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Merck (in 2009): Open for Innovation?

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More innovative. More customer-focused. Leaner and more agile. These are the defining characteristics of the new Merck we are continuing to build . . .

—2008 Merck Annual Report to Shareholders

DR. MERVYN TURNER, Merck's newly appointed Chief Strategy Officer, had never faced a more challenging time in his 23 years with the company. He worried about the expiration of eminent patents on existing drugs, an empty drug pipeline, an adverse regulatory environment, an increasingly competitive marketplace, and a harsh economic climate. With all these challenges to overcome, Merck was more reliant on the development of blockbuster drugs than ever before. In the past, Merck's significant investment in internal research and development (R&D) was a strategic advantage with which few companies could compete. However, Merck's pipeline of potential new drugs seemed to be drying up. With the U.S. and international laws favoring generic drug-makers and offering shorter exclusivity periods for patents, drug companies had less time to make up for significant R&D investments. In order for Merck to stay competitive, Dr. Turner felt strongly that change was necessary. Merck needed to innovate.

Dr. Turner remembered what Dr. Roy Vagelos, former Merck CEO and Chairman, had repeatedly told him: "Organizations that don't change don't last unless they are in some very isolated, unchallenging environment. Organizations . . . need to be revitalized periodically if only because people tend to settle into routines and drop out of touch with their changing environments. One role of a leader is to convince people, before the fact, that they should change."[1]

The position of Chief Strategy Officer at Merck was a new one, and Dr. Turner knew it was his job to envision a game-changing strategy that would restore Merck's long-term leadership in the pharmaceutical industry. He also knew he would need the insights and support of his strategy team to get this monumental task accomplished. That is why he called this meeting—to ask the company's strategic leadership to come up with a detailed analysis and set of recommendations to move Merck toward a more innovative future.

He looked around at the faces of his new strategy team, comprised of executives, directors, mid-level managers, and several eager MBA interns, took a deep breath, and determinedly spoke: "There is no doubt that innovation is the way forward."[2] The expectant eyes continued to stare at Dr. Turner while he patiently explained what he knew they had to do. "Merck accounts for about 1 percent of the biomedical research in the world. To tap into the remaining 99 percent, we must actively reach out to universities, research institutions, and companies worldwide to bring the best of technology and potential

Alicia Horbaczewski of Merck (GT MBA '10) and Professor Frank T. Rothaermel prepared this case from public sources.

products into Merck. The cascade of knowledge flowing from biotechnology and the unraveling of the human genome—to name only two recent developments—is far too complex for any one company to handle alone."[3]

Dr. Turner knew that what he was talking about would have been considered heresy just a few years before. Merck's identity as a science-led company was deeply rooted in its history of having a strong competence in internal research and systems that churned out blockbuster drug after blockbuster drug. Yet Merck's former model, focused on internal R&D, would no longer suffice in an industry where thousands of innovative ideas were generated daily, both inside and outside the company. Importantly, Merck's recent $41 billion "reverse-merger" with Schering-Plough represented a significant step away from a closed R&D model toward a more open innovation strategy. Following the industry trend of consolidation from major to mega-drug companies, Merck was starting to move past its tradition of relying solely on its own internally grown research. However, the company's ability to capitalize fully on this investment depended heavily on whether—and how—Merck's strategy team would embrace any ideas that originated from outside the walls of Merck's hallowed laboratories.

Merck & Co. History

Merck is a global research-driven company that discovers, develops, manufactures, and markets a broad range of innovative products to improve human and animal health. Merck was founded in 1668, when pharmacist Friedrich Merck acquired an apothecary in Darmstadt, Germany. Some 200 years later, Emanuel Merck built a pharmaceutical and chemical company that led to steadily increasing sales and international expansion. In 1891, Merck & Co. was established in Germany and emerged as one of the largest producers of prescription drugs in the world. After World War I, the Merck family, along with their shareholders, incorporated as a U.S. firm with no ties to the original German parent company.

Over the next few decades, Merck developed prominence as a research powerhouse, attracting the most highly respected scientists from around the world. By 1950, five Merck researchers had won Nobel prizes for their contributions to medicine. Head scientists were successful in the recruitment and retention of superior research personnel because Merck maintained an academic, university-like atmosphere in which scientists were given freedom to explore their personal research interests. The hallways in the research sites in Rahway, New Jersey, and Boston had academic disciplines written on them, such as "Biology" and "Chemistry." With a campus-like setting, world-renowned scientists, and cutting-edge research, Merck became known as "The Harvard of Pharma."

By 1989, Merck had expanded to six divisions, 70 business units, 13,000 products, 21,000 employees, and production facilities in 27 countries. Merck's internally focused, research-driven culture received accolades for excellence in the industry, landing it on *BusinessWeek*'s list of Top 10 Most Valuable Companies from 1987 to 1990.[4] *Fortune* magazine anointed Merck as the most-admired company in America from 1987 to 1993.[5] Even people who knew nothing about the pharmaceutical industry had heard of Merck.

Yet Merck has been unable to replicate its past successes for almost two decades. For the second time in recent years, Merck's 2008 revenues fell by 1 percent from $24.2 billion in 2007. (**Exhibits 1 and 2** contain Merck's 2009 income statement and balance sheet.) This decline was largely due to lower sales of Fosamax, which lost its patent for the treatment and prevention of osteoporosis. Also contributing to the loss of revenue were the still lower sales of the cholesterol-lowering drug Zocor, which lost market

exclusivity for all formulations in the United States in 2006. Merck has three more key product patents due to expire in upcoming years: in 2010, Cozaar/Hyzaar (to treat hypertension); in 2012, Singulair (to treat asthma and allergic rhinitis); and in 2012, Maxalt (to treat migraine headaches).

Adding tremendous pressure on Dr. Turner to devise a winning strategy for the future was the largest drug recall in history. Merck invested almost $1 billion in the R&D of the arthritis and acute-pain medicine Vioxx, which had been brought to market in a record time of just six years. Upon the launch of Vioxx in May 1999, Merck's revenues increased by over 10 percent. However, increasing controversy in the medical community over the allegation that Vioxx caused heart attacks and strokes tarnished Merck's otherwise spotless reputation. On September 30, 2004, Merck announced the voluntary withdrawal of Vioxx from the market. The recall 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 almost overnight. Merck has been burdened by lawsuits ever since, and it is estimated that legal liabilities have cost Merck up to $30 billion thus far.[6]

"Reverse-Merger" with Schering-Plough

In 2008, Merck had 59,000 employees, sales revenues of $23.9 billion, and a market value of $44.4 billion. Schering-Plough (SP) with 51,000 employees had sales revenues of $18.5 billion and a market value of $32.6 billion.[7] The joining of these two former rivals in March 2009 was seen as a necessary step toward diversification and increased economies of scale, propelled by imminent patent expirations and increasing pressure from shareholders, government, and customers to control costs. Under the proposed agreement, the newly combined Merck would rank second in market share (5.5 percent) and fifth in market capitalization ($77 billion) worldwide. (See **Exhibits 3–5** for comparative rankings and financial data for the global leaders in the pharmaceutical industry. **Exhibit 6** shows Merck's and SP's blockbuster drugs, with sales over $1 billion annually.)

Merck Chairman and CEO Dick Clark justified the deal as follows: "The combined company will benefit from a formidable R&D pipeline, a significantly broader portfolio of medicines, and an expanded presence in key international markets, particularly in high-growth emerging markets."[8,9] As a result of acquiring SP, Merck would gain over 20 new compounds in stage 2 or stage 3 of the FDA approval process. Merck would also benefit from SP's globally diverse portfolio, increasing Merck's international sales from $10.5 billion to $25 billion (**Exhibit 7** shows the sales structure of the new company), with operations in over 140 countries. For the first time in its history, Merck expected that more than 50 percent of its revenues would come from outside of the United States.[10] In addition, Merck's yearly savings resulting from this merger were forecast to be as large as $3.5 billion after 2011.

On November 4, 2009, Merck completed its merger with SP. The new company used the name "Merck" in the United States and Canada and went by "MSD" elsewhere in the world. The deal was structured as a "reverse-merger" to permit SP to bypass a change-of-control clause in a drug partnership it had with Johnson & Johnson (J&J). SP and J&J shared the rights to the blockbuster drugs Remicade and Simponi, which have generated a combined net present value of $6.9 billion.[11] Under the "change-of-control" clause, J&J would acquire the full rights to the drugs if SP were to be taken over. Under the "reverse-merger" agreement, SP technically survived the merger with respect to accounting practices, although it renamed itself as Merck, was run by Merck's CEO, and was headquartered at Merck's base in Whitehouse Station, New Jersey. Merck's original shareholders controlled 68 percent of the

combined company, while the new board was comprised of 14 members from Merck and just 3 directors from SP.[12] Additionally, only about 40 percent of SP's senior leaders joined the new Merck.[13]

Despite the new company's elaborate legal structure, J&J claimed that the practical reality was that Merck had in effect acquired SP, and filed suit in court.[14] The companies resolved their dispute through arbitration in April 2011. Merck (SP) agreed to relinquish marketing rights in all territories outside the United States, except Europe, Russia, and Turkey. In addition, profits in the "retained" territories would be split equally between the two companies, and Merck would make a one-time payment of $500 million to J&J. Despite the financial loss, investors viewed the resolution of the dispute positively. Merck's shares rose 2.7 percent on the day of the announcement.[15]

This "reverse-merger" was the first major external venture Merck had participated in since 2006, when Dr. Turner led Merck's acquisitions of biotechnology firms GlycoFi and Abmaxis for a combined total of $480 million. In December of that same year, Dr. Turner also led the much larger acquisition of Sirna Therapeutics for $1.1 billion. Such strategic purchases helped to strengthen Merck's drug pipeline, and its stock price immediately rose more than 1 percent to a total of $34.84.[16] After Merck's announcement of the merger with SP, however, SP's stock rose by 14 percent to end the day at $20.13 a share, while Merck's stock price fell 7.7 percent to close at $20.99 a share.[17]

Dr. Turner knew that the upcoming year would be tough and thought about what his boss, CEO Dick Clark, told the media on the day the SP merger was announced: "This is a uniquely complementary match. . . . The combined company will be well-positioned for sustainable growth through scientific innovation."[18] Dr. Turner felt intense pressure as Merck's first Chief Strategy Officer to deliver on that promise of a more innovative, more customer-focused, leaner, and more agile Merck for customers, employees, and the scientific community, as well as for Merck itself.[19]

Consolidation of the Pharmaceutical Industry

The pharmaceutical industry is one of the largest and most profitable in the world. In 2006, biotechnology and pharmaceutical companies combined created approximately 700,000 direct jobs and 3.2 million total indirect and induced jobs in the United States alone.[20] In 2009, the U.S. pharmaceutical market grew by 1 to 2 percent to approximately $300 billion, while global sales increased at 3 to 5 percent to surpass $775 billion, reflecting sustained growth in key emerging countries tempered by a slower pace in more established markets.[21] However, the rate of annual growth in the pharmaceutical market has been decreasing steadily since its peak in 2001 (see **Exhibit 8**), because the industry has been facing a slew of ongoing problems.

Perhaps most importantly, companies are anticipating severe declines in sales in upcoming years as several blockbuster products lose their patents. The pharmaceutical industry in total is expected to lose as much as $65 billion through 2012 (see **Exhibit 9**). As a result, many drug companies—like Merck—have recently acquired or merged with others to keep their pipelines full of potential drug candidates. Novartis bought Chiron for $5.4 billion in 2006; AstraZeneca bought MedImmune for $15.6 billion in 2007. In the same year that Merck spent $41 billion to take on SP, Pfizer announced its takeover of Wyeth for $68 billion, and the Swiss firm Roche bought the remaining 44 percent of shares of biotech wunderkind Genentech for $47 billion. In March 2009, the CEO of Eli Lilly declared that the company, even after it had acquired ImClone for $6.5 billion, was still looking for additional acquisitions worth as much as $15 billion.[22]

This wave of mega-mergers was seen as necessary to mitigate the risk of developing new commercially successful products and to replenish the diminishing drug pipelines faced by major pharmaceutical companies. Horizontal consolidation, however, may not address the lack of innovation in the industry as a whole. Many analysts fear that consolidation, while facilitating cost containment, will hinder breakthrough R&D needed to procure long-term, life-saving drugs. The concern is that "making R&D bigger does not make it more efficient,"[23] and that the large, bureaucratic organizations created through such mega-deals stifle the innovation needed to create new knowledge and products.

Drug Discovery, Development, and the FDA Approval Process

In the United States, drugs are developed by pharmaceutical companies without any significant help from the government.[24] The science-driven process for drug development takes an average of 12 years and may exceed $1 billion. (See **Exhibit 10** for details on the stages of the drug-development process.) It is estimated that out of every 5,000 to 10,000 compounds screened in the discovery phase, only 250 enter preclinical testing. Only five of those molecules enter the three phases of clinical testing, which is where most of the drug development costs are incurred. Companies must conduct large-scale clinical trials, in hundreds of patients, to demonstrate that a drug has adequate safety and efficacy before filing a new drug application (NDA) with the Food and Drug Administration (FDA). An FDA advisory council then reviews the data provided by the company and holds a public hearing to determine if approval will be granted.

Drug development has always been a costly and risky process, but expenses have risen sharply in recent years. R&D expenditures among Pharmaceutical Research and Manufacturers of America (PhRMA) members grew from $8.4 billion in 1990, to $26 billion in 2000, to $50.3 billion in 2008.[25] As a whole, the pharmaceutical sector invested a record $65.2 billion in R&D in 2008.[26] At the same time, average sales per patented product fell from $457 million in 1990 to $337 million in 2001 (in inflation-adjusted 1999 U.S. dollars).[27] These figures suggest the declining productivity of research and development in the pharmaceutical industry.

Despite increasingly expensive R&D efforts, fewer molecules are being approved by the FDA than ever before (see **Exhibit 11**). Moreover, only one of every five drugs that hit the market actually achieves enough financial success to recoup its investment.[28] However, when a new drug provides a breakthrough for the health of a large patient population, it may reach sales levels of a blockbuster. A blockbuster drug in the 1980s and 1990s was one whose annual sales topped $500 million. Since 2000, a blockbuster drug must have annual sales of at least $1 billion.

Despite predictions that the business model based on patent-protected blockbuster drugs is slowly dying, the number of blockbuster drugs has actually tripled in the last decade.[29] In 2006, 101 drugs each sold more than $1 billion worldwide.[30] Of these, 18 were biotechnology innovations, compared to only 3 biotech products in 2000 (see **Exhibit 12**).[31] The rapid rise of the biotechnology industry seemed to promise a solution to the R&D drought in pharmaceutical companies' pipelines, attracting more than $40 billion of venture capital to date.[32] Major pharmaceutical firms rushed to partner with biotech companies, hoping to discover the next great medical breakthrough and then apply their competencies in development, distribution, and marketing to maximize its profit potential. In fact, between 25 and 40 percent of current sales by major pharmaceutical companies are from products that originated in the biotechnology sector.[33]

However, biotechnology has hardly been the hoped-for panacea for the pharmaceutical companies' R&D problems. Instead of providing cheaper and more lucrative alternatives to traditional pharmaceuticals, the average cost of R&D of a new biotechnology drug was $1.2 billion, quite similar to the average cost per new drug launched by a major company, at $1.3 billion in 2004.[34] This has caused the profits of biotechnology firms to remain close to zero, even while revenues have grown dramatically. Instead of accelerating FDA approval at decreased costs, the short-term alliances biotech companies once formed with pharmaceutical giants were now thought to hinder innovation instead of spread scientific knowledge. This fueled industry consolidation even further, as major pharmaceutical companies sought to merge with or acquire biotechnology firms in an effort to become more diversified and build joint long-term capabilities.

Merck found this new industry terrain especially challenging. The company had long relied on its ability to pump out blockbuster after blockbuster drug from its internal research pipeline. It would charge a premium under patent protection for the duration of the legally set exclusivity periods for existing drugs to help cushion the company's R&D costs for the next blockbuster. Former CEO Henry Gadsden had once said, "We'd cut back in every part of the company. We'd cut back in sales and promotion. We'd tighten up our production. We'd do everything we could to hold down costs. But we'd try very hard not to cut back on research because that's our future."[35] Even in today's troubling times, Merck saw a 57 percent drop in profit in the first quarter of 2009, but Merck increased its investment in R&D by 14 percent to $1.2 billion.[36] Based on current industry trends, Mr. Turner was not sure this money was well spent.

U.S. Health Care Reform and the Generic Challenge

Pharmaceutical companies are facing additional price pressures driven by changes in U.S. and worldwide regulatory restrictions on the industry. In March 2010, Congress approved and President Obama signed the Affordable Care Act into law, creating significant uncertainties for the health care industry. Under the new law, patients have increased access to health care, whether through Medicaid, subsidized employer plans, or state-run medical exchanges. Insurance companies are no longer able to impose lifetime limits, and coverage can no longer be denied for preexisting conditions. Nearly everyone is required to get insurance or pay a penalty.[37] One change likely to benefit both pharmaceutical firms and patients is that insurers may no longer drop or limit coverage on individuals who participate in clinical trials for cancer or other life-threatening diseases.[38]

Pharmaceutical firms rank second only to the tobacco industry in the corporations-hated-most department[39] and have frequently been blamed by politicians for the nation's health care woes. In an attempt to place pharmaceutical companies in a positive public relations light, PhRMA made an unexpected $80 billion pledge over the next 10 years to help pay for health care reform. Its hope was to position pharmaceutical companies to take advantage of the enormous new customer base that would be created by expanding health care coverage. PhRMA's investment could potentially backfire, though, if the government uses its increased purchasing power to squeeze margins on prescription drugs and accelerate the shift to generics.

However, the generic drug manufacturers also have a strong political lobby, the Generic Pharmaceutical Association (GphA). GphA is perceived as the voice of the American public, demanding ever-lower prices for drugs and pushing for importation of lower-priced drugs from foreign companies such as Israeli-based Teva Pharmaceuticals, the largest supplier of generic prescription medicines in the United States.[40] In 2003, generic drugs comprised 54 percent of the market. That figure leaped

to 72 percent of total pharmaceutical sales in 2008.[41] In 2006, eight of the top 10 drugs launched in the United States were generic products, while 61 percent of senior prescriptions were generic.[42] Generic companies incur no expense for the discovery or the development of the new drugs they copy; such R&D expenses fall solely on the innovator.

The legal basis for generic drugs dates back to the Hatch-Waxman Act of 1984, otherwise known as the Drug Price Competition and Patent Term Restoration Act of 1984. Under the Hatch-Waxman Act (which does not apply to biologics), the FDA may approve a generic drug in the form of an Abbreviated New Drug Application (ANDA) if the generic company can establish that its product is "pharmaceutically equivalent" to the drug it wishes to copy.[43] No clinical trials are required, which confers an important advantage on the generic manufacturers over the brand-name companies that developed the original compound. This law was the foundation for cheap generics copying the work of large pharmaceuticals without the up-front risk or cost, and selling at a discount.

When a generic company files an ANDA, it also makes a patent certification claim, the most disruptive of which is Paragraph IV, alleging that the listed patent is invalid and will not be infringed upon. This provides generic companies with the right to copy an innovator's drug as soon as its exclusivity period elapses. The standard exclusivity period is five years for a new chemical entity, but there are additional provisions: seven years for "orphan drugs" (indications with a prevalence of less than 200,000 cases per year), three years for a new use or formulation, and six months for a pediatric drug.[44]

The generic industry continued to grow with the 2003 Medicare Act Amendments, which implemented several new rights for generics and limitations for the pharmaceutical industry. First, it increased regulation regarding agreements between generic companies and innovators. Next, it considered not one company, but all generic companies that file on the same day to be "first-filers," each with legal claims against the original patent. As a result, 2003 became the year that many more generic companies than ever before began to embrace Paragraph IV challenges as a viable strategy. As a result, by 2007 over 160 generic companies had active Paragraph IV filings, compared with fewer than 40 in 2001 (**Exhibit 13**).[45] A multitude of new players entered the generic industry, with the result that pharmaceutical companies like Merck now find virtually all of their commercially viable products under attack as soon as their patent protection expires. There is a delicate balance between providing accessible, reasonably priced drugs for today and investing in the development of new innovative drugs for the future. If the generic industry continues to gain strength, cheap but old drugs will likely persist while the introduction of new and innovative drugs will decline.

After 10 years of resistance, biotech companies have recently started to lobby Congress to allow the FDA to approve generic biotechnology products. Biotechnology firms have never faced the generic competition that makers of chemical-based drugs have when their patents expire. The FDA currently lacks authority to approve generic biotechnology products, but as the political clout of the generic drug industry increases, this may soon change. "With nowhere else to turn, BIO (the Biotechnology Industry Organization) and PhRMA now want to come to the table to cut a deal. They want unprecedented and excessive market exclusivity and patent protections to ensure their monopolies," said Kathleen Jaeger, President of the Generic Pharmaceutical Association.[46] With such increasing pressures from the political sphere, regulatory environment, and generic competition, the strategic mantra for the pharmaceutical CEO or Chief Strategy Officer is simple: innovate or die.

Open Innovation[47]

According to the closed-innovation philosophy adopted by most pharmaceutical giants in the 20th century, successful innovation requires complete control. A company would generate its own ideas and develop, manufacture, market, and distribute the resulting products alone. This closed approach has worked especially well for Merck in the past, forming a virtual circle in which fundamental scientific breakthroughs led to new drugs and increased sales, which were in turn poured back into more R&D investment to create more new discoveries.[48] However, with the rise of the Internet and the increased mobility of knowledge workers (individuals, such as scientists, engineers, physicians, and consultants, valued for their ability to work with complex information and data), companies heavily dependent on human capital are increasingly unable to protect their intellectual property, causing the closed-innovation system to break down. This effect is further compounded by the ready availability of venture capital to fund risky startups. Dr. Turner knew that the closed-innovation paradigm and self-reliance Merck had grown accustomed to would not work in this age of open innovation.

In contrast, open innovation involves companies opening up their business models by actively searching for and exploiting outside ideas, as well as allowing unused internal technologies to flow to the outside where other firms can unlock their latent economic potential (see **Exhibit 14**). Firms actively seek external R&D by bringing in new human capital, engaging in strategic alliances, or acquiring technology ventures, while continuing to innovate internally. At the same time, any internal inventions that the firm decides not to pursue should be considered for commercialization through licenses, spin-offs, or joint ventures. Research indicates that fewer than half of 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, patented technology too often remains on the shelf.[49] Such inefficiencies in the innovation market are overcome when companies open up and share ideas and technology, permitting them to flow freely to where they can be most efficiently developed. See **Exhibit 15** for a comparison of closed- and open-innovation principles.

Open innovation comes with incredible risks with which many scientists, fiercely protective of their research and intellectual property, do not feel comfortable. It may be difficult for a company to capture the value that open innovation creates. While open innovation systematically increases the availability of knowledge by finding highly capable partners for scientists to collaborate with, it also inevitably leads to the loss of individual control over potentially invaluable technology. As a result, a company may end up giving away a billion-dollar patent to its direct competitor because it does not understand the value of a discovery. This loss of control coupled with uncertain monetary outcomes led many scientists to wonder whether open innovation was worth all the hype. Was it really necessary to change?

Yet Dr. Turner had seen a number of smaller upstarts, such as Amgen, Genentech, and Genzyme, successfully parlay their research discoveries to become major players in the biotechnology industry through open innovation.[50] Moreover, some of Merck's smaller and more formidable competitors were already well on their way to leveraging external research capabilities. For example, InnoCentive, a formerly wholly owned subsidiary of Eli Lilly, offers firms a mechanism to facilitate the development and commercialization of new technology. Using a global network of independent researchers, InnoCentive acts as a knowledge broker and facilitates the exchange of technological know-how, primarily associated with chemistry and biotechnology. Through this system of open innovation, InnoCentive has realized a success rate that is higher than the traditional internal R&D approach, at approximately one-sixth the cost.[51] Meanwhile, as a consequence of its historically closed R&D system, Merck had the lowest percent of new approved drugs based on externally derived technology at only 13 percent (see **Exhibit 16**), whereas Bristol-Myers, Sanofi-Aventis, and Roche had approximately 80 percent of their

new drugs coming from external sources. Dr. Turner passionately believed that Merck also needed to become more open, but knew that implementing this change would not be easy.

Open Innovation at Merck

Merck suffered from the "not invented here" syndrome, meaning that if a product was not created and developed at Merck, it could not be good enough. Merck's culture and organizational systems perpetuated this logic, which assumed that since they hired the best people, the smartest people in the industry must work for Merck, and so the best discoveries must be invented at Merck. Merck led the industry in terms of R&D spending, because Merck believed that if it was the first to discover and develop a new drug, it would be the first to market. In 2009, Merck was ranked as the fourth most successful company by total number of active R&D projects (see **Exhibit 17**), a considerable point of pride for Merck's personnel. Changing from a closed-innovation system to operating within an open-innovation network would require a fundamental shift in Merck's culture and mindset. Merck's researchers were simply not accustomed to listening to "outsiders."[52] To begin changing the behavior of Merck's top scientists, Dr. Turner had sent them to a "charm school" where they could learn courtesy and manners to use when corresponding with non-Merck people.

Dr. Turner knew that innovation attempts often fail in large and historically successful companies. But he was optimistic that Merck could change based on its past successful experiences with several open-innovation initiatives, including the hepatitis B vaccine in the 1980s, the Merck Gene Index Project in the 1990s, and Merck Bioventures in the 2000s. Additionally, Merck was already tapping into external knowledge held in the scientific community through informal networks, conference attendance, publications, and creative business arrangements with other scientific organizations. In fact, Merck actively encouraged its researchers to publish their findings in medical and scientific journals. Dr. Turner himself was the author of more than 80 articles in peer-reviewed journals and had served on the editorial board of a number of scientific journals.[53] He firmly believed that the need to foster connectivity with the external environment outweighed the potential losses associated with publication of once-proprietary intellectual knowledge.[54]

Overall, the number of publications by dedicated pharmaceutical companies doubled to 40,000 from 1990 to 2003, illustrating the increasing participation in open science across the industry (see **Exhibit 18**). Based on this trend, Dr. Turner knew it was more important than ever to be connected to the wider scientific community by collaborating across institutional boundaries with other companies and universities. Research has shown that "the extent of this collaboration is positively related to private sector research productivity,"[55] and the more collaboration a company has in co-authorships, the greater its chance of discovering a new drug. Having a large number of such collaborations is also positively associated with the number of important patents a firm acquires.[56]

Dr. Turner was also hopeful because research has shown that past productivity is the most important predictor of a research program's future success. A company's past success in attaining FDA approval for any therapeutic class is significantly and positively associated with the probability of a new project's successful outcome.[57] "The keys to this determinant are the 'knowledge capital' accumulated by the program as an organizational unit as well as the skills and experience of individual scientists," allow-

ing for the ability to exploit internal spillovers of knowledge.[58] Merck's historical success in bringing new drugs to market should make it an attractive candidate for partnerships with other organizations, if Merck can learn to embrace such relationships.

Ultimately, Dr. Turner knew that Merck people took their founder's mission seriously, and they truly wanted to help improve lives. The words of George W. Merck form the basis of Merck's corporate philosophy: "We try to never forget that medicine is for the people. It is not for profits. The profits follow, and if we have remembered that, they have never failed to appear. The better we have remembered it, the larger they have been." It would be his job as Chief Strategy Officer to convince them that the best way to put patients first would be to open Merck up to external innovation. In short, he needed his own people to believe what he so ardently stressed to potential licensing partners. "Most of the world's biomedical research takes place outside of our laboratories, so we charge our scientists with building a 'virtual lab'—the blending of the best scientific programs from internal research and external collaborations. We want to help you to take your great science and turn it into great medicine. We want to help you make a difference in the lives of patients all around the world. That's why we are all in this together."[59]

Show Time: Should Merck Implement an Open-Innovation Strategy, and if So, How?

Merck's management used to believe strongly that a merger would jeopardize the company's scientific culture. The team had decided that "Merck would not consider large-scale mergers which might provide short-term benefits, but would not add to long-term growth prospects of the company."[60] In light of the recent "reverse-merger" with SP, Dr. Turner could not help but reflect on how drastic times called for new measures. With 55 percent of SP's new drugs originating from external sources, this merger represented a significant step toward opening up Merck's boundaries and promoting open innovation.

The merger with SP was nevertheless a very risky strategy. Research has shown that between 1993 and 1998, no correlation between the size of the R&D budget and productivity was found in 40 pharmaceutical firms. Another study showed that as companies merged, the number of development projects declined by 34 percent as merged companies trimmed their product pipelines.[61] Consequently, most mergers in the pharmaceutical industry created neither synergies nor shareholder value. Two equally large and unique organizations such as Merck and SP would be incredibly difficult to integrate, especially considering the differences in their corporate cultures. Dr. Turner wondered what dangerous side-effects the merger might inflict on Merck's vaunted scientific capabilities. The merger was also adding increased complexity to Merck's structure, businesses, and geography of operations. Many implementation issues remained to be managed.

And yet, Dr. Peter Kim, current President of Merck Research Laboratories, had recently reflected on the integration with SP as follows: "The talent and dedication of Schering-Plough scientists [have] helped to build an outstanding clinical development pipeline. . . . The Schering-Plough and Merck pipelines are remarkably complementary and will greatly increase our ability to deliver important new medicines to patients. I believe the combined pipeline will be the best in the industry, by far."[62] Combined with Merck's expertise in early-stage collaborations, the new company was poised to

dramatically improve the diversity of platform technologies and hence the number of new compounds they develop. In many ways, this merger could provide the impetus to bring the words of former CEO Ray Gilmartin to fruition. At an offsite meeting with the management committee in July 2000, Mr. Gilmartin had confidently stated that it was time to "break away" from the rest of the pharmaceutical industry: "We have more chemical entities moving through early development than ever before in our history. This is the most productive time ever for Merck research."

Open Innovation at Merck?

Looking out at his strategy team, Dr. Turner could see that not all were convinced that open innovation was the way to go. Still, Dr. Turner persisted. "Pharmaceutical companies will have to grow more outward-facing to source innovation wherever it can be found. . . . Ideas know no boundaries and science is an international language. We really have to embrace that and think about the world as our oyster of opportunity!"[63] But in the back of his mind, even Dr. Turner had his doubts. Can open innovation really help Merck meet the needs of its customers in creative and cost-effective ways that also bring value to its shareholders? If so, how can Merck change from its current legacy R&D structure to one that promotes more open innovation without jeopardizing the strong, scientific-led culture that made Merck famous? How was he to lead his team to execute his vision of open innovation as its winning, long-term strategy? And how does the SP merger fit into an open innovation strategy? The team went to work. . . .

EXHIBIT 1 Selected Financial Data for Merck & Co., Inc. and Subsidiaries (U.S. $ in millions)

	2009	2008	2007	2006	2005	2004	2003
Sales	$27,428.30	$23,850.30	$24,197.70	$22,636.00	$22,011.90	$22,938.60	$22,485.90
Net income	$12,899.20	$7,808.40	$3,275.40	$4,433.80	$4,631.30	$5,813.40	$6,830.90
Earnings per common share assuming dilution	$5.65	$3.64	$1.49	$2.03	$2.10	$2.61	$3.03
Cash dividends paid per common share	$1.52	$1.52	$1.52	$1.52	$1.52	$1.49	$1.45
Average common shares outstanding assuming dilution (millions)	2,273.20	2,145.30	2,192.90	2,187.70	2,200.40	2,226.40	2,253.10
Total assets	$112,089.70	$47,195.70	$48,350.70	$44,569.80	$44,845.80	$42,572.80	$40,587.50
Net cash flows provided by operating activities	$3,392.00	$6,571.70	$6,999.20	$6,765.20	$7,608.50	$8,799.10	$8,426.50
Capital expenditures	$1,460.60	$1,298.30	$1,011.00	$980.20	$1,402.70	$1,726.10	$1,915.90
Net income as % of average total assets	16.2%	16.3%	7.0%	9.9%	10.6%	14.0%	15.5%
Number of stockholders of record	175,600	165,700	173,000	184,200	172,077	216,100	233,000
Number of employees	100,000	55,200	59,800	60,000	61,500	62,600	63,200

Source: Merck & Co. Annual Reports.

EXHIBIT 2 Consolidated Balance Sheet
Merck & Co., Inc. and Subsidiaries (U.S. $ in millions)

Merck & Co., Inc. and Subsidiaries, December 31, 2009 ($ in millions)

	2009	2008	2007	2006	2005	2004	2003
Assets							
Current Assets							
Cash and cash equivalents	$ 9,311.4	$ 4,368.3	$ 5,336.1	$ 5,914.7	$ 9,585.3	$ 2,878.8	$ 1,201.0
Short-term investments	293.1	1,118.1	2,894.7	2,798.3	6,052.3	4,211.1	2,972.0
Accounts receivables	6,602.9	3,778.9	3,636.2	3,314.8	2,927.3	3,627.7	4,023.6
Inventories (excludes inventories of $345.2 in 2007 and $416.1 in 2006 classified in Other assets)	8,055.3	2,283.3	1,881.0	1,769.4	1,658.1	1,898.7	2,554.7
Prepaid expenses and tax	4,165.9	7,756.3	1,297.4	1,433.0	826.3	858.9	775.9
Total current assets	28,428.6	19,304.9	15,045.4	15,230.2	21,049.3	13,475.2	11,527.2
Investments	432.3	6,491.3	7,159.2	7,788.2	1,107.9	6,727.1	7,941.2
Property, Plant and Equipment (at cost)							
Land	666.7	386.1	405.8	408.9	433.0	366.6	356.7
Buildings	12,210.3	9,767.4	10,048.0	9,745.9	9,479.6	8,874.3	8,016.9
Machinery, equipment and office furnishings	16,173.6	13,103.7	13,553.7	13,172.4	12,785.2	11,926.1	11,018.2
Construction in progress	1,817.5	871.0	795.6	882.3	1,015.5	1,641.6	1,901.9
Less allowance for depreciation	12,594.6	12,128.6	12,457.1	11,015.4	9,315.1	8,094.9	7,124.7
Property, Plant and Equipment, Net	18,273.5	11,999.6	12,346.0	13,194.1	14,398.2	14,713.7	14,169.0
Goodwill	11,923.1	1,438.7	1,454.8	1,431.6	1,085.7	1,085.7	1,085.4
Other Intangibles, Net	47,655.8	525.4	713.2	943.9	518.7	679.2	864.0
Other Assets	5,376.4	7,435.8	11,632.1	5,981.8	6,686.0	5,891.9	5,000.7
Total Assets	**$112,089.7**	**$47,195.7**	**$48,350.7**	**$44,569.8**	**$44,845.8**	**$42,572.8**	**$40,587.5**

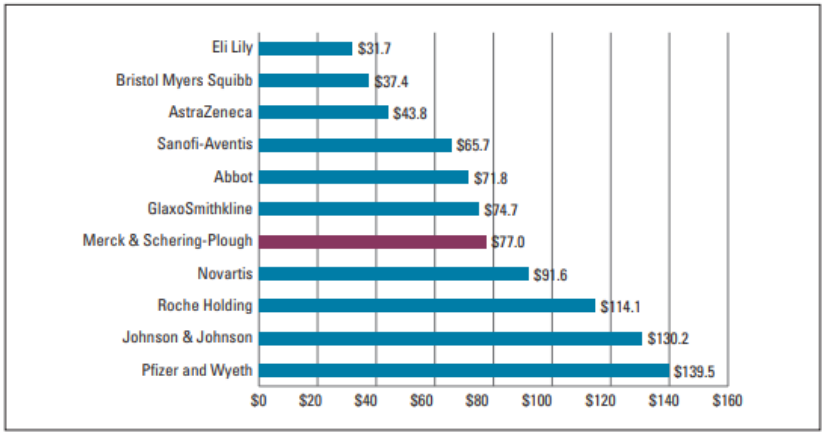
(continued)

EXHIBIT 2 (Continued)

	2009	2008	2007	2006	2005	2004	2003
Liabilities and Stockholders' Equity							
Current Liabilities							
Loans payable and current portion of long-term debt	$1,379.2	$2,297.1	$1,823.6	$1,285.1	$2,972.0	$2,181.2	$1,700.0
Trade account payable	2,236.9	617.6	624.5	496.6	471.1	421.4	735.2
Accrued and other current liabilities	9,453.8	9,174.1	8,534.9	6,653.3	5,381.2	5,288.1	3,772.8
Income tax payable	1,285.2	1,426.4	444.1	3,460.8	3,649.2	3,012.3	2,538.9
Dividends payable	1,189.0	803.5	831.1	826.9	830.0	841.1	822.7
6% Mandatory convertible preferred stock	206.6	—	—	—	—	—	—
Total Current Liabilities	15,750.7	14,318.7	12,258.2	12,722.7	13,303.5	11,744.1	9,569.6
Long-Term Debt	16,074.9	3,943.3	3,915.8	5,551.0	5,125.6	4,691.5	5,096.0
Deferred Income Taxes and Noncurrent Liabilities	18,771.5	7,766.6	11,585.3	6,330.3	6,092.9	6,442.1	6,430.3
Stockholders' Equity							
Common stock, one cent par value							
Authorized - 6,500,000,000 shares	1,781.3	29.8	29.8	29.8	29.8	29.8	29.8
Other paid-in capital	39,682.6	8,319.1	8,014.9	7,166.5	6,900.0	6,869.8	6,956.6
Retained earnings	41,404.9	43,698.8	39,140.8	39,095.1	37,918.9	36,626.3	34,142.0
Accumulated other comprehensive loss	(2,766.5)	(2,553.9)	(826.1)	(1,164.3)	52.3	(45.9)	65.5
Stockholders' equity before deduction for treasury stock	80,102.3	49,493.8	46,359.4	45,127.1	44,901.0	43,480.0	41,193.9
Less treasury stock, at cost:	21,044.3	30,735.5	28,174.7	27,567.4	26,984.4	26,191.8	25,617.5
Total Merck & Co., Inc. Stockholders' Equity	59,058.0	18,758.3	18,184.7	17,559.7	17,916.6	17,288.2	15,576.4
Noncontrolling Interests	2,434.6	2,408.8	2,406.7	2,406.1	2,407.2	2,406.9	3,915.2
Total Equity	61,492.6	21,167.1	20,591.4	19,965.8	20,323.8	19,695.1	19,491.6
Total Liabilities and Stockholders' Equity	**$112,089.7**	**$47,195.7**	**$48,350.7**	**$44,569.8**	**$44,845.8**	**$42,572.8**	**$40,587.5**

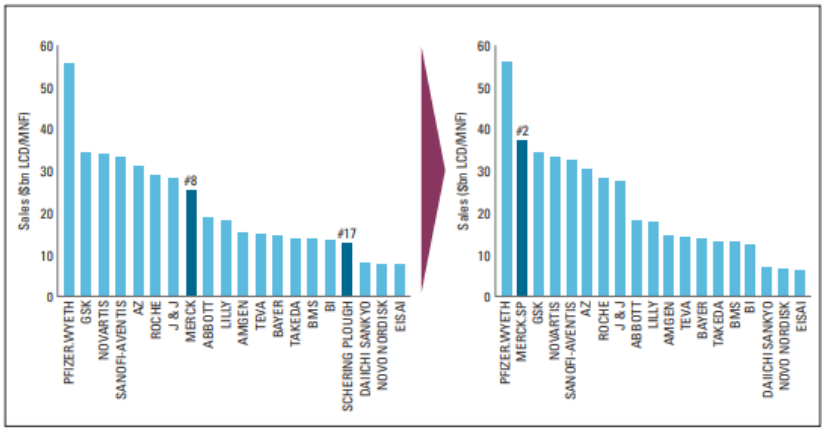
Source: Merck & Co. Annual Reports

EXHIBIT 3 The New Landscape: The Largest Pharmaceutical Players by Market Capitalization if Pending Deals Are Completed (U.S. $ in billions)



Source: Adapted from "Merck to buy rival for $41 billion," *The Wall Street Journal*, March 10, 2009.

EXHIBIT 4 Global Rankings of Pharmaceutical Firms by Market Share: The Combined Merck (including SP) Will Rank #2 Globally with 5.5 Percent Market Share vs. Pfizer-Wyeth's 8.2 Percent



Source: Adapted from *IMS Health MIDAS MAT*, December 2008.

EXHIBIT 5 Financial Data for the Global Leaders in the Pharmaceutical Industry

Company	Merck	Pfizer / Wyeth	Glaxo Smith Kline	Novartis	Astra Zeneca	Johnson & Johnson
Market capitalization	**$114.4**	$143.6	$109.7	$122.2	$63.6	$173.1
Revenue	**$19.57**	$45.82	$42.62	n/a	32.05	$60.53
Employees	**55,200**	81,800	99,003	99,834	66,100	118,700
Revenue / employee	**$354,600**	$560,100	$430,559	n/a	$484,900	$509,900
Net income	**$3.6 B**	$8.134 B	$7.752 B	n/a	7.225	$12.77
Shares outstanding	**3.099 B**	8.07 B	2.831 B	2.274	1.448	2.759
Annual earnings /share	**$1.93**	$1.22	$2.41	n/a	$4.12	$4.62
P/E ratio	**19.13**	14.59	25.2	n/a	10.67	13.58
Annual dividends / share	**$1.52**	$0.66	$1.93	$1.00	$3.80	$1.96
Dividend yield	**4.12%**	3.71%	4.99%	3.70%	8.65%	3.12%
Trade price	**$37.58**	$17.68	$39.25	$54.27	$43.95	$63.54

Source: Adapted from WolframAlpha, February 16, 2010.

EXHIBIT 6 Merck's and Schering-Plough's Blockbuster Drug Lineup

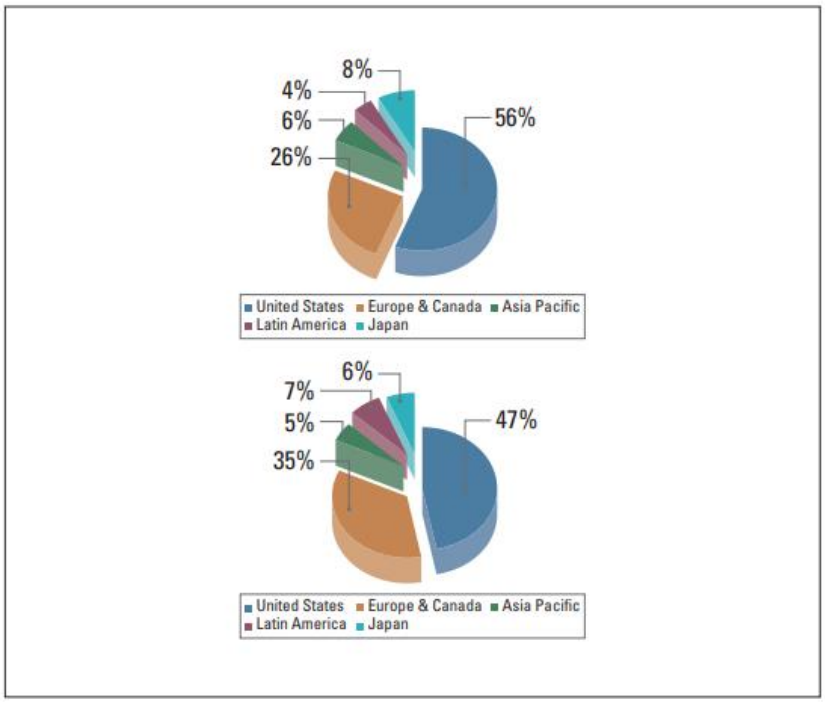
	Drug	Indication	2008 Sales
Merck	Singular	Asthma	$4.3 bn
	Cozaar/Hyzaar	Hypertension	$3.6 bn
	Gardasil	HPV vaccine	$1.4 bn
	Januvia	Diabetes	$1.4 bn
Schering-Plough	Remicade	Inflammatory diseases	$2.1 bn
	Nasonex	Allergies	$1.2 bn
	Temodar	Brain tumors	$1.0 bn
Merck-SP Joint Venture	Zetia/Vytorin	Cholesterol	$4.6 bn

Source: "Merck to buy rival for $41 billion," *The Wall Street Journal*, March 10, 2009.

EXHIBIT 7 Merck's Sales Structure (before and after the SP reverse-merger)

Merck had $23.9 billion in 2008; $10.5 billion were in international sales.

Merck, combined with Schering-Plough, had $46.9 billion in 2008; $25 billion were in international sales.



Source: Adapted from Merck's Announcement to Investors, 2009.

EXHIBIT 8 Global Pharmaceutical Sales, 2001–2008

	2001	2002	2003	2004	2005	2006	2007	2008
Total world market (current U.S. $ in billions)	393	429	499	560	605	648	715	773
Growth over previous year (growth rate in constant U.S. $)	11.8%	9.2%	10.2%	7.9%	7.2%	6.8%	6.6%	4.8%

Global Pharmaceutical Sales vs. Growth, 2004–2010

Source: Adapted from IMS Health Market Prognosis (includes IMS Audited and Unaudited markets). All information current as of March 2009. www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/Global_Pharma_Sales_2001-2008_Version_2.pdf.

