



## OUTSIDE COUNSEL

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### *Potential Securities Fraud: 'Storm Warnings' Clarified*

In a securities fraud action, the statute of limitations begins to run when the shareholder has either actual or inquiry notice—the latter triggered by “storm warnings”—that the defendant made a fraudulent misrepresentation.<sup>1</sup>

Earlier this month, a split panel of the U.S. Court of Appeals for the Third Circuit reversed a lower court's decision to dismiss a securities class action filed against Merck & Co. (Merck) on the grounds that it was time-barred.<sup>2</sup> In holding that the shareholders' claims were timely filed, the court clarified a significant ambiguity in its inquiry-notice jurisprudence, i.e., whether a shareholder's duty to investigate potential fraud is triggered by evidence of possible or probable wrongdoing. While the Court held that evidence of possible wrongdoing suffices, the opinion makes clear that something more than a theoretical possibility is required.

#### **Factual Background**

In May 1999, the Food and Drug Administration (FDA) approved Merck's Vioxx, a nonsteroidal anti-inflammatory drug (NSAID) used in the treatment of arthritis and other acute pain. Most NSAIDs, such as aspirin, ibuprofen, and naproxen, function by inhibiting two enzymes: (i) cyclooxygenase-1 (COX-1), which is associated with the maintenance of gastrointestinal (GI) mucus and platelet aggregation, and (ii) cyclooxygenase-2 (COX 2), which is associated with the response to pain and inflammation. The inhibition of COX-1 leads to harmful GI side effects. Because Vioxx was designed to suppress COX-2 without affecting COX-1, Merck marketed Vioxx as possessing the benefits of traditional NSAIDs without the harmful GI side effects.

Prior to FDA approval, Merck commenced the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, which compared Vioxx to naproxen, the active ingredient in brand-name



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pain relievers such as Aleve and Naprosyn. Although the study showed that Vioxx had a GI safety profile superior to that of naproxen, it also showed that Vioxx users had a higher incidence of cardiovascular (CV) events than naproxen users. Merck disclosed the results of the VIGOR study in a press release on March 27, 2000, which emphasized Vioxx's superior GI safety profile but also noted the increased incidence of CV events. Significantly, the press release attributed the CV results to the beneficial effects of naproxen's blocking of platelet aggregation rather than to any harmful effects of Vioxx (Naproxen Hypothesis).

The VIGOR study results were widely reported in the press, medical journals, and securities analyst reports. Many analysts noted that the key issue with the Naproxen Hypothesis was whether naproxen lowered heart attack risk or whether Vioxx increased it. While many analysts noted that the Naproxen Hypothesis was unproven, some concluded that it was the most likely explanation for the increased CV events observed in the VIGOR study. Ultimately, the Naproxen Hypothesis proved incorrect, and Merck voluntarily withdrew Vioxx from the market in September 2004 over safety concerns.

#### **Procedural History**

On Nov. 6, 2003, shareholders filed the first of several securities fraud class action complaints a few weeks after the media reported: (i) results from a Harvard study that found an increased risk of heart attacks among Vioxx users; and (ii) significantly declining Vioxx sales. The

complaint alleged that Merck and certain of its directors and officers intentionally misrepresented the safety profile and commercial viability of Vioxx. Upon defendants' motion, the district court dismissed all shareholder claims as being time-barred, holding that shareholders were on inquiry notice of the alleged fraud more than two years before they filed suit (i.e., prior to Nov. 6, 2001).<sup>3</sup>

#### **Relevant Standard**

The court of appeals agreed that all of the claims would be untimely if shareholders should have known of the basis of their claims prior to Nov. 6, 2001. Before conducting a factual analysis, though, the court first needed to resolve whether inquiry notice is triggered by evidence of possible or probable wrongdoing. Acknowledging that the court's precedent contained language supporting both formulations,<sup>4</sup> the court held that “probability, in the sense of a nearly certain likelihood, of wrongdoing is not necessary to trigger storm warnings in this circuit.” Thus, the issue of whether shareholders, “in the exercise of reasonable diligence, should have known of the basis for their claims depends on whether they had sufficient information of possible wrongdoing to place them on inquiry notice or to excite storm warnings of culpable activity.”<sup>5</sup>

That being said, “possible wrongdoing” is not to be interpreted in the literal sense. The court reviewed the information set forth by the parties “with an eye toward the practical effect of drawing the inquiry notice line at a particular date. In this vein, [the court] emphasized that undergirding the inquiry notice analysis is the assumption that a plaintiff either was or should have been able, in the exercise of reasonable diligence, to file an adequately pled securities fraud complaint as of an earlier date.”

#### **Storm Warnings Analysis**

The court recognized—and practitioners should take note—that the characterization of the basis of the claims affects the inquiry notice analysis. For example, the circuit court reversed the district court's finding that five classes of information,

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