuals as Co-Lead Plaintiffs

pursuant to Section 21D(a)(3)(B) of the Exchange Act, 15 U.S.C. §78u-4(a)(3)(B); and (ii) the appointment of Milberg and SSB as Co-Lead Counsel. Judge Engelhardt of the Eastern District of Louisiana approved the Stipulation and entered the Order on February 26, 2004.

40. On August 9, 2004, Lead Plaintiffs filed their Second Amended Complaint which added Scolnick as a defendant.

41. On November 1, 2004, following Merck's September 30, 2004 worldwide withdrawal of Vioxx due to its cardiovascular risks, *The Wall Street Journal* ("WSJ") published an article reporting for the first time internal Merck emails and other documents further demonstrating, in Co-Lead Counsel's opinion, that the Defendants understood during the Class Period that Vioxx was harmful, yet kept the drug on the market for years.

42. On November 8, 2004, the lead plaintiffs filed their Third Amended Complaint, which expanded the Class Period to end on October 29, 2004.

**D. New York State's Motion to Intervene and the Transfer of the Action to the District of New Jersey**

43. After the September 30, 2004 withdrawal of Vioxx, numerous additional Vioxx-related cases against Merck were filed in several jurisdictions, including in several venues in the District of New Jersey (the "New Jersey Court" and, after February 23, 2005, the "Court"), the Eastern District of Louisiana and the Eastern District of Pennsylvania. On November 10, 2004, Defendants moved the Judicial Panel on Multidistrict Litigation (the "MDL") for an order transferring and coordinating the Vioxx investor suits. In addition, several plaintiffs in these new actions filed motions in the New Jersey and Louisiana courts to replace or supplement the Court-appointed Lead Plaintiffs and Co-Lead Counsel.

44. On November 30, 2004, the Comptroller of the State of New York, as Administrative Head of New York State and Local Retirement Systems Fund (the "NYSCRF")

and as Trustee of the NYSCRF, moved to intervene in the *Pringle* action, for the appointment of NYSCRF as Lead Plaintiff and for approval of its selection of lead counsel.

45. NYSCRF also filed its own securities class action in the U.S. District Court for the District of New Jersey (the “*NYSCRF* Action”). In the *NYSCRF* Action, the NYSCRF argued that the September 2004 withdrawal of Vioxx was a material new development that required the re-opening of the Lead Plaintiff appointment process, due in part to plaintiffs (including NYSCRF) filing securities cases in the U.S. District Court for the District of New Jersey, where Merck is headquartered, following the September 2004 withdrawal of Vioxx and the November 2004 *WSJ* article.

46. On December 10, 2004, the then-Lead Plaintiffs filed a motion in the *NYSCRF* Action to intervene, to strike NYSCRF’s motion to be appointed lead plaintiff or, alternatively, to stay the *NYSCRF* Action pending further proceedings in the Eastern District of Louisiana.

47. Although fully briefed, the District Courts in New Jersey and Louisiana stayed decision on those lead plaintiff substitution and/or expansion motions until the decision by the MDL, including on NYSCRF’s motions.

48. Pursuant to 28 U.S.C. § 1407, by Order of the Judicial Panel on Multidistrict Litigation dated February 23, 2005, in *In re Merck & Co., Inc. Securities, Derivative & “ERISA” Litigation*, MDL No. 1658, the *Pringle* Action, into which all related securities actions pending in the Eastern District of Louisiana were consolidated, was transferred to the District of New Jersey and assigned to Judge Stanley R. Chesler for coordinated or consolidated pretrial proceedings with all related securities actions pending in the District of New Jersey.

49. On March 21, 2005, Judge Chesler held a hearing at which time the Lead Plaintiffs, NYSCRF, and other plaintiffs presented arguments to the Court concerning the proper

appointment of the lead plaintiff.

50. On April 8, 2005, Judge Chesler, who has presided over the Action since it was transferred to the District of New Jersey for pretrial proceedings to the present, entered an Order, which: (i) confirmed the appointment of Messrs. Reynolds, LeVan, Nathanson, and Haber as lead plaintiffs; (ii) confirmed Plaintiffs' choice of Milberg and SSB as Co-Lead Counsel; and (iii) denied as moot the motions by NYSCRF and other investors to intervene and have themselves appointed as lead plaintiffs.

**E. The Motion to Partially Lift the PSLRA Discovery Stay**

51. Prior to the eventual resolution of Defendants' motions to dismiss substantially in Lead Plaintiffs' favor, which did not occur until August 8, 2011, as discussed below, there was an automatic stay of discovery in this Action imposed by the PSLRA. Yet, during that time, litigants had brought numerous types of civil actions against Merck concerning the CV risks of Vioxx, and various government agencies and prosecutors had launched investigations into Merck's conduct regarding the CV risks of Vioxx.

52. Accordingly, on May 9, 2005, Lead Plaintiffs filed a motion to partially lift the mandatory discovery stay imposed by the PSLRA, for the purposes of obtaining copies of (i) documents that Defendants previously produced to litigants in other Vioxx civil litigations against Merck; and (ii) documents that Defendants previously produced to governmental entities.

53. On May 16, 2005, Defendants opposed Lead Plaintiffs' motion for partial lifting of the PSLRA discovery stay. In their memorandum, Defendants argued that Lead Plaintiffs were not entitled to relief from the PSLRA stay because there was no risk that evidence would not be preserved, there was no risk of undue prejudice, the discovery request was not "particularized," and the burden on Defendants was irrelevant.

54. Lead Plaintiffs filed their reply brief in further support of their motion to lift the

PSLRA discovery stay on May 21, 2005. In their brief, Lead Plaintiffs argued that (i) “exceptional circumstances” existed to modify the stay; and (ii) Defendants’ view of what “particularized” means was at odds with applicable case law and logic.

55. On May 26, 2005, the Court held a hearing on Lead Plaintiffs’ motion and on July 8, 2005, the Court granted Plaintiffs’ motion to partially lift the PSLRA discovery stay. The Court held that, since the parties in the related Vioxx shareholder derivative and ERISA actions had reached a stipulation regarding the production of documents in those actions, “to the extent Defendants have reached agreements with Derivative Plaintiffs and ERISA Plaintiffs regarding discovery, Defendants shall produce all discovery produced to Derivative Plaintiffs and ERISA Plaintiffs to Securities Plaintiffs.”

**F. Litigation with the Merck Insurers**

56. In their Fourth Amended Complaint, filed on June 9, 2005, the lead plaintiffs, among other things, added as named Defendants twenty of Merck’s insurers and invoked the provisions of the Louisiana Direct Action Statute (“DAS”).

57. On December 8, 2005, certain of Merck’s insurers moved to dismiss those claims against them, arguing that Plaintiffs’ claims against the insurers could not be asserted in this federal action because the DAS is solely procedural and not substantive in nature. The insurers also argued that the federal securities laws provide Plaintiffs’ exclusive rights and remedies and preempt the DAS. Other insurers moved to dismiss on grounds of lack of personal jurisdiction and based on an arbitration agreement in one of the insurance policies.

58. On March 9, 2006, the parties stipulated to the dismissal of Plaintiffs’ claims against a number of the Merck insurers, termed the “American Arbitration Insurers.” And, on April 4, 2006, the parties stipulated to the dismissal of Plaintiffs’ claims against the Merck insurers termed the “Foreign Arbitration Insurers.”

**G. Defendants' Original Motion to Dismiss the Complaint**

59. On August 12, 2005, Defendants moved to dismiss the Fourth Amended Complaint. Defendants argued that all of Lead Plaintiffs' claims were time-barred because, by November 2001, more than two years before the first securities fraud complaint was filed in November 2003: (i) there was a well-publicized debate about the CV safety of Vioxx, which provided adequate "storm warnings" to investors of Defendants' alleged fraud; (ii) numerous claimants had already filed Vioxx-related product liability suits against Merck, including class action lawsuits; and (iii) on September 17, 2001, the FDA issued a publicly available Warning Letter to Merck asserting that the Company had misrepresented the CV safety profile of Vioxx. Thus, Defendants argued, investors were placed on "inquiry notice" of the facts upon which Lead Plaintiffs' claims are based by April 2000, or at the latest by September 2001, and this barred Lead Plaintiffs' claims under the applicable statute of limitations because Lead Plaintiffs did not file suit until more than two years later, in November 2003. Defendants moved to dismiss on several additional grounds as well, such as failure to plead materially false statements and lack of loss causation allegations.

60. On March 16, 2006, Lead Plaintiffs Reynolds, LeVan, Nathanson, and Haber filed an omnibus brief in opposition to Defendants' motions to dismiss, arguing, among other things, that Lead Plaintiffs' Complaint was timely because Defendants failed to establish that Lead Plaintiffs were on inquiry notice as evidenced by the speculative nature of reports by company outsiders, Defendants' alleged continuing scheme to conceal Vioxx's risks, the failure of product liability suits to put the putative class on inquiry notice, and the market's shock at the ultimate revelation of Vioxx's risks.

**H. Mississippi PERS' Motion to Intervene**

61. On October 26, 2006, Miss. PERS filed a motion to intervene in the Action and to require the lead plaintiffs to appear at a hearing concerning their adequacy under the PSLRA and

Fed. R. Civ. P. 23.

62. On November 14, 2006, the then-existing Lead Plaintiffs opposed Miss. PERS' motion to intervene and filed a Cross-Motion for an Order Approving Lead Plaintiffs' Selection of Brower Piven as an additional Co-Lead Counsel. On November 20, 2006, Miss. PERS filed a Reply Memorandum in Further Support of its Motion and opposed the lead plaintiffs' cross-motion.

63. Lead Plaintiff Nathanson subsequently voluntarily withdrew as a lead plaintiff in the Action, and the remaining individual Lead Plaintiffs – Reynolds, LeVan, and Haber – determined that it was in the best interests of the Class to add Miss. PERS as a Lead Plaintiff and its counsel, BLB&G, as an additional Co-Lead Counsel in the Action.

64. As a result, on January 12, 2007, the then-current Lead Plaintiffs wrote Judge Chesler to inform the Court of their agreement to resolve Miss. PERS' motion to intervene. The letter stated that Miss. PERS would be substituted as Co-Lead Plaintiff for Nathanson. The letter further proposed the addition of BLB&G and Brower Piven as Co-Lead Counsel and attached a Stipulation and Proposed Order setting forth that structure.

65. The Court held a hearing on January 25, 2007 concerning the proposed leadership structure. That day, the Court signed and ordered the implementation of the proposed Stipulation.

**I. The Dismissal of the Complaint, and Lead Plaintiffs' Successful Appeal to the Third Circuit**

66. At a March 26, 2007 hearing, Judge Chesler held oral argument on Defendants' motions to dismiss.

67. On April 12, 2007, Judge Chesler granted Defendants' motions to dismiss Plaintiffs' Complaint on statute of limitations grounds and dismissed the action in its entirety as time-barred. The Court held that investors were on inquiry notice on or before November 6, 2001

because, by that time, the FDA issued Merck a Warning Letter that, according to the Court, “charge[d] Merck with engaging in deceptive and misleading conduct with regard to the safety profile of VIOXX.” *In re Merck & Co., Inc. Sec., Derivative & “ERISA” Litig.*, 483 F. Supp. 2d 407, 419 (D.N.J. 2007). Because the Court held that Plaintiffs’ claims were untimely filed, the Court did not address the other arguments raised by Defendants in their motions to dismiss.

68. The District Court’s dismissal of the Action in its entirety was a serious blow to the class and, if it were upheld, would have meant that class members would recover nothing to compensate them for the fraud against them. On May 9, 2007, Lead Plaintiffs appealed the dismissal to the U.S. Court of Appeals for the Third Circuit.

69. On August 3, 2007, Lead Plaintiffs filed their opening Appellants’ Brief with the Third Circuit.

70. On October 7, 2007, Defendants filed their Appellees’ Brief. Defendants argued that the District Court correctly determined that all class members, including Lead Plaintiffs, were on inquiry notice of their claims on or before November 6, 2001. Specifically, Defendants argued that “storm warnings” existed by October 9, 2001 because: (i) the “mix of information” available to investors by October 9, 2001 was sufficient to trigger “storm warnings”; (ii) Lead Plaintiffs’ arguments as to why “storm warnings” did not exist by the time of an October 9, 2001 *New York Times* article in which Defendant Scolnick discussed two possible interpretations of the VIGOR results (and that the Naproxen Hypothesis was the likeliest one) were unavailing; and (iii) the “storm warnings” that had gathered by October 9, 2001 were not dissipated by Defendants’ alleged reassurances.

71. On October 26, 2007, Lead Plaintiffs filed their reply brief with the Third Circuit. Lead Plaintiffs argued that: (i) Defendants applied the wrong standard for “inquiry notice”; (ii)



Defendants ignored the gravamen of Lead Plaintiffs' securities fraud claims; (iii) the claims of investors who purchased shares on or after November 6, 2001 were timely; and (iv) Lead Plaintiffs' claims under Section 20A of the Exchange Act were timely.

72. On June 24, 2008, the Third Circuit held oral argument on Lead Plaintiffs' appeal, and, on September 9, 2008, the Third Circuit reversed the District Court's dismissal of the Action in a 2-1 decision. *See In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 543 F.3d 150, 172 (3d Cir. 2008).

**J. Lead Plaintiffs' Victory at the U.S. Supreme Court**

73. On January 15, 2009, Defendants filed their petition for *writ of certiorari* of the Third Circuit's decision to the U.S. Supreme Court. Lead Plaintiffs retained David Frederick of Kellogg, Huber, Hansen, Todd, Evans & Figel, P.L.L.C. as their Supreme Court specialist to argue the appeal.

74. In Defendants' petition for *writ of certiorari*, they argued that the Courts of Appeals used three different "approaches" for determining when the statute of limitations begins to run and that, under the law of any Circuit other than the Ninth and Third Circuits, Plaintiffs' claims would be untimely.

75. On March 23, 2009, Lead Plaintiffs opposed Defendants' petition. In the Opposition, Lead Plaintiffs argued that the statute of limitations had not expired when Lead Plaintiffs filed their securities fraud suit. Lead Plaintiffs also argued that the Third Circuit properly concluded that no "storm warnings" of the alleged fraud existed more than two years prior to the filing of the original complaint. Because the Court found no "storm warnings," it had no need to (and did not) address the second prong of the statute of limitations test at the time: whether, once Lead Plaintiffs allegedly received "storm warnings," a reasonably diligent investigation would have yielded sufficient details of the fraud to file a complaint. Thus, Lead Plaintiffs argued that

Defendants' petition did not implicate any Circuit split or warrant further review.

76. On April 7, 2009, Defendants filed a reply brief in further support of their petition.

In it, Defendants argued that:

It cannot seriously be disputed that the Courts of Appeals are sharply divided on the proper interpretation of the "inquiry notice" standard for the accrual of securities fraud claims. Indeed, since this petition was filed, the Third Circuit has issued an opinion in another case that reaffirms the split and solidifies the Third Circuit's position on the outskirts of inquiry notice jurisprudence.

Reply Brief for Petitioners, *Merck & Co., Inc. v. Reynolds*, 2009 WL 953638, at \*1 (U.S. 2009).

77. On April 22, 2009, then-Solicitor General Elena Kagan submitted a Brief for the United States as *Amicus Curiae* in connection with the petition for writ of certiorari in *Trainer Wortham & Co. v. Betz*, No. 07-1489 ("*Betz*"), which posed the same Question Presented as the Defendants' petition here. That *amicus* brief significantly increased the likelihood that the Supreme Court would grant Defendants' petition in this Action. The Solicitor General wrote that "the courts of appeal have been inconsistent in their application" of the inquiry notice standard and that "[t]he petition for a writ of certiorari in [*Merck v. Reynolds*] might present an opportunity for the Court to explore the various approaches in a case in which the differences could affect the outcome." Brief for the United States as *Amicus Curiae*, *Trainer Wortham & Company, Inc. v. Betz*, 2009 WL 1090416, at \*18 n.6 (U.S.).

78. On May 11, 2009, Defendants submitted a Supplemental Brief to the Supreme Court in further support of their petition, calling the Supreme Court's attention to the Solicitor General's brief in *Betz*.

79. On May 13, 2009, Lead Plaintiffs filed with the Supreme Court a Supplemental Brief to address Defendants' arguments on the *Betz* case. Lead Plaintiffs argued that the Solicitor General was incorrect to suggest that this Action would be a proper vehicle for resolving the issues

on appeal.

80. On May 26, 2009, the Supreme Court granted Defendants' petition for *writ of certiorari*, and Defendants filed their opening brief with the Supreme Court on August 10, 2009. Defendants argued that Lead Plaintiffs were on inquiry notice of their securities fraud claim more than two years before the original complaint was filed.

81. On October 19, 2009, Lead Plaintiffs filed their brief in opposition to Defendants' appeal. Lead Plaintiffs argued that the limitations period begins with discovery of the elements of a violation, including scienter. Lead Plaintiffs further argued that the Complaint was timely filed because: (i) they were not on inquiry notice prior to November 2001; and (ii) they had no means to discover the facts constituting Merck's violation.

82. On October 26, 2009, numerous persons and organizations filed *Amicus Curiae* briefs in support of Lead Plaintiffs' position at the Supreme Court.

83. On November 12, 2009, Defendants filed their reply brief to Lead Plaintiffs' opposition brief at the Supreme Court. Defendants argued that Lead Plaintiffs were on inquiry notice of their securities fraud claim more than two years before the initial complaint was filed because: (i) to be on inquiry notice, a plaintiff need not possess information specifically relating to scienter; (ii) under any standard, respondents were on inquiry notice more than two years before the initial complaint was filed; and (iii) Lead Plaintiffs offered no alternative explanation for when they were on inquiry notice. Defendants further argued that Lead Plaintiffs' claim was untimely under 28 U.S.C. § 1658(b).

84. On November 30, 2009, the U.S. Supreme Court held oral argument on Defendants' appeal, and David Frederick argued the issues on behalf of Lead Plaintiffs.

85. On April 27, 2010, in a unanimous 9-0 decision authored by Justice Breyer, the

U.S. Supreme Court affirmed the decision of the Court of Appeals for the Third Circuit that Lead Plaintiffs' Complaint was timely filed. *Merck & Co. v. Reynolds*, 559 U.S. 633, 637 (2010). The Supreme Court's decision on this matter was a landmark victory for investors that clarified the statute of limitations standards for securities fraud claims and returned the Action to the District Court.

**K. Lead Plaintiffs' Successful Opposition to Defendants' Second Round of Motions to Dismiss**

86. On March 10, 2010, while Defendants' appeal was pending at the U.S. Supreme Court, Lead Plaintiffs filed a Consolidated Fifth Amended Complaint with the District Court. The Complaint reflected new factual developments and was drafted to withstand the Court's scrutiny under evolving legal standards.

87. On June 18, 2010, following the Supreme Court's April 27, 2010, decision in Plaintiffs' favor, Defendants again moved to dismiss the Action (on grounds other than the statute of limitations, which the Court had not previously considered). In particular, with respect to Lead Plaintiffs' Section 10(b) claims, Defendants principally argued that:

- a. Lead Plaintiffs failed to adequately allege actionable misstatements or omissions;
- b. Lead Plaintiffs failed to show that each Defendant actually believed Vioxx was prothrombotic and that the Naproxen Hypothesis was false, thereby failing to adequately plead scienter;
- c. Lead Plaintiffs had not adequately pled loss causation, as Lead Plaintiffs had not connected any decline in Merck's stock price to the disclosure of the alleged concealed facts; and
- d. Lead Plaintiffs failed to state a claim for alleged misstatements or omissions concerning the safety profile of Vioxx because they were judicially estopped from making those claims, and the alleged misstatements were immaterial based on the Vioxx CV risk information that was already present in the market during the Class Period.

88. Also on June 18, 2010, Defendant Scolnick filed a motion to dismiss Lead

Plaintiffs' Complaint, in which he incorporated the arguments in his co-defendants' motion to dismiss. Defendant Scolnick's motion also argued that the Section 10(b) claim against him should be dismissed because he did not make the majority of the alleged misstatements and omissions at issue, the statements attributed to him were not actionable, and the Complaint's scienter allegations as to him were insufficient as a matter of law.

89. On August 9, 2010, Lead Plaintiffs filed their Omnibus Opposition to Defendants' Motions to Dismiss. The brief argued, among other things, that Defendants made false assurances as to Vioxx's lack of pro-thrombotic effect, materially misleading statements regarding the Naproxen Hypothesis, and misrepresentations concerning Vioxx's safety profile and its role in Merck's sales and revenue. Lead Plaintiffs further argued that Defendants' attempts to dismiss claims tied to misrepresentations and omissions made prior to Merck's announcement of the Naproxen Hypothesis should fail, as Defendants repeatedly made material misstatements regarding Vioxx's safety and commercial viability prior to that time.

90. On September 17, 2010, Defendants filed reply briefs in further support of their Motions to Dismiss the Fifth Amended Class Action Complaint.

91. In a letter filed October 5, 2010, Lead Plaintiffs drew the Court's attention to *Schleicher v. Wendt*, 618 F.3d 679 (7th Cir. 2010), a Seventh Circuit decision that addressed a line of Fifth Circuit cases that Defendants relied on for the first time in their reply memorandum in support of their motion to dismiss. On October 14, 2010, Defendants (other than Scolnick) filed a response to Plaintiffs' October 5, 2010 letter.

92. On March 31, 2011, Plaintiffs wrote a letter to the Court to draw the Court's attention to the then-recent Third Circuit decision in *In re: DVI, Inc. Securities Litigation*, 639 F.3d 623 (3d Cir. 2011). The *DVI* decision also rejected the line of Fifth Circuit cases that

Defendants had relied upon in their reply brief in support of their motions to dismiss. On April 4, 2011, Defendants filed with the Court a letter response to Plaintiffs' March 31, 2011 letter and Defendant Scolnick joined in it.

93. On July 12, 2011, the Court heard lengthy oral argument on Defendants' motions to dismiss.

94. On August 8, 2011, the Court largely denied Defendants' motions to dismiss. The Court upheld Lead Plaintiffs' Section 10(b) claims as to Defendants Merck, Reicin and Scolnick (and dismissed the other individual Section 10(b) defendants), and upheld the Section 20A insider trading claim as to Defendant Scolnick (and dismissed that claim against defendants Gilmartin, Frazier, Lewent, Anstice, Wold-Olsen, Clark and Kelley). The Court also rejected Lead Plaintiffs' assertion that the Class Period should continue after September 30, 2004 through news that was reported by the *WSJ* on November 1, 2004. The Court dismissed Lead Plaintiffs' Exchange Act Section 20(a) control person claim against Defendant Scolnick to the extent it was based on misrepresentations following his retirement from Merck.

**L. Class Certification**

95. On April 10, 2012, Lead Plaintiffs filed their opening motion to certify the Action as a class action, seeking the Court's certification of a class comprised of all persons and entities who, from May 21, 1999 to September 29, 2004, inclusive, purchased or otherwise acquired Merck common stock or call options, or sold Merck put options, and were damaged thereby. Lead Plaintiffs' motion included the expert declaration of Dr. David Tabak, which set forth the evidence in support of the efficiency of the market for Merck securities.

96. The parties then engaged in extensive class certification discovery:

- (i) On December 21, 2011, Defendants served their First Set of Requests for the Production of Documents on the Lead Plaintiffs. The First Set was comprised of 14 document requests. Lead Plaintiffs responded and objected

to those Requests on February 6, 2012.

- (ii) On January 27, 2012, Defendants served on Lead Plaintiffs their First Set of Interrogatories. Lead Plaintiffs responded to those interrogatories on March 6, 2012, with each Lead Plaintiff submitting its own separate Set of Responses.
- (iii) On April 16, 2012, Defendant Scolnick served his First Set of Document Requests on Miss. PERS concerning Miss. PERS' claim that it purchased Merck stock contemporaneously with Scolnick's sales of Merck stock on October 25, 2000. Miss. PERS responded to that Request on May 16, 2012.
- (iv) On April 24, 2012, Defendants served their Second Set of Requests for the Production of Documents on Lead Plaintiffs. The Second Set was comprised of 8 document requests. Lead Plaintiffs responded and objected to those Requests on May 24, 2012.
- (v) On May 17, 2012, Defendants served their Third Set of Requests for the Production of Documents on Miss. PERS. Miss. PERS responded and objected to those Requests on June 18, 2012.

97. In response to Defendants' Document Requests, Co-Lead Counsel collected and produced documents from the Lead Plaintiffs. Co-Lead Counsel also worked with their clients to prepare them for their depositions on class certification issues and defended those depositions on the following dates:

- (i) Steven LeVan: June 4, 2012 in New York, NY;
- (ii) Richard Reynolds: June 13, 2012 in New York, NY;
- (iii) Jerome Haber: June 27, 2012 in Los Angeles, CA; and
- (iv) Two representatives of Miss. PERS: July 11, 2012 in New York, NY.

98. Defendants also deposed Lead Plaintiffs' investment advisors, and Co-Lead Counsel reviewed those advisors' documents and prepared for and participated in their depositions.

Those depositions occurred on the following dates:

- (i) Fayez Sarofim & Co.: July 6, 2012 in Houston, TX;
- (ii) Oppenheimer: July 12, 2012 in New York, NY;
- (iii) ING: July 17, 2012 in New York, NY;

- (iv) Ingalls & Snyder: July 18, 2012 in New York, NY;
- (v) J.P. Morgan: July 20, 2012 in New York, NY; and
- (vi) Northern Trust: July 23, 2012 in Chicago, IL.

99. Defendants opposed Lead Plaintiffs' motion for class certification on August 13, 2012. Defendants principally argued that Lead Plaintiffs had failed to put forward sufficient evidence of the efficiency of the market for Merck securities and that the Lead Plaintiffs were inadequate to serve as class representatives. Defendant Scolnick also individually opposed Lead Plaintiffs' motion to certify the Action as a class action on August 13, 2012. Defendant Scolnick filed a brief in which he incorporated the arguments contained in his Co-Defendants' Opposition to Lead Plaintiffs' motion. Additionally, Defendant Scolnick argued that Miss. PERS lacked standing to bring a Section 20A insider trading claim against him, and that Miss. PERS did not satisfy the "typicality" or the "adequacy" requirements of Rule 23(a).

100. In connection with Defendants' opposition to Lead Plaintiffs' motion for class certification, Lead Plaintiffs argued that Defendants' expert (Professor Paul Gompers or "Professor Gompers"<sup>4</sup>) adopted an impossibly high standard for proving market "efficiency" that would require proof that "every transaction price" for Merck stock during the Class Period fully, immediately and "correctly" reflected all information.

101. Professor Gompers was deposed in Boston on the substance of his opinions. Plaintiffs served subpoenas on Professor Gompers' consulting firm, Cornerstone, which Cornerstone and Merck opposed, and Merck subsequently retained a different expert on market

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<sup>4</sup> Professor Gompers is the Eugene Holman Professor of Business Administration at Harvard Business School. He received his A.B. *summa cum laude* in biology from Harvard College in 1987. After spending a year working as a research biochemist for Bayer Chemical AG, he attended Oxford University on a Marshall Fellowship where he received an M.Sc. in Economics. Professor Gompers then completed his Ph.D. in Business Economics at Harvard University in 1993.



efficiency and damages issues.

102. On November 8, 2012, amid the parties' disputes on the Cornerstone subpoenas, Lead Plaintiffs filed their reply brief in further support of their motion for class certification, which included a reply declaration by Dr. Tabak. In their reply brief, Lead Plaintiffs argued that the market for Merck stock was efficient, investors in Merck stock options were entitled to a presumption of reliance, Lead Plaintiffs had properly invoked the presumption of reliance under *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972) ("*Affiliated Ute*"), Lead Plaintiffs met the standard of "typicality" and "adequacy" under Rule 23(a), and Miss. PERS had standing to represent investors with Section 20A claims against Defendant Scolnick.

103. On January 30, 2013, following this full briefing, the Court granted Lead Plaintiffs' motion and certified a class consisting of all persons and entities who, from May 21, 1999 to September 29, 2004, inclusive (the "Certified Class Period"), purchased or otherwise acquired Merck Common Stock or Merck Call Options, or sold Merck Put Options (*i.e.*, the "Certified Class"), and appointed the Lead Plaintiffs as Class Representatives and Co-Lead Counsel as Class Counsel. The Court agreed with Lead Plaintiffs' and Dr. Tabak's position that the markets for Merck securities were efficient because Merck traded on a highly efficient market, the New York Stock Exchange.

104. On August 6, 2013, the Court entered an Order directing that notice be sent to potential members of the Certified Class ("Certified Class Notice").

105. Beginning on September 4, 2013, the Certified Class Notice was sent to putative Certified Class members. More than 1.5 million copies of the Certified Class Notice were mailed to potential members of the Certified Class.

**M. The Sixth Amended Complaint**

106. On March 15, 2013, Lead Plaintiffs moved for leave to file a Sixth Amended

Complaint and submitted a brief in support thereof. Lead Plaintiffs sought to amend their Complaint to add allegations concerning, and to bring within the scope of this Action, among other things, the November 1, 2004 publication of the *WSJ* article discussing previously-undisclosed internal Merck documents allegedly showing that Merck knew of Vioxx's CV risks years before its withdrawal from the market. Upon release of that news, the price of Merck stock fell sharply, and it was Lead Plaintiffs' position that that stock price decline was properly within the scope of Lead Plaintiffs' claims.

107. Lead Plaintiffs also moved to add two alleged materially false and misleading statements by Defendants Merck and Reicin regarding the 4% aspirin-indicated subgroup claim. Specifically, Lead Plaintiffs alleged that Defendants publicly buttressed the Naproxen Hypothesis with the materially false and misleading claim that the excess in heart attacks observed in VIGOR was disproportionately due to the effects observed in only 4% of the VIGOR patients whom Merck claimed needed, but did not receive, aspirin prophylaxis and for whom they claimed Naproxen treatment thus acted as a substitute for such prophylaxis (the "4% claim").

108. Defendants opposed Lead Plaintiffs' motion to amend the Complaint. Defendants asserted that the November 1, 2004 *WSJ* article revealed "nothing about Merck's substantial Vioxx-related litigation exposure" and argued that Merck's increased litigation exposure was not within the "zone of risk" concealed by the alleged fraud. Defendants also argued that their statements concerning the 4% claim were neither false nor misleading. Furthermore, Defendants argued that under *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135 (2011), the *New England Journal of Medicine* ("*NEJM*"), and not Merck or Dr. Reicin, "made" the misstatement concerning the 4% claim appearing in the November 23, 2000 *NEJM* article publishing the full VIGOR results.

109. On May 6, 2013, Lead Plaintiffs filed a reply brief to Defendants' opposition to the motion for leave to file an Amended Complaint.

110. On May 29, 2013, the Court granted Lead Plaintiffs' request to file a Sixth Amended Complaint with respect to the 4% statements, but denied it with respect to the November 1, 2004 *WSJ* article because, according to the Court, "This lawsuit is not premised on allegations that Merck misrepresented or concealed from investors material facts concerning Merck's exposure to liability stemming from products liability suits and consumer fraud claims related to the alleged cardiovascular risks of Vioxx."

**N. Lead Plaintiffs' Opposition to Defendants' Motion for Judgment on the Pleadings**

111. On May 3, 2012, Defendants filed a motion for judgment on the pleadings, arguing that: (i) certain of the alleged misrepresentations were not actionable under the securities laws; and (ii) Lead Plaintiffs did not state a claim under Section 20(a) of the Exchange Act for control person liability with respect to certain current and former Merck officers who had previously been dismissed from Lead Plaintiffs' Section 10(b) claims.

112. On June 4, 2012, Lead Plaintiffs opposed that motion. Lead Plaintiffs argued that: (a) Defendants' statements concerning Vioxx sales performance and outlook were materially false and misleading when made; (b) Defendants' purportedly accurate factual recitations in fact misled investors concerning the true commercial value of Vioxx at the time they were made; (c) Defendants' projections of future growth were not "puffery;" and (d) Defendants' statements were not protected by the safe harbor. Lead Plaintiffs additionally argued that they pled the control person Defendants' "culpable participation" in the fraud with particularity and that they were not required to do so to state a Section 20(a) claim.

113. On August 29, 2012, the Court granted in part and denied in part Defendants'

motion. The Court dismissed Lead Plaintiffs' Section 10(b) claims predicated on statements which the Court found to be inactionable. The Court also dismissed the Exchange Act Section 20(a) control person claim as to individual defendants Anstice, Frazier, Gilmartin, Henriques, Kim, Lewent and Wold-Olsen. However, Lead Plaintiffs were successful in upholding alleged materially false statements where the Defendants attributed Vioxx's commercial performance in part to Vioxx's "overall safety profile."

**O. Fact Discovery**

**1. The Pursuit of Extensive Discovery from Defendants**

114. Over the course of the litigation, Lead Plaintiffs vigorously pursued the production of documents by Defendants, and pressed Defendants to correct numerous specific deficiencies in Defendants' production.

115. On January 13, 2012, Lead Plaintiffs served on Defendants their First Set of Requests for the Production of Documents to Defendants, which was comprised of 100 Requests. That day, the parties also exchanged their Initial Disclosures.<sup>5</sup>

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<sup>5</sup> Lead Plaintiffs subsequently served on Defendants additional discovery requests. On August 10, 2012, Lead Plaintiffs served Lead Plaintiffs' Second Set of Requests for the Production of Documents, which comprised a single request for all documents concerning Defendant Scolnick's sale of Merck stock on or about October 25, 2000. Lead Plaintiffs also served a single Interrogatory that day requesting the identification of all trade information concerning Defendant Scolnick's October 25, 2000 sale of Merck stock. On October 9, 2012, Lead Plaintiffs served their Second Set of Interrogatories on Defendants, which was comprised of 8 interrogatories. On October 11, 2012, Lead Plaintiffs also served Plaintiffs' Second Set of Interrogatories on Defendant Scolnick (which comprised two interrogatories focused on Defendant Scolnick's stated explanations for his October 2000 stock sales) and Plaintiffs' Third Set of Document Requests on Defendant Scolnick (which comprised four document requests focused on Scolnick's stated explanations for his October 2000 stock sales). On February 1, 2013, Lead Plaintiffs served their Third Set of Interrogatories, which consisted of a single interrogatory requesting that Defendants identify the names and titles of each person who participated in drafting or revising Merck's public statements that Lead Plaintiffs alleged were materially false and misleading. On May 10, 2013, Lead Plaintiffs served their First Set of Requests for Admissions Directed to Defendants concerning the authenticity and admissibility of certain of Lead Plaintiffs' deposition exhibits.

116. On March 1, 2012, Defendants served their Responses and Objections to Lead Plaintiffs' First Set of Requests for the Production of Documents.

117. On May 25, 2012, following discussions between the parties, Lead Plaintiffs wrote a letter to Magistrate Judge Shipp to bring to the Court's attention disputes concerning deficiencies in Defendants' document production.

118. Defendants submitted a letter to the Court on May 29, 2012, arguing that any discovery disputes needed to be raised with the Court jointly by both sides, and Lead Plaintiffs responded to that letter on May 31, 2012. On June 11, 2012, Defendants then filed a letter to substantively respond to Plaintiffs' May 25, 2012 letter.

119. The parties held a telephonic meet-and-confer on July 25, 2012 to discuss discovery issues. During the July 25, 2012 telephonic meet-and-confer, the parties discussed: (i) the total numbers of depositions that Lead Plaintiffs may take in this case; and (ii) the extent to which Lead Plaintiffs would agree to Defendants' requests concerning (a) permitting Defendants an unrestricted ability to admit testimony in this case by previously-deposed witnesses in any other Vioxx litigation and (b) limiting Lead Plaintiffs' depositions in this case of any previously deposed witnesses in any prior Vioxx case only to "new" topics, shared with Defendants in advance. Lead Plaintiffs attempted to facilitate a resolution and compromise on these issues with Defendants, but those efforts did not result in a compromise.

120. On August 8, 2012, Lead Plaintiffs filed a letter that informed the Court of a dispute between the parties concerning the number and scope of depositions that Lead Plaintiffs would take in the case. Lead Plaintiffs argued that Defendants were resisting Lead Plaintiffs' efforts to take any depositions in this Action beyond the 10 permitted by the Federal Rules of Civil Procedure without special permission because, according to them, Lead Plaintiffs should rely on the

depositions that other plaintiffs had taken in prior Vioxx-related personal injury cases. As a result, Lead Plaintiffs sought an Order from the Court that would: (i) permit Lead Plaintiffs to depose 40 witnesses plus the named individual defendants; and (ii) adopt Lead Plaintiffs' proposal concerning the admissibility of prior testimony.

