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The Need for Kaleidoscopic Views in Strategic Management

Paul J.H. Schoemaker – The Wharton School – June 23, 2023

ABSTRACT

Many strategic analyses favor a single discipline approach over multi-disciplinary examinations which risks intellectual balkanization in the field of strategy. The more complex and long term a real-world strategic analysis is, the more integrated perspectives will be needed to develop a complete picture descriptively and prescriptively. As an illustration, I examine how the pharmaceutical giant Merck developed an innovative drug called Vioxx for arthritis pain during the 1990s. The long arc of this multi-facetted case raises epistemic questions for the field of strategic management about how to develop holistic perspectives of complex real-world business situations. My Vioxx analysis shows that organizational contexts, mental models, personal agendas, leadership dynamics and other factors played key roles in this protracted saga, with important lessons for managers in other industries. This case underscores the need for more kaleidoscopic approaches in the field of strategy research to counter disciplinary fragmentation.

The pharmaceutical giant Merck and Co developed an innovative drug Vioxx for arthritis during the early1990s and marketed it aggressively up to its sudden withdrawal from the global market in 2004. The drug's evolution entailed complex scientific, medical, regulatory, legal, marketing and ethical issues. Not all were handled well, eventually resulting in excessive patient deaths, mega lawsuits and damage estimates as high as $50 billion for Merck. This complex Vioxx story requires multiple perspectives to discern the primary drivers of the organizational and strategic failures that ensued. The case will be examined across three stages covering (i) pre-drug launch deliberations, (ii) Merck's tactics and decisions post FDA approval, and (iii) fending off critics until Vioxx's withdrawal globally. One key challenge is that complex cases like Vioxx will not easily yield to a single discipline analysis. Incomplete data, limited experimental controls, and complex dynamics over a decade make conclusive scientific proof elusive in case studies like

Vioxx. Interdisciplinary views are especially needed in strategic management when top echelon decisions are made that cross functions, reach widely across the enterprise and require long term perspectives. Adopting a kaleidoscopic approach naturally instills intellectual modesty due to surfacing new information, challenging mental frames, and highlighting important inferential gaps, each of which can help counter-balance narrow monochromatic perspectives.

A kaleidoscope is literally an instrument containing loose bits of colored materials placed between two mirrors so that changes of light position reflect a variety of patterns. Its figurative meaning, as used in this paper, refers to examination approaches that offer variegated views and conceptual angles. As Kanter (2009) noted, "in a kaleidoscope, a set of fragments forms a pattern, but it isn't locked into place." If you move it or change your angle of view, entire new patterns may emerge. Strategic management is in need of this to better understand how leaders navigate organizations amid dynamic changes over time. The research challenge in field studies is essentially two-fold: marshalling enough diagnostic evidence to garner diverse descriptive insights and offering robust prescriptive advice that respects pertinent aspects of the case at hand. In line with the *Strategic Management Review*'s focus on exploring fundamental strategic questions (Leiblein and Reuer, 2020), this paper offers some paradigmatic extensions, lessons from practice, and deeper strategic issues that still need better resolutions. My paper complements similarly oriented strategy reflections by Rumelt et al (1994), Ghemawat (2016), Drnevich et al (2020), and Teece (2020), using a retrospective analysis of how Merck's very promising pain drug Vioxx eventually became a tragic saga spanning over a decade.

To position this paper conceptually, the following perspectives and assumptions guided my approach. One, much recent scholarship in strategic management and beyond favors a disciplinary approach. Two, while there are benefits to a focused disciplinary analysis, the complexity and interdependence of many strategic problems requires a system-level assessment. Three, the purpose of this paper is to illustrate some of the dangers inherent in focusing too narrowly on a single perspective or theory. Four, the Merck Vioxx case will illustrate how disciplinary-focused approaches can support a series of locally beneficial choices that overall yield devastatingly poor outcomes. This case shows how seasoned leaders made tragic choices with incomplete data that shaded a cascade of inferences over a period of years. While Merck's

Vioxx decisions at first appeared to be quite successful, disparate weak signals emerged that culminated in a sudden and very costly withdrawal of a novel pain medicine touted as a super-aspirin.

At the time of withdrawal in 2004, Vioxx had risen to annual sales of $2.5 billion per year, covering 20 million patients and was well on its way to becoming one of Merck's most successful drugs ever. Given its long history as an *ethical* company that aspired to rank patients above profit, Merck eventually had to withdraw the drug. The pros and cons of Merck's drastic decision to do this voluntarily, after a long period of internal denial, have been carefully analyzed by Oberholzer-Gee and Inamdar (2004). By then, however, most of the Vioxx damage had occurred and it proved to be enormous:

- The very day Merck withdrew Vioxx globally, its stock dropped more than 25% (a $28 billion hit in market value) plus more losses later when clinical data fraud was alleged.
- In total, 27,000 damage claims, representing 47,000 plaintiff groups, were filed as lawsuits against the company, estimated to cost between $10 and $24 billion to settle.
- The *New England Journal of Medicine* said it was "hoodwinked" by Merck and withdrew its Vioxx article claiming that it omitted multiple cases of heart attack.
- The human toll was estimated at 88,000 heart attacks (causing 38,000 death) in the USA, and 140,000 heart attacks globally due to Vioxx (amounting to 55,000 deaths).

To understand the twists and turns that Merck experienced with Vioxx requires more than one specific model of strategy or decision making. A multiplicity of lenses will be needed, across multiple layers of organizational analysis, to appreciate the cumulative effects of flawed strategic decisions by different executives and functional managers. The most challenging part is to appreciate the various connections over time between key decisions and the people involved.

