MHE-FTR-029
1259927628
REV: JANUARY 2, 2015

TEACHING NOTE

Merck & Co., Inc.

Structure of the Case

The case features CEO Kenneth Frazier as he contemplates Merck's future in light of a difficult external environment and multiple internal challenges. The 2009 megamerger with Schering-Plough (SP) was a major step toward a more open approach to innovation, but it has proven to be more difficult to implement than expected. On the plus side, Merck acquired a strong late-stage pipeline of drugs and extended its geographical reach to emerging markets. However, two lead candidates integral to the valuation of the transaction have since stalled in development, raising questions as to whether Merck will be able to recoup its investment. These setbacks, along with a lackluster financial performance in the post-SP-merger years, are leading some Merck scientists to question the move toward open innovation. Nevertheless, Mr. Frazier and Roger Perlmutter, the president of research, both believe it is more important than ever to maintain the company's openness to external as well as internal ideas.

The case describes Merck's history as a science-led, research-based company. Merck has produced numerous star researchers and was anointed the most admired company in America by *Fortune* from 1987 to 1993. Since then, Merck has been unable to duplicate its past successes, and its current patents are expiring rapidly. The pressure to produce another blockbuster drug has been especially high since Merck recalled Vioxx, an arthritis and acute-pain medicine, in 2004. Related lawsuits have cost Merck up to $30 billion in legal liabilities.

The next section describes Merck's "reverse merger" with SP, announced in March 2009. The combined company boasts 106,000 employees and sales revenues of $42 billion, and ranks second in market share in the global pharmaceutical industry. Even more importantly, Merck gained access to over 20 new compounds in stages 2 and 3 of the FDA approval process. The buyout was Merck's first major external venture since 2006, and as noted previously, has met with mixed results.

To put Merck's recent activities in context, the case provides background information on the pharmaceutical industry's trend of consolidation from major to mega-drug companies. Consolidation is seen as a necessity because the major pharmaceutical companies expect to lose billions of dollars due to expiring patents and need to replenish their diminishing drug pipelines. While megamergers were the norm through 2011, recently the trend has shifted toward more focused acquisitions aligned

Professor Frank T. Rothaermel and Research Associate Michael McKay (Ph.D., Chemistry) prepared this case from public sources. The authors are indebted to Alicia Ellberger of Merck & Co., Inc. for her contributions to an earlier version of this case, and to Professor Marne Arthaud-Day for superb case content editing.

with existing therapeutic strengths and the shedding of non-core businesses. The tax inversion phenomenon has also led to an increase in cross-border acquisitions. However, many analysts fear that consolidation, while addressing cost containment, will hinder breakthrough R&D needed to procure life-saving drugs.

The case also describes the risky and costly process of drug discovery, development, and FDA approval. Only one out of about 10,000 molecules is ultimately approved by the FDA, and it takes an average of $1 billion and 12 years to develop a single new drug. Meanwhile, pharmaceutical companies like Merck are facing serious challenges as a result of recent health care reforms and increased competition from cheaper generics.

The case then explains the difference between closed and open innovation. Closed innovation, in which a company performs its own R&D internally, has been the dominant paradigm for the past century. However, the rise of the Internet, increased mobility of knowledge workers, and difficulty in protecting proprietary ideas are causing a breakdown in the system. As a result, companies are starting to open up their business models by actively searching for and exploiting outside ideas. Open innovation also involves a willingness to allow unused internal technologies to flow to the outside where other firms can unlock their latent economic potential. Many biopharmaceutical companies have already embraced a more open approach to innovation and have realized increased R&D success at lower costs.

Merck's commitment to open innovation is about to be tested in light of competitive challenges to its hepatitis C virus (HCV) products. One of the successes of the SP merger was the 2011 approval of a new biologic that boosted the cure rate for HCV from 40 to 75 percent. In 2013, however, Gilead launched a new treatment (a nucleoside analog) that can be taken as a once-a-day pill with a cure rate of 80 to 90 percent. Since then, multiple companies have sought approval for a variety of combination therapies with even higher response rates. The problem is that Merck has no expertise in developing nucleoside analogs and does not have the time to develop this expertise in-house. Consequently, Mr. Frazier and Mr. Perlmutter are contemplating the acquisition of nucleoside specialist Idenix to retain Merck's stronghold in the HCV market. Several of Idenix's HCV compounds have encountered problems in clinical development, making this a high risk (but potentially very high return) proposition, especially for a company with ambivalent feelings toward "outsiders."

Suggested Questions

ANALYSIS: FOCUS ON EXTERNAL AND/OR INTERNAL ENVIRONMENTS

1. **What does the structure of the pharmaceutical industry look like according to Porter's five forces)? Is it an attractive industry? Why or why not?**

2. **Looking at Merck's strengths, weaknesses, opportunities, and threats, determine if Merck can gain and sustain a competitive advantage in the pharmaceutical industry. Why or why not?**

FORMULATION: FOCUS ON BUSINESS, CORPORATE, AND/OR GLOBAL STRATEGY

3. Analyze Merck's innovation strategy; does it need fixing? Why or why not?

4. Can open innovation help Merck meet the needs of its customers in creative and cost-effective ways that also bring value to its shareholders? Why or why not?

IMPLEMENTATION: FOCUS ON RECOMMENDATIONS AND HOW TO EXECUTE THEM

5. Assuming open innovation is the path to follow, what implementation issues would you expect? How should Merck overcome its cultural resistance to change?

6. Is the acquisition of Idenix an appropriate response to competition in the HCV market? Why or why not?

Suggested Answers

ANALYSIS: FOCUS ON EXTERNAL AND/OR INTERNAL ENVIRONMENTS

1. What does the structure of the pharmaceutical industry look like according to Porter's five forces)? Is it an attractive industry? Why or why not?

Porter's five forces can be utilized to determine the overall attractiveness of an industry (see Exhibit TN-1). MarketLine has an Industry Profile entitled *United States - Pharmaceuticals* (Reference Code: 0072-0372) published in April 2014, which provides a sample five forces analysis of the pharmaceutical industry. Additional reports are available for other sectors of the health care industry including biotechnology and generics.

Suppliers: Large pharmaceutical firms exert strong pricing pressures on smaller chemical suppliers; many have also backward-integrated into chemical manufacturing. Product quality is highly regulated, making differentiation difficult. Thus, supplier power is *low*, except for some specialized ingredients and manufacturing processes.