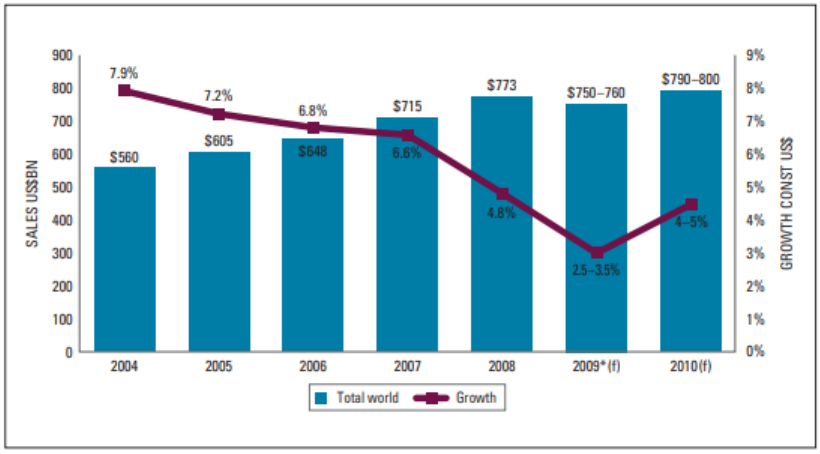
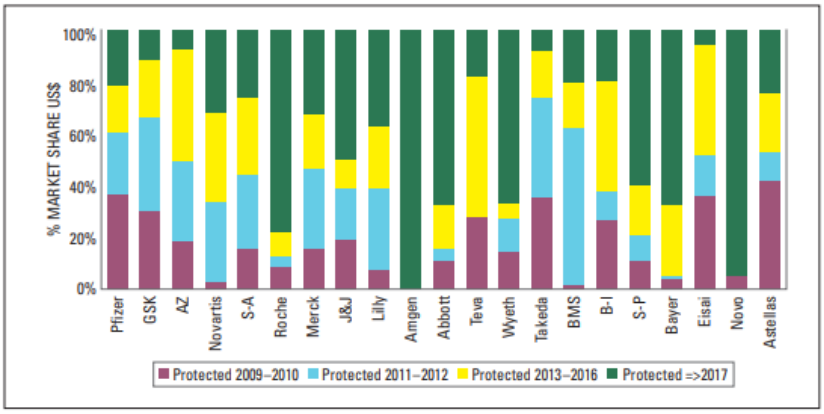


EXHIBIT 9 Top 20 Global Corporations: Exposure to Loss of Exclusivity



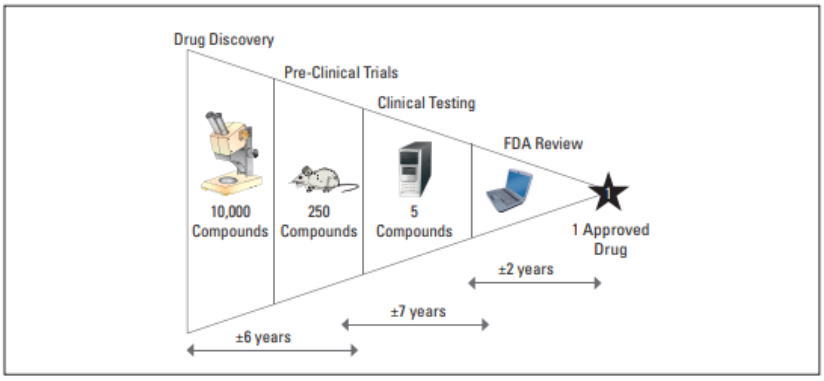
Source: Adapted from IMS Health, MIDAS, Market Segmentation, Rx only, December 2008, 27 market segmentation countries.

EXHIBIT 10 Stages in Drug-Discovery Process

Compound Success Rates by Stages

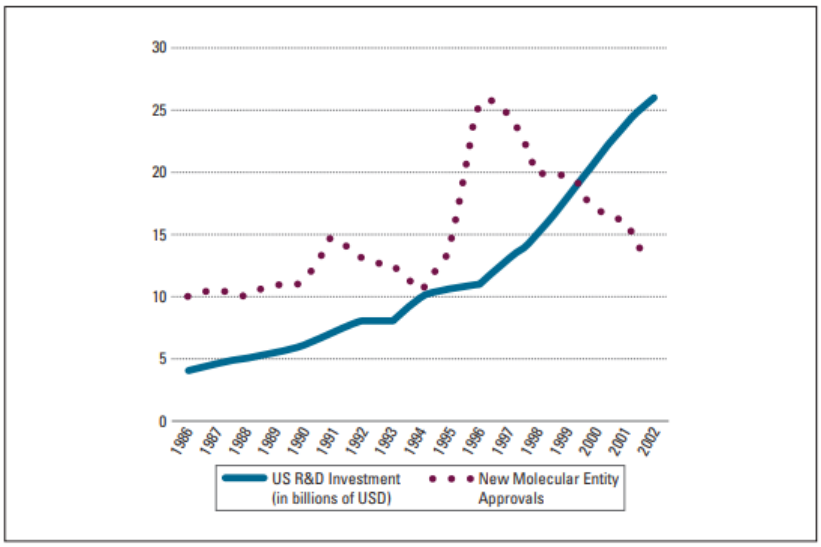
Preclinical Trials: Laboratory and animal testing

Clinical Testing: Phase 1: 20–100 healthy volunteers used to determine safety and dosing range
Phase 2: 100–500 patient volunteers used to determine safety and efficacy
Phase 3: 1,000–5,000 patient volunteers used to generate statistically significant data about safety and efficacy over a longer time period



Source: Adapted from Drug Discovery and Development: Understanding the R&D Process, www.innovation.org; CBO, Research and Development in the Pharmaceutical Industry, 2006.

EXHIBIT 11 R&D Investment and New Drug Approvals



Note: Includes biological products.

Source: Adapted from Datamonitor, PhRMA. *Acumen Journal of Sciences,* Vol. 1, Issue II.

EXHIBIT 12 Top Biotechnology Drugs by Sales

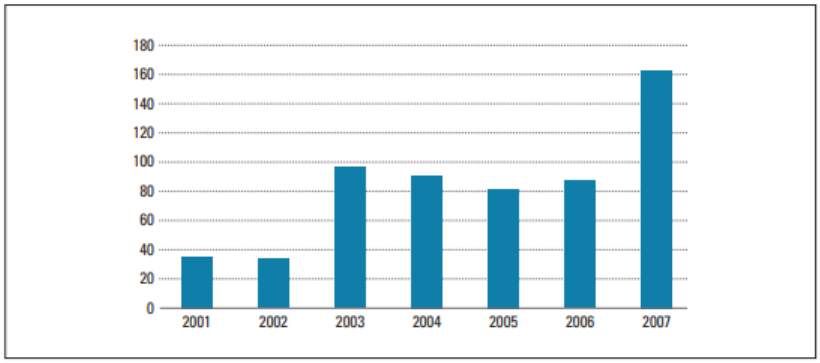
There are at least 23 protein therapeutics with sales of $1 billion or more. Below are aggregate sales figures recorded by the companies listed. Average annual exchange rates were used to convert to U.S. dollars in certain cases.