1. Selective Literature Review

The first academic account of Vioxx published was a seven-part case study by faculty of the Harvard business school (Simons, Rosenberg and Kindred, 2009) written from a CEO and Board

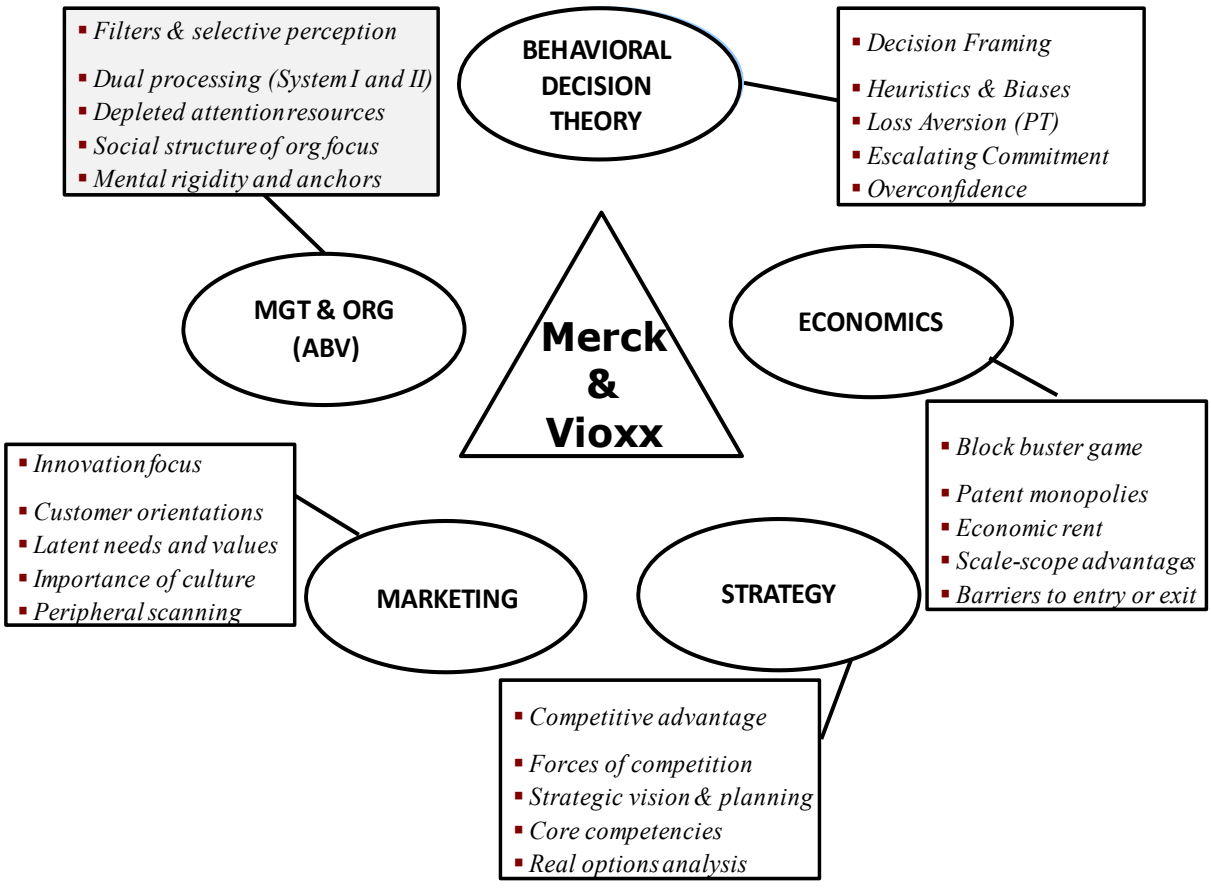
perspective. The case starts with the crucial 1985-1999 period during which some top Merck drugs went off patent, a new outside CEO was appointed (for the first time ever) and various clinical trials were underway in pursuit of a super aspirin to overcome the gastrointestinal problems of existing pain medicines. During the first MBA class, students have to assess the value of a new drug (Vioxx) and evaluate its safety and efficacy based on trial data handed out ahead of time. Students are asked to role-play Merck's new CEO (Ray Gilmartin) who needs to respond quickly to unfolding events, handle reputation and franchise risks, and remain true to Merck's *core values*. This includes how best to communicate with doctors, patients, media, regulators and other stakeholders. In a subsequent class, students receive additional information about troublesome risks of heart attacks and strokes emerging among some patients taking Vioxx. The case then shifts its focus toward making high stakes decisions about "gray" innovation areas, rising public criticisms, FDA concerns, stakeholder pressures, and whether to withdraw the drug from the market globally in order to put patients ahead of profit.

The top echelon view adopted in this Harvard teaching case, as well as the Instructor Note, suggest that Merck's CEO and Board acted properly given what they knew. The case focused mostly on the CEO's decision to withdraw Vioxx worldwide after serious safety concerns surfaced over years, with multiple options laid out for students. The case closes by enumerating numerous legal problems that Merck faced, with damage estimates for Vioxx running as high as $50 billion (in 2005 dollars). Given the specific lesson plan of the case, it did not dwell on how the R&D and marketing functions interacted with each other, nor how little Merck's top echelon was involved in asking critical questions. Also, a variety of weak signals that emerged lower down in the organization - as well as from sources outside such as charges of data manipulation - were not covered much in the case given its limited learning objectives.

To understand the full Vioxx story requires wide angle views as well as deeper probes about what took place and why. Figure 1 highlights the main disciplinary lenses I shall use to shed additional lights on the complex Vioxx case. The italicized terms in this chart, plus italicized text below, underscore the value of using multiple disciplinary lenses, as follows. Starting with **marketing theory**, an in-depth research study of Vioxx was published by Jasper, Leenders and O'Shannassy (2019) in the *Journal of Strategic Marketing*. The authors attributed Vioxx's

failure primarily to imbalances in Merck's orientation toward *customers*, *competitors* and inter-functional coordination. The marketing perspective addresses the demand side of the firm, with special attention to consumers and rivals. It includes a focus on unmet or *latent needs*, *market segmentations*, scanning the horizon for *weak signals* and exploring *innovations* of various kinds (from incremental to radical). On the operational and tactical sides of marketing, the traditional focus was on product, price, place, and promotion (known as *the four Ps* in Phil Kotler's (2001) classic marketing text book). Data analytics and AI have since been added as important components of the marketing lens although these digital technologies feature as well in the other four lenses to be examined.

Figure 1 – **Five Disciplinary Lenses Relevant to the Vioxx Case**



Proceeding clockwise, the next lens listed in Figure 1 represents long-standing **management and organization theories** that date back to Herbert Simon (1947) who characterized organizational behavior as a very complex network of attentional processes. This information processing view was elaborated by Cyert and March (1963) who emphasizing *bounded rationality*, local search, *satisficing* rather than optimizing, the *heuristic* nature of decision making, and the *quasi resolution* of conflict. Nelson and Winter (1982) further illuminated bounded rationality by highlighting the stable *routines* organizations use to handle information overload. A more recent sub-lens known as the *attention-based view* (ABV) likewise addresses the issue of mental overload. Ocasio (1997) defined organizational attention as the socially structured pattern of focus by decision makers within an organization. It concerns the sum total of key players' attention within a given context of strategy, design, priorities, processes, incentives and *culture*. Unlike individual attention (Kahneman, 1973), it is not easy to reorient the brain of the firm to a different direction (Beer, 1972). Organizational dynamics often drive how ambiguous signals are encoded in order to match problems with solutions, for a given *context* and state of *mindfulness* (Weick & Sutcliff, 2006).