Buyers: This is a *moderate* force, as buyers (wholesalers, insurers, physicians, and policy makers) are concentrated and control patient access to prescription medications. With the expanded enrollments in Medicare and Medicaid under the Affordable Care Act (ACA), the federal government will likely be taking a stronger interest in controlling pharmaceutical prices.

Buyer power increased significantly in the 1990s, when employers began paying managed care organizations (MCOs) to manage the increasing costs of health care. These organizations gained extensive bargaining power, restricting the type, number, and prices of drugs in their "formularies," or

list of approved drugs. The share of the U.S. population covered by MCOs rose from just 5 percent in 1980 to 80 percent in 1993 to over 90 percent in 2001.[1] In response, companies doubled their sales forces between 1995 and 2001 to more than 80,000 people.[2] Merck viewed this trend with disdain, as one senior research scientist explains, "Many other drug companies are successful because they shout louder, not because they make better drugs."[3]

In the 1990s the FDA changed its policy to allow "direct-to-consumer" (DTC) advertising of prescription drugs. By 1999, 50 pharmaceutical companies had spent $1.7 billion on print, television, and other media to advertise their products. Studies indicated that if a patient discussed an advertised drug with their doctor, 60 percent received a prescription for it, providing companies with an avenue to influence which drugs are prescribed.

New Entrants: The threat of new entrants is *low*. The costs associated with years of research and development, manufacturing, and government regulatory compliance discourage most new competitors from entering the market. University laboratories are a potent source of new technologies, but they cannot commercialize their innovations independently.

Competitive Rivalry: This is a *moderate-to-strong* force as industry consolidation has resulted in fewer, large competitors with roughly equal resources. Most large companies tend to target the same therapeutic area, racing to develop and patent the next blockbuster drug, creating a protected market for at least the first five years. Competitive pressures are somewhat mitigated by an increasing demand from aging baby boomers and emerging economies.

Substitutes: Perhaps the *strongest* force affecting branded pharmaceutical products is the increasing demand for generic pharmaceuticals. Because generic drug companies do not have the costs associated with research and development, they can sell "pharmaceutical equivalents" for 60 percent to 90 percent less than branded products. Nondrug treatments and neutraceuticals are other viable substitutes for some prescription medications. Switching costs are low for patients, though they may be higher at policy-making levels.

Summary: The pharmaceutical industry is a relatively attractive industry with significant profit potential, provided it can continue to innovate proprietary new drugs to offset the threat of generics and other substitutes. Significant barriers to entry keep new competitors out, while industry consolidation has granted major pharmaceutical companies significant power over suppliers. Rivalry is high due to a limited number of large, equally balanced competitors, but it is mitigated by anticipated growth in sales, especially in emerging markets. Buying power is concentrated in the hands of physicians, insurers, and policy makers, but it can be partially counteracted through innovation (creating "must have" products) as well as advocacy and advertising efforts.

2. Looking at Merck's strengths, weaknesses, opportunities, and threats, determine if Merck can gain and sustain a competitive advantage in the pharmaceutical industry. Why or why not?

A list of Merck's strengths, weaknesses, opportunities, and threats is provided next (see Exhibit TN-2). This analysis highlights the fact that Merck is going through a time of transition. In the past, Merck's superior in-house research capability was its primary source of competitive advantage. Merck had been known to hire the best scientists from all over the world in order to stay on the cutting edge of developmental research. Today, however, expertise in the medical and biomedical fields is widely dispersed across numerous companies, universities, and countries, diluting Merck's previous claim to

fame. Merck now produces less than 1 percent of all biomedical research worldwide. This shift in the external environment is forcing Merck to adapt by opening up its R&D engine.

The merger with Schering-Plough represented a major step toward a more open innovation paradigm. This integration of mega-companies added 20 new NMEs in stages 2 and 3 of the FDA approval process to Merck's drug pipeline and significantly extended Merck's reach in emerging markets. Some implementation problems are to be expected with any acquisition, especially one of this magnitude, but the major restructuring efforts and expenses are now complete. The clinical development issues encountered with vorapraxar and sugammadex were unfortunate in timing, but they are also not unusual occurrences in the high-risk business of drug development. The major challenge for Merck's leadership now is to keep the organization moving forward toward open innovation and to avoid letting these minor setbacks become excuses to close the door to future transactions and outside ideas. Otherwise, Merck stands to fall even further behind its competitors who are already well on their way to leveraging external research capabilities. It already has the lowest percentage of new approved drugs based on externally derived technology, and the company has fallen from third to sixth place in the total number of active R&D projects.

The proposed Idenix acquisition could arguably provide a unique *opportunity* for Merck to leverage its *strengths* (lessons learned from SP merger, brand equity in the HCV market, past successful launch of Vectrelis, biologics expertise of Roger Perlmutter) against its *weakness* (no experience in nucleoside development) to counteract a potent competitive *threat* (Gilead's recent approvals, other competitor products in development) and capitalize on a highly lucrative market segment. If successful, analysts predict that Merck and Gilead would emerge as the two major players in the HCV therapeutic area.

FORMULATION: FOCUS ON BUSINESS, CORPORATE, AND/OR GLOBAL STRATEGY

3. Analyze Merck's innovation strategy. Does Merck's innovation engine need fixing? Why or why not?

Merck can attribute its past high performance to its superior in-house research capability.[4] As *the* world-class research-driven pharmaceutical company, it is Merck's scientists—not marketing or finance gurus—that have historically led the company toward greatness. Prior to 1950, no less than five Merck employees won Nobel prizes for their contributions to medicine. Dr. Max Tischler, who joined Merck in 1937, was honored with inventing the concept of development research. A legend for almost 50 years, Dr. Tischler was inducted into the Inventors Hall of Fame in 1982 and received the National Medal of Science in 1987. Several other company scientists have turned into high-profile executives and CEOs. Dr. Ed Scolnick, a renowned Harvard-educated scientist, joined Merck in 1982 and served as president of the celebrated Merck Research Labs (MRL) for 17 years. Dr. Roy Vagelos, CEO from 1984–1994 and chairman of the board from 1986–1994, directed Merck's scientists not only toward high-risk projects that could aid in the discovery of breakthrough products, but also toward making great contributions to medical science.

Merck's employees are justifiably proud of their internal R&D capabilities. In 2012, Merck was ranked as the third most successful company by total number of active R&D projects. In 2013, Merck spent approximately 17 percent of its (declining) revenues on R&D, despite the expenses associated with the SP acquisition and subsequent restructuring efforts. Only 13 percent of Merck's newly

approved drugs have been based on externally derived technology. This contrasts to an industry average of almost 50 percent, while many competitors like Astrazeneca, Bristol-Myers, Sanofi-Aventis, and Roche are well above 80 percent.

Recently, Merck has been having difficulty replicating its past successes. Revenues have been declining largely due to a variety of core products losing market exclusivity. Two key products lost patent protection in 2012 (Singulair to treat asthma and allergic rhinitis and Maxalt for migraine headaches). By 2013, the company's worldwide sales reached just $44 billion, a year-on-year decline of 7 percent. And Merck faces the prospect of even more patent expirations in the near future. Of greatest concern is the loss of market exclusivity for two products which contributed 8 percent of all sales in 2013: Nasonex (corticosteroid for the treatment of nasal allergy symptoms, in 2014) and Remicade (biologic capable of treating a broad range of inflammatory diseases, in 2015). At annual sales of $1.34 and $2.27 billion respectively, a decline in sales of these two drugs will seriously affect Merck's revenue stream. In addition, Merck's 2004 withdrawal of Vioxx continues to be a significant drain in terms of both finances and reputation. It is estimated that legal liabilities have cost Merck in excess of $30 billion thus far.[5] Merck also faces ongoing litigation related to Fosamax, a treatment for osteoporosis, which has been identified as a possible cause of femoral fractures and general bone necrosis/weakness.[6] Claims have not yet reached the magnitude of Vioxx, but the ongoing court battles are tarnishing Merck's reputation even further. These are the reasons that many analysts think that Merck's innovation strategy is in need of some fixing.

Merck has already been tapping into external knowledge through informal networks, conference attendance, and publications. The need to foster connectivity with the external environment outweighs the potential losses associated with publication of once proprietary intellectual knowledge.[7] However, Merck needs even more sharing of knowledge from inside and outside of company borders. Merck's 2009 "reverse merger" with Schering-Plough, its first major external venture since 2006, was a major step toward an open-innovation strategy, but much more work is still needed.

4. What is open innovation? Can open innovation help Merck meet the needs of its customers in creative and cost-effective ways that also bring value to its shareholders? Why or why not?

A closed-innovation philosophy has dominated drug development for the past several decades. Closed innovation requires complete internal control of the R&D process; a company generates its own ideas and then develops, manufactures, markets, and distributes each new product alone. In the past, this has created a virtuous and self-sustaining cycle for companies like Merck, where fundamental scientific breakthroughs would create new products and generate increased sales, which would in turn be poured back into more R&D investment to create more breakthroughs.[8] However, with the rise of the Internet and the increased mobility of knowledge workers, companies that are heavily dependent on human capital are increasingly unable to control and protect their proprietary knowledge, causing a breakdown in the closed-innovation system.

In contrast, open innovation involves companies opening up their business models by actively searching for and exploiting outside ideas. At the same time, open innovation permits unused internal technologies to flow to the outside where other firms can unlock their latent economic potential. In open-innovation markets, ideas flow freely to where they can be developed most efficiently. For example, a company may develop a novel technology, but not have the time, resources, or insight to develop it further. Through open innovation, the company can partner with, sell, or license that technology to another firm who then commercializes it, creating value for both parties. Thus, open innovation

increases efficiency through the sharing of resources while improving effectiveness through intellectual cross-pollination across disciplines, cultures, and geographies.

Many view open innovation as a way to overcome the dearth in new drug development. In the pharmaceutical industry, rising development costs and shorter product life cycles are causing companies to become increasingly cautious of exorbitant expenditures for innovation. The pharmaceutical industry has seen aggregate R&D spending increase 250 percent since 1993, while the number of new drug submissions to the FDA has fallen by more than 70 percent.[9] Additionally, less than half of these companies actually use their patented technologies because the innovation either costs too much to develop, its potential value is uncertain, or it does not fit the company's business strategy. As a consequence, much patented technology is left sitting on the shelf.[10] Such inefficiencies in the innovation market are overcome when companies open up and share ideas and technology.

Merck's early open-innovation efforts. One reason to be optimistic about Merck's ability to open its innovation processes further is its past record of successful open-innovation initiatives. These include the development of a hepatitis B vaccine in the 1980s, the Merck Gene Index Project in the 1990s, and the creation of Merck BioVentures in the 2000s. Each is described in more detail next.

Hepatitis B vaccine. In the 1980s, a combination of visionary scientists, strong internal communication mechanisms, and a celebrated CEO allowed Merck to out-innovate its competitors and develop an affordable vaccine for hepatitis B.[11] Dr. Maurice Hilleman, a biologist at the Merck Institute for Therapeutic Research, convinced top management of the need to develop an effective vaccine for hepatitis B. Dr. Hilleman is known for having developed more than 40 vaccines, including those that help prevent measles, mumps, rubella, and chickenpox, and is credited with saving more lives than any other scientist in the 20th century.[12] "Among the many pursuits of mankind, none can be more rewarding than that of preventing diseases by procedures which derive from the practice of vaccinology," Dr. Hilleman said. "Vaccines, together with sanitation and nutrition, have served as principal tools employed in public health to increase the health and lifespan of human beings."[13]

Under Dr. Hilleman's leadership, Merck began to assemble the capabilities and knowledge base to develop a subunit hepatitis B vaccine made from purified human blood. By 1981, the company had a serum-based vaccine available for general use. However, the initial formulation was expensive and had a lead time longer than any other vaccine at the time. In addition, production in large quantities was hampered by the need for blood from hepatitis B carriers, while plasma-based vaccines were starting to raise public safety concerns in light of the newly discovered AIDS virus.[14] Although Merck spent more than $8 million (roughly $28 million in 2008 dollars) on upgrading its production facilities, the company simply did not have the necessary capabilities in-house to make large-scale vaccine production possible.

Working with Dr. Roy Vagelos, the renowned scientist turned CEO, Dr. Hilleman realized that Merck would need to reach out to its connections in the scientific community for help. Merck thus hired outside microbiologists to refocus the firm's laboratories on applying new developments in recombinant DNA technology to vaccine research. Dr. Vagelos also established a collaborative research program with prominent scientist William Rutter at the University of California, San Francisco, which eventually led to the development of a novel technique used to insert genetic information into DNA, termed genetic splicing.[15] This new process ensured that the vaccine contained no contamination from other sources and also facilitated production in large quantities.[16] Merck then spent considerable time and effort to develop the internal capability to produce a recombinant yeast-derived antigen, rather than the previous blood plasma–derived antigen. The resulting vaccine was the first of its kind for use in

humans and was approved by the FDA in 1986 after nine years of research.[17] Known as Recombivax HB, it became the sixth-largest blockbuster drug to license the Cohen-Boyer recombinant DNA patent.[18] This medical success, however, would not have happened without the open sharing of knowledge and technology with the larger scientific community.

Merck Gene Index Project. In 1995, Merck announced its new Gene Index project, based on genomics, in cooperation with Washington University and other research centers. Genomics involves characterizing the genetic basis of diseases and using the information to identify promising drug targets. Genomic knowledge of humans and other species "could potentially transform medicine by introducing safer and more effective drugs, expanding the range of diseases that are treatable, and improve diagnosis."[19] The Merck Gene Index project was pivotal in ensuring that genetic sequencing information would remain publicly available. Dr. Ben Shapiro, a leading scientist who was later appointed to the MRL Executive Committee explained, "In the early 1990s, Merck researchers saw that companies could potentially obtain patents associated with specific genes. We thought this was a dangerous situation not just for us, but for all biomedical research. So, we decided to fund a consortium of academic researchers to identify the *expressed sequence tags* (EST) associated for each gene."[20]

All sequencing data discovered by the Gene Index project are sent to the EST division of GenBank, which publishes the information within 48 hours after receipt. GenBank was built by the National Center for Biotechnology Information (NCBI), and acts as a central repository of publicly available gene sequence information. As a result, no one has advance access to, nor can they delay or restrict the release of, any of the sequence data submitted to GenBank. This includes Merck scientists, who gain access to the data via the same public processes available to all interested researchers.[21] By opening up and sharing its genomic data, Merck ensured that all players in the industry would have an equal opportunity to search for cures, and that no one could block access to a disease area by patenting a particular gene.

Merck BioVentures. In December 2008, Merck announced the establishment of a new division called Merck BioVentures, which would use the glyco-engineering technology gained with the acquisition of GlycoFi in 2006. This technology involves the use of yeast cells for more rapid development of protein-based (or biotech) products.[22] Merck's intention is to develop a competitive advantage in producing follow-on biotechnology drugs with greater yields. "Follow-on biologics" are loosely equivalent to generic versions of biotech-style drugs,[23] and are expected to undergo tremendous growth through 2017 due to patent expirations of leading biologics. A Merck spokesperson explained: "We are diversifying our R&D activities, promoting technological changes and bringing together complementary R&D activities to drive innovation at Merck. . . . Our strategy of scientific diversification facilitates innovation and provides a sustainable approach that sets Merck apart in an industry that is increasingly focused on specialty medicines."[24] Merck spent over $1.5 billion on BioVentures through 2015.

IMPLEMENTATION: FOCUS ON RECOMMENDATIONS AND HOW TO EXECUTE THEM

5. Assuming open innovation is the path to follow, what implementation issues would you expect? How should Merck overcome its cultural resistance to change?

As stated in the case, Merck suffers from the "not invented here" syndrome, meaning that if it is not created and developed at Merck, it simply cannot be good enough. Merck's culture and organizational systems perpetuate this logic, which assumes that since Merck hires the best people, the smartest

people in the industry must work for Merck, and so the best discoveries must be invented at Merck. Merck leads the industry in terms of R&D spending because Merck believes that if it is the first to discover and develop a new drug, it will be the first to market it. Thus, moving from a closed system to an open-innovation network represents a fundamentally new mindset for Merck's renowned scientists.

Importantly, Merck's open-innovation initiative has the support of the senior leadership (CEO Kenneth Frazier) and a passionate new project champion (Roger Perlmutter). *New leadership* is one of the primary ways by which firms can institute cultural change because of the role that top executives play in setting up an organization's structure, resource-allocation process, and reward system. The *merger with Schering-Plough* provided an opportunity to cull best practices from both firms and combine them into a new and improved way of doing things. Change is inevitable with any large-scale M&A and implementation challenges are to be expected. None of the issues encountered thus far (restructuring, failure of two compounds in clinical trials, lackluster financial returns, internal resistance from employees) are insurmountable and they certainly do not warrant abandoning open innovation altogether.

The fact that the transition has not gone as smoothly as hoped does make Mr. Frazier and Dr. Perlmutter's jobs more difficult, however. One of their ongoing challenges is to ensure that Merck's new approach to research and development is fully embraced by the company's employees despite any hiccups experienced along the way. Otherwise, such events might be used as an excuse to resist change and/or revert to Merck's former closed research model. The concern is that *organizational inertia*, defined as a firm's resistance to changes in the status quo, might result in Merck's failure to adapt to changes in its external environment (see Exhibit TN-3). When a firm's core competency (such as Merck's expertise in internal R&D) no longer has a good fit with the external environment, it is known as a *core rigidity*.

One potentially useful approach to instituting open innovation at Merck is the "unfreeze – change – refreeze" model of change management, described next.

Step 1: Unfreeze the culture (get the organization ready for change)

- Establish a sense of urgency to change the culture by communicating a new vision and strategic initiatives.
- Form a coalition with enough power to lead the change.

An important part of Step 1 is to develop a strategic communication plan detailing what changes are being made, why they are important, and how they are consistent with Merck's mission and reputation as a top research institution. Presumably, Merck's prior leadership pointed out Merck's past successes with open-innovation initiatives, such as its development of an affordable hepatitis B vaccine in the 1980s, the Gene Index project in the 1990s, and its launch of Merck BioVentures in 2008. Similarly, Mr. Frazier should continue to highlight the benefits of Merck's ongoing and active involvement with the external scientific community through informal networks, conferences, publications, and creative business arrangements with other scientific organizations. At the same time, it would be helpful to frame the SP merger as a vital learning experience, pointing out the positives (increased market power, expanded reach into emerging markets, broader product pipeline, approval of new drugs like Vectrelis) gained despite some of the hiccups that occurred along the way. After undertaking such a large megamerger and emerging successfully, Merck's employees are actually better prepared for any future transactions due to learning curve effects.

Step 2: Changing the culture (implement the changes)

- Put managers in place who agree with new strategy.
- Empower employees to act on new vision.

Mr. Frazier's predecessor laid a strong foundation for an open-innovation strategy by encouraging scientists to publish their research and sending them to "charm school" to learn how to be courteous when corresponding with non-Merck people. Now, Merck has two new managers strategically placed to lead the company through the next phase of its transition. Mr. Frazier is the last senior executive hired by P. Roy Vagelos, who led Merck during its prime in the 1980s. As a 35-year veteran, Frazier knows the company's heritage well and is determined to reinvigorate Merck's innovative culture; he was one of the chief engineers of the SP merger. He sees his main responsibility as "creat[ing] an environment where really talented, smart, committed people want to show up and [discover new drugs]." One of his most decisive moves thus far has been to hire Roger Perlmutter as head of R&D to spearhead his strategic vision. Mr. Perlmutter left Merck in 2001 because he did not think the company was being innovative enough. While at Amgen, Perlmutter built an R&D group from the ground up and helped bring eight new medicines to market, developing a valuable expertise in protein-based therapeutics.[25]

Step 3: Refreeze the culture (solidify the change into the "new normal")

This step is where Dr. Turner should continue to consolidate improvements, reassess changes, and make ongoing adjustments. One way to solidify open innovation as the "new normal" is to stay active in the M&A market. While it might be tempting to wait until all the dust is settled from the SP merger, purchasing another firm sooner as opposed to later sends a strong signal that Merck intends to be a player in the external marketplace. Pursuing the Idenix acquisition (or another deal that makes strategic sense) solidifies the perception that M&A is now another option in Merck's discovery toolbox, alongside its historical competencies in internal research and strategic alliance formation. Like any other skill, firms hopefully get better at M&A with practice, assuming they are willing to learn from past mistakes. While open innovation is the *intended strategy*, how it is eventually implemented at Merck will be a function of both the original vision and adaptations made along the way (*emergent or bottom-up strategy*).

6. Is the acquisition of Idenix an appropriate response to competition in the HCV market? Why or why not?

Note: *The case takes some literary license with the sequencing of 2014 events in the HCV market in order to present a compelling strategic question. In reality, Merck announced the acquisition of Idenix on June 9, 2014 and subsequently completed the deal on August 5, 2014. While the approval of Gilead's Harvoni (October 2014) and AbbVie's Viekira Pak (December 2014) were anticipated, they were not known facts at the time of Merck's decision.*

Merck has emerged from the SP merger—a significant *internal shift*—with valuable lessons learned. The major restructuring efforts (changes in *organization design, structure, processes and procedures*) are complete and the company is starting to see a modest financial return on its investment. It is important for Mr. Frazier to maintain Merck's forward momentum toward open innovation, though this could be accomplished through a variety of initiatives and does not necessarily require another acquisition.

The primary pressure for an acquisition at this time is coming from the external environment. Namely, Merck has lost the upper hand in the HCV market to Gilead with the approvals of Sovaldi and Harvoni in 2013 and 2014, respectively. Other competitors are likewise racing to enter the fray. The standard of care for HCV has been elevated to a combination therapy administered as a single pill per day, for eight to 12 weeks, with cure rates of 95 percent and above. To remain competitive, Merck has to create its own combination pill with at least equal efficacy and match or beat Gilead at price; to do so, it must either partner with or acquire a company with an active nucleoside program. There is no time to develop this new area of expertise internally.

One news story reported that Merck was one of several companies (including Johnson & Johnson, AbbVie, and Bristol-Myers Squibb) to approach Idenix after it published positive results from a Phase 2 trial of its lead nucleoside candidate in spring 2014.[26] According to Perlmutter, however, Merck was already in talks to partner with Idenix when another company made a bid to acquire the company, setting off a bidding war. Merck has a combination of two HCV drugs of its own in late-stage clinical trials and believes that by adding a third drug (specifically a nucleoside), it can create a single pill to treat all disease subtypes in just four weeks. Merck and Idenix were also pursuing separate patent infringement cases against Gilead's Sovaldi, and may have greater leverage in court by joining their claims.[27]

Because of these competitive pressures, Merck was forced to make a bid to acquire (as opposed to ally with) Idenix at a price premium. Merck paid $3.85 billion for Idenix in August 2014, based on a tender offer of $24.50 per share in cash. This value was roughly 3.4 times the trading value of Idenix stock ($7.23 per share) on the Friday prior to the Monday on which the acquisition was announced. Merck justified the premium based on market size, noting that there are 150 million people worldwide with HCV, including 3 million Americans, and that many of these Americans are expected to obtain health care coverage under the ACA.[28]

Despite the fact that the deal has been concluded, it is still worthwhile to debate whether the potential returns outweigh the risks. Consider the following facts:

- Phase 2 trial data are preliminary in nature and the Idenix drugs can still run into significant safety and efficacy issues.[29] Idenix has previously had to pull several lead candidates from clinical development, as noted in the case.
- Bristol-Myers Squibb spent $2.5 billion for Inhibitex in 2012[30] to gain access to its nucleoside analog but later had to write off the investment when the drug showed significant safety issues (heart and kidney problems).[31]
- There are other potential acquisition targets with nucleoside technology, such as Achillion Pharmaceuticals.[32] Perhaps more time to conduct better due diligence would reveal a better acquisition candidate.

Statistically, it is important to remember that only about 20 percent of M&As typically realize the expected synergies and bring additional value to both firms. With respect to the pharmaceutical industry, research has shown that there is no correlation between the size of a company's R&D budget and productivity (in other words, bigger is not necessarily better). Another study showed that merged companies tend to trim their product pipelines, resulting in a 34 percent decline in the overall number of development projects. A more general warning is that while open innovation is valuable, acquisitions should never become a substitute for internal R&D (though this is not likely to happen at Merck anytime soon).

Updates

Carroll, J. "Merck's hepatitis C cocktail drug fails a 4-week challenge." http://www.fiercebiotech.com/story/mercks-hepatitis-c-cocktail-drug-fails-4-week-challenge/2014-11-10. Accessed November 10, 2014.

In November 2014, Merck revealed that its combination of grazoprevir/elbasvir with Sovaldi (sofosobuvir) cured 94.7 percent of cirrhotic patients (treatment naïve) at eight weeks, but achieved cure rates of only 80 percent at six weeks and 38.7 percent at four weeks. Patients without cirrhosis achieved a cure rate of 86.7 percent at six weeks, which fell short of the 90 percent rate achieved by competitors. Gilead's stock increased on the news, as its combination therapy Harvoni remains the clear market leader until Merck can develop its drugs in combination with the nucleoside acquired from Idenix. Merck previously planned a series of Phase 2 studies for its proprietary triple-drug cocktail with an 8-week treatment benchmark. Merck's dual regimen at 12 weeks was comparable with competitors' products and continued to gain share in the market.

Additional Resources

1. Merck-Idenix deal:
   http://video.cnbc.com/gallery/?video=3000282622 (1:53). *Behind the Merck-Idenix deal* (June 9, 2014). News story explaining the business rationale behind the Merck-Idenix deal.

   http://video.cnbc.com/gallery/?video=3000282640 (2:31). *Merck buys Idenix for $3.85 billion* (June 9, 2014). A more critical news story that explains the bidding war that led to Merck paying a high premium to purchase Idenix.

2. Merck-SP merger:
   http://www.msnbc.msn.com/id/29592960/ns/business-us_business/t/drugmaker-merck-buy-schering-plough/ (5:00). *Drugmaker Merck to buy Schering-Plough* (March 9, 2009). This link contains a news story announcing Merck's plans to buy Schering-Plough, a deal worth roughly $41 billion.

   http://www.pharmatelevision.com/Video/636-Merck-Pamela-Demain.aspx (16:22, the first five minutes are available as a preview). *Merck & Co.: Merging with Schering-Plough and future plans* (April 1, 2010). This is a Pharma Television interview with Pamela Demain, Executive Director of Corporate Licensing at Merck. She discusses how the merger has affected both internal and external research and development efforts.

3. **Some additional background on Vioxx—The biggest drug withdrawal in history.**

On September 30, 2004, Merck announced the voluntary withdrawal of the acute painkiller Vioxx from the market. Vioxx was used to treat illnesses such as osteoarthritis without the adverse gastrointestinal side-effects associated with ibuprofen and aspirin. Merck invested almost $1 billion in the research and development of the new drug, which had been completed at a record speed of six years. Vioxx was supposed to be Merck's next big blockbuster to make up for $4 billion in losses due to patent expiration on five of its current blockbuster drugs including Pepcid and Zocor.[33]

Upon the launch of Vioxx in May 1999, Merck's revenues increased by over 10 percent. By 2003, two million people worldwide were using Vioxx, and sales totaled more than $2.5 billion, almost 11 percent of Merck's total annual revenues.[34] However, increasing controversy in the medical community over the allegation that Vioxx caused heart attacks and strokes tarnished Merck's otherwise spotless reputation. Merck denied the allegations while continuing to study the drug's side-effects with longer-term studies. The final results of the three-year Adenomatous Polyp Prevention (APPROVe) placebo-controlled study were undeniable. Researchers found that after 18 months of taking Vioxx, risks for heart problems had in fact doubled in the Vioxx group compared to those who received the placebo.[35]

The recall of Vioxx had a terrible impact on Merck's stock price and adversely affected the sales of Merck's other drugs. Shares fell 27 percent to $33, eradicating $27 billion in market value overnight. Before the withdrawal, Merck had anticipated earnings per share of $3.11 to $3.17. After it pulled Vioxx from the market, Merck's earnings per share fell to between $0.50 and $0.60.[36] "We are taking this action because we believe it best serves the interests of patients," said then-Chairman and CEO Raymond V. Gilmartin. "Although we believe it would have been possible to continue to market Vioxx with labeling that would incorporate these new data."[37] Many employees, investors, and patients wished that Merck had not recalled the drug, but rather added health warnings on the label, like many other drug companies did. Vioxx was the only drug that truly helped some patients with severe pain. In the wake of the Vioxx recall, Raymond Gilmartin was replaced as CEO by Richard Clark in May 2005.[38]

Merck has been burdened by lawsuits ever since. On August 19, 2005, Merck was found liable for the wrongful death of a man who had taken Vioxx and died from a heart attack in 2001. The plaintiff sought damages based on the premise that "Merck knew about the serious cardiovascular risks associated with Vioxx but continued to market this defective drug while downplaying these risks."[39] The Texas jury awarded the plaintiff more than $250 million; 10 of the 12 jurors found that Merck had acted irresponsibly and meant the damage award to be a lesson for all pharmaceutical companies. Since then, Merck has fought every lawsuit in court and has not been found guilty in any other cases. Nevertheless, Merck paid $4.85 billion to settle legal battles with over 47,000 groups or plaintiffs suing for damages in 2007. Vioxx allegedly caused 130,000 heart attacks and strokes and 55,000 deaths. A company spokesperson estimates that Merck has paid up to $30 billion in legal liabilities thus far.[40]

Contact your local representative from McGraw-Hill Education (http://shop.mheducation.com/store/paris/user/findltr.html) for information about access to financial analysis spreadsheets.

EXHIBIT TN-1 Applying Porter's Five Forces Model to Analyze the Structure of the Pharmaceutical Industry

Factors Leading to...	Power of Suppliers	Power of Buyers	Threat of New Entrants	Interfirm Rivalry	Threat of Substitutes
High threat		Concentrated wholesalers buy from manufacturers. Physicians decide what to prescribe to patients. Insurers and policy makers decide which drugs receive coverage. Strong political pressure to lower health care expenses. Increased comparative effectiveness research. Drug effectiveness trumps brand loyalty.	University laboratories are a potent source of new technologies, but they usually cannot commercialize innovations independently.	Industry consolidation has resulted in fewer large and balanced competitors. Most large pharmaceutical and biotech firms target similar therapeutic areas. First product to market itself has competitive advantage, as late-comers must demonstrate additional benefits. High exit barriers due to specialized investments.	Generics are a major threat for pharmaceuticals. Biotech and pharmaceutical products may be substitutes for one another. Drugs may work for more than one indication, cannibalizing existing products. Switching costs are low for patients (may be higher at policy level).
Moderate threat	Supplier power may be higher when specialized ingredients or facilities are needed.		Individual customer switching costs are low if generics are available. Brand equity is not as significant if the new drug works better.		For some indications, nondrug treatments may be viable alternatives. Neutraceuticals may be available for some indications.