121. On August 10, 2012, Defendants responded to Lead Plaintiffs' letter. Defendants argued that the number and scope of depositions should be limited because of the large body of existing testimony from prior cases. Defendants argued that deposition discovery in the action should make use of the existing sworn testimony of witnesses previously deposed, and that the parties should be permitted no more than 30 depositions per side.

122. During an August 20, 2012 status conference, the Court made certain discovery rulings on the disputes between the parties that are memorialized below.

123. On September 19, 2012, Lead Plaintiffs sent a letter to the Court providing, as the Court requested, a joint proposed Order that memorialized the Court's August 20, 2012 discovery rulings. The rulings, as set forth in the Order, included that: (i) Lead Plaintiffs and Defendants were granted leave to take 40 non-expert depositions; and (ii) the issue of whether Defendants would be required to produce to Lead Plaintiffs certain documents that Defendants previously produced to the government in connection with Vioxx-related investigations would be further considered by the Court.

124. On October 5, 2012, Magistrate Judge Waldor issued a Letter Opinion deciding Plaintiffs' motion on the question of whether Defendants must produce documents to Lead Plaintiffs that they previously produced to the Department of Justice ("DOJ"). In that Opinion, Magistrate Judge Waldor held that Defendants must produce those documents, finding that, pursuant to *Westinghouse Elec. Corp. v. Republic of Philippines*, 951 F.2d 1414, 1431 (3d Cir.

1991), because Merck had voluntarily disclosed documents to the government over which it now claimed privilege, it cannot establish that those documents are privileged.

125. On October 12, 2012, Defendants filed a letter with the Court requesting a stay of the Court's October 5, 2012 ruling that required Merck to produce previously privileged material that Merck had provided to the government.

126. On October 19, 2012, Defendants filed their appeal of Magistrate Judge Waldor's ruling requiring them to produce documents to Lead Plaintiffs that they previously produced to the DOJ.

127. On November 5, 2012, Lead Plaintiffs opposed Defendants' appeal in a brief that argued that the Third Circuit has rejected the principle of "selective waiver," and also rejected the Second Circuit's approach to the issue.

128. On November 13, 2012, Defendants filed their reply briefs in further support of their appeal of Magistrate Judge Waldor's ruling.

129. On December 12, 2012, the Court issued an Opinion and Order denying Defendants' appeal of Magistrate Judge Waldor's October 5, 2012 Opinion and Order insofar as the October 5, 2012 Opinion and Order held that Defendants must produce to Lead Plaintiffs documents that had been produced by Merck to the DOJ in connection with a government investigation.

130. On January 28, 2013, the Court held an in-person status conference to discuss discovery issues (which included the issues related to Cornerstone and Professor Gompers, discussed above in connection with class certification).

131. In a letter dated February 14, 2013, Lead Plaintiffs wrote to Magistrate Judge Waldor attaching a proposed Order memorializing the Court's rulings at the January 28, 2013

status conference and alerting Magistrate Judge Waldor of Judge Chesler's January 30, 2013 decision to certify the case as a class action. The proposed Order, among other things: (i) permitted Lead Plaintiffs to depose a representative from Cornerstone Research regarding payments made to Professor Gompers if Defendants continued to use Professor Gompers as their expert; and (ii) granted Cornerstone Research's request for heightened protection and limited disclosure of the deposition, transcript, and exhibits. Defendants did not continue to use Professor Gompers in the Action after this Order.

## **2. The Review of Millions of Pages of Documents**

132. In addition to pursuing discovery from Defendants, Lead Plaintiffs also served more than 60 subpoenas on third parties requesting their production of documents.

133. During the review of documents produced by Defendants and third parties, the documents were hosted in an Internet-based document database, and the attorneys who reviewed them attended regular meetings over the course of the Action to analyze and discuss with Co-Lead Counsel the most relevant or "hot" documents that the reviewing attorneys found.

134. In total, attorneys reviewed more than *35.8 million* pages of documents produced by Defendants and third parties in the Action.

## **3. The Pursuit of Extensive Deposition Discovery**

135. During the extensive fact and expert discovery in the case that ensued, Co-Lead Counsel took 31 fact depositions of current and former Merck employees and third parties. Specifically, the following witnesses were deposed on the following dates:

- (1) Scott A. Reines (Vice President of Clinical Research at Merck Research Laboratories ("MRL")): December 20, 2012 in Princeton, NJ;
- (2) Mark Stejbach (Merck Senior Director of Investor Relations): January 9, 2013 in Boston, MA;



- (3) Laurence J. Hirsch III (Vice President of Medical Communications and Head of Public Relations at MRL): January 16, 2013 in New York, NY;
- (4) Barry Gertz (Senior Vice President of Clinical Sciences at MRL): January 24, 2013 in New York, NY;
- (5) Christine Fanelle (Merck Director of Public Affairs): February 8, 2013 in Lebanon, NJ;
- (6) Jan D. Weiner (Merck Executive Director of U.S. Human Health Public Affairs): February 14, 2013 in Philadelphia, PA;
- (7) Mary-Elizabeth Blake (Merck Director of Public Affairs): February 27, 2013 in Lebanon, NJ;
- (8) Joshua Chen (Merck Biometrician): March 1, 2013 in Roseland, NJ;
- (9) Deborah Shapiro (Merck Senior Director of Biostatistics and Research Sciences): March 6, 2013 in New York, NY;
- (10) Raymond Bain (Merck Vice President): March 21, 2013 in Philadelphia, PA;
- (11) Adam Schechter (Merck Executive Director of Arthritis, Analgesia & New Products): April 5, 2013 in Philadelphia, PA;
- (12) Alan Nies (Merck Senior Vice President of Clinical Sciences in MRL): April 16, 2013 in Houston, TX;
- (13) Peter DiBattiste (Director of Cardiovascular Clinical Research at MRL): April 19, 2013 in Doylestown, PA;
- (14) Garret FitzGerald (Merck consultant and Professor at the University of Pennsylvania): April 23, 2013 in Philadelphia, PA;
- (15) Wendy Dixon (Merck Vice President of Marketing): May 3, 2013 in New York, NY;
- (16) James Bolognese (Merck Senior Director of Clinical Biostatistics): May 8, 2013 in Rahway, NJ;
- (17) Briggs Morrison (Merck Executive Director of Worldwide Clinical Data Management): May 14, 2013 in New York, NY;
- (18) John Oates (Merck consultant and Professor of Pharmacology at Vanderbilt University): May 16, 2013 in Nashville, TN;
- (19) Eliav Barr (Merck Senior Director of Biologics Clinical Research at MRL): May 21, 2013 in Philadelphia, PA;

- (20) Douglas J. Watson (Merck Director of Epidemiology): May 22, 2013 Philadelphia, PA;
- (21) Beth Seidenberg (Merck Vice President of Pulmonary/Immunology Department): May 29, 2013 in Palo Alto, CA;
- (22) Edward Scolnick (President of MRL (1985-2002) and President *Emeritus* of MRL (2002-2004)): May 31, 2013 in Boston, MA;
- (23) Peter Kim (President of MRL): June 4, 2013 in Philadelphia, PA;
- (24) David Anstice (Merck President of Human Health): June 6, 2013 in Philadelphia, PA;
- (25) Alise Reicin (Merck Executive Director and Therapeutic Area Head, then Vice President of Clinical Immunology & Analgesia): June 7, 2013 in New York, NY;
- (26) Raymond Gilmartin (Chairman, President, and CEO of Merck): June 12, 2013 in New York, NY;
- (27) James Neaton (Merck consultant and Professor of Biostatistics, University of Minnesota School of Public Health): June 13, 2013 in Minneapolis, MN;
- (28) Robert E. Silverman (Merck Senior Director of Regulatory Affairs): June 19, 2013 in Blue Bell, PA;
- (29) Charlotte McKines (Merck Executive Director, Therapeutic Business Unit for Arthritis & Analgesia): July 23, 2013 in Blue Bell, PA;
- (30) Loren Laine (Merck consultant and gastroenterologist at the University of Southern California (currently at Yale Medical School)): August 5, 2013 in New Haven, CT; and
- (31) Carlo Patrono (Merck consultant and Professor of Pharmacology, University of Rome “La Sapienza” School of Medicine): August 13, 2013 in Rome Italy.

**P. Lead Plaintiffs’ Highly-Qualified Experts**

136. Given the complex nature of this Action, it was critical for Lead Plaintiffs to retain highly qualified experts. As a result, Lead Plaintiffs retained the following individuals as experts in the following fields:

- (i) Dr. David Tabak

Dr. Tabak testified as an expert in market efficiency, economics, and damages resulting from securities law violations. Dr. Tabak is a Senior Vice President at National Economic Research Associates, Inc. (“NERA”) Consulting. In the area of securities class actions, Dr. Tabak and others at NERA have testified primarily for defendants on topics including class certification, liability, materiality, affected trading volume, and damage calculations in cases with allegations such as improper valuations, accounting irregularities, and merger disputes.

(ii) Dr. Douglas Zipes

Dr. Zipes testified as an expert in cardiology and pharmacology. Dr. Zipes is a Distinguished Professor at Indiana University School of Medicine and *Emeritus* Professor of Medicine, Pharmacology, and Toxicology at the Krannert Institute of Cardiology at Indiana University, a practicing cardiologist, an experienced basic scientist and clinical trial investigator, and a published author of numerous medical journal articles and textbooks, as well as co-editor of Braunwald’s Heart Disease, regarded as the authoritative text in cardiology.

(iii) Dean David Madigan

Dean David Madigan testified as an expert in statistics and biostatistics. He is Professor and former Chair of Statistics at Columbia University (“Columbia”) where he teaches both introductory and advanced statistics. He also serves as Executive Vice President for Arts and Sciences and Dean of the Faculty at Columbia. Prior to his appointments at Columbia, Dean Madigan served as Dean of Physical and Mathematical Sciences at Rutgers University, where he also was Professor of Statistics and Director of the Institute of Biostatistics, and as Assistant, then Associate Professor in Statistics at the University of Washington.

(iv) Dr. Mark Woodward

Professor Mark Woodward testified as an expert in biostatistics and epidemiology. He currently serves as Professor of Statistics and Epidemiology at the University of Oxford (UK), Conjoint Professor of Biostatistics at the University of Sydney, Australia, and Adjunct Professor of Epidemiology at Bloomberg School of Public Health, Johns Hopkins School of Medicine in Baltimore.

(v) Dr. David A. Kessler

Dr. David A. Kessler testified as a regulatory expert on the United States Food and Drug Administration. He is currently Professor of Pediatrics and Epidemiology and Biostatistics at the University of California, San Francisco. In 1990, Dr. Kessler was appointed by President George H.W. Bush as Commissioner of the FDA and confirmed by the Senate. He continued to serve in that position under President Clinton until February 1997. As FDA Commissioner, Dr. Kessler had ultimate responsibility for implementing and enforcing the U.S. Food, Drug and Cosmetic Act and was responsible for overseeing five Centers within the FDA.

(vi) Mr. Harry C. Boghigian

Mr. Harry C. Boghigian testified as an expert in pharmaceutical marketing and sales. He is a pharmaceutical executive with over 40 years of domestic and international experience in product portfolio management, product commercialization, and marketing of pharmaceutical products who has extensive experience in general management, sales, marketing, direct-to-consumer advertising, strategic planning, and business execution of pharmaceutical companies. Mr. Boghigian is currently President of Pharma Consultants LLC, a consulting firm which he founded in 2001 which assists entrepreneurs, start-up and small to medium size healthcare companies, as well as advertising agencies, in all areas of pharmaceutical sales and marketing. Prior to this, Mr. Boghigian worked at the pharmaceutical company Hoffmann-La Roche Ltd. for 30 years.

(vii) Dr. David Y. Graham

Dr. David Y. Graham testified as a rebuttal expert in gastroenterology. He is a Professor of Medicine and Molecular Virology and Microbiology at Baylor College of Medicine in Houston, Texas (“Baylor”) where he teaches medical students, physician assistant students, graduate students, residents, and gastroenterology fellows on such topics as NSAID damage, peptic ulcers and their complications. Dr. Graham has been teaching at Baylor for over 30 years.

137. On July 12, 2013, Lead Plaintiffs served on Defendants expert reports by Dr. Tabak (368 pages, including substantive exhibits), Dr. Zipes (128 pages), Dean Madigan (80 pages), Dr. Woodward (66 pages), Dr. Kessler (38 pages), and Mr. Boghigian (78 pages).

138. On August 13, 2013, Defendants served seven expert reports on Plaintiffs by the following experts in the following disciplines: Dr. Lawrence H. Brent (rheumatology), Dr. Christopher M. James (damages), Dr. Lisa D. Rarick (FDA and pharmaceutical regulation), Dr. David J. Sales (gastroenterology), Dr. Douglas E. Vaughan (cardiology), Dr. Nicholas A. Flavahan (pharmacology), and Henry G. Grabowski (marketing). On August 20, 2013, Defendants served an additional expert report by Dr. Robert D. Gibbons (statistics) on Plaintiffs.

139. Lead Plaintiffs served their experts’ extensive expert rebuttal reports on Defendants on September 4, 2013 (September 11, 2013 for the rebuttal reports of Dr. Madigan and Dr. Woodward due to Defendants’ late submission of the Gibbons Report). The rebuttal reports spanned the following lengths: Dr. Tabak (319 pages, including substantive exhibits), Dr. Zipes

(67 pages), Dr. Madigan (66 pages), Dr. Woodward (44 pages), Dr. Kessler (37 pages), Mr. Boghigian (57 pages), and Dr. Graham (83 pages).

140. Defendants' Counsel and Co-Lead Counsel took and defended the depositions of the Parties' expert witnesses on the following dates and in the following locations:

<b>Expert</b>	<b>Date</b>	<b>Location</b>
Dr. David Tabak	July 12, 2012 (class certification) November 8, 2013 (merits)	New York, NY
Dr. Paul Gompers	September 11, 2012 (class certification)	Boston, MA
Dean David Madigan	October 9, 2013	New York, NY
Dr. Mark Woodward	October 11, 2013	New York, NY
Dr. Douglas Zipes	October 16, 2013	New York, NY
Dr. David Kessler	October 18, 2013	San Francisco, CA
Mr. Harry Boghigian	October 23, 2013	New York, NY
Dr. Lisa Rarick	October 29, 2013	Washington, D.C.
Dr. Robert D. Gibbons	November 1, 2013	Chicago, IL
Dr. David Y. Graham	November 6, 2013	New York, NY
Dr. Douglas E. Vaughan	November 8, 2013	New York, NY
Dr. David J. Sales	November 12, 2013	Chicago, IL
Dr. Nicholas A. Flavahan	November 14, 2013	New York, NY
Dr. Lawrence H. Brent	November 15, 2013	Philadelphia, PA
Dr. Christopher M. James	November 22, 2013	New York, NY

**Q. The Responses to Defendants' Contention Interrogatories**

141. On June 13, 2013, Defendants served on Lead Plaintiffs their First Set of Contention Interrogatories. One set was served by Defendants Merck and Reicin, and another set was served by Defendant Scolnick.

142. On December 13, 2013, Lead Plaintiffs served on Defendants their Responses and Objections to the Defendants' Contention Interrogatories. The Responses set forth in significant detail the facts supporting Lead Plaintiffs' claims against the Defendants, cited more than 1,350 documents, and spanned 543 single-spaced pages. The Responses were the product of thorough discovery review and months of work.

**R. Lead Plaintiffs' Successful Opposition to Defendants' Motions for Summary Judgment**

143. On January 17, 2014, Defendants moved for summary judgment, arguing that there was no evidence that any Defendant intentionally or recklessly deceived investors and that Lead Plaintiffs could not prove damages because the purportedly undisputed facts demonstrated that Vioxx was commercially viable. Defendant Scolnick also moved for summary judgment arguing that Lead Plaintiffs could not establish their Section 10(b) claim against him, and that Miss. PERS' Section 20A claim fails against him. Defendant Scolnick also argued that Plaintiffs' Section 20(a) claim fails because Lead Plaintiffs could not establish a predicate violation of the Exchange Act by Merck and could not show that Defendant Scolnick was a "culpable participant" in the alleged fraud.

144. Lead Plaintiffs opposed Defendants' motions on March 14, 2014. Lead Plaintiffs submitted a 90-page memorandum of law in opposition to Defendants' motions for summary judgment. The Opposition detailed the facts of the case including that: (i) Defendants rushed Vioxx to market to "preserve" Merck; (ii) Defendants made and caused false and misleading

statements and omissions in the pre-VIGOR and post-VIGOR time periods; (iii) Merck designed VIGOR to minimize any adverse CV result; and (iv) Merck withdrew Vioxx from the market in September 2004 and Vioxx remained off the market as of the filing, which is still true today.

145. Lead Plaintiffs' Opposition further argued that: (i) Defendants Scolnick and Reicin acted with scienter; (ii) Defendant Merck acted with scienter; (iii) Defendant Scolnick was liable for the materially false statements he made and those he controlled through the date of his retirement; (iv) Lead Plaintiff Miss. PERS had standing to bring the Class's Section 20A insider trading claim against Defendant Scolnick; (v) Lead Plaintiffs could prove damages at trial based on various jury determinations regarding Vioxx's commercial viability; and (vi) Defendant Scolnick was a "culpable participant" in the alleged fraud.

146. On April 11, 2014, Defendants Merck and Reicin filed their reply papers in further support of their motions for summary judgment. Defendants' reply memorandum argued that: (i) there was no evidence that Defendants knowingly or recklessly misled investors with the four pre-VIGOR statements regarding "the most common side effects reported in clinical trials" or Vioxx's "safety" profile; (ii) there was no evidence that Defendants intentionally or recklessly misled investors in making the 29 post-VIGOR statements regarding the Naproxen Hypothesis and Merck's clinical trial data for Vioxx; and (iii) there was no evidence to support Lead Plaintiffs' expert's damages model.

147. Also on April 11, 2014, Defendant Scolnick submitted his reply memorandum of law in further support of his motion for summary judgment.

148. On May 13, 2015, the Court entered an Order largely denying Defendants' motions for summary judgment. Specifically, the Court granted Defendants' summary judgment motions *only* with respect to: (i) statements made by Merck between May 21, 1999 and March 26, 2000,

*i.e.*, the alleged misstatements prior to public announcement of the results of VIGOR on March 27, 2000; and (ii) a December 2001 statement by Defendant Scolnick in a *Bloomberg News* article. The Court otherwise denied summary judgment.

**S. Mock Trial**

149. In order to test and refine the Lead Plaintiffs' presentation of the detailed factual evidence, Co-Lead Counsel conducted an informative mock trial exercise from July 29-30, 2014. Following the mock trial, Co-Lead Counsel and their jury consultants devoted many hours of analysis to the results of those presentations and the reactions of the mock jurors to various issues and evidence presented, which gave Co-Lead Counsel valuable insight into the strength and weaknesses of their arguments. At the time of settlement, Co-Lead Counsel were also planning for a second round of mock jury exercises.

**T. Motions to Exclude the Two Defense Experts Most Subject to Challenge at the *Daubert* Stage**

**1. Dr. Christopher James**

150. Testimony from Dr. Christopher James would have been critical to any attempt by Defendants to support their affirmative truth-on-the-market defense and Defendants' theory of damages. In their Motion to Limit the Testimony of Dr. James, Lead Plaintiffs argued, among other things, that Dr. James' proffered truth-on-the-market expert opinion failed even the most lenient test for admissibility under Rule 702 of the Federal Rules of Evidence.

151. Defendants opposed Plaintiffs' motion on September 18, 2015, and, on September 28, 2015, Lead Plaintiffs filed a reply brief in support of their motion to limit Dr. James' testimony.

**2. Dr. Lisa Rarick**

152. On August 28, 2015, Lead Plaintiffs filed a Motion to Limit the Testimony of Dr. Lisa D. Rarick. Dr. Rarick, Defendants' FDA expert, was a critical witness to supporting



Defendants' arguments regarding Merck's compliance with FDA regulations and "sound scientific practice." Specifically, Dr. Rarick had opined that Merck could not add a warning to its own drug label because that was the province of the FDA. In their Motion to Limit the Testimony of Dr. Rarick, Lead Plaintiffs argued, among other things, that Dr. Rarick's proffered opinions were irrelevant to the litigation, unreliable speculation, factually and legally wrong (including contrary to Supreme Court precedent), and far beyond the scope of her purported qualifications.

153. Defendants opposed Plaintiffs' motion on September 18, 2015, and on September 28, 2015, Lead Plaintiffs filed a reply brief in further support of their motion to limit the testimony of Dr. Rarick.

**U. The Defense of Plaintiffs' Expert Testimony at the *Daubert* Stage**

154. On August 28, 2015, Defendants filed seven motions *in limine* to exclude: (i) the proffered expert testimony of Dr. Tabak; (ii) certain expert opinions proffered by Dr. Zipes; (iii) certain expert opinions proffered by Dean Madigan; (iv) the proffered expert testimony of Mr. Boghigian; (v) certain expert opinions proffered by Dr. Kessler; (vi) the proffered expert testimony of Dr. David J. Graham of the FDA; and (vii) the proffered expert and/or lay opinion testimony of Drs. Gregory Curfman, James Fries, and Eric Topol. As of the time of the settlement in this Action, the Court had not yet ruled on these outstanding motions.

**1. Dr. David Tabak**

155. On August 28, 2015, Defendants moved to preclude the expert opinions of Plaintiffs' damages expert, Dr. David Tabak. Lead Plaintiffs faced a significant risk of losing their ability to use Dr. Tabak's damages model due to Defendants' attack on his use of assumptions such as the commercial viability, and FDA labeling, of Vioxx that purportedly did not "fit" the case.

156. On September 18, 2015, Lead Plaintiffs filed their Opposition to Defendants'

motion to exclude Dr. David Tabak's expert opinions. In their Opposition, Lead Plaintiffs argued that Defendants did not take issue with Dr. Tabak's qualifications, his analyses of market efficiency, or his event study damages methodology; rather, Defendants took issue with Lead Plaintiffs' other affirmative evidence. In other words, Defendants were merely disagreeing with whether Plaintiffs' trial proof supported Dr. Tabak's damages analysis, which was not a basis to disqualify Dr. Tabak under *Daubert*.

## **2. Dr. Douglas Zipes**

157. On August 28, 2015, Defendants moved to exclude large portions of Dr. Zipes' expert opinions, such as (i) Dr. Zipes' opinion that Merck should have never brought Vioxx to market; (ii) Dr. Zipes' opinions on Vioxx's proper labeling; and (iii) Dr. Zipes' opinion that Vioxx is more harmful than Celebrex. Defendants also argued that the Court should broadly prohibit Dr. Zipes from reciting factual narratives at trial.

158. On September 18, 2015, Lead Plaintiffs opposed Defendants' motion to exclude Dr. Zipes' testimony. Plaintiffs' brief explained that under the Third Circuit's "trilogy of restrictions on expert testimony: qualification, reliability and fit," Dr. Zipes was well qualified to opine that Merck should have withdrawn Vioxx or sold it only with a cardiovascular Black Box warning after VIGOR. Plaintiffs argued that, as a cardiovascular expert, Dr. Zipes understands the grave danger of CV risk, has extensive experience (including on advisory committees), and relies on drug labels every day when prescribing drugs to patients. Indeed, doctors like Dr. Zipes have repeatedly given such testimony in prior cases.

## **3. Dean David Madigan**

159. On August 28, 2015, Defendants moved to preclude the expert opinions of Plaintiffs' statistics expert, Dean David Madigan. In their motion to exclude Dean Madigan's testimony, Defendants argued, among other things, that his testimony about the results of certain

analyses of Merck's safety data from its Alzheimer's trials failed to satisfy *Daubert's* "fit" requirement because they were not probative of Defendants' scienter. Specifically, Defendants argued that Dean Madigan had "conceded" that the methodology he employed in performing the analyses in question departed from Merck's own pre-specified methodology and, therefore, could tell the jury nothing about what Defendants knew during the Certified Class Period.

160. On September 18, 2015, Lead Plaintiffs filed their Opposition to Defendants' motion to preclude Dean Madigan's testimony. Lead Plaintiffs argued that Defendants mischaracterized Dean Madigan's proffered opinions. Specifically, Dean Madigan opined that the analyses of Merck's Vioxx safety data he presented flowed entirely from Merck's pre-specified methodology, from Merck's own data, and from the Company's chosen endpoints. Lead Plaintiffs also argued that the analyses that Merck performed during the Class Period made it clear that the challenged analyses were essential to evaluating Vioxx's safety.

#### **4. Mr. Harry Boghigian**

161. On August 28, 2015, Defendants filed a motion to exclude the testimony of Plaintiffs' drug marketing expert witness, Harry Boghigian. In their *Daubert* motion, Defendants argued that Mr. Boghigian's testimony concerning the post-VIGOR time period should be excluded in its entirety because it was based on unsupported assumptions and no discernible or reliable methodology. Defendants also argued that to the extent Mr. Boghigian provided a methodology for determining commercial viability, he failed to apply it to his opinion in this Action.

162. On September 18, 2015, Lead Plaintiffs opposed Defendants' motion to limit or exclude Mr. Boghigian's testimony. Lead Plaintiffs argued, among other things, that: (i) Mr. Boghigian had extensive experience and specialized knowledge of pharmaceutical sales and marketing based on his over 40 years of employment in the industry; (ii) he utilized a reliable,

standard cost/benefit methodology in arriving at his opinions regarding the commercial viability of Vioxx with a Black Box warning; (iii) the hypotheticals he opined upon were not only permissible, but extensive evidence existed to support them; and (iv) his opinions “fit” with the facts of the pre-VIGOR market dynamics and were supported by the facts of the post-VIGOR time period.

## **5. Dr. David Kessler**

163. On August 28, 2015, Defendants filed a motion to preclude the testimony of Plaintiffs’ FDA expert, Dr. David Kessler. Defendants argued that Dr. Kessler’s opinions regarding the legal obligations of pharmaceutical companies should be excluded because his legal opinions usurped the Court’s role to provide the law to the jury, and the independent duty that he imposed on pharmaceutical companies was baseless and contrary to law. Defendants further argued that Dr. Kessler’s opinions regarding the FDA’s lack of resources and post-withdrawal reforms were irrelevant and unduly prejudicial. To the extent that Dr. Kessler opined about CV safety signals prior to Vioxx’s initial approval, Defendants noted that the Court had already rejected the relevance of evidence from that time period and argued it should likewise be excluded from Dr. Kessler’s expert testimony.

164. On September 18, 2015, Lead Plaintiffs opposed Defendants’ motion to exclude the expert opinions of Dr. Kessler. In their Opposition to Defendants’ motion, Lead Plaintiffs argued that Dr. Kessler was not offering opinions on Merck’s legal obligations or on the ultimate legal conclusions of the case, but rather, he was explaining what was widely understood in the industry that informed how drug companies such as Merck viewed their role versus that of the FDA regarding drug safety. Furthermore, courts had routinely ruled as admissible Dr. Kessler’s testimony regarding the independent responsibilities of drug manufacturers (as understood by industry participants and by regulators). Lead Plaintiffs also argued that Dr. Kessler’s opinions

regarding pre-approval tests and post-Class Period events were relevant and provided important context for his opinions regarding Class Period practices and to rebut Defendants' FDA experts.

**6. Dr. David J. Graham**

165. On August 28, 2015, Defendants moved to preclude the testimony of Dr. David J. Graham. Dr. Graham, the FDA's Associate Director for Science and Medicine, Office of Drug Safety, Center for Drug Evaluation and Research during the Class Period, was important to rebut Defendants' heavy (and, in the view of Lead Plaintiffs, misleading) reliance on the FDA's approval of Vioxx. Lead Plaintiffs relied on Dr. Graham's video testimony for his percipient factual testimony regarding a large study he performed of Vioxx (the "Kaiser" study), as well as his first-hand experiences at the FDA in monitoring and regulating drugs after the FDA approved them for marketing. However, in an abundance of caution, Lead Plaintiffs designated Dr. Graham's testimony regarding the FDA's internal policies and procedures as potential expert testimony. Defendants moved to preclude that testimony by levying a number of attacks against Dr. Graham's reliability and qualifications.

166. On September 18, 2015, Lead Plaintiffs opposed Defendants' motion to limit or exclude the testimony of Dr. Graham. Lead Plaintiffs argued that (i) Defendants did not challenge Dr. Graham's qualifications as a drug safety and FDA expert to offer his analyses; (ii) Dr. Graham's testimony regarding his first-hand experience at the FDA was percipient testimony and should not be subject to challenge as "unreliable"; (iii) Defendants wrongly contended that Dr. Graham's testimony did not "fit" this case; for example, they omitted any mention of Dr. Graham's Kaiser study and its role in this case, including that it related to one of the specific false statements in this case as noted by the Court; and (iv) without any legal foundation Defendants contended that, as a matter of law, Dr. Graham could not be heard to criticize the FDA because of vague and unsupported "preclusion" principles. However, there remained the possibility that the Court might

accept one of Defendants' attacks on Dr. Graham. If so, Lead Plaintiffs would have been at a distinct disadvantage, because they expected to also rely on Dr. Graham's testimony in rebutting Defendants' defense at trial that the FDA approved Vioxx as safe and effective.

#### **7. Drs. Curfman, Topol and Fries**

167. On August 28, 2015, Defendants filed a motion to exclude the testimony of Drs. Gregory Curfman, James Fries, and Eric Topol – third-party doctors who had discussed with Merck issues related to the safety of Vioxx during the Class Period. In Defendants' motion, they argued that Drs. Curfman, Fries, and Topol did not qualify as specialized lay opinion witnesses because, as medical doctors, their opinions were based on their generalized expertise as scientists and physicians. Defendants further argued that Lead Plaintiffs could not offer their opinions as experts because they failed to disclose them as experts within the timeframe set by the Court's Scheduling Order, and Defendants would be prejudiced because the witnesses were never deposed in this case. Defendants also contended that even if Lead Plaintiffs were allowed to offer these witnesses as experts, their opinions were inadmissible under Rule 702 and *Daubert* because they had not shown that these witnesses employed reliable methodologies or that their opinions "fit" the facts and issues of the case.

168. On September 18, 2015, Lead Plaintiffs filed their Opposition to Defendants' motion to exclude the testimony of Drs. Curfman, Topol and Fries. As Lead Plaintiffs argued, these doctors were percipient witnesses to key events during the Class Period and participated in the supposed "debate" at the core of Merck's defense. These independent witnesses came to very different conclusions than Merck did about the safety of Vioxx, communicated their conclusions about Vioxx's dangers to Merck at the time of the events in question, and saw first-hand how Merck tried to silence Vioxx's critics. Limitation or exclusion of their testimony could have weakened Lead Plaintiffs' counter-arguments against Defendants' defense that a widespread

debate was ongoing regarding the CV risks of Vioxx during the Class Period.

**V. Motions *in Limine***

169. At the time that the parties reached the Settlement, Lead Plaintiffs had already drafted, among others, the following motions *in limine* and were preparing to finalize them for filing (but the Action settled before they were due):

- (i) Motion in Limine No. 1: To preclude any suggestion that the FDA's or other drug agencies' review or approval for sale of Vioxx means that Defendants' statements regarding the safety of Vioxx cannot be challenged, that the government endorsed or approved the accuracy and completeness of Defendants' public statements regarding Vioxx's safety or Defendants' public statements concerning Naproxen, or that the information Defendants provided to the FDA satisfied Defendants' disclosure obligations under the securities laws.
- (ii) Motion in Limine No. 2: To preclude any reference to whether any Plaintiffs, Defendants, their employees, investment advisers, consultants, witnesses or their family members took Vioxx, Celebrex, Bextra or other selective Cox-2 inhibitors.
- (iii) Motion in Limine No. 3: To preclude Defendants from presenting evidence that a black box warning was added to Celebrex and other NSAIDs after the end of the Class Period.
- (iv) Motion in Limine No. 4: To preclude testimony by Drs. FitzGerald, Oates or Patrono regarding Defendants' state of mind.
- (v) Motion in Limine No. 5: To preclude reference to the SEC's supposed approval of Merck's public disclosures or the SEC's failure to prosecute or take action against Merck.
- (vi) Motion in Limine No. 6: To preclude Defendants from arguing that Plaintiffs and class members "gambled" on their investments or "took a risk" on Merck securities, or making similar claims.
- (vii) Motion in Limine No. 7: To preclude reference to Merck's, and current and former Merck employees' (including the Individual Defendants'), alleged good works, commitment to patient safety, life-saving efforts or products, scientific research and development efforts or expenditures, charitable contributions, and/or character.
- (viii) Motion in Limine No. 8: To preclude reference to the number of persons Merck employs in New Jersey, or the size of Merck's operations in New Jersey.
- (ix) Motion in Limine No. 9: To preclude reference to any effect that a judgment for Plaintiffs might have on Merck or the Individual Defendants, the ability of

patients to purchase or have available medications, the cost of medicine or insurance, the viability of the pharmaceutical industry, or that a judgment against Defendants may result in layoffs or people losing their jobs.

- (x) Motion in Limine No. 10: To preclude reference to the Class's or individual plaintiffs' actual or estimated aggregate damages.
- (xi) Motion in Limine No. 11: To preclude reference to the Plaintiffs; or, in the alternative, to preclude reference to Plaintiffs' investments, investment strategies, size, purported sophistication, location, other litigation experience, arrangements with counsel, and other irrelevant and/or prejudicial information.
- (xii) Motion in Limine No. 12: To preclude reference to any purported "litigation crisis," "lawsuit crisis," "lawsuit abuse," "lawyer driven litigation" or similar terms or phrases, or attacks on the integrity of Plaintiffs' counsel or references to the conduct of Plaintiffs' counsel unrelated to this litigation.
- (xiii) Motion in Limine No. 13: To preclude reference to Plaintiffs' (or the Court's) dismissal, amendment, changes to or withdrawal of any claims, Defendants, Plaintiffs, theories of liability or allegations.
- (xiv) Motion in Limine No. 14: To preclude introduction of complaints filed against Merck and/or Pfizer during the Class Period, including personal injury and securities complaints.
- (xv) Motion in Limine No. 15: To preclude introduction of post-Class Period sales of Celebrex and introduction of Pfizer Form 10-Ks, 10-Qs and other post-Class Period Pfizer public filings.
- (xvi) Motion in Limine No. 16: To preclude Defendants from offering expert or specialized lay opinion testimony through witnesses not identified as offering such testimony in the parties' Joint Pretrial Order.
- (xvii) Motion in Limine No. 17: To preclude any mention of, or introduction of evidence regarding, any statements or proposals by Plaintiffs in the *Honeywell* Action with respect to attempting to opt back into the Class.
- (xviii) Motion in Limine No. 18: To preclude evidence or argument regarding declines in Merck's stock price without evidence that the declines were statistically significant.
- (xix) Motion in Limine No. 19: To preclude Defendants from arguing or offering evidence of Individual Plaintiffs' purported lack of standing.

170. Lead Plaintiffs were also preparing the following trial brief motions:

- (i) Motion that, if Defendants argue to the jury that Defendants never stated publicly that it was "certain" or "unambiguous" (or using similar words) that Naproxen's



purported cardio-protective effect explained the difference in cardiovascular events in the VIGOR trial, or that Defendants Reicin or Merck did not author the November 2000 *NEJM* article about the VIGOR results, then Lead Plaintiffs would be permitted to add Defendant Scolnick's December 12, 2000 statement that the Naproxen Hypothesis was the unambiguous explanation for the VIGOR results, and Merck's November 23, 2000 press release announcing the VIGOR *NEJM* paper, to the verdict sheet.

- (ii) Motion that, if Defendants presented a truth-on-the-market defense, Plaintiffs would be permitted to present evidence concerning the Vioxx-related disclosures in the November 1, 2004 *WSJ* article, and Merck's corresponding stock price decline in response to the article, to rebut Defendants' truth-on-the-market defense.
- (iii) Motion to preclude Defendants from asserting a reliance-on-counsel defense related to the drafting, review, editing, making, or approval of Defendants' allegedly false and misleading public statements, including because Defendants did not produce the contents of privileged communications during discovery.
- (iv) Motion to preclude Defendants from arguing that Lead Plaintiff Miss. PERS or other Plaintiffs or class members must have purchased the actual Merck shares sold by Defendant Scolnick in order to sustain their Section 20A claim against him, or to ensure that a charge in accordance with the Court's prior rulings on this issue is read to the jury.
- (v) Motion to preclude Defendants from arguing that Lead Plaintiffs must prove Vioxx actually "causes" heart attacks to a medical degree of certainty (including the preclusion of defense expert Dr. Vaughan's "causation" conclusion).