The next relevant lens is **behavioral decision theory** (BDT) which is rooted in cognitive psychology and concerned with problem *framing*, *intelligence gathering*, *choice procedures* and *learning from feedback* (Russo and Schoemaker, 2002). In addition, there is the important meta-decision stage which addresses such questions as: (i) are we solving the right problem, (ii) who should be involved in the decision, and (iii) which phase deserves the most attention? As firms grow, they must manage increasingly complex decision processes which may strain the adequacy of the heuristics employed to achieve approximate rationality. Increased complexity tends to create unwelcome biases in the decision- making process. A well-known example is the *sunk cost fallacy* and the related phenomenon of *escalating commitment* to existing courses of action (Schultze et al., 2012). Psychologically, *losses* - especially those that are quantified and recorded such as write-offs of major investments - loom larger than comparable gains or *opportunity costs* (Tversky and Kahneman, 1974). Uncovering cognitive or emotional biases in managerial judgments requires delving more deeply into strategy, *governance*, *incentives* and broader organizational contexts.

The remaining two lenses in Fig 1 concern different approaches to strategic analysis which in early days drew heavily on **micro-economics**. However, a fundamental premise of strategic planning is in conflict with a core belief of economics and finance: the near impossibility of systematically creating durable *excess returns*. If the aim of strategic management (for firms and consultants) is to outperform rivals on a sustainable basis, they may embark on mission impossible. A basic tenet of microeconomics is that such attempts are unlikely to succeed in the long run, nor in the short run if there is *free entry and exit*. According to neoclassical economics, the sources of profits are not to be found in the firm but rather in the *structure of the industry*, especially the nature and balance of its *competitive forces* (Caves 1980; Porter 1980). Without some protective barriers, earning sustainable economic rent will be quite elusive. Traditionally, the field of neo-classical economics emphasized the rational side of markets and firms, but over time it expanded into other domains such as addiction, crime, discrimination, marriage, regulations and the law (Becker, 1976). Also, advances in behavioral economics have lessened its reliance on rationality assumptions such as *utility maximization*, market efficiency or rational expectations among economic agents (Camerer, 1999).

Formal academic research in **business strategy** originally evolved from the more static, structural industrial views of Michael Porter (1980 & 1985), which were rooted in industrial organization, *equilibrium models* and *antitrust theory*. Over time these economic views gave way to internal perspectives about an organization's *unique resources* and capabilities (Barney, 1991; Amit and Schoemaker, 1993; Hamel and Prahalad, 1994). The Schumpeterian views of Teece et al (1997 & 2007) emphasizes creative destruction and the importance of *dynamic capabilities* to continually adapt to change (see also Eisenhardt and Martin, 2000). Other important literature streams in strategy, overlapping with some of the earlier lenses mentioned, focused on *ambidextrous leadership* (O'Reilly and Tushman, 2008) as well as *managerial cognitions* (Hodgkinson et al, 1999). But the academic field of strategy remains poised on the horns of a dilemma (Schoemaker, 1990). One horn (or lemma) holds that under strong competitive pressure high rationality will prevail and economic rents will dissipate. The other horn posits that the players in this competitive game are flawed human beings who operate from limited cognitive abilities and *repertoires*.

The above five discipline-based perspectives, as well as others (see Ghemawat, 2002; Bindra et al, 2019; Bolland, 2020), can offer valuable strategic insights ex post but seldom will any single perspective fully capture all that is relevant. Real-world business cases published in the strategic management literature therefore need to guard against *intellectual balkanization*. The ancient Hindu parable of six blind men touching different parts of a newly encountered creature, an elephant, reminds us that diverse perspectives without integration can result in vehement disagreement, *overconfidence* and a paucity of essential understanding. Although Figure 1 depicts the main disciplines I draw upon, the items listed in each box are by no means complete nor mutually exclusive across these disciplines. In addition, other relevant lenses may be needed such as finance, group dynamics, human resources, public relations, sociology, and technology. This richness highlights the challenge of developing kaleidoscopic views that (i) get to the essence of the issues, (ii) don't overwhelm the analysis, (iii) respect complementarities and (iv) suppress bias. To do so, I shall examine the Vioxx case across three stages of development and assess the relevance of different lenses.

2. Early Background About Vioxx

Merck & Co started the development of a new generation of anti-inflammatory pain medicines in 1992 for conditions such as arthritis, headaches, and muscular pain. The aim was to develop an anti-inflammatory therapy devoid of the common side effects associated with non-steroidal anti-inflammatory drugs (NSAIDs) like Advil (ibuprofen), Aleve (naproxen), Aspirin, Motrin, and Nuprin. These pain medicines are widely sold over the counter in the US (over $50 billion in 2010) but can also cause gastrointestinal problems in patients, especially when used over an extended period of time. The reason is that a natural enzyme in the human body called cyclooxygenase (COX) tends to reduce pain and inflammation while also causing stomach ulcers and colon bleeding at times. A key scientific medical discovery in 1990 that the COX enzyme contains two isoforms, referred to as COX-1 and COX-2, led to the promising idea of only blocking the "detrimental" COX-2 isoform. The remaining isoform (COX-1) could then further alleviate inflammation and pain, while maintaining gastrointestinal integrity, as explained in Weintraub (2017).

The Hunt for A Super-Aspirin

Medical scientists recognized that the market potential for an improved NSAID would be enormous since it could potentially replace the entire class of NSAIDs. Around 2002, about 23 million people suffered arthritis in America alone and standard pain drugs (NSAIDs) were used by about 45 million people in the US. Also, there was hope that if COX-2 inhibitors proved to be safe when taken on a sustained basis, these new drugs could possibly prevent Alzheimer's disease, colon cancer and more. These highly appealing commercial implications were the foundation for a new Merck drug named Vioxx becoming its top strategic priority. The company badly needed a *blockbuster* of this kind because Merck's other mega drug revenues would be declining as several established brands neared *patent expiration* and declining *entry barriers.*

Pursuing high growth was central to Merck's strategy under CEO Raymond Gilmartin, who came from outside the pharmaceutical industry (Werth, 2013), in contrast to his celebrated predecessor Roy Vagelos who had been promoted from inside through R&D to CEO and Chairman. Gilmartin's early background was in management consulting with Arthur D. Little and later at Becton Dickinson (medical devices) where he became CEO and eventually chairman. Gilmartin joined Merck's in 1994 and was the first CEO ever to be appointed from outside Merck since its founding in 1891. Although experienced in healthcare broadly, he was new to pharma research and thus his leadership style relied heavily on delegation. Vioxx was envisioned to be the cornerstone of Merck's continued growth and the drug was mostly driven by the R&D and marketing functions at the company. Their decisions were not deeply scrutinized by either Gilmartin or the Board given the strong track records of these two functions over time.

The enormous promise of COX-2 drugs was widely touted in a 1998 New Yorker article as being a magical "super aspirin". Merck was not the only company responding to the huge opportunity that COX-2 inhibition could bring. A research group at Searle, then part of Monsanto, was also pursuing the development of a COX-2 inhibitor. Although Searle did not have the scientific depth and other resources of Merck, its smaller and more agile research team was singularly focused on COX-2 development. Merck planned to leverage its formidable corporate platform and scientific expertise to beat Searle in developing a superior COX-2 drug. The two companies were in a close race to get FDA approval to bring their drugs to the market as quickly as

possible. The stakes were very high for both companies, the competition was intense and Merck had already fallen behind Searle because of a miscalculation in selecting the best dose for testing.

Searle's COX-2 inhibitor was approved by the FDA in January of 1999 and Merck's COX-2 inhibitor in May of that year. The initial FDA submission of each company had been focused on meeting the safety and efficacy standards needed, without any data necessary to claim superiority relative to the NSAID class. It still remained to be shown that the new COX-2 inhibitors were conclusively better in reducing gastrointestinal problems than established NSAIDs or that they might work for other ailments. Producing credible clinical data (post FDA approval) that reflect real world practices would be essential in establishing this improved class of drugs as a truly new standard of medical care. Both Searle and Merck had separately planned their own follow-up research using large gastrointestinal outcomes studies to convincingly address this issue. To avoid muddying the FDA approval waters, both companies delayed these important secondary studies to speed up the critical research they needed for the initial FDA seal of approval.

Perspectives from Different Disciplines

The micro-economic lens readily explains why Vioxx became such a central focus and *anchor* in Merck's *strategic vision*, starting with breakthrough scientific discoveries published in 1991 and an early competitor (Searle) being ahead in research to develop a super aspirin. Merck's R&D division pushed for an aggressive Vioxx strategy, enabled by limited technical oversight from its new outside CEO and fueled by a psychological mindset of being on the loss side relative to rival Searle. In addition, Merck was losing market ground as some of its other leading drugs were going off patent which shifted the top echelon's focus toward growth and *monopoly rents* from patents. Merck's research leaders wanted to swing for the fences with Vioxx given its enormous game changing potential if successful. To gain *competitive advantage*, Merck limited its safety testing to what was narrowly needed for initial FDA approval, while delaying broader clinical test about efficacy and safety.

Judged from a strategy perspective, Merck's staged approached to R&D testing constituted a rational flexible options approach (Huchzermeier & Loch, 2001) which is suitable in cases of high risk, uncertainty as well as ambiguity, while ignoring truly random noise. Merck had

carefully fine-tuned its R&D pipeline, ever since Judy Lewent became CFO in the 1990s, by using *real options* theory. Using decision trees to assess the value of new information and remaining flexible, longitudinal portfolio optimization was practiced (Nichols, 1994). But using its 'small sample' pilot approach in pharma to get FDA approval entailed some risk of overlooking infrequent but serious side effects. Although the *a priori* chance of developing a block buster drug is very low, Merck's strong historical track record of scientific excellence may have overshadowed this low base rate. Further, as highlighted in prospect theory (Kahneman & Tversky, 1979), loss-side framing in the face of long shot gambles often induces risk-taking, both due to the convex shape of the value function for losses and the overweighing low probabilities. As such, managers' cognitions favored strong risk-taking bolstered further by Merck's strategy of making Vioxx triumphant (Eggers and Kaplan, 2009).

Merck's shift toward risk taking also reflected its weak product pipeline and that it had fallen behind Celebrex in pursuing that 'super aspirin' drug. Another relevant behavioral bias was Merck's 'escalation of commitment' in the face of recurring bad news (Staw, 1981). This may have fueled *rigidity* and overconfidence among senior R&D leaders who failed to conduct serious contingency planning in case Vioxx would fail. Other strategic issues may be relevant to Vioxx as well, such as special features of a mature industry in transition (toward generics and biologics), the long value chain of pharmaceutical development, and its complex regulatory environment. The competitive race to win big with a blockbuster drug, and the duopoly dynamics between two main rivals, could likewise benefit from industrial economic as well as institutional perspectives. There are also important leadership dynamics to be explored since Merck hired an outside CEO to meet ambitious growth targets, having by-passed its powerful head of R&D who very much wanted to become CEO himself.

3. How The Vioxx Fiasco Unfolded

Following FDA approval, Merck launched its major gastrointestinal outcomes study called VIGOR in January of 1999 to extend the range of Vioxx applications. With the support of external researchers, a medical safety review board and numerous hospitals, they enrolled more than 8,000 patients suffering from rheumatoid arthritis. Various criteria had been specified upfront to qualify patients for the study, in part to control for complications related to other

medical conditions or drugs being taken. Already behind one rival, Merck tried to execute this study as quickly as possible in hope of leap frogging Searle and become the best in this new super class of drug. A down-side risk of clinical haste, however, is laxer applications of pre-specified enrollment criteria for patients by agencies or doctors incented to sign up patients quickly (Alexander, 2015). Monetary *incentives* may have started to dilute organizational safety considerations in this case (Cho & Hambrick, 2006).

During the initial planning of VIGOR in 1996, leaders received an internal memo warning that if Vioxx was compared to a NSAID drug with anti-platelet properties, such as Aleve, it might look inferior clinically (Morrison, 1998). If Aleve indeed reduces the risk of heart attacks or strokes due to its presumed blood thinning effects, Vioxx could score poorly in a direct comparison. But Aleve had not yet been shown clinically to reduce heart attacks or strokes in significant ways, so this risk was deemed trivial and was dismissed by Merck. Also, this hypothetical design warning was voiced well before any real concerns about cardiovascular safety with Vioxx had surfaced in trials. In hindsight, the internal memo was prescient although the warning constituted a weak cue in an evolving drug risk story in which type 1 and 2 cognitive processes needed to be balanced (Laureiro-Martinez & Brusconi, 2018).

An additional weak warning signal arose from an earlier study that Merck funded in October of 1997 to assess the potential effect of Vioxx on kidney function. This research was conducted by Garret FitzGerald at the University of Pennsylvania with healthy young adult volunteers. Unexpectedly, it showed that Vioxx inhibited the production of prostacyclin, which is an important regulator of platelets and blood vessels. Professor FitzGerald realized immediately that inhibition of prostacyclin could possibly be problematic for patients with cardiovascular disease. But these potential risks had not yet been clinically observed by FitzGerald's team since they had only tested young healthy volunteers. FitzGerald was keen to explore its potential effect on older patients but Merck didn't support that idea when it was proposed in 1997. Going further, Merck delayed permission for FitzGerald (2004) to publish his current findings in an academic journal until after Vioxx was approved by the FDA. FitzGerald's team then decided separately to run some replication studies on the Searle compound, Celebrex, which demonstrated that it likewise inhibited prostacyclin production. These twin findings suggested a broader risk effect for new

COX-2 inhibition drugs. But to conclusively settle Vioxx's risk of cardiovascular concerns would require a placebo controlled clinical study with older patients, which Merck did not want to fund or otherwise support.

Moving Ahead Full Steam

Instead, Merck launched several other large long-term studies of Vioxx, in addition to the VIGOR safety trial, to explore additional commercial applications of COX-2 inhibitors for Alzheimer's disease as well as colon polyps. Some of these studies were supervised by independent *data safety monitoring boards* (DSMB) to ensure that clinical trials could be promptly stopped if serious safety issues arose in the treatment group. DSMBs are allowed to unblind data prematurely at key points along the way, to see how patients are faring in the treatment versus control group. Naturally, none of the other people involved in the drug trial would be allowed to have an early peek at interim data, as this would compromise and possibly invalidate the entire study by FDA standards.

After one of the scheduled reviews of safety data in May 1998, the DSMB monitoring VIGOR decided to send a letter to the Merck physician managing the trial (Alise Reicin), requesting that a formal plan be prepared to analyze cardiovascular safety prior to unblinding the study. The Merck team overseeing the study feared that this request was prompted by the emergence of cardiac safety issues in the accumulating blinded data set. This concern aligned with the earlier warnings of FitzGerald regarding prostacyclin inhibition; in addition, some serious potential cardiovascular consequences had by now been published elsewhere. The Merck team, led by Beth Seidenberg, initially replied that the requested cardiovascular safety analysis plan would not be added to avoid unacceptable delays in the trial. The DSMB responded by re-emphasizing the necessity of their request, which was about as strong as they could be given their advisory role and limited power. Merck, however, once again decided not to honor their request to assess emerging safety risks.

Nonetheless, Merck's head of research, Edward Scolnick, had become anxious about the safety of Vioxx ever since FitzGerald's earlier prostacyclin pilot data. He decided to contact a junior

Merck statistician assigned to the DSMB at her home after work, to get some insight into the blinded data from the ongoing trial. This was in fact a very serious breach of protocol and the statistician rightly resisted Scolnick's request for information by saying she needed to check on it first. The following day she met with her own boss who resolutely told her not to share any blinded information with Merck's head of research.

When the all-important VIGOR study was finally unblinded in 2000, it convincingly demonstrated that Vioxx had a better gastrointestinal safety profile than the Naproxen comparator (Aleve). But this clinical benefit was offset by a statistically significant higher incidence of serious cardiovascular side effects such as heart attacks and strokes among the patients taking Vioxx. This adverse finding explains why the DSMB had requested an analysis plan for cardiovascular safety prior to unblinding and further validated the concerns expressed early on in the 1996 memo to Beth Seidenberg (Vioxx's team leader).

Perspectives from Different Disciplines

Notable instances of Merck's misplaced *attention* include repeated misreads of weak signals about the cardiovascular risks of Vioxx. Also, the violation of an ironclad clinical norm by the head of R&D to get an early peek at the data is morally very troubling. Furthermore, Merck launched a new scientific journal in Australia to promote its own research and listed noted researcher advisors without their permission (see Jasper et al, 2019). These ethical lapses suggest a serious *escalation of commitment* at Merck to stick with the Vioxx plan, plus perhaps willful blindness (Heffernan, 2011) in pursuit of a blockbuster drug. Throwing good money after bad has been linked in BDT to self-justification, confirmation bias, *loss aversion*, sunk costs bias and impression management (Kelly and Milkman, 2013). From a *strategy* view, it is striking that no contingency plans were developed to handle downside risks nor any systemic scenario planning (Schoemaker, 2022). Merck essentially doubled down on Vioxx and launched additional clinical trials to broaden its medical use by doctors. We lack sufficient process insight to judge to what extent groupthink, blind ambition and misaligned incentives are to blame, together with other contextual factors. Hoping for the best is understandable but failure to devise contingency plans in case of disastrous trial outcomes is puzzling and imprudent.

This unforced error proved very costly since it essentially closed the door for any subsequent Vioxx repositioning once convincing adverse risk data emerged, in contrast to the Celebrex drug which remained on the market. In addition, a costly early *blind spot* occurred when Merck designed its crucial VIGOR trial and chose Aleve as the main comparator drug in the control group. This was a risky choice in view of an early warning about possible anti-platelet effects. But the respected and strong-willed leader of R&D, Edward Scolnick, allowed little room for such doubts and tightly controlled the R&D group. Also, Merck's new CEO was not well versed in pharmaceutical research which made it awkward for him to challenge Scolnick, who had been passed over for CEO. As Cummings and Knott (2018) discussed, outside CEOs can present unwelcome innovation challenges, including diverting attention away from weak signals at the edges. *Narrow framing* combined with highly focused attention tends to restrict *peripheral scanning* as demonstrated in several famous invisible gorilla experiments by Chabris and Simons (2010). Deeper analyses would need to be conducted about possible psychoanalytic forces at play as well, as emphasized by Kets de Vries (1994) and reflected in the hard-won lessons of CEOs profiled by Useem (2021).