Product	Company	2005 Sales (in US$)	2006 Sales (in US$)	Change (in %)
Enbrel	Amgen, Wyeth, Takeda	3.70	4.40	20
Aranesp	Amgen	3.30	4.10	26
Rituxan/MabThera	Biogen Idec, Genentech, Roche	3.30	3.90	16
Remicade	J&J, Schering-Plough, Tanabe	3.00	3.60	20
Epogen/Procrit/Eprex	Amgen, Kirin, Johnson & Johnson	3.30	3.20	–4
Herceptin	Genentech, Roche	1.70	3.10	82
Epogen	Amgen, Kirin	2.80	2.90	0
Neulasta	Amgen	2.30	2.70	18
Human insulins (A)	NovoNordisk	2.50	2.50	1
Avastin	Genentech, Roche	1.30	2.40	77
Lantis/Lantus	Sanofi-Aventis	1.40	2.20	53
Humira	Abbott	1.40	2.00	46
Insulin analogs	NovoNordisk	1.20	1.80	50
Neorecormon	Roche	1.80	1.80	–2
Avonex	Biogen Idec	1.50	1.70	11
Rebif	Merck Serono	1.30	1.50	14
Neupogen	Amgen, Kirin	1.40	1.30	–1
Humalog	Eli Lilly	1.20	1.30	8
Pegasys	Roche	1.10	1.20	4
Betaseron/Betaferon (B)	Bayer Schering	1.00	1.20	20
Erbitux	ImClone, Bristol-Myers, Merck KGaA	0.70	1.10	57
Synagis	MedImmune	1.10	1.10	0
Cerezyme	Genzyme	0.90	1.00	7

Note: (A) Sales includes related insulin products; (B) 2006 estimated from 1Q-3Q06 sales; $B.

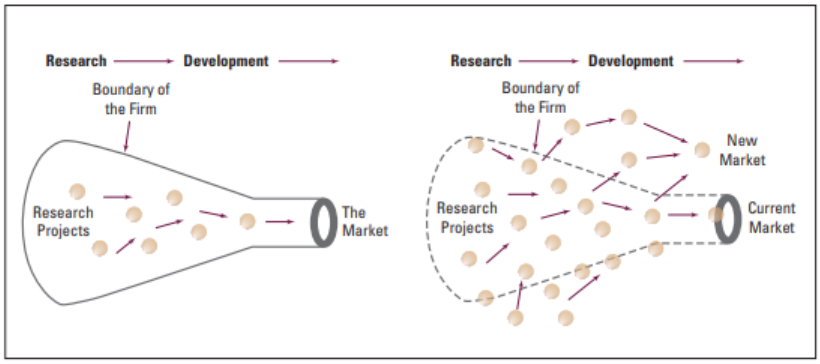
Source: Lawrence, S. (2007), "Billion dollar babies—Biotech drugs as blockbusters," *Nature Biotechnology* 25: 380–382.

EXHIBIT 13 ANDAs with a Paragraph IV Challenge



Source: *The Paragraph Four Report: Annual Trends,* from Parry Ashford Inc., 2008.

EXHIBIT 14 The Closed-Innovation Model The Open-Innovation Model



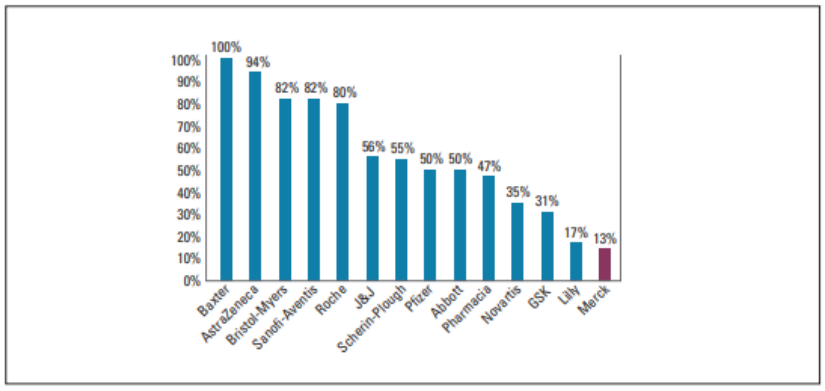
Source: Adapted from Chesbrough, H. (2003), "The era of open innovation," *MIT Sloan Management Review,* Spring: 35–41.

EXHIBIT 15 Contrasting Principles of Closed and Open Innovation

Closed Innovation	Open Innovation
The best and brightest people in our industry work for us.	We need to work with smart people inside and outside our company because not all the smart people work for us.
We must discover the best molecules, develop them, manufacture them, and distribute them internally in order to profit from our investment R&D.	While internal R&D is needed to claim competitive value, external research can also create significant value for the company.
If we are the first to discover a molecule, we will be the first to get it to market and thus profit from its development.	Our company does not have to originate the molecule to actually profit from it in the market.
The company that succeeds in first getting an innovative drug to the market will win.	Creating a more open business model will be more successful in the long run than getting an innovative drug to the market first.
If we discover, develop, and create the most and the best molecules in the industry, we will win.	If we tap into the plethora of internal and external ideas in the industry, we will win.
We must control our intellectual property, so that our competitors don't profit from our ideas.	We should share our intellectual property with others and profit from others' use of our intellectual property, whenever it advances our business model.

Source: Adapted from Chesbrough, H. (2003), *Open Innovation: The New Imperative for Creating and Profiting from Technology* (Boston, MA: Harvard Business School Press).

EXHIBIT 16 Percent of New Approved Drugs, Based on Externally Driven Technology, 1989–2004



Source: FDA Orange Book and U.S. Patent and Trademark Office.

EXHIBIT 17 Top 10 Companies by R&D Projects League Table

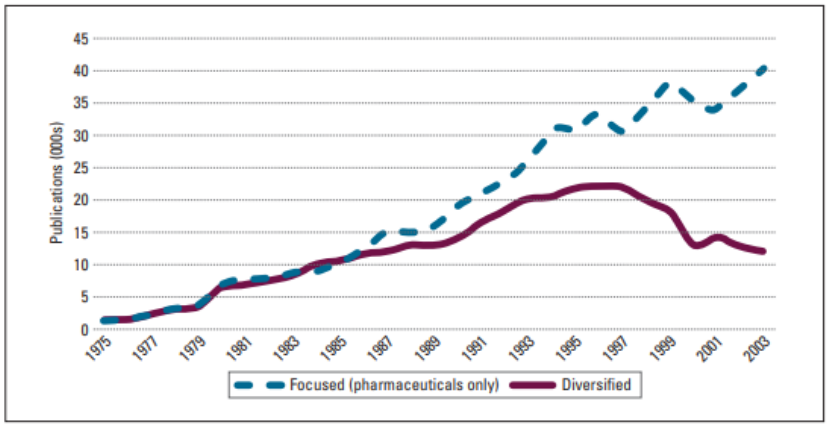
The table below summarizes the top 50 companies in PharmaProjects, a database tracking pharmaceutical development from early preclinical study through to launch or discontinuation. It lists companies in descending order by total number of active research and development (R&D) projects (excluding suspended products). Each company's total R&D products are separated into the number of drugs originating from its own research and the number of drugs it has licensed-in. The table also shows subtotals at 10 place intervals. The percentage values represent the number of drugs in R&D as a proportion of the total number of R&D projects listed in PharmaProjects in March 2009.

Position February 2009	No. of R&D Drugs	No. of Own Drugs	No. Under License
1 GlaxoSmithKline *	228	141	87
2 Pfizer *	199	150	49
3 Sanofi-Aventis *	176	125	51
4 Merck & Co *	**165**	**109**	**56**
5 AstraZeneca *	157	113	44
6 Novartis *	156	94	62
7 Hoffmann-La Roche *	133	83	50
8 Johnson & Johnson	128	73	55
9 Eli Lilly *	117	88	29
10 Wyeth	101	75	26
Subtotal: top 10	**1560 (16.6%)**	**1051 (11.2%)**	**509 (19.4%)**

*Pharma-Documentation-Ring member company

Source: www.p-d-r.com/ranking/Top50_Mar09.pdf. For further information, see www.pharmaprojects.com. Copyright Informa UK Ltd 2009. All rights reserved.

EXHIBIT 18 Publications by Pharmaceutical Firms in Scientific Journals



Source: Hess, A. M., and F. T. Rothaermel (2010), "Sensing, seizing, and strategic renewal: A micro-foundation model of dynamic capability formation," working paper, Georgia Institute of Technology.

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