171. Lead Plaintiffs were also preparing to file a motion to bifurcate the trial into common and plaintiff-specific stages in order to prevent Defendants from emphasizing issues specific to individual plaintiffs, including numerous direct action and opt-out plaintiffs, at trial. While Defendants believed that the trial should be bifurcated, they were proposing a significantly different approach to the bifurcation issue than Lead Plaintiffs were.

#### **W. The Exchange of Pretrial Materials and the Joint Pretrial Order**

172. In connection with a July 13, 2015 status conference, Magistrate Judge Waldor ordered that the Court would hold the final pretrial conference on September 25, 2015, and that the final joint pre-trial order ("JPTO") was due to be filed on or before September 11, 2015. The

Court also directed the parties to meet-and-confer with regard to the scheduling of *Daubert* and *in limine* motions.

173. On August 11, 2015, the Court held another conference with all parties to discuss pretrial scheduling. On August 27, 2015, as a follow-up to the August 11 conference, the Court issued an Order setting trial in the Action to begin on March 1, 2016, with the final pretrial conference to occur on January 8, 2016.

174. In the late summer and fall of 2015, the parties scheduled and coordinated their numerous pretrial exchanges of the proposed contents of the final JPTO. This included extensive drafting and revision of the parties' (i) positions on bifurcation; (ii) proposed Stipulated Facts, Requests for Judicial Facts and Contested Facts; (iii) page and line numbers of designated testimony (and objections and counter-designations thereto); (iv) statements of jurisdiction; (v) lists of pending and contemplated motions/trial briefs; (vi) consents and objections to witnesses; (vii) consents and objections to the qualifications of experts; (viii) exhibit lists (and objections thereto); (ix) lists of legal issues; and (x) the draft and final Pretrial Order. These were voluminous documents.

175. On November 10, 2015, Magistrate Judge Waldor held a teleconference with counsel to discuss the status of the JPTO.

176. On November 12 and 16, 2015, the parties held meet-and-confer sessions on the JPTO. During the meet-and-confers, the parties discussed the possibility of reaching agreements with respect to proposed trial witnesses; exhibits; stipulated facts; contested facts; motions *in limine*; confidentiality at trial; sequestration of witnesses; and judicial notice.

177. On November 17, 2015, Magistrate Judge Waldor held a teleconference with counsel to discuss the status of the meet-and-confers and the JPTO.

178. On November 20, 2015, following numerous exchanges between the parties of proposed material for the JPTO, Lead Plaintiffs filed the final Pretrial Order (a massive undertaking which spanned 2,170 pages) with the Court.

179. On November 24, 2015, the Court held a conference to discuss the JPTO, and the Court requested that the parties continue to engage in meet-and-confers to further narrow any issues in dispute.

180. Lead Plaintiffs and Defendants then participated in lengthy meet-and-confer sessions on December 9, 2015 and December 14, 2015 to discuss, negotiate, and resolve issues regarding the JPTO.

#### **X. The Risk of Potentially Dispositive U.S. Supreme Court Decisions**

181. During the course of the Action, the U.S. Supreme Court issued numerous decisions impacting the scope of securities fraud liability, and Lead Plaintiffs successfully argued that those decisions should not result in the dismissal of any of Plaintiffs' claims in this Action. These decisions include many on which Judge Chesler ruled for the first time in any action. Each of these decisions – *Matrixx*, *Janus*, *Halliburton*, and *Omnicare* – was directly on point with Lead Plaintiffs' case and could have been case-dispositive.

##### **1. *Matrixx***

182. On March 23, 2011, while Defendants' motions to dismiss were pending, Lead Plaintiffs submitted a letter seeking to draw the Court's attention to the Supreme Court's decision in *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27 (2011). In their motions to dismiss, citing the then-governing Third Circuit precedent of *Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000), Defendants argued that none of their statements concerning Vioxx's safety or commercial prospects was materially false or misleading because none of the adverse information concerning Vioxx's safety that they omitted to disclose "would [have] establish[ed] a definitive link between

Vioxx and increased cardiovascular risk.”

183. In *Matrixx*, the Supreme Court expressly rejected the argument that adverse information relating to a drug’s safety must rise to the level of statistical significance in order to be material. Lead Plaintiffs’ letter argued that applying the *Matrixx* analysis in this case led to the conclusion that Lead Plaintiffs adequately pled materiality based on the existence of an undisclosed “plausible causal relationship” between Vioxx and CV events. The letter also drew parallels between the scienter allegations in *Matrixx* and the scienter allegations in this case. The letter noted that Lead Plaintiffs’ Complaint alleged concerns about the drug, pressure and intimidation of the medical community, and affirmatively false statements which were found to be sufficient indicia of scienter in *Matrixx*. Plaintiffs’ letter also chronicled how the Complaint alleged indicia of scienter exceeding that in *Matrixx*, with allegations regarding internal emails evincing Defendants’ belief that Vioxx was pro-thrombotic, intentional design of studies to avoid generating adverse data, and manipulation of statistically significant adverse clinical trial data.

184. Defendants responded to Lead Plaintiffs’ March 23, 2011 letter in a letter filed March 25, 2011. In the letter, Defendants argued that *Matrixx* was of “very limited relevance” to this Action because, they argued, Lead Plaintiffs abandoned on appeal misstatements of fact regarding Vioxx, leaving only misstatements of opinion.

185. In the Court’s August 8, 2011 Opinion denying Defendants’ motions to dismiss, Judge Chesler cited *Matrixx* for the point that, “Merck’s position—that the lack of data supporting a conclusive link between Vioxx and heart attacks precludes the undisclosed information from meeting the materiality standard—is belied by the Supreme Court’s recent discussion of materiality in *Matrixx*.”

## **2. Janus**

186. On July 6, 2011, prior to oral argument on Defendants’ second round of motions to

dismiss, Defendant Scolnick brought to the Court's attention the Supreme Court's then recent decision in *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135 (2011). In *Janus*, the Supreme Court held that only the person who actually "makes" an alleged misstatement can be liable to a private plaintiff under Section 10(b) of the Exchange Act, and that the "making" of a statement requires that the speaker have "ultimate authority" to issue it. Seven statements in Lead Plaintiffs' Complaint were signed or otherwise attributed to Defendant Scolnick, but under his interpretation of *Janus* they were not "made" by him because he asserted that he lacked "ultimate authority" over them. The letter argued that there was a parallel between *Janus* and this case because Merck, not Dr. Scolnick personally, was required to file Merck's SEC filings.

187. On July 7, 2011, Lead Plaintiffs responded that Defendant Scolnick was directly quoted in the documents in question, personally signed SEC filings, and, as a corporate officer, director, and a member of Merck's Management Committee, caused Merck to issue numerous allegedly false and misleading public statements. Lead Plaintiffs also argued that *Janus* applies to a situation where two separate corporate entities are at issue, not to the actions of internal corporate agents. In the Court's August 8, 2011 decision denying Defendants' motions to dismiss, the Court adopted that rationale and rejected Defendant Scolnick's *Janus* argument. Defendants also raised later in the litigation whether, under *Janus*, Defendants or the *NEJM* made Merck's 4% claims in the *NEJM* VIGOR article. The Court rejected that argument in granting Plaintiffs' motion to amend the Complaint to include those alleged false statements.

### **3. *Halliburton***

188. In a letter dated November 23, 2013, Defendants wrote to inform the Court of the U.S. Supreme Court's grant of certiorari in *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398 (2014) ("*Halliburton II*"), to review the fraud-on-the-market presumption under *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), and to seek a stay of dispositive motions in this Action pending a

decision in *Halliburton II*. Defendants argued that the decision in *Halliburton II* would have a significant impact on the merits of this case, since this Action is based upon the fraud-on-the-market presumption of reliance. In a letter dated November 25, 2013, Lead Plaintiffs wrote to Judge Chesler opposing Defendants' request for an open-ended stay of dispositive motion briefing pending a decision in *Halliburton II*, because it would severely prejudice Lead Plaintiffs and the Certified Class, and because, even if *Halliburton II* overturned the fraud-on-the-market doctrine under *Basic*, Lead Plaintiffs would still be entitled to a presumption of reliance under *Affiliated Ute*.

189. The parties then exchanged an additional round of letters on the issue on November 27, 2013. Defendants argued that Lead Plaintiffs could not invoke a presumption of reliance under *Affiliated Ute* in the absence of the fraud-on-the-market presumption because the Court had already implicitly determined that Lead Plaintiffs primarily alleged misrepresentations rather than both misrepresentations and omissions, and as such, the presumption under *Basic* applied rather than the presumption under *Affiliated Ute*. Defendants further reiterated that the sole issue before the Court was whether it made sense for the parties to expend substantial resources briefing dispositive motions with the possibility that the decision in *Halliburton II* could dispose of Lead Plaintiffs' case *in its entirety*. In response, in a letter filed that same day, Co-Lead Counsel wrote to Judge Chesler that: (i) the only court at the time of the letter that decided the same issue denied the request for a stay; (ii) Defendants previously raised and lost their arguments on numerous occasions regarding the *Affiliate Ute* presumption; (iii) Defendants ignored controlling Third Circuit precedent that rejected their view that the *Affiliated Ute* presumption did not apply where a combination of misrepresentations and omissions was alleged; and (iv) if Defendants have other grounds for summary judgment independent of issues raised in *Halliburton II*, there would be no

reason for Defendants not to file their summary judgment motions on those issues.

190. On December 19, 2013, Magistrate Judge Waldor denied Defendants' request for a stay. In its decision in *Halliburton II*, the Supreme Court ultimately declined to overrule the presumption of reliance in securities fraud suits based on the "fraud on the market" doctrine set forth in *Basic v. Levinson*.

#### **4. *Omnicare and Freidus***

191. In a letter dated March 25, 2015, Lead Plaintiffs wrote to Judge Chesler to alert the Court of the Supreme Court's recent decision in *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318 (2015) ("*Omnicare*"), which supported Lead Plaintiffs' theory of the case and undermined Defendant Scolnick's arguments in his summary judgment motion that Lead Plaintiffs must prove that he subjectively disbelieved the statements at issue. Lead Plaintiffs had argued that Defendant Scolnick subjectively disbelieved his statements about the Naproxen Hypothesis and that he lacked a reasonable basis for those statements, and *Omnicare* confirmed that Lead Plaintiffs did not need to prove subjective disbelief to survive summary judgment. On March 25 and 31, 2015, Defendants responded to Lead Plaintiffs' March 25, 2015 letter, arguing that *Omnicare* addressed the falsity of statements under Section 11 of the Securities Act, and not Lead Plaintiffs' Section 10(b) claims, and that *Omnicare* acknowledged that certain fields of study necessarily involve legitimate debates involving dissenting opinions about genuinely held beliefs.

192. In addition, in a letter dated April 2, 2015, Lead Plaintiffs alerted the Court to the U.S. Supreme Court's post-*Omnicare* remand of *Freidus v. ING Groep*, 135 S. Ct. 1698 (2015), as supplemental authority to *Omnicare* and in further support of their opposition to Defendants' motions for summary judgment. Lead Plaintiffs argued that in vacating and remanding *Freidus* with instructions to reconsider it in light of *Omnicare*, the Supreme Court confirmed that *Omnicare*

effectively overruled the holding in *Fait v. Regions Financial Corp.*, 655 F.3d 105 (2d Cir. 2011), which *Freidus* entirely relied upon in requiring subjective disbelief, and on which Defendant Scolnick relied to support his contention that Lead Plaintiffs must prove that Defendants subjectively disbelieved the statements at issue. On April 6, 2015, Defendant Scolnick wrote to Judge Chesler in response to Lead Plaintiffs' April 2, 2015 letter. He reiterated his arguments set forth in his March 31, 2015 letter to the Court that: (i) under *Omnicare*, a plaintiff alleging affirmative misrepresentations in opinions must demonstrate that the defendant did not genuinely believe the opinion; and (ii) the standard under Section 11 articulated in *Omnicare* did not apply to the standard under Section 10(b), in which scienter is a required element. Defendant Scolnick further sought to distinguish *Freidus* and *Fait* from the issues in this Action, noting that *Freidus* and *Fait* both involved claims under the Securities Act, not the Exchange Act, which is at issue here.

193. On May 13, 2015, the Court largely denied Defendants' motions for summary judgment. In denying Defendants' motions, Judge Chesler agreed with Plaintiffs and found that, on the issue of falsity, "[t]he Supreme Court's *Omnicare* decision, dealing with a securities fraud claim based on statements of opinion, illuminates this Court's Section 10(b) scienter analysis as it relates to Defendants' expressed support of the naproxen hypothesis." The Court also found that, "as Plaintiffs have argued, the *Omnicare* Court's analysis squares with the earlier holdings in this case, by both this Court and the Third Circuit, that Defendants' opinion concerning the naproxen hypothesis may constitute securities fraud if Defendants either subjectively disbelieved the opinion they asserted or lacked a reasonable basis for their expressed belief."

#### **Y. Mitigation of Other Serious Risks to the Class**

194. Lead Plaintiffs addressed many other very serious risks that the Class could recover nothing in this Action. First, those Settlement Class members who purchased before March 27,



2000 and after September 30, 2004 were out of court as a result of this Court's rulings on Defendants' motions to dismiss and for summary judgment. Those investors would recover nothing in this Action absent a post-trial appeal of the dismissal of claims of purchasers in those periods. Nonetheless, settlement provides for some recovery for these investors. Second, as to all Settlement Class members, Lead Plaintiffs faced substantial hurdles to victory on the merits.

195. For example, Defendants' principal defense in their motions for summary judgment was the argument that they were embroiled in a reasonable and public scientific debate and embarked on a quest for the truth. To rebut those claims, Lead Plaintiffs developed a record demonstrating that, not only did Defendants believe that Vioxx was pro-thrombotic, but numerous third parties (including the FDA and Merck's own consultants) privately put them on notice that Vioxx was harmful, and that Defendants lacked a reasonable basis for their public claims that Naproxen is cardio-protective.

196. Lead Plaintiffs also focused on Defendants' purported truth-on-the-market defense. Even after Lead Plaintiffs won their appeal to the Third Circuit and demonstrated to the Supreme Court that the market was not on notice of Defendants' fraud as of November 2001 (two years before Plaintiffs filed suit), Lead Plaintiffs still needed to rebut Defendants' purported evidence that the market was aware of Defendants' understanding that Vioxx was pro-thrombotic. Lead Plaintiffs did so by arguing that there was no evidence reliably used by Defendants' expert Christopher James demonstrating "truth on the market" until Merck finally withdrew Vioxx from the market on September 30, 2004.

197. In addition, Lead Plaintiffs worked to rebut Merck's defense that only the FDA may change a drug's warning label, and that the FDA repeatedly determined Vioxx was safe. According to Defendants' FDA expert (Dr. Lisa Rarick), since the FDA reviewed the available

data on Vioxx's CV risks and repeatedly approved Vioxx for sale as safe and effective, Merck was precluded from making any changes to the Vioxx label that would have disclosed to investors the serious risks of the drug. As Lead Plaintiffs point out, courts previously criticized Dr. Rarick's opinions and limited her ability to opine that a drug company could not change its own label.

198. Lead Plaintiffs also worked to rebut Defendants' statistical defenses. For example, Lead Plaintiffs developed several cogent rebuttals to Defendants' complicated defense – never advanced in any previous litigation – that a particular statistical analysis during the Class Period allayed any concerns Merck might have had about the statistical power of its Vioxx safety data. This included contacting and obtaining a writing from a former Merck statistician while he was in India that Plaintiffs' statistical expert, Dean Madigan, relied upon in his expert report.

199. Lead Plaintiffs also retained and worked with statistical experts qualified to respond to Defendants' defense that the APPROVe results were "new" information. Throughout the litigation, Defendants repeatedly argued that, prior to the fall of 2004, they did not have placebo-controlled data showing that Vioxx was harmful, and that, as soon as they first had that information from the APPROVe trial in 2004, they promptly withdrew Vioxx, and therefore did not commit securities fraud. To rebut that argument, Lead Plaintiffs worked with Plaintiffs' statistical expert, Dean Madigan, who opined that the same increased CV risk that Merck pointed to in the APPROVe trial that finally led to Vioxx's withdrawal from the market was repeatedly disregarded by Merck much earlier, starting in July 2000, and thereafter with the steady accumulation of more adverse Vioxx trial data.

200. Lead Plaintiffs also developed and proffered a viable damages methodology. In his analysis, Plaintiffs' damages expert, Dr. Tabak, segregated the negative impact of Vioxx's withdrawal on Merck's stock price into three distinct causes: lost Vioxx sales; the negative impact

on the approvability of Merck's follow-on Cox-2 inhibitor, Arcoxia; and the increased litigation liability caused by Vioxx's withdrawal. Dr. Tabak's analysis supported the inclusion of all three of these elements of loss in Plaintiffs' damages calculations. However, there was a real risk that the Court might determine that, for example, only the Vioxx sales component of the stock drop was attributable to Plaintiffs' claims. As Plaintiffs demonstrated in their opposition to Defendants' motion to exclude Dr. Tabak's testimony, Lead Plaintiffs developed numerous facts that supported inclusion of all elements of Dr. Tabak's analysis in the calculation of damages. The dismissal of the *Pfizer* securities fraud class action concerning Celebrex on the eve of trial in that case based on a purportedly flawed damages methodology (which the Second Circuit Court of Appeals only recently overturned for reasons unique to that case) strongly demonstrates the risks Plaintiffs faced in navigating complex damages issues in this Action.

201. Lead Plaintiffs also simplified the complex scientific issues in the case through mock trial presentations and follow-on discussions and preparations with their jury consultant. A serious risk in the litigation was the highly complex medical and statistical issues at the heart of this case based on the CV risk of an FDA-approved drug. Lead Plaintiffs grappled with how to present these highly complex issues in numerous ways, including by formulating analogies and explanations to describe the issues to a lay audience.

**Z. The Mediations, Settlement Negotiations, and Preliminary Approval of the Settlement**

202. The Action only settled after the parties took part in numerous settlement conferences and mediation sessions with Judges Chesler and Waldor, the mediator (The Honorable Layn R. Phillips), and defense counsel.

203. The Court held settlement conferences with the parties on October 27, 2011, March 23, 2012, May 14, 2012, and September 30, 2013. Despite the Court's and the parties' best efforts,

these settlement discussions took years of effort.

204. On September 19, 2014, the parties agreed to retain Judge Phillips as a private mediator after the Court suggested private mediation. On October 8, 2014, in advance of an upcoming mediation session scheduled for October 13, 2014, Judge Phillips held a meeting with only the Plaintiffs' side of the mediation. The October 13, 2014 mediation was unsuccessful and a previously-scheduled second day of mediation for November 5, 2014 was cancelled. There were no settlement talks between the parties thereafter for a substantial period of time.

205. Then, following the Court's ruling on summary judgment, Judge Phillips held the next mediation session on September 11, 2015 in New York. Following that mediation and a series of discussions among the parties, the Court and the mediator, the parties reached an agreement in principle to settle the Action on December 17, 2015, over one year after the prior mediation efforts and less than three months before trial. Thereafter, the parties held teleconferences with the Court to apprise the Court of the terms of the settlement and to discuss related issues.

206. After the Action settled, Co-Lead Counsel drafted the settlement Stipulation and worked with Defendants to negotiate and finalize its terms, as well as the accompanying order, form of judgment and notices.

207. On February 8, 2016, Lead Plaintiffs filed their motion for preliminary approval of the Settlement with the Court, and also requested approval of the notice to the Settlement Class, and scheduling of the final approval hearing. Lead Plaintiffs also proposed for the Court's approval a schedule for the mailing and publication of notice to the Settlement Class, and the deadlines for submitting Claims and for opting out of the Settlement Class, opting back into the Settlement Class, or objecting to the proposed Settlement.

208. On February 11, 2016, the Court entered the Preliminary Approval Order, which preliminarily approved the Settlement, certified the Settlement Class for settlement purposes, and set a schedule to govern deadlines for the settlement proceedings.

#### **IV. RISKS OF CONTINUED LITIGATION**

209. The Settlement provides an immediate and certain benefit to the Settlement Class in the form of a total combined cash recovery of \$1.062 billion (including funds for attorneys' fees and litigation expenses, and the fees of the Special Master appointed by the Court regarding the award of attorneys' fees and expenses).<sup>6</sup> The Settlement, if approved, will represent the second largest securities class action recovery within the Third Circuit and the largest securities class action settlement ever with a pharmaceutical company defendant.

210. Although Co-Lead Counsel believe that Lead Plaintiffs have a strong case for liability – and negotiated the Settlement on this basis – the claims against Defendants nonetheless presented a number of significant challenges that created significant risks with respect to obtaining a verdict at trial and maintaining that judgment on appeal. As mentioned above, and explained in specific detail below, Defendants had substantial defenses with respect to liability, loss causation and damages in this case. Thus, while Lead Plaintiffs had successfully brought the litigation to the verge of trial, succeeding in substantially withstanding Defendants' motions to dismiss and for summary judgment, completing fact and expert discovery, certifying a class, and engaging in substantial pre-trial preparations, there were nonetheless substantial risks that Defendants might

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<sup>6</sup> The total settlement amount of \$1.062 billion consists of \$830 million for the Settlement Class Fund and \$232 million for the Fee/Expense Fund. To the extent the Court awards attorneys' fees and Litigation Expenses in an amount less than \$232 million, any amount remaining in the Fee/Expense Fund, after the payment of the Special Master fees and any Taxes owed by the Fee/Expense Fund, will be credited to the Settlement Class Fund and will not revert back to any of the Defendants or their insurers.

prevail on numerous pre-trial motions at trial or succeed on post-trial motions, or appeals, which could lead to Lead Plaintiffs and the Settlement Class achieving no recovery at all, or achieving a lesser recovery than the Settlement Funds after additional months or years of litigation.

**A. Risks of Proving Scierter**

211. Lead Plaintiffs faced the very real risk that a jury would conclude that Defendants did not act with the requisite scierter. In order to prove scierter, Lead Plaintiffs would need to demonstrate that Defendants subjectively disbelieved or lacked a reasonable basis for the Naproxen Hypothesis and other alleged false claims that Vioxx was safe. Lead Plaintiffs also needed to establish that Defendants knew or recklessly disregarded that Defendants' Vioxx CV safety data, used by Defendants to support their alleged false statements, lacked statistical power.

212. Although Lead Plaintiffs uncovered significant evidence during discovery that supported a finding of Defendants' scierter, Defendants presented many facts and counter-arguments in opposition. At the summary judgment stage, this Court recognized that it was faced with a "dense and extensive" record, and that Merck made "plausible arguments, with citations to the record, responding to Plaintiffs' points." 2015 WL 2550472, at \*1, \*23 (D.N.J. May 13, 2015).

213. For example, Lead Plaintiffs faced a serious risk that the jury might be swayed by testimony of Merck's outside consultants, Drs. FitzGerald, Oates, and Patrono, regarding Defendants' state of mind, which could paint Defendants in a favorable light and support Defendants' contention that Defendants did not act with scierter. While, as discussed above, Co-Lead Counsel had drafted a motion *in limine* to preclude such testimony, there was no guarantee that the Court would grant it. In addition, several Merck executives (including Defendants Scolnick and Reicin) asserted that they and their family members personally took Vioxx during the Class Period. This might have persuaded jurors that Defendants could not have believed Vioxx was unsafe.

214. Proving scienter would also entail significant and complex expert testimony. For instance, the testimony of Lead Plaintiffs' expert in biostatistics, Dean Madigan, was crucial to establishing Defendants' scienter with respect to the alleged materially false and misleading statements, including Defendants' statements that Merck's data showed "no difference" in CV risk between Vioxx and non-naproxen comparators, while Defendants' expert opined to the contrary. The jury would be asked to determine which interpretation is more fully supported by the evidence among extraordinarily complex scientific and technical theories. As a result, Lead Plaintiffs would need to explain, to a lay jury, numerous statistical and scientific concepts such as statistical significance, confidence intervals, Bayesian analysis, intention-to-treat analysis, and subgroup analyses, as well as cardiology, epidemiology and pharmacology, necessary to understand the case. Success was not a foregone conclusion in such an endeavor.

215. Moreover, no Defendant ever admitted wrongdoing, and Defendants vigorously disputed that they acted with scienter in their various motions to dismiss and motions for summary judgment, and they would continue to vigorously dispute these issues at trial. And, while Lead Plaintiffs had gathered significant evidence in support of a finding of scienter through their discovery efforts, the Individual Defendants would themselves likely testify at trial that they truly believed Vioxx was safe and that it provided significant benefits to patients. Lead Plaintiffs also faced obstacles in showing that Defendant Scolnick's trading in Merck stock demonstrated his scienter. The SEC never pursued a case against Defendant Scolnick for his stock trades and Plaintiffs would be asking jurors to rule on allegations that he disputed and he would offer numerous personal reasons for the sales.

216. The difficulty of establishing scienter was further compounded by the fact that Defendants would be able to buttress their own assertions of no wrongdoing in connection with

the VIGOR trial or the marketing of Vioxx by citing to the fact that the FDA scrutinized the data and repeatedly approved the drug's labeling. Defendants would also continue to contend at trial that the FDA's independent review and approval of Vioxx as safe and effective demonstrated that Defendants lacked scienter, and validated their statements. Given that the clinical testing required by FDA rules and regulations to approve a drug for sale typically takes several years to complete and is designed to evaluate the risks and benefits of innovative medicines, the FDA approval of Vioxx represented a substantial hurdle to Lead Plaintiffs' success at trial.

**B. Risks of Establishing Materiality**

217. Throughout the litigation, Defendants asserted, and planned to present to the jury, a truth-on-the-market defense. Specifically, Defendants argued that significant information about Vioxx's CV risk was in the public domain during the Class Period, and that Defendants could not be held liable for simply being part of a public "scientific debate" over Vioxx's CV risk.

218. In support of this argument, Defendants would continue to point to discussions in securities analyst reports, medical journals and media outlets, which questioned the CV safety profile of Vioxx. For example, after the VIGOR results were publicized, analysts expressed the opinion that Vioxx may be pro-thrombotic and made critical statements about Merck's meta-analysis. Dr. Eric Topol, then Chairman of Cardiovascular Medicine at the Cleveland Clinic, also published a medical journal article that stated "available data raise a cautionary flag about the risk of cardiovascular events with COX-2 inhibitors" in August 2001. While Lead Plaintiffs believed they developed strong counter-arguments to Defendants' truth-on-the-market defense, materiality is a jury question and there was a real risk that the jury could conclude the market was aware of the CV risks posed by Vioxx and find that the alleged misrepresentations and omissions were not material.



**C. Risks of Proving Falsity**

219. To prove their case, Plaintiffs would also have to show that Defendants made materially false and misleading statements (and/or material omissions). Defendants would likely have presented evidence at trial that purported to show that, when the VIGOR results were disclosed, the Naproxen Hypothesis was a legitimate scientific explanation reasonably believed by Defendants. Defendants would also likely present to jurors post-Class Period research suggesting that all NSAIDs may be pro-thrombotic, with the exception of naproxen, and thereby suggested that Naproxen is an outlier among these drugs. In addition, as discussed above, Merck employees testified that they actually believed the Naproxen Hypothesis, and that Vioxx could be on the market today.

220. Defendants would also likely argue that their statements about Vioxx's purported "favorable cardiovascular safety profile" were in response to negative media and analyst reports publicly debating the potential CV risk of Vioxx. A jury might have determined that Merck's statements were not false or misleading but rather a legitimate difference in scientific opinion in which the members of the scientific community, including Merck, presented alternative hypotheses in "public debate" to explain the VIGOR results.

**D. Risks of Establishing Loss Causation and Damages**

221. Should Lead Plaintiffs have succeeded in establishing materiality, falsity and scienter, considerable risks remained with respect to establishing loss causation and damages.

222. To establish loss causation, Lead Plaintiffs would have to prove that their losses on their Merck investments were proximately caused by Defendants' alleged fraud (*e.g.*, the concealing of material adverse information about Vioxx's CV risks). One significant risk faced by Lead Plaintiffs in proving this element would be Defendants' contention that investors knew during the Class Period that Vioxx *might* present a CV risk, and that, therefore, Merck stock price

declines at the end of the Settlement Class Period were not caused by Defendants' alleged misstatements or non-disclosures. This truth-on-the-market defense could have posed the risk that Lead Plaintiffs and the Settlement Class would recover nothing.

223. Defendants would also likely argue that nobody, not even Merck, knew for certain that Vioxx raised CV risk until the results of the APPROVe study established it, and that Merck promptly disclosed the adverse APPROVe results and withdrew the drug only days later. Indeed, Defendants would have argued that the withdrawal of Vioxx from the market – and the resulting substantial decline in the price of Merck stock on September 30, 2004 – was a direct result of the availability of the newly-unblinded APPROVe results, rather than the correction of any prior alleged misrepresentations, and thus the alleged misrepresentations could not be causally linked to the drop in Merck's stock price on September 30, 2004.

224. Lead Plaintiffs also faced significant risks in establishing damages, including from Defendants' attacks on elements of Lead Plaintiffs' damages model. If successful, those attacks would have eliminated or drastically reduced the amount of recovery for the class. Defendants would likely have attacked the damages model put forth by Lead Plaintiffs' damages expert arguing, for example, that only the portion of the stock price declines related to lost sales of Vioxx could be attributed to the alleged fraud (and not the portions related to Vioxx's anticipated follow-on Cox-2 inhibitor, Arcoxia, or increased liability related to personal injury suits after Vioxx's withdrawal). Had any of Defendants' arguments been accepted in whole or in part, that could have eliminated or, at a minimum, significantly limited any potential recovery.

225. Lead Plaintiffs also faced having to prove at trial that had the truth about Vioxx's CV risk been known to the market following the results of the VIGOR study, Merck would have had to withdraw Vioxx from the market or label it with a Black Box warning at that time, and that,

with a Black Box warning, Vioxx would not have been commercially viable. If Lead Plaintiffs failed to convince the jury on those points, it would significantly reduce, or eliminate, Plaintiffs' recoverable damages. At trial, Defendants would have likely argued, among other things, that: (i) Vioxx would have been commercially viable during the Class Period even if it had a Black Box warning label; (ii) the FDA and outside consultants believed in the GI benefits of Vioxx and that they outweighed any potential CV risks of the drug for many patients; and (iii) despite the fact that Pfizer's competing Cox-2 inhibitor Celebrex has a Black Box warning today, Celebrex continues to enjoy commercial sales of billions of dollars per year.

226. Indeed, Defendants repeatedly asserted that they would vigorously present their potentially dispositive arguments on damages at trial and, even if Lead Plaintiffs prevailed, on appeal. In fact, over the course of the litigation, Defendants were successful in arguing that Defendants were not liable for pre-VIGOR alleged false statements, or for damages arising from the revelations of Vioxx's CV risk in the November 1, 2004 *WSJ* article, following the withdrawal of Vioxx. The Court's findings on these issues already decreased the class's potentially recoverable damages at the time of settlement (barring any appeal by Plaintiffs which would itself be lengthy and fraught with risk).

#### **E. Other Risks**

227. In addition to these principal risks relating to establishing the required elements of liability and damages, this case also presented a number of other litigation risks related to the complex and scientific nature of the claims and the stage of the litigation.

##### **1. Risks of Jury Confusion and the Battle of Experts**

228. Succeeding at trial would have presented unique challenges given, among other things, the highly technical nature of the alleged fraud here at issue. For example, to prove their case, Lead Plaintiffs needed to establish that Merck was in possession of material, undisclosed

facts showing that the Naproxen Hypothesis lacked a reasonable basis, and that Vioxx was pro-thrombotic. The complex statistical and scientific facts supporting Lead Plaintiffs' claims might not have been easily understood by a jury and were vigorously disputed by Defendants, who offered alternative explanations that they asserted were supported by exhibits, testimony and experts.

229. Given the factual complexity of the underlying issues, at trial, there would be extensive detailed testimony from Merck's fact witnesses, as well as competing expert testimony relating to damages, loss causation and the meaning and importance of the underlying evidence relevant to scienter (including the reasonable conclusions that could be drawn from VIGOR and other Vioxx studies). While Lead Plaintiffs had spent substantial time working with their experts and on preparing the best way to explain these complicated issues to a jury at trial, there is no doubt that Defendants would also have been able to present potentially credible expert testimony on these topics. This "battle of the experts" and the resulting uncertainty as to whose expert the jury might credit created additional litigation risks here.

230. In addition, other facts and circumstances might also have threatened to confuse or improperly sway the jury. First, the FDA's repeated approval of Vioxx as "safe and effective" for sale in the United States might have led the jury to refuse to second-guess the regulator's judgment on the safety of the drug. Moreover, Vioxx's successor, the Cox-2 inhibitor Arcoxia is still sold outside the United States. There was also a risk that jurors might have been swayed by the fact that the SEC never filed a securities fraud case against Merck regarding its statements about Vioxx. Moreover, because the trial would have taken place in New Jersey, where Merck is headquartered, jurors may have been reluctant to award a large verdict against a local company that employs thousands of New Jersey residents.

## 2. Risks Presented by *Daubert* Motions

231. At the time the Settlement was reached, the parties had filed and opposed competing *Daubert* motions, in which Defendants were seeking to exclude or limit critical testimony that Lead Plaintiffs intended to offer through their experts. Had Defendants prevailed in excluding any of this testimony, the presentation of many aspects of Lead Plaintiffs' case would have been extremely difficult. Indeed, limitations on expert testimony can be devastating to a securities case.

232. For example, Defendants moved to preclude the expert opinions of Lead Plaintiffs' damages expert, Dr. Tabak. Lead Plaintiffs faced a risk of losing their ability to use Dr. Tabak's damages model due to Defendants' attack on his use of assumptions that purportedly did not "fit" the case.

233. Defendants also moved to exclude large portions of Dr. Zipes' expert opinions, such as Dr. Zipes' opinion that Merck should have withdrawn Vioxx, or labeled it with a Black Box warning, after VIGOR. Dr. Zipes was a key expert witness for Lead Plaintiffs on the complex scientific issues concerning Vioxx's CV risk. Any limitations on Dr. Zipes' pivotal testimony could have severely jeopardized the class's recovery.

234. Defendants also moved to preclude the expert opinions of Lead Plaintiffs' statistics expert, Dean Madigan. As discussed above, Dean Madigan was a key expert for Plaintiffs, and his testimony was important to establish that Defendants knew or recklessly disregarded Vioxx's CV risk years before learning the APPROVe results. Any limitations imposed on his testimony would have made proving Defendants' scienter difficult. In addition, Defendants moved to exclude the testimony of Plaintiffs' drug marketing expert witness, Mr. Boghigian. Mr. Boghigian's testimony was important to explain what the likely impact of a Black Box warning would have been on Vioxx's sales and Merck's ability to market Vioxx at all, and was therefore highly relevant to

damages issues.

235. Defendants also moved to preclude the testimony of Lead Plaintiffs' FDA expert, Dr. Kessler. Plaintiffs intended to offer Dr. Kessler's testimony to rebut Defendants' claims that, since the FDA approved Vioxx, the FDA's judgment on the safety of Vioxx and its proper labeling should not be second-guessed by the jury. Dr. Kessler would provide critical context and explanation to the jury regarding the FDA process, practical restrictions on the FDA's resources and authority at the time, and the expected role of drug manufacturers within this framework, as well as his analysis of specific Vioxx-related evidence. Limitations or restrictions on Dr. Kessler's testimony might have significantly weakened Lead Plaintiffs' counter-arguments against Defendants' FDA defense.

236. At the time of the settlement, all of Defendants' *Daubert* motions were still pending and Lead Plaintiffs still faced potential negative risks from them.

### **3. Risks Presented by Other Motions *in Limine***

237. In addition, at the time the Parties reached the Settlement, Plaintiffs had prepared draft motions *in limine* to limit certain arguments by Defendants that Plaintiffs considered improper, and Defendants had contemplated filing other *in limine* motions, in which they would seek to exclude Plaintiffs' presentation of key evidence, such as Merck's "rush to market" Vioxx, evidence of Defendant Scolnick's stock sales, evidence of the FDA's true capabilities, and testimony from important witnesses. If certain of Lead Plaintiffs' motions had been denied or if Defendants succeeded on their motions, it would have also presented enormous obstacles to Lead Plaintiffs' presentation of their claims.

238. For example, if Defendants' anticipated motion to exclude evidence concerning Defendant Scolnick's stock sales were successful, Lead Plaintiffs would not be able to proceed with evidence concerning an important motive for one of the Individual Defendants to make

alleged false statements. Moreover, if Lead Plaintiffs' motion *in limine* to preclude Defendants from introducing evidence concerning Celebrex sales had been denied, Lead Plaintiffs would have needed to present a mini-trial to the jury to distinguish Vioxx from Celebrex and show why Celebrex - an entirely different drug from Vioxx - has enjoyed some commercial success in the post-Class Period timeframe despite being labeled with a Black Box warning.

#### **4. Risks Related to the Bifurcation of Trial**

239. Particularly after the Court consolidated for trial this class action with the numerous pending direct and opt-out actions, there existed the risk that Defendants would frame the trial so as to emphasize issues that were specific to individual plaintiffs, including the numerous direct action and opt-out plaintiffs, and thereby attempt to distract jurors away from Merck's alleged misconduct. As a result, Plaintiffs focused on that risk and drafted a motion to bifurcate the common class issues to a first phase of the trial and leave the remainder of the plaintiff-specific issues to a post-liability second phase. That issue was still pending at the time of the settlement but posed a risk to Lead Plaintiffs' ability to properly frame the issues for the jury. If Lead Plaintiffs did not prevail on that motion, Defendants would be able to emphasize at trial issues specific to individual plaintiffs, including numerous opt-out plaintiffs, and thereby make success at trial more difficult.

#### **5. Risks of Post-Trial Motions and Appeal**

240. Even if Lead Plaintiffs succeeded in obtaining a class-wide judgment at trial, Defendants almost certainly would have pursued post-trial motions to overturn the verdict and an appeal. Defendants are well funded and represented by experienced counsel who would be expected to continue to mount a zealous and thorough defense to the class's claims for relief not only before and during a full trial on the merits, but afterwards, through post-trial motions and appeals. On their inevitable appeal(s), Defendants would have an opportunity not only to seek to

overturn the judgment on the jury's verdict (assuming that Lead Plaintiffs succeeded at trial) but also to revisit the legal issues they had raised in their earlier dispositive motions.

**F. The Settlement is Reasonable in Light of the Risks and the Potential Recovery in the Action**

241. Lead Plaintiffs and Co-Lead Counsel submit that the Settlement is well within the range of reasonableness in light of the best possible recovery and all the attendant risks of litigation discussed above. Had the class of Merck investors from March 27, 2000 through September 29, 2004 overcome all of the substantial litigation risks noted above and achieved a judgment that was upheld on appeal, the maximum recoverable damages would have been approximately \$13.4 billion.<sup>7</sup> This maximum estimated amount, based on the analysis of Lead Plaintiffs' damages expert, Dr. Tabak, assumes victory at trial, a 100% participation rate by all Settlement Class members in the required post-trial claims process, and recovery of damages based on declines in Merck's stock price due to three distinct causes: (i) the loss of anticipated Vioxx sales; (ii) the negative impact of Vioxx's withdrawal on the approvability of Merck's follow-on Cox-2 inhibitor, Arcoxia; and (iii) the increased personal injury litigation liability tied to Vioxx's withdrawal.

242. Another significant risk was that the Court, in its *Daubert* rulings, or the jury at trial, might determine that only the Vioxx sales component of the decline in Merck's stock price was attributable to Lead Plaintiffs' claims. If damages based on the negative impact on Arcoxia were eliminated (either at the *Daubert* stage or at trial), then maximum damages would drop to

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<sup>7</sup> The Settlement Class is broader than the Certified Class, as limited by the Court's Opinions, and includes investors with dismissed claims, who (a) acquired Merck securities during the May 21, 1999 to March 26, 2000 period or (b) suffered losses as a result of the November 1, 2014 alleged corrective disclosure. Additional recoverable damages for those two categories of loss are approximately \$4.3 billion. However, had the case gone to trial, based on the Court's prior rulings, the Certified Class would not have been able to recover any of those additional damages, which would only have been available if the Court's rulings were overturned on appeal and Plaintiffs then prevailed in a second trial



approximately \$11.9 billion. If damages based on both the impact on Arcoxia and personal injury liability were excluded, the maximum damages would be approximately \$9.5 billion. Accordingly, the \$1.062 billion total Settlement represents approximately 8% to 11.2% of estimated potential maximum damages, assuming Lead Plaintiffs prevailed on all questions of liability and all class members who could claim did claim. However, assuming 100% or full class participation in estimating individual class member recoveries in the Settlement is too conservative – particularly here, given the long pendency of the case – and thus claimants who do participate in the Settlement by filing valid proofs of claim can expect to recover a higher percentage of their damages. Moreover, as noted above, Defendants’ potential arguments that Vioxx would have continued to be commercially viable even with a Black Box warning might further have reduced the potential damages that could be established based on the loss of Vioxx sales.

243. Moreover, as discussed above, if a jury or the Court had credited even some of Defendants’ arguments with respect to liability, the class might have recovered significantly less or even nothing. Given those substantial risks, Co-Lead Counsel believe that the Settlement is a favorable outcome for the Settlement Class and fair, reasonable and adequate to the Settlement Class.

**V. LEAD PLAINTIFFS’ COMPLIANCE WITH THE COURT’S PRELIMINARY APPROVAL ORDER REQUIRING ISSUANCE OF NOTICE**

244. The Preliminary Approval Order directed that the Notice of (I) Proposed Settlement and Plan of Allocation; (II) Settlement Fairness Hearing; and (III) Motion for an Award of Attorneys’ Fees and Reimbursement of Litigation Expenses (the “Settlement Notice”) and Proof of Claim and Release Form (“Claim Form”) be disseminated to the Settlement Class; set deadlines for Settlement Class Members to submit objections to the Settlement, the Plan of Allocation and/or the Fee and Expense Application, request exclusion from the Settlement Class or opt back into the

Settlement Class; and set a final approval hearing date of June 28, 2016. ECF No. 951.

245. The Preliminary Approval Order also authorized Co-Lead Counsel to retain Epiq Class Action & Claims Solutions, Inc. (“Epiq”) as the Claims Administrator in the Action and ordered Epiq to cause copies of the Court-approved Settlement Notice and Claim Form (together, the “Settlement Notice Packet”) to be mailed to potential Settlement Class Members within 25 business days after the entry of the Preliminary Approval Order. The Preliminary Approval Order also ordered that the Settlement Notice and Claim Form be published on the website designated for this Action, [www.merckvioxsecuritieslitigation.com](http://www.merckvioxsecuritieslitigation.com), contemporaneously with the mailing of the Notice Packet, and that the Summary Notice be published once in *The Wall Street Journal* and three times over internet newswires not later than 20 calendar days after the mailing of the Notice Packet.

246. A description of the terms of the Settlement and the proposed Plan of Allocation are set forth in the Settlement Notice, which also provides potential Settlement Class Members with, among other things, a description of their right to object to any aspect of the Settlement, the Plan of Allocation, and/or Co-Lead Counsel’s request for an award of attorneys’ fees and reimbursement of litigation expenses and the manner for submitting a Claim Form in order to be eligible to receive a payment from the Settlement. The Settlement Notice informs Settlement Class Members of Co-Lead Counsel’s intention to apply for an award of attorneys’ fees in the amount not to exceed 20% of the Settlement Funds,<sup>8</sup> and for reimbursement of litigation expenses paid or incurred in connection with the prosecution and resolution of the Action, as well as PSLRA awards, in an amount not to exceed \$19 million. The Settlement Notice informs members of the

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<sup>8</sup> The Settlement Funds is described as \$1.062 billion, the sum of the \$830 million Settlement Class Fund and the \$323 million Fee/Expense Fund, plus interest on those amounts.

Settlement Class who were not members of the previously certified Certified Class (*i.e.*, persons and entities whose only purchases or acquisitions of Merck Common Stock or Merck Call Options, or sales of Merck Put Options during the Settlement Class Period occurred from September 30, 2004 through October 29, 2004) of their right to request exclusion and the manner and deadline for doing so.<sup>9</sup> The Settlement Notice also informs recipients that if they previously submitted a request for exclusion in connection with the Certified Class Notice that they may elect to opt back into the Settlement Class and be eligible to receive a payment from the Settlement, and sets forth the manner and deadline for doing so.

247. As set forth in the Declaration of Stephanie A. Thurin Regarding (A) Mailing of the Claim Packet; (B) Publication of the Summary Settlement Notice; and (C) Report on Requests for Exclusion Received to Date (“Thurin Decl.”) attached as Exhibit 2 hereto, on or before March 18, 2016, Epiq disseminated 1,341,133 copies of the Settlement Notice Packet to potential Settlement Class Members and nominees by first-class mail. *Id.* ¶ 8. As of April 28, 2016, a total of 1,907,361 Settlement Notice Packets had been mailed to potential Settlement Class Members and nominees. *Id.* ¶ 10.

248. In accordance with the Preliminary Approval Order, Epiq caused the Summary Notice to be published in *The Wall Street Journal* and transmitted over the *PR Newswire* on March

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<sup>9</sup> The Certified Class Notice was previously mailed to potential members of the Certified Class in September 2013 to notify them of, among other things: (i) the Action pending against the Defendants; (ii) the Court’s certification of the Action to proceed as a class action on behalf of the Certified Class; and (iii) their right to request to be excluded from the Certified Class, the effect of remaining in the Certified Class or requesting exclusion, and the requirements for requesting exclusion. As set forth on Appendix 1 to the Stipulation, 516 requests for exclusion were received in connection with the Certified Class Notice. In the Preliminary Approval Order, the Court determined that “there shall not be a second opportunity for Settlement Class Members who were also members of the Certified Class to exclude themselves from the Settlement Class.” ECF No. 951, at ¶ 15.

29, 2016, to be transmitted over the *Business Wire* on March 31, 2016 and over *Globe Newswire* on April 5, 2016. See Thurin Decl. at ¶ 11.

249. The Court-ordered deadline for Settlement Class Members to file objections to the Settlement, the Plan of Allocation and/or the Fee and Expense Application or to request exclusion from the Settlement Class (if eligible to do so) is May 14, 2016. To date, 8 objections to the Settlement have been received. As the deadline for submitting objections has not passed, Co-Lead Counsel will address all objections, including the 8 objections received to date, in their reply papers to be filed with the Court on May 24, 2016.

## **VI. ALLOCATION OF THE PROCEEDS OF THE SETTLEMENT**

250. Pursuant to the Preliminary Approval Order, and as set forth in the Notice, all Settlement Class Members who would like to participate in the distribution of the Net Settlement Fund<sup>10</sup> must submit a valid Claim Form with all required information postmarked no later than September 12, 2016. As set forth in the Notice, the Net Settlement Fund will be distributed among Settlement Class Members according to the plan of allocation approved by the Court.

251. Lead Plaintiffs' damages expert developed the proposed Plan of Allocation in consultation with Co-Lead Counsel. The objective of the Plan of Allocation is to equitably distribute the Net Settlement Fund to those Settlement Class Members who suffered economic losses as a proximate result of the wrongdoing alleged in the Action. Co-Lead Counsel believe that the Plan of Allocation provides a fair and reasonable method to equitably allocate the Net Settlement Fund among those Settlement Class Members.

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<sup>10</sup> The Net Settlement Fund is defined as the Settlement Class Fund less: (i) any Taxes owed by the Settlement Class Fund and (ii) any Notice and Administration Costs, *plus* any amount credited from the Fee/Expense Fund after the Court's award of attorneys' fees and Litigation Expenses and after payment of the fees of the Special Master appointed by the Court regarding the award of attorneys' fees and expenses and any Taxes owed by the Fee/Expense Fund.

252. The Plan of Allocation is set forth at pages 9 to 15 of the Settlement Notice. *See* Thurin Decl. Ex. A at pp. 9-15. As described in the Settlement Notice, calculations under the Plan of Allocation are not intended to be estimates of, nor indicative of, the amounts that Settlement Class Members might have been able to recover at trial or estimates of the amounts that will be paid to Authorized Claimants pursuant to the Settlement. Instead, the calculations under the plan are only a method to weigh the claims of Settlement Class Members against one another for the purposes of making an equitable allocation of the Net Settlement Fund.

253. Under the Plan of Allocation, a Claimant's Recognized Claim is calculated based on the estimated artificial inflation in the prices paid for Merck Common Stock and Merck Call Options or artificial deflation in the prices received for Merck Put Options on each day during the Settlement Class Period, as determined by Lead Plaintiffs' damages expert. Lead Plaintiffs' damages expert reviewed publicly available information regarding Merck and performed statistical analyses of the price movements of Merck Common Stock, Merck Put Options and Merck Call Options and the price performance of relevant market and peer indices during the Settlement Class Period and calculated the alleged artificial inflation or deflation by isolating the losses in the Merck Securities that resulted from the alleged violations of the federal securities laws, eliminating losses attributable to market factors, industry factors, or Company-specific factors unrelated to the alleged violations of law, and adjusting for the strength of the claims asserted in the Action. The amount of artificial inflation in Merck Common Stock on each day of the Settlement Class Period is set forth in a table attached to the Settlement Notice, and the artificial inflation and deflation in Merck Call Option and Put Options are set forth in tables available to Settlement Class Members on the settlement website.

254. Recognized Loss Amounts are calculated under the Plan of Allocation based

primarily on the difference in the amount of alleged artificial inflation (or deflation in the case of Put Options) in the Merck Securities at the time of purchase or acquisition and the time of sale. In order to have a Recognized Loss Amount, a Settlement Class Member who purchased or acquired Merck Securities (or wrote Put Options) from May 21, 1999 through September 29, 2004, must have held those Merck Securities through at least the close of trading on September 29, 2004, and with respect to Common Stock or Call Options contracts purchased/acquired and Put Options contracts sold from September 30, 2004 through October 29, 2004, those securities must have been held through at least the close of trading on October 29, 2004. For securities purchased and sold before the first corrective disclosure date, or purchased and then sold between the two disclosures there is no recovery because any loss suffered by that investor would not have been caused by the alleged fraud.

255. The Plan of Allocation includes two adjustments to reflect the relative weakness of certain claims that were dismissed by the Court, but that are nevertheless being compensated under the Settlement. First, to account for the Court's dismissal of all claims arising from the alleged November 1, 2004 corrective disclosure, the change in artificial inflation attributable to the November 1, 2004 corrective disclosure has been reduced by 90%. Second, to account for the Court's dismissal of claims related to alleged misstatements made by Defendants before March 27, 2000, the Recognized Loss Amounts and Recognized Gain Amounts for Merck Common Stock purchased or acquired from May 21, 1999 through March 26, 2000 is 10% of the Recognized Loss or Gain Amount that would otherwise be calculated for those transactions. Otherwise, the Plan of Allocation uses inflation amounts and methodology the same as Plaintiffs would have offered at trial.

256. Claimants can also have a Recognized Gain Amount on certain transactions if, for

example, they purchased Merck Common Stock and then sold it during the Settlement Class Period at a time when the alleged artificial inflation was greater on the date of sale than the date of purchase. A Claimant's Recognized Gain Amounts, if any, will be offset against his, her or its Recognized Loss Amounts to determine the Claimant's Net Recognized Loss Amount. In addition, the Claims Administrator will determine whether a Claimant had an overall market gain or loss on the Claimant's transactions in Merck Securities during the Settlement Class Period and, if a Claimant had a market gain from his, her or its overall transactions in Merck Securities during the Settlement Class Period, the Claimant will not be eligible to recover. To the extent that a Claimant suffered an overall market loss but that loss was less than the Claimant's Net Recognized Loss Amount calculated under the Plan, the Claimant's Recognized Claim shall be limited to the amount of his actual market loss.

257. The Net Settlement Fund will be allocated to Authorized Claimants on a *pro rata* basis based on the relative size of their Recognized Claims.

258. In sum, the Plan of Allocation was designed to fairly and rationally allocate the proceeds of the Net Settlement Fund among Settlement Class Members based on the losses they suffered on transactions in Merck Securities that were attributable to the conduct alleged in the Action. Accordingly, Co-Lead Counsel respectfully submit that the Plan of Allocation is fair and reasonable and should be approved by the Court.

## **VII. THE FEE AND EXPENSE APPLICATION**

259. In addition to seeking final approval of the Settlement and Plan of Allocation, Co-Lead Counsel are making an application to the Court for a collective award of attorneys' fees on behalf of all Plaintiffs' Counsel, and reimbursement of litigation expenses incurred during the course of the Action.

260. With the approval of Lead Plaintiffs, Co-Lead Counsel are applying for a fee award

of 20% of the Settlement Funds (*i.e.*, \$212,400,000 plus interest accrued thereon) on behalf of all Plaintiffs' Counsel (the "Fee Application"). Co-Lead Counsel also request reimbursement in the amount of \$9,473,356.02 from the Settlement Fund for litigation expenses paid or incurred in connection with the prosecution and resolution of the Action. The total amount of out-of-pocket expenses requested for reimbursement together with the costs and expenses of the Lead Plaintiffs (*i.e.*, \$9,582,068.52) is well below the maximum expense amount of \$19 million set forth in the Settlement Notice.

261. The legal authorities supporting the requested fees and expenses are set forth in the accompanying Fee Memorandum. The primary factual bases for the requested fees and expenses are summarized below.

**A. The Requested Fee is Fair and Reasonable**

262. Based on the extensive efforts expended on behalf of the Settlement Class in over 12 years of litigation, the extraordinary result achieved, the substantial risks of the litigation and the contingent nature of their representation, Co-Lead Counsel submit that the request for an award of attorneys' fees in the amount of 20% of the Settlement Funds is justified and should be approved. As set forth in the accompanying Fee Memorandum, the requested 20% award, and the resulting very modest multiplier of the lodestars reported by all plaintiffs' counsel of approximately 1.03, are both within the range of fee awards in other class action litigation and are justified here in light of the extent and quality of counsel's work.

**1. The Significant Time and Labor Devoted to the Action**

263. The work undertaken by Co-Lead Counsel in investigating and prosecuting this case and arriving at the present Settlement in the face of substantial risks has been time-consuming and challenging. As more fully set forth above, the Action settled only after Co-Lead Counsel overcame multiple legal and factual challenges, including an appeal to the U.S. Supreme Court,



the completion of extensive fact and expert discovery, including 59 depositions and the review of over 35 million pages of documents, numerous rounds of dispositive motions, and significant trial preparation and pre-trial motion practice.

264. At all times throughout the pendency of the Action for a period of over 12 years, Co-Lead Counsel's efforts were driven and focused on advancing the litigation to bring about the most successful outcome for the class, whether through settlement or trial. The substantial time and expense expended here have achieved precisely such an outcome, and accordingly, this factor weighs strongly in favor of Co-Lead Counsel's Fee Application.

**2. A Lodestar Cross-Check Confirms the Reasonableness of the Fee Application**

265. As described in the Fee Memorandum, the requested fee percentage is not only fair and reasonable under the percentage method but, based on the lodestars reported by plaintiffs' counsel, a lodestar cross-check confirms the reasonableness of the fee.

266. Attached hereto as Exhibit 3A to 3S are declarations from all plaintiffs' counsel in support of the request for an award of attorneys' fees and reimbursement of litigation expenses. Included with each firm's declaration is a schedule that summarizes the lodestar reported by each firm, as well as the expenses incurred by category (the "Fee and Expense Schedules"). In particular, the attached declarations and the Fee and Expense Schedules contained within each report the amount of time spent on this case by each attorney and professional support staff employed by plaintiffs' counsel through February 15, 2016, and the lodestar calculations based on their current billing rates. For attorneys or professional support staff who are no longer employed by plaintiffs' counsel, the lodestar calculations are based upon the billing rates for such person in his or her final year of employment. The first page of Exhibit 3 is a chart that collects the information set forth in the plaintiffs' counsel's declarations, listing the reported hours expended,

lodestar amounts and litigation expenses for each plaintiffs' counsel's firm, based on the data provided in its declaration, and gives totals for the numbers provided.<sup>11</sup> Further detail about the work reported in the Action by each of the plaintiffs' counsel firms is set forth in each of the firm's respective individual declarations attached hereto as Exhibits 3A to 3S.

267. As summarized in Exhibit 3 hereto, plaintiffs' counsel report a total of 448,502.72 hours in the investigation, prosecution and resolution of the Action. The resulting total lodestar is \$205,611,776.90. The vast majority of the total reported lodestar – 93% – is reported by Co-Lead Counsel.<sup>12</sup>

268. The requested 20% fee equals \$212.4 million and therefore, under the lodestar approach, the requested fee yields a multiplier of approximately 1.03 on the reported lodestar. We believe such a multiplier is fair and reasonable based on the risks of the litigation, the quality of the representation, the excellent results obtained, and awards in similar cases. Indeed, as discussed in the Fee Memorandum, the requested multiplier is at the very low end of the range of multipliers typically awarded by Courts in this Circuit and nationwide in cases involving significant contingency fee risk and settlements of similar magnitude. *See* Fee Memorandum at 10-12.

### **B. The Quality of Co-Lead Counsel's Representation**

269. A number of considerations may be relevant to assessing the quality of class counsel's representation of a plaintiff class, including the Court's own observations, class counsel's experience and standing at the bar, and the quality of opposing counsel. Ultimately,

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<sup>11</sup> Through each declaration, each firm is reporting its own firm's respective attorneys' time and expenses.

<sup>12</sup> Co-Lead Counsel will continue to perform legal work on behalf of the Settlement Class should the Court approve the proposed Settlement. Additional resources will be expended assisting Settlement Class Members with their Claim Forms and related inquiries and working with the Claims Administrator, Epiq, to ensure the smooth progression of claims processing.

however, the acid test for evaluating “quality of the representation” is the quality of the results achieved for the class members whom counsel were appointed to represent.

**1. The Excellent Results Obtained from Co-Lead Counsel’s Efforts**

270. Here, for the reasons previously detailed above, Co-Lead Counsel respectfully submit that the Settlement Funds, consisting of an aggregate of \$1.062 billion in cash is an extraordinary result for the Settlement Class. Indeed, the result achieved for the Settlement Class reflects the superior quality of Co-Lead Counsel’s representation. Reached after twelve years of dedicated effort that included a successful 9-0 appeal to the Supreme Court of the United States, and less than three months before trial, the Settlement is the result of Co-Lead Counsel’s hard work, persistence and skill in a case that presented significant litigation risks.

**2. The Court’s Observations as to the Quality of Co-Lead Counsel’s Work**

271. The Court may, of course, also take into account its own observations of the quality of Co-Lead Counsel’s representation during the course of this litigation. Co-Lead Counsel have appeared on multiple occasions before the Court, and the Court has reviewed numerous letters to the Court, motions and briefing submitted by Co-Lead Counsel, including, *inter alia*, several detailed amended complaints, briefing in opposition to Defendants’ two rounds of motions to dismiss, briefing in support of class certification, briefing in opposition to Defendants’ motions for judgment on the pleadings and for summary judgment, and the numerous submissions in connection with pre-trial motions and both preliminary and final approval of the Settlement. Although this work represents only a fraction of the total work performed by Co-Lead Counsel throughout the pendency of the Action, Co-Lead Counsel respectfully submit that the quality of that work is reflective of the quality, thoroughness and professionalism of the effort that Co-Lead Counsel have devoted to all aspects of this Action.

### **3. The Standing and Expertise of Co-Lead Counsel**

272. Co-Lead Counsel are highly experienced in prosecuting complex litigation, particularly securities class actions, and worked diligently and efficiently in prosecuting this Action. As demonstrated by the firm resumes attached to their respective declarations (*see* Exhibits 3A, 3B, 3C and 3D hereto), Co-Lead Counsel are among the most experienced and skilled firms in the securities litigation field, and each firm has a long and successful track record in securities cases throughout the country.

### **4. Standing and Caliber of Defense Counsel**

273. The quality of the work performed by Co-Lead Counsel in attaining the Settlement should also be evaluated in light of the quality of the opposition. Here, Defendants were represented by Cravath, Swaine & Moore LLP, Paul, Weiss, Rifkind, Wharton & Garrison LLP, Schulte Roth & Zabel LLP, and Hughes Hubbard & Reed LLP. These firms vigorously represented the interests of their respective clients. In the face of this experienced, formidable, and well-financed opposition who aggressively litigated the Action on behalf of their clients until the “eve” of trial, Co-Lead Counsel were nonetheless able to persuade Defendants to settle the case on terms highly favorable to the Settlement Class – a fact which makes Co-Lead Counsel’s success here all the more impressive.

## **C. The Risks and Unique Complexities of the Litigation**

### **1. The Risks Undertaken By Co-Lead Counsel in Pursuing this Action**

274. This Action presented exceedingly novel procedural and substantive legal challenges from the outset. As discussed in Section IV above, Co-Lead Counsel were required to contend with, among other things, very serious obstacles to proving scienter and falsity and serious loss causation and damages issues, all of which arose in a factually complicated context that required substantial work with complex scientific and statistical issues.

## **2. The Risks of Contingent Litigation**

275. As a general matter, it should be observed that there are numerous cases where plaintiffs' counsel in contingent-fee cases such as this have expended thousands of hours, only to receive no compensation whatsoever. This prosecution was undertaken by Co-Lead Counsel on a contingent-fee basis, and the risks assumed by Co-Lead Counsel (as described above), and the time and expenses incurred without any payment (as described above), were substantial.

276. From the outset, Co-Lead Counsel understood that they were embarking on a complex, expensive and lengthy litigation with no guarantee of ever being compensated for the substantial investment of time and money the case would require. In undertaking that responsibility, Co-Lead Counsel were obligated to ensure that sufficient resources were dedicated to the prosecution of the Action, and that funds were available to compensate staff and to cover the considerable costs that a case such as this requires. With an average lag time of several years for cases of this type to conclude, the financial burden on contingent-fee counsel is far greater than on a firm that is paid on an ongoing basis. Indeed, plaintiffs' counsel have worked over a span of a dozen years and have received no compensation during the course of the Action and have advanced or incurred over \$9 million in expenses in prosecuting the Action for the benefit of the Settlement Class.

277. Co-Lead Counsel also bore the risk that no recovery would be achieved. As discussed herein, from the outset, this case presented multiple risks and uncertainties that could have prevented any recovery whatsoever.

278. Moreover, for decades the U.S. Supreme Court (and many lower courts) have repeatedly and consistently recognized that it is in the public interest to have experienced and able counsel enforce the securities laws and regulations pertaining to the duties of officers and directors of public companies. Indeed, as recognized by Congress through the passage of the PSLRA,

vigorous private enforcement of the federal securities laws can only occur if private investors, particularly institutional investors, take an active role in protecting the interests of shareholders. If this important public policy is to be carried out, courts should award fees that adequately compensate plaintiffs' counsel, taking into account the risks undertaken in prosecuting a securities class action.

279. The risks assumed by Co-Lead Counsel in connection with the Action, and the time and expenses incurred without any payment, were extensive. Co-Lead Counsel's persistent efforts in the face of substantial risks and uncertainties have resulted in a very significant recovery for the benefit of the Settlement Class. In circumstances such as these, and in consideration of Co-Lead Counsel's hard work and the extraordinary result achieved, the requested fee of 20% of the Settlement Amounts and reimbursement of \$9,473,356.02 in expenses, as detailed below, is reasonable and should be approved.

**D. The Reaction of the Settlement Class to the Fee Application**

280. In accordance with the Preliminary Approval Order, more than 1.9 million Notice Packets have been mailed to potential Settlement Class Members and nominees advising them that Co-Lead Counsel would seek an award of attorneys' fees in the amount of 20% of the Settlement Amounts and reimbursement of expenses paid or incurred in connection with the prosecution and resolution of the Action in an amount not to exceed \$19 million. *See* Thurin Decl. ¶ 10. Additionally, the Court-approved Summary Notice was published in *The Wall Street Journal* on March 29, 2016 and transmitted over three internet newswires from March 29, 2016 through April 5, 2016. *Id.* at ¶ 11. The Settlement Notice, Claim Form and other important documents related to the Action and the Settlement, including the Stipulation, have also been posted on the website for this Action, [www.merckvioxxsecuritieslitigation.com](http://www.merckvioxxsecuritieslitigation.com), where they can be accessed and downloaded by Settlement Class Members or other interested individuals. *Id.* at ¶ 15. As noted

above, the deadline set by the Court for Settlement Class Members to object to the amount of attorneys' fees and expenses set forth in the Settlement Notice is May 14, 2016 and that date has not yet passed. To date, Co-Lead Counsel are aware of only 2 objections to the amount of fees set forth in the Settlement Notice. Co-Lead Counsel will address all objections received in their reply papers to be filed with the Court on May 24, 2016.

**E. The Reimbursement of the Requested Expenses is Reasonable**

281. Co-Lead Counsel also seek reimbursement from the Fee/Expense Fund for litigation expenses that were reasonably incurred by plaintiffs' counsel in connection with commencing, prosecuting and resolving the claims asserted in the Action against Defendants in the total aggregate amount of \$9,473,356.02.

282. From the beginning of the case, Co-Lead Counsel were aware that they might not recover any of their expenses, and, at the very least, would not recover any of their out-of-pocket expenses until the Action was successfully resolved. Thus, Co-Lead Counsel were motivated to, and did, take significant steps to minimize expenses whenever practicable without jeopardizing the vigorous and efficient prosecution of the case.

283. As set forth in the Fee and Expense Schedules (attached to Exhibit 3 hereto), plaintiffs' counsel have reported a total of \$9,473,356.02 in unreimbursed litigation expenses in connection with the prosecution of the Action for which they are seeking reimbursement. Plaintiffs' counsel's expenses are set forth in detail in each of the firms' respective declarations, each of which identifies the specific category of expense, *e.g.*, online legal and factual research, experts' fees, out-of-town travel costs, the costs of document management and litigation support, photocopying, telephone, fax and postage expenses, and other costs actually incurred for which Co-Lead Counsel seek reimbursement. A summary chart of all plaintiffs' counsel's reported expenses by category is attached hereto as Exhibit 4.

284. Of the total amount of expenses, over \$4.5 million, or approximately 48%, was expended on experts and consultants. As discussed above, Lead Plaintiffs retained and Co-Lead Counsel worked extensively with the following experts: (i) Dr. David Tabak, Lead Plaintiffs' expert in economics and damages, who testified concerning the efficiency of the market for Merck Securities, loss causation issues and damages, and helped prepare Lead Plaintiffs' Plan of Allocation; (ii) Dr. Douglas Zipes, an expert in cardiology and pharmacology; (iii) Dean David Madigan, an expert in statistics and biostatistics; (iv) Dr. Mark Woodward, an expert in biostatistics and epidemiology; (v) Dr. David A. Kessler, a former Commissioner of the FDA, who testified as an expert on FDA-related matters; (vi) Mr. Harry C. Boghigian, an expert in pharmaceutical marketing and sales; and (vii) Dr. David Y. Graham, Lead Plaintiffs' rebuttal expert in gastroenterology. These experts were essential to the overall prosecution of the Action. Notably, in addition to the individual Defendants and the availability of Merck's employees, many of whom are undeniably experts in their fields, to Co-Lead Counsel's knowledge, Defendants retained nine experts in the course of the Action. The need to join issue with, and rebut, Defendants and their experts was essential to Lead Plaintiffs' success in this Action. In addition to consulting with Co-Lead Counsel in developing the case, Lead Plaintiffs' experts produced a total of 13 expert reports and all seven of these experts were deposed by Defendants. Co-Lead Counsel also retained other experts that served only a consulting role, rather than testifying role in the Action.

285. Another large component of the expenses, \$1,654,795.25 or approximately 17% of the total expense amount related to document review and production and litigation support. Co-Lead Counsel had to retain the services of vendors to, among other things, (i) maintain the electronic database through which the millions of pages of documents produced were reviewed; (ii) have documents processed so that they would be in searchable format; (iii) convert and upload



hard documents so that they would be electronically searchable; and (iv) produce documents to Defendants in response to their document requests on the Lead Plaintiffs. Co-Lead Counsel also retained a trial consulting firm to conduct mock trials, analyze the results of the deliberations of mock jurors, and prepare deposition excerpts and exhibits for trial.

286. Another \$713,228.59, or approximately 7.5%, was expended on costs of retaining specialized and local counsel. The largest expense in this category was the retention of specialized Supreme Court counsel, which was paid on an hourly and non-contingent basis and ultimately billed a total of over \$530,000 for its time. The retention of this well-qualified, specialized Supreme Court counsel was a wise investment for the class as the counsel's work contributed critically to Lead Plaintiffs' unanimous victory at the Supreme Court, allowing the entire case to be resurrected following its dismissal in the District Court. This category also includes non-contingent fees paid to local counsel in certain foreign jurisdictions to aid with service of process and other matters in those jurisdictions.

287. Another large component of the litigation expenses was for online legal and factual research, which was necessary to prepare the complaint filed in the Action, research the law pertaining to the claims asserted, oppose Defendants' motions to dismiss and motions for summary judgment, and brief numerous other motions during the course of the litigation. The charges for on-line research amounted to \$1,039,578.70, or 11% of the total amount of expenses.

288. Additionally, Co-Lead Counsel paid \$109,605.37 for mediation fees assessed by the mediator in this matter, Judge Phillips.

289. The other expenses for which plaintiffs' counsel claim reimbursement are the types of expenses that are typically incurred in litigation and routinely charged to clients billed by the hour. These expenses include, among others, court fees, costs of service of process, costs of out-

of-town travel, copying costs, long distance telephone and facsimile charges and postage and delivery expenses.

290. The expenses reported by plaintiffs' counsel, which total \$9,473,356.02, were necessary to the successful investigation, prosecution and resolution of the claims asserted in the Action against Defendants.

291. The Settlement Notice informed potential Settlement Class Members that Co-Lead Counsel would be seeking reimbursement of expenses in an amount not to exceed \$19 million and that the costs and expenses of Lead Plaintiffs could be sought as part of the request for reimbursement of Litigation Expenses. Even if the requested PSLRA awards sought by Lead Plaintiffs Miss. PERS (\$98,712.50) and Haber (\$10,000) are added to the request of plaintiffs' counsel (*i.e.*, \$9,582,068.52), the total amount is still significantly below the \$19 million that Class Members were advised could be sought. To date, no objection has been raised as to the maximum amount of Litigation Expenses set forth in the Settlement Notice, including the amount sought to be reimbursed to the Lead Plaintiffs.

292. Co-Lead Counsel respectfully submit that the expenses incurred by plaintiffs' counsel are fair and reasonable and should be reimbursed in full.

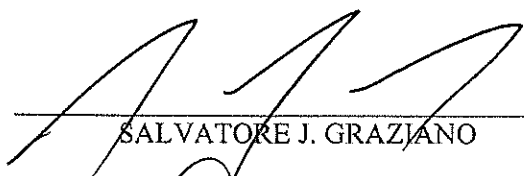
## **VIII. CONCLUSION**

293. In view of the significant recovery to the Settlement Class and the very substantial risks of this litigation, as described above and in the accompanying Settlement Memorandum, Co-Lead Counsel respectfully submit that the Settlement should be approved as fair, reasonable and adequate and that the proposed Plan of Allocation should be approved as fair and reasonable. In addition, based on the significant recovery in the face of substantial risks; the efforts of Co-Lead Counsel; the novel issues faced; the quality of work performed; the contingent nature of the fee; the complexity of the case; and the standing and experience of Co-Lead Counsel, as described

above and in the accompanying Fee Memorandum, Co-Lead Counsel respectfully submit that a fee in the amount of 20% of the Settlement Amounts should be awarded to Plaintiffs' Counsel; and that litigation expenses in the amount of \$9,473,356.02 should be reimbursed in full.

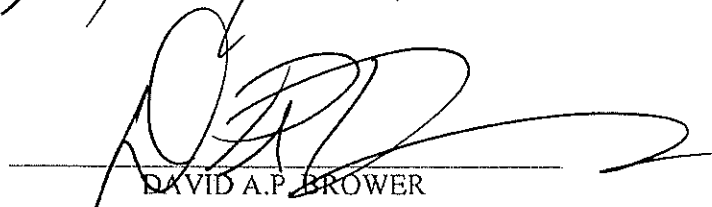
We each declare, under penalty of perjury under the laws of the United States, that the foregoing is true and correct to the best of our knowledge.

Dated: April 28, 2016  
New York, New York



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SALVATORE J. GRAZIANO



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DAVID A.P. BROWER



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MATTHEW A. KUPILLAS



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MARK LEVINE