Summary of Speaker Presentations
Young & Partners Pharmaceutical Senior Executive Summit
Co-Sponsored by
Pharmaceutical Executive Magazine and Young & Partners
"Executive Summit: Emerging Strategic and
Financial Issues in the Pharmaceutical Industry"
December 14, 2009
Yale Club
50 Vanderbilt Avenue - New York City

12:00 P.M. **Lunch and Speaker**
"Transformational Change to Drive High Performance"
Fred Hassan, Former Chairman and CEO, Schering-Plough

1:00 P.M. **"The Pharmaceutical Market: Trends and Forecasts"**
Doug Long, Vice President, IMS Health Inc.

1:30 P.M **The Current and Future State of the Pharmaceutical Industry"**
Peter Young, President, Young & Partners

"Health Care Reform: What Will It Do to the Pharma Industry?"
William Looney, Editor-in-Chief, Pharmaceutical Executive

2:15 P.M. "**Pharma and Biotech M&A: Driving Factors in the Market"**
Peter Young, President, Young & Partners

"Pharma's View of M&A"
Charles H. Simmons, Vice President, Corporate Development, Bristol-Myers Squibb

3:15 P.M. **"Cutting Edge Patent Issues Affecting Pharma/Biotech"**
David K. Barr, Partner, Kaye Scholer
Daniel L. Reisner, Partner, Kaye Scholer

4:15 P.M. **Speaker Roundtable**
Moderator: Peter Young, President, Young & Partners
Participants: Executive Summit Speakers

5:00 P.M. Concluding Comments

Summaries of the Speaker Presentations

(These summaries were prepared by Young & Partners and were not reviewed by the speakers.)

CONFERENCE SPEAKERS

Transformational Change to Drive High Performance

Fred Hassan, Former Chairman & CEO, Schering-Plough

The key elements for success are to assemble the right team of people, and build an environment where people are motivated to give their best. To achieve this goal, companies should have people that are competent, aligned, passionate, courageous and tenacious so that together they can do what cannot be done in conventional situations. People with these qualities can win together while having fun. Schering-Plough experienced a dramatic transformation: it went from a wounded company in prolonged decline into a high performance competitor for the long-term. Free Cash Flow grew from $940 million in the year 2003 to over $2 billion in 2008. The "transformation formula" is to assemble strong people and to energize and inspire people in a high performance culture that delivers executional excellence.

The Schering-Plough strategy has been to keep it simple and steady. There is only one strategy for everyone, which is to grow the top line, grow the R&D pipeline, reduce costs, and invest wisely. The key takeaways for success are to assemble the right team of people, build an environment where people are motivated to give their best, and have people who are competent, aligned, passionate, courageous, and tenacious, so they can achieve goals together. The formula for transformation is to:

- Assemble Strong People: experience is valuable, but attitude is critical. For senior managers, emotional intelligence is a must.
- Create a "Roadmap": tell a "story" and launch a "journey", give a sense of hope and a future, build alignment and common purpose.
- Make It Matter: Build a sense of higher purpose, focus the entire organization on customers and patients, reinforce a high performance way of working, make it "real", and get people engaged. Earn the trust of doctors, patients, customers and other stakeholders as champions for the company that provide a steady flow of science-based medicines and services.
- Create a "How To" that is modeled from the top: a globally integrated business model that sets a clear and simple way of working. It focuses on elements that are 'musts' for achieving the organization's goals in an integrated global matrix, and gives urgency and priority from the top. Schering-Plough leader behaviors are shared accountability and transparency, cross-functional teamwork and collaboration, listening and learning, benchmarking and continuously improving, coaching and developing others, and business integrity.
- Engage and Align Through to the Front Lines: the company focuses on creating a small company in a big company. It intensely communicates strategy, direction and the "why" directly to all colleagues.

The Pharmaceutical Market: Trends and Forecasts

Doug Long, Vice President, IMS Health Inc.

2009 has been a challenging year for the pharmaceutical industry and yet the industry has been resilient. Sales are expected to grow 4.5%-5.5% in 2009 in the US despite the economic recession. The US market is expected to grow at 3-5% in 2010. Sales growth measures, however, remain at historically low levels. Key factors supporting growth are protected brands price growth, increasing generic volume and less price deflation, approvals of innovative therapies, few notable safety events, and demographic factors. Countering these factors are protected brands volume decline, patent expiries, slow uptake of recently launched products, and greater substitution of generics. Generics now hold more than 70% of scripts (17.5% of sales). New Therapy starts are moving away from brands in 17 chronic therapy classes. Risk Evaluation and Mitigation Strategies are becoming prominent in all of FDA's safety-related actions. Label revisions, including black box warnings, are used more often than ever before.