(continued)

EXHIBIT TN-1 (Continued)

Factors Leading to...	Power of Suppliers	Power of Buyers	Threat of New Entrants	Interfirm Rivalry	Threat of Substitutes
Low threat	Many chemical materials suppliers are available. Highly regulated industry, so minimal opportunities for differentiation. Low switching costs for large drug companies. Larger pharmaceutical firms have investments in chemical manufacturing. Suppliers are unlikely to forward-integrate (except possibly generics).	Market-based pricing system. Low threat of backward integration. High importance of pharmaceuticals to end users.	Industry is highly regulated by FDA. Takes time and money to develop proprietary technology through R&D. High capital requirements for manufacturing. Requires sophisticated sales force. Formularies restrict which drugs may be prescribed.	Demand for product is increasing with aging of baby boomers. Emerging economies are relatively untapped markets. Consolidation has lowered intensity of rivalry in developed markets.	Nature of threat depends on comparative effectiveness.
Overall Assessment:	Low	Moderate	Low	Moderate to High	High

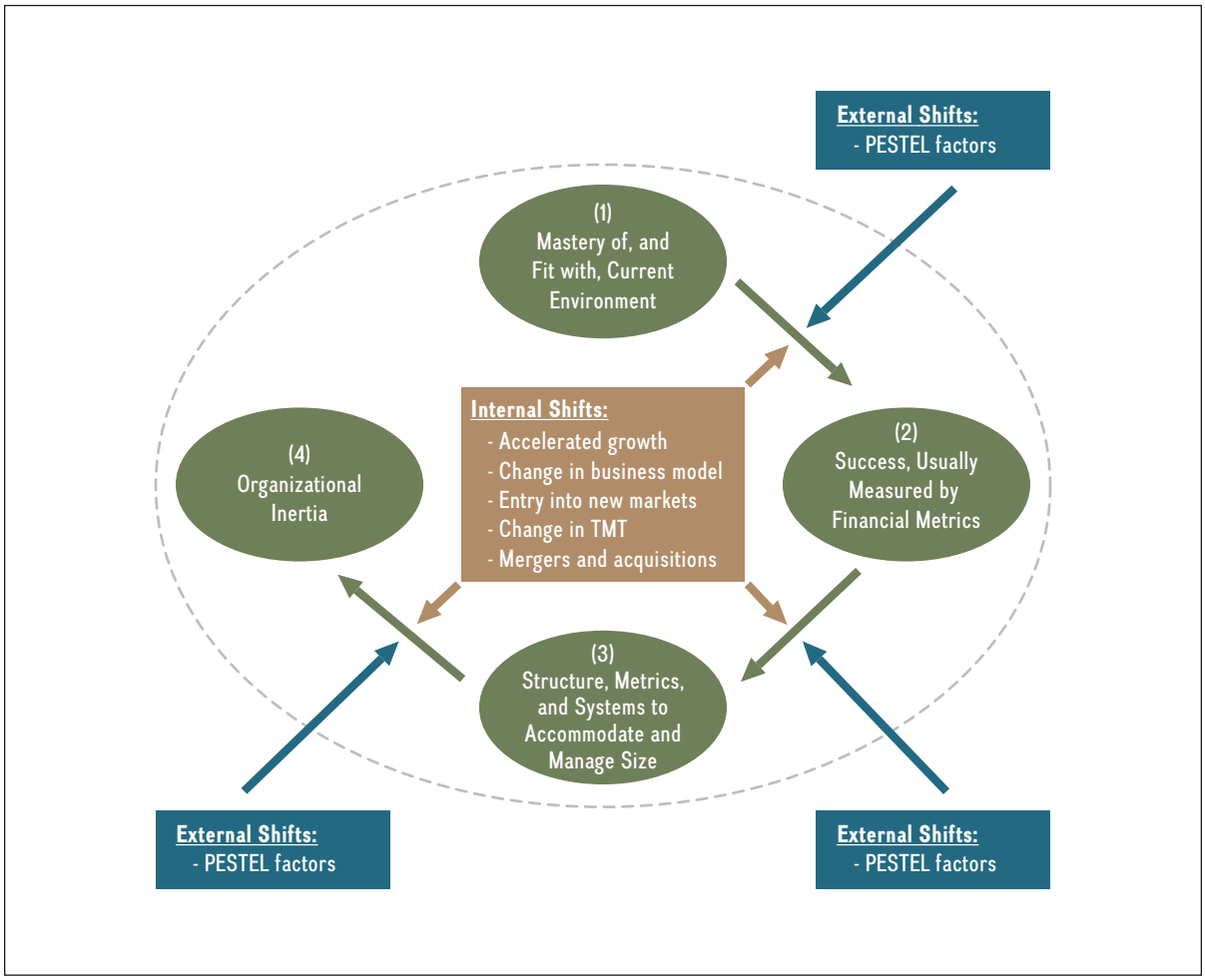
Source: Courtesy of F.T. Rothaermel.

EXHIBIT TN-2 A SWOT Analysis of Merck

Strengths	**Weaknesses**
Scientific reputation	Patent expiration for key blockbuster brands: Maxalt, Singulair, Nasonex, and Remicade
Internal R&D programs	Historical reliance on closed innovation
Global presence expanded by SP merger	Internal resistance to open innovation
Enhanced product pipeline due to SP merger	Rebate charges and health care reform fees under ACA
Brand equity	Smaller tie-ins with biotech
Strong recent new product launches, exemplified by the Januvia/ Janumet and Isentress brands	(Over)reliance on blockbuster development model
Leading position in global vaccine market, supported by comprehensive roll-out of new products such as Gardasil	Vioxx recall and reputational effects
Successful launch of Vectrelis for treatment of HCV in 2011	Global restructuring costs
Completed major restructuring	Poor financial (stock) performance following SP merger
Lessons learned from SP merger	Development issues with vorapaxar and sugammadex (acquired from SP)
Ranked "best in class" as alliance partner by BCG	Other integration issues from SP merger
Hiring of Roger Perlmutter as president of research (biologics expertise)	Decline in ranking by total number of active R&D projects
	Lack of experience in nucleoside development
Opportunites	**Threats**
Expanded patient pool under ACA	Slow projected industry growth
Create a generic division	Unfavorable U.S. political climate
Entry into emerging markets	U.S. government health care regulations
Therapy area diversification toward markets such as diabetes and oncology	Cost containment efforts by insurers (pricing pressures and inclusion in formularies)
Increased investment in biologics	Strong competitors
International acquisition for tax inversion	Exponential growth in generic competition including recent provisions for "biosimilar" approvals
Acquisition of Idenix to create combination therapy with Vectrelis for treatment of HCV	Litigation (Vioxx and Fosamax)
	Gilead's approval for Solvadi and Harvoni for treatment of HCV
	Additional HCV therapies being developed by AbbVie and BMS

Source: Courtesy of F.T. Rothaermel.

EXHIBIT TN-3 Impact of Organizational Inertia on a Firm's Ability to Adapt to Its External Environment



Source: Rothaermel, F.T. (2018), Strategic Management, 4th edition. Burr Ridge, IL: McGraw-Hill.

Endnotes

1 Gilbert and Sarkar (2007), "Merck: Conflict & Change." *Harvard Business School*. May 4, 2007.

2 "Making More of Pharma's Sales Force," *McKinsey Quarterly*, Issue 3, 2002.

3 Gilbert and Sarkar (2007), "Merck: Conflict & Change."

4 Gambardella A. (1992), "Competitive Advantage from In-House Scientific Research: The U.S. Pharmaceutical Industry in the 1980s," *Research Policy*, 21: 391–407.

5 "Jury Finds Merck Liable in Vioxx Death and Awards $253 Million," *The New York Times*, August 19, 2005.

6 "Judge Wants More 'Bellwether' Trials In Litigation Over Merck's Fosamax," *The Wall Street Journal*, February 7, 2011.

7 Henderson R., and Cockburn I. (1994), "Measuring Competence? Exploring Firm Effects in Pharmaceutical Research," *Strategic Management Journal*, 15: 63–84.

8 Chesbrough, Henry (2003), "Open Innovation. The New Imperative for Creating and Profiting from Technology," *Harvard Business School Press*, Boston, MA.

9 Raynor M. E., and Panetta J. A. (2005), "A Better Way to R&D?" *Harvard Business School Publishing*.

10 Chesbrough, Henry (2007), "Why Companies Should Have Open Business Models," *MIT Sloan Management Review*, 48: 2.

11 Hess, A. M., and Rothaermel, F. T. (2009), "Corporate Entrepreneurship and Dynamic Capability Formation," *Working Paper, Georgia Institute of Technology*.

12 "Inaugural Maurice Hilleman/Merck Award Given for Lifetime Work in Vaccines," *The Daily*, Merck & Co. intranet, May 20, 2009.

13 "Merck Scientist Receives International Award for Advancement in Public Health," *The Daily*, Merck & Co. intranet, February 3, 2003.

14 Galambos L., and Sewell J. E. (1995), "Networks of Innovation," *Cambridge University Press*, Cambridge, UK.

15 Ibid.

16 Patlack M. (2000), "The Hepatitis B story," *Beyond Science, A National Sciences Publication*, 2: 1–8.

17 Ibid.

18 Year, F. M., "Commercializing Cohen-Boyer 1980–1997." In proceedings of the REER Conference, Atlanta. IS THIS SHADING HERE ON PURPOSE?

19 Pisano, Gary (2006), "Discovering the Future: R&D Strategy at Merck," *Harvard Business School Publishing*, 7:19.

20 Ibid.

21 Merck Gene Index Press Release (1995), http://www.bio.net/bionet/mm/bionews/1995-February/001794.html.

22 "Merck Forms BioVentures Division and Expects to Lead in Follow-On Biologics," *PharmaManufacturing.com*, December 11, 2008.

23 Merck press release (2009), "Merck & Co., Inc. Acquires Biologic Manufacturing Capabilities and Developmental Follow-On Biologics Portfolio from Insmed," http://www.merck.com/newsroom/press_releases/corporate/2009_0212.html.

24 "Merck Outlines Long-Term Prospects and Progress on Strategic Plan at 2008 Annual Business Briefing," *Fierce Biotech*, December 9, 2008, http://www.fiercebiotech.com/press-releases/merck-outlines-long-term-prospects-and-progress-strategic-plan-2008-annual-business-b#ixzz0PrhkfCVY.

25 http://www.forbes.com/sites/matthewherper/2013/04/17/merck-could-return-to-greatness-if-ceo-can-leave-his-own-past-behind/3/.

26 http://video.cnbc.com/gallery/?video=3000282622.

27 http://dealbook.nytimes.com/2014/06/09/merck-to-acquire-idenix-pharmaceuticals/?_r=0.

28 Ibid.

29 http://video.cnbc.com/gallery/?video=3000282640.

30 http://dealbook.nytimes.com/2012/01/07/bristol-myers-to-buy-inhibitex-for-2-5-billion/.

31 http://dealbook.nytimes.com/2014/06/09/merck-to-acquire-idenix-pharmaceuticals/?_r=0.

32 Ibid.

33 "Business Biographies: Raymond V. Gilmartin," *Answers.com*, Business & Finance.

34 Petersen, Mitchell A. (2007), "Vioxx: Too Risky for Merck?" *Kellogg School of Management*.

35 Ibid.

36 "Vioxx Press Release," Merck press release, September 30, 2004.

37 Merck Press Release (2004), "Merck Announces Voluntary Worldwide Withdrawal of VIOXX," Sept. 30, http://www.merck.com/newsroom/vioxx/pdf/vioxx_press_release_final.pdf.

38 http://www.washingtonpost.com/wp-dyn/content/article/2005/05/05/AR2005050501115.html.

39 "First Vioxx Lawsuit Settled," August 19, 2005, www.adrugrecall.com. Accessed September 9, 2009.

40 Berenson, Alex (2005), "Jury finds Merck Liable in Vioxx Death and Awards $253 Million," *The New York Times*, August 19.