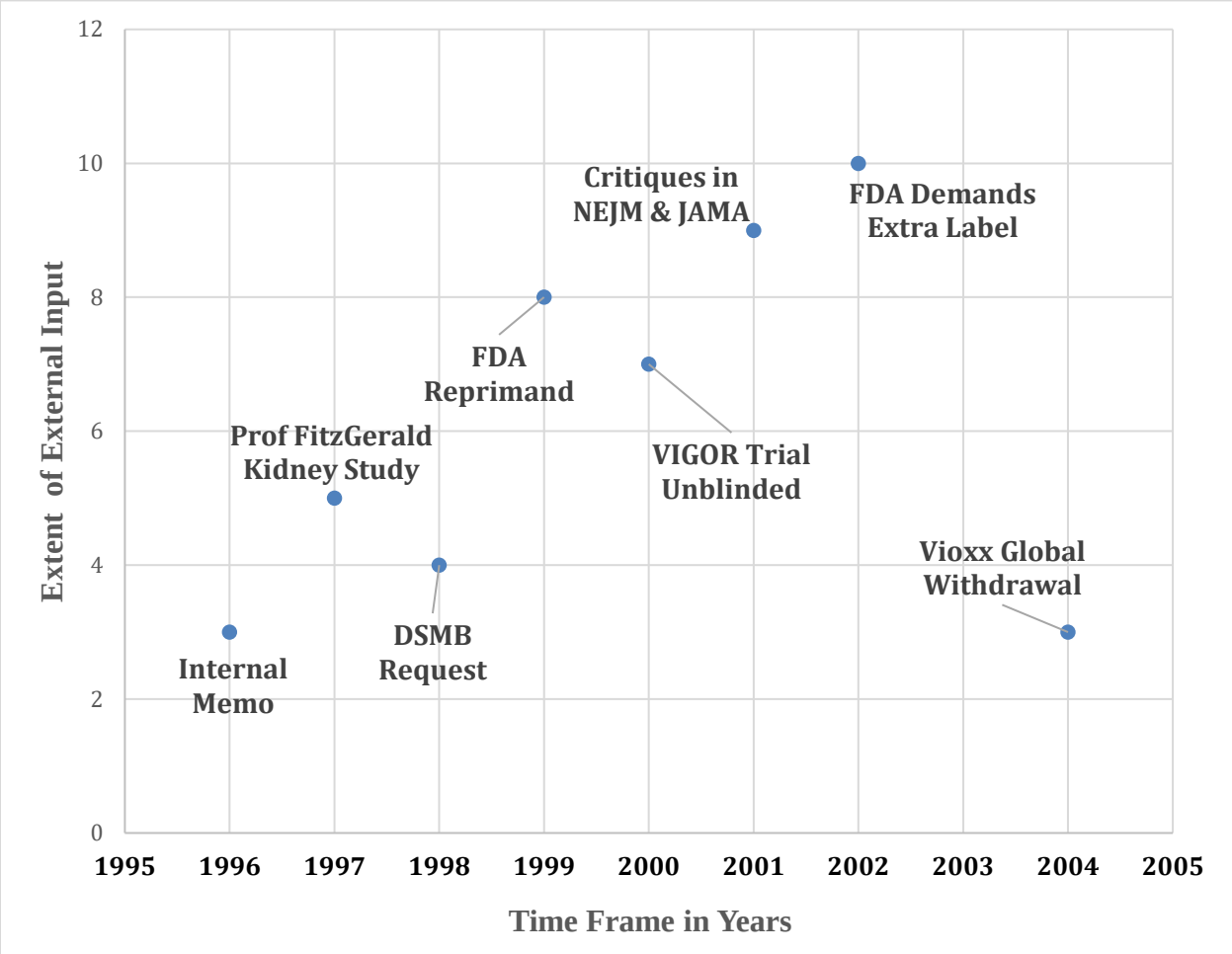
4. Circling the Wagons at Merck

The shocking finding of serious cardiovascular side effects was met with consternation and denial at first inside Merck. The head of R&D, Edward Scolnick, initially attributed the cardiovascular signal to the prostacyclin mechanism identified by FitzGerald. However, the trial's lead manager, Alise Reicin, posited an alternative explanation to help exonerate Merck. She argued that Vioxx did not increase the risk of heart attacks and strokes but that Aleve reduced this risk in certain patients as a consequence of an anti-platelet effect. Her implied argument was that if another comparison drug had been chosen, Vioxx would not have shown increases in cardiovascular side effects compared to that alternate control group.

To further boost Vioxx's presumed safety, Merck merged the safety data of all its completed and ongoing Vioxx clinical trials in one meta-study. Since this aggregate data set failed to show a clear increase in cardiovascular risk, Merck communicated these meta findings to the FDA as well as broadly to physicians. But since the number of cardiovascular events in these studies was still low, outside experts thought the meta-analysis was not statistically meaningful. Absence of

evidence, they argued, was not evidence of absence in this meta study. Furthermore, additional deaths from Vioxx had been observed as well, especially in the Alzheimer's trials. But some of these deaths could not be definitively attributed to cardiovascular causes, so Merck downplayed their significance in its communications to the FDA and subsequent publications. Figure 2 offers a visual summary of the multiple early warning signals that Merck misread, some of which came from inside the organization and others from outside during the eight years from 1996 to 2004.

Figure 2 – **Key Warning Signals About Vioxx's Safety**



Reicin's comparator theory, although not implausible, was regarded very skeptically by outside experts from the start. The best studied drug with an anti-platelet effect known to affect cardiovascular risk was aspirin. But no clinical study of aspirin had ever shown this risk to be close in magnitude to that observed in VIGOR. Although this did not exclude the possibility of a

contributory anti-platelet effect to the VIGOR outcomes per se, it made Fitzgerald's original prostacyclin hypothesis much more likely. Explaining away the problematic VIGOR outcomes as an exclusive consequence of Aleve's anti-platelet effect was enthusiastically embraced by the company and the promotion of Vioxx continued full steam. In response, the FDA sent Merck a warning letter in September of 2001 regarding its one-sided promotion of Vioxx. Additional concerns about the safety of Vioxx were also raised in scientific articles and the press, prompting an even stronger FDA response. In April of 2002, it ordered Merck to add a clear precautionary warning regarding cardiovascular risks on the Vioxx label itself.

Finally, in September 2004, the results of the APPROVe colon polyp prevention study came out and unequivocally showed the serious cardiovascular risks of Vioxx. The DSMB informed Merck about the heightened cardiac risk on Thursday September 30th 2004 and this conclusive signal led Merck to withdraw Vioxx from the market globally a week later. This startling corporate decision inadvertently created the impression that the safety issue found was unique to Vioxx and just a Merck problem. However, a very similar colon polyp study was still ongoing with Celebrex, which subsequently showed an increase in cardiovascular risk as well. So, this adverse side effect was not unique to Vioxx but likely common to COX-2 inhibitors in general, as originally speculated in 1997 by Fitzgerald (2004). Nonetheless, Pfizer (which had purchased Searle in 2003) took a different approach than Merck and kept Celebrex on the market. Its studies involved different dosages, duration and patients, and did not reveal as many side-effects. However, additional warnings were widely added by these companies and regulators in the US, as well as in other countries, about prescribing COX-2 inhibitors (Sooriakumaran, 2006).

Perspectives from Multiple Disciplines

Merck's attention remained trained on making Vioxx the first and best to market in this promising new class of super drugs, which left little slack to attend to worrisome peripheral signs until it was too late. The overall focus was on *scale and scope economics* by expanding Vioxx's treatment options for Alzheimer's, polyps and kidney diseases, with insufficient regard to possibly fatal side-effects. Merck had delayed and blocked publications about Fitzgerald's original platelet concerns and ignored the DSMB's repeated requests to prepare a plan to monitor

cardiovascular safety prior to unblinding the VIGOR study. Concerned about this request, the head of R&D improperly contacting a junior DSMB researcher and then, ominously, Merck's project leader of Vioxx suddenly resigned.

In the language of Rerup's (2009) triangular *attention model*, Merck leaders paid lop-sided attention to competing goals akin to what caused Novo Nordisk's crisis with insulin production. Rerup examined this parallel pharma case of a global leader in diabetics and concluded that crises can only be prevented if important goals remain stable, vivid and coherent within leaders' attention fields over time and across organizational levels. This in-depth case study about compromised safety and quality showed "how Novo Nordisk created learning barriers that interfered with triangulating attention to issues across the chain of command." These barriers included organizational distractions (a merger in the Novo Nordisk case), lack of discipline in sharing knowledge and a *culture* of presumed superiority. Both Novo Nordisk and Merck were considered preeminent pharma companies prior to their crises, which explains some of their reluctance to acknowledge weak signals of concern early on. Ironically, the assumption of being world class in their fields may have fostered a sense of invulnerability and an overrated ability to recover from setbacks.

Presumed excellence can cause deep *cognitive dissonance* among leaders when confronted with negative signals, even when the data are clear. After the VIGOR study was unblinded, the data revealed serious side effects which Merck at first denied and then tried to rationalize away. Its *defensive routines* started with a speculative theory that most outside experts rejected. Merck continued nonetheless by aggressively pushing an updated meta-analysis which outside experts also viewed skeptically. Undeterred, its leaders pushed ahead with a big PR campaign to doctors which prompted the FDA to issue a stern warning letter, followed by a mandatory order to place precautionary warning labels on the drug's packages. Merck's attention was clearly skewed toward fighting the data and the outside world at a time when it was still possible to prepare contingency plans. For example, Merck could have narrowed the drug's indications or added a black label warning in order to keep Vioxx available for younger healthy people. Its defiant posture until the very end, however, prevented such moves and could be viewed in BDT terms as

manifestations of groupthink, willful blindness or a last-ditch effort to double-down and go for broke.

5. Remaining Challenges for Strategic Management Theory

The above section about circling the wagons at Merck connects with broad literatures in the social sciences, humanities, and anthropology about our human propensity to deny reality when it becomes too burdensome. As sociologist Cohen (2001) showed in his book *States of Denial*, this pathology is not limited to just individuals and groups but can afflict entire nations as he illustrated with apartheid's reign in South Africa and slavery in many countries well before. To remain grounded in reality, leaders need to heed the advice of J.K. Paasikivi, a former president of Finland, whose statue in Helsinki proclaims that "the beginning of all wisdom is recognition of facts." This often is very hard in organizations and would require thick research descriptions (Geertz, 2008) to fully understand in any specific organizational culture. Figure 3 provides one rationale of the reinforcing connections that could explain the Vioxx debacle from a behavioral perspective. Alternative accounts, based on lenses rooted in other disciplines, could be developed as well about Vioxx but assessing additional ones in detail is beyond the scope of this paper. The aforementioned marketing account by Jaspers et al (2019) for example constitutes a coherent and comprehensive marketing narrative that would ideally be integrated with other Vioxx lenses.

Figure 3 - **Deconstructing the Vioxx Debacle at Merck**

A. Antecedent Conditions:

- Strong need for another blockbuster drug; empty pipeline
- Already behind Searle's Celebrex in being first to market
- History of great success in R&D and launching blockbusters
- Highly talented team exuding self-confidence; best & brightest
- Betting all the marbles on Vioxx and going all out to win big
- Little self-doubt or interest in risk analysis & contingency planning

B. Responses to Warning Signals

1. Early weak signals about possible cardiac side effects ignored or dismissed
2. Launching new expansion trials, rather than safety studies, to expand Vioxx's use
3. Vigorous defense of Vioxx's safety after negative heart attack data from VIGOR trial
4. Pushing a dubious rationalization story with doctors, which prompt FDA warnings
5. Continuing to ignore signals about cardiac risk from important external sources
6. No contingency planning to prepare for possible adverse trial results

C. Final Merck Decisions after Further Bad News

1. Sudden worldwide withdrawal of Vioxx, after just 5 days of internal deliberations
2. Denying any responsibility, followed by full court efforts to fight any legal claims
3. Too deep in now to keep Vioxx alive (like Celebrex), under a Black Label warning
4. Further evidence of little contingency planning; Merck caught behind the eight ball

To achieve deeper integration across the field of strategic management, researchers shall need to address our growing problem of intellectual balkanization. In the Vioxx case alone, I drew on five main disciplinary views plus some subsidiary ones (see Figure 1), many of which have their own primitives, constructs, nomenclature, and theoretical assumptions. We can reduce some of these fractures by aligning the rivaling dictionaries deployed in our own Tower of Babble, or by downplaying intellectual nuances in concepts or methods that do not make a real difference. But when also considering the many jars and spigots from which researchers and consultants can metaphorically draw conceptual ingredients, plus the many pots and utensils via which explanatory stews can be concocted, how do we know which brews are really best? Figure 4 lists 35 concepts I mentioned in this paper plus illustrative Vioxx linkages for this case alone. The number 35 understates the paper's total concepts, but offers enough variety to illustrate the ex-post challenges researchers face when garnering conclusive and generalizable insights based on inductive studies of complex, extended real-world cases (Eisenhardt, 1989).

Figure 4 – **Perspectives from Five Different Disciplines**

	Lenses Used		*Concepts Referenced re Vioxx*	*Examples of Where/Why Relevant*
A	MARKETING SCIENCE	1	Customer needs	Merck lost side of patients & doctors
		2	Competitive focus	Singularly obsessed with Celebrex
		3	Phil Kotler's four Ps	Classic marketing management model
		4	Business segmentation	Pain drugs; Alzheimer's & Colon cancer
		5	Innovation management	Too R&D driven; remote CEO & Board
		6	Market-driven strategies	Lobsided focus on one leading rival
		7	Inter-functional relationships	Insufficient internal triangulation
B	MANAGEMENT & ORGANIZATION THEORIES	1	Satisficing & Local search	Narrow goals; short term view
		2	Bounded rationality	Early warning signals missed
		3	Organizational routines	Ignoring Safety Board requests
		4	Attention-based view	Focus on being first to market
		5	Organizational rigidity	Little continency planning
		6	Mindfulness	Imbalances in stakeholder priorities
		7	Enterprise design	R&D dominant; weak top governance
C	BEHAVIORAL DECISION THEORY	1	Heuristics & biases	Anchored on Celebrex & speed to market
		2	Prospect theory - Loss aversion	Already being behind fueled risk-taking
		3	Decision framing	Narrow boundaries & yardsticks
		4	Overconfidence	Lack of systematic scenario planning
		5	Escalation of commitment	Doubling down after bad news
		6	Willful blindness	Repeatedly distorting reality
		7	Cognitive dissonance	Embracing weak rationalizations
D	MICRO-ECONOMICS	1	Industry structure	Dry pipelines; rise of generics & biologics
		2	Monopoly rents	Patent protections; high prices
		3	Value chain	Vertical integration; pipeline portfolios
		4	Entry and/or exit barriers	Regulatory hurdles & capital needed
		5	Other barriers to competition	Talent; substitutes; regulators
		6	Duopoly dynamics	Two main rivals for super-aspirin
		7	Incentive alignment	Doctors paid to enroll patients quickly
E	BUSINESS STRATEGY	1	Competitive advantage	Merck's superior R&D platform of old
		2	Real options analysis	Staged approach to drug development
		3	Scenario planning	Largely absent in face of high risks
		4	Dynamic capabilities	Poor adaptation to clinical setbacks
		5	Strategic vision	Growth & profit; less patient focus
		6	Ambidextrous leadership	Balancing risk-return; short-long term
		7	Types of Innovation	Vioxx was a disruptive mega-innovation

Although the Vioxx saga is just one case example of many in strategic management research, it raises serious challenges for academic researchers conducting field research. Developing complete descriptive accounts about a case like Vioxx is only half the challenge in strategic management. The other half is how to develop normatively grounded practical advice for managers and leaders when still in the midst of complex cases like Vioxx. Strategy theory cannot make progress in field studies or case analyses unless scholars can answer the strategy questions raised in Figure 5 with more confidence, specificity and evidence than is available today. We should avoid approaching complex strategy cases like Rorschach tests into which we project our own mental models or predilections. Leveraging kaleidoscopic lenses is one safeguard here, especially if conducted by cross-disciplinary research teams (Gigerenzer, 2022) that jointly tackle real world challenges (Reibstein et al, 2009).

Figure 5 – **Challenges for Strategy Research in Field Settings**

1. Importance of inter-disciplinary research teams when analyzing complex real-world cases
2. Framing issues correctly in terms of focal topics, scope boundaries and time periods studied
3. Tracking back the early seeds of key organizational manifestations to its antecedent conditions
4. Acknowledging limitations in field research about what is knowable or analyzable scientifically
5. Discerning the indirect influences of culture within and across the boundaries of organizations
6. Being clear upfront about shareholder vs stakeholder views when making evaluative judgments
7. In cases like Vioxx, how to define markets and customers: doctors, hospitals, patients, society?
8. Distinguishing driving forces like finance, sales, marketing, R&D, growth, etc. in an organization
9. How to assess if the organizations being examined were vulnerable or vigilant at key moments?
10. Finding balanced integration approaches when drawing on multiple disciplinary research lenses
11. Articulating a meta-theory to justify and handle kaleidoscopic views as counters to balkanization
12. Examining how other academic disciplines managed integrate complementary theories or not
13. Identifying key sub-streams in strategic management and mapping out their deeper relationships

14. Moving strategy research from pre-paradigmatic toward integrated unified theory development

Encouraging in this regard is the increase in NSF funding of research projects with *multiple* principal investigators, rather than just one, which NSF deems a proxy for interdisciplinarity (Buyalskaya et al, 2021). In strategy research, such teams should base their descriptive analyses and prescriptive advice on syntheses that do not favor any single academic discipline *a priori*. Some intellectual slants are to be expected given the high degrees of specialization found in research teams but their diversity - if wisely composed - should help guard against egregious blind spots. A deep conundrum can arise, however, when different disciplinary lenses for a complex case are not complementary but instead pose irreconcilable perspectives. Graham Allison's (1971) classic book the *Essence of Decision* examined this for the Cuban Missile crisis and a recent article by Li et al (2022) contrasted competing contemporary views of China. These and other integrative challenges lie beyond my present scope but will be addressed in a subsequent companion paper aimed at conceptually closing the research loop for the field of strategic management.

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Author Bio: served on the faculties of University of Chicago, Cedep at Insead and the Wharton School; was research director of Wharton's Mack Center for Innovation Management; authored twelve books (most recent one on scenario planning); numerous articles about decisions under uncertainty, strategy, innovation and leadership; founder and chairman of several companies.

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