The maturation of the pharmaceutical industry is driving the need for new strategies. In the past, the industry was characterized by blockbuster-focused R&D, a high cost, high ROI representative-driven commercial model where the physician was the key decision maker, and products were formulated as pills or injections. In the future, pharmaceutical companies will pursue specialty focused R&D; a higher risk & cost, a high efficiency commercial model where the sales rep is de-emphasized and the payer is the key decision maker and the product is an "outcome." Key factors in the 5-year outlook for the pharmaceutical industry are patent expiries ($91bn exposed to generics through 2013) and weaker performance from newly introduced products and healthcare reform/legislation. Volatility in the forecast is high over the five year term given the level of change anticipated. Longer-term upsides to pharma growth are possible because of the growing share of the healthcare budget for pharmacotherapy, accelerated uptake of healthcare information technology, increased diagnosis of asymptomatic conditions, improved compliance and persistency rates, expanded patient access to healthcare, greater clinical evidence of drug efficacy, emergence of new therapeutic platforms, an aging population and economic development.

The Current and Future State of the Pharmaceutical Industry

Peter Young, President, Young & Partners

The business model of pharmaceutical companies has changed compared to 10 to 20 years ago. The cost of drug development has soared and the time to commercialization has increased to over 12 years. Competitive pressures from generic drugs, lackluster R&D productivity and pricing pressures are all impacting pharma companies. There have been a number of high profile development failures at advanced stages as well as product withdrawals. Drug development productivity has been on a downward spiral, and patents continue to expire in large numbers. New competitors are emerging from India and China. In response, pharma companies have shifted their strategies and are pursuing new business models. Although it is not clear which models will be most successful, there are some conclusions one can draw today. Potentially weak strategies include the narrow pursuit of the old Big Pharma business model, most mega mergers, and the creation of larger, but still weak regional players through regional mergers. Potential winning strategies include heavy use of biotech methods, alliances with and acquisitions of biotech companies, restructuring of research to be more nimble and collaborative, willingness to stop research projects earlier, and focusing on singles and doubles rather than just home runs.

The future outlook for pharma companies is mixed, as pharma companies struggle to realign their business models. The stock market will continue to penalize the ethical pharma industry as long as the structural changes are being implemented. Pharma industry multiples are below market multiples now and will continue to suffer until the industry outlook improves and regulatory uncertainty is resolved. In 2009 and beyond, M&A activity will be high as pharma companies merge or acquire to achieve scale and enhance their product pipelines. Some of the pharma mergers have achieved a measure of success with regard to cost and marketing synergies, and in the case of acquisitions of biotechnology companies, an increase in product pipelines and commercial products. Debt issuance has surged in 2009 as the market has opened up for investment grade debt. We expect this trend to continue and non-investment grade debt will be issued more sporadically. Equity issuance will continue to be moderate as the IPO and general equity issuance markets continue to be difficult. Demand for low-cost drugs (generics) is enormous, the number of mega brands coming off patent is significant, and branded pharma companies are jumping into the generics market. Generic companies will continue to do well as long as they achieve growth, but with high volatility. There are signs that specialty pharma companies are faring better than big pharma due to their more focused product development activities, flexibility with regard to targeted market size, focus on particular therapies/markets, and willingness to aggressively acquire products.

Health Care Reform: What Will it Do to the Pharma Industry?

William Looney, Editor-in-Chief, Pharmaceutical Executive

Figuring out "how to win" is a challenge in this environment. We need predictability and now there is a lack of it. There is radical change in the way drugs are compensated in the system. The US is the single biggest market in the pharma industry and Health Care Reform ("Reform") may cause challenges for the industry we have not seen before. The key objective, which is a very long haul, is to cover the uninsured. The Reform offers expanded access to government entitlements and a federal subsidy for insurance. There will be new taxes on insurers, individuals and employers, and obligations for new people to participate. This Reform hopes to improve quality and efficiency, and depoliticize future changes. In other words, the objectives are to preserve system flexibility, diversity (many insurers, not one) and choice. The Feasibility Test, or does the rhetoric match the reality, shows that the cost calculations are "fuzzy." The Reform causes frontloading of revenues and lagging of benefits, unrealistic Medicare savings, optimistic tax revenue projections, continuing insurance coverage gaps, and differing views on reform's impact on the current insured population. Further, there is no broad industrial policy commitment to health innovation. The elements of a final "grand bargain" are: insurance plan reform, federal oversight of benefit design and coverage, expanded coverage for the uninsured, growth in federal/state entitlements, individual mandate and employer tax subsidies, institutional support for value-based care, comparative effectiveness, and selective tax increases.

Consensus on Health Care Reform is not a given, and key points are controversial. There are no real alternative pathways, and there is a need for a "decisive" end result. Reform's Stage II is the issue of what comes next. One has to be aware of the mess and legislation that comes after Reform. Regulations need to be written to implement the current outcome. The Reform process will be slow, incremental, and driven by interest groups. The hallmark of the US health care system is flexibility and diversity. The implications of this reform are: more health spending, failure to bend the cost curb, no fixed national budget for health care, increased payer alignment and government oversight, redistribution of the payment pie (specialty vs. commoditized primary care), and deteriorating climate for home-grown R&D. On the other hand, the bright spots include tax credits and reimbursement path for diagnostics which should facilitate personalized medicine and rewards for cancer therapies. Liquidity remains a priority for biotech investors, and it is not clear what effect larger deficits will have on venture capitalists. We will need to look at foreign precedents as fraying social safety nets require more public-private partnering.

Pharma's View of M&A

Charles H. Simmons, Vice President, Corporate Development, Bristol-Myers Squibb

In December 2007, Bristol-Myers Squibb embarked on a strategy to transform BMS into the best of pharma and biopharma, a company that would be agile and entrepreneurial with an accountable culture. Today, R&D is very productive, operating performance is very strong, and productivity has improved. The company has strong margins and an improved cash position with a $10 billion projected cash balance. We have achieved our "string of pearls" strategy of completing small licensing and acquisition transactions. One example is the acquisition of Medarex in a $2.4 billion tender offer completed in the third quarter of 2009. This transaction helps to address the patent issues which BMS will face in 2013 and beyond. In addition, in the course of the year we have completed several smaller transactions in Egypt, Pakistan, Indonesia, and Australia, which is part of our strategy to align our business and strategy with a broad geographic footprint.

Another critical element of our strategy was the decision to focus on the biopharma business and divest our healthcare assets, which was very successful. In the beginning of 2008, we completed the sale of BMS' medical imaging business for just over $500M, which was our first divestiture of healthcare assets. In mid 2008 we sold our wound care business (Convatec) for over $4 billion to a private equity firm. The deal was signed in the second quarter and closed in the third quarter, which was the early stage of the financial crisis but was one of the largest LBO transactions during that period of time. In the first quarter of this year, we completed the IPO of 17% of our Mead Johnson nutritional business (produces Enfamil, an infant formula product), which raised just under $800 million in proceeds. It was the biggest IPO in some time and was completed in the first quarter of 2009 when the capital markets were still strained. To confirm the fact that the market was very responsive to our efforts, earlier this month we launched a $7.5 billion exchange offer for Mead Johnson. The Mead Johnson transaction consists of an exchange of 170 million shares of Mead Johnson for 260 million shares of BMS and will be both cash flow positive and accretive to earnings per share starting in 2010. When it is completed, we will have shifted BMS into a highly focused biopharma company. In summary, in December of 2007 we launched a strategy to combine the best of biotech and the best of pharma. Since then, we have delivered on all of our key operational, financial, and transactional goals.

Pharma and Biotech M&A: Driving Forces in the Market

Peter Young, President, Young & Partners

In the first three quarters of 2009, pharma M&A volume was only 19 deals over $25 million in value completed worth $10.2 billion versus 48 deals worth $51.1 billion in 2008. There were no mega deals completed and deal activity slowed dramatically, including only four deals over $1 billion in value. However, two mega deals were announced that have closed since the end of the third quarter: Pfizer's acquisition of Wyeth and Merck's acquisition of Schering-Plough. In fact, as of September 30, the value of deals announced but not closed was $148.7 billion (16 deals), heavily dominated by the two deals above which will turn 2009 into a very active year. On the biotech side, there were 11 biotech M&A deals worth $4.9 billion in the nine months ended September 30, 2009. There was only one deal greater than $1 billion in equity value. Acquisitions of biotech companies by big pharma and big biotech companies have continued. However, many of the larger biotechs have been purchased and buyers feel less of a sense of urgency to acquire biotech companies given the alternative options to license or form alliances. As of September 30, there were 7 deals worth $2.5 billion that had been announced but not closed. This is indicative of the modest pace of the biotech M&A market. Deal volumes have been high for the last 8 years, but volume in the first three quarters of 2009 has slowed.

The outlook for pharma M&A in the future is one of relatively high activity as pharma companies merge or acquire to achieve scale or to enhance their product pipelines. The Pfizer purchase of Wyeth in October and the Merck purchase of Schering-Plough in November will cause 2009 M&A dollar totals to soar. The need to fill the shrinking drug pipeline will continue to fuel mergers and acquisitions, in-licensing arrangements, and the formation of partnerships and joint ventures.

On the biotech side, there will be successes and failures by individual companies, but overall biotech companies will continue to demonstrate their ability to develop new drugs at a faster pace than the larger pharma companies. The downside is that funding of biotech companies has become far more difficult with the global financial crisis and the shutdown in the IPO and debt financing markets. A large number of biotech companies will be forced out of business or take very dilutive financings to stay alive. The two biotech M&A themes are pharma and big biotech acquisitions of biotech companies for pipeline enhancement and consolidation of research products and services, but the size of deals has declined as the inventory of more established biotech companies has been depleted.

Cutting Edge Patent Issues Affecting Pharma/Biotech

David K. Barr, Partner, Kaye Scholer

What are the current trends in pharmaceutical patent cases affecting the concept of obviousness and patentability? The Supreme Court's 2007 decision in *KSR v. Teleflex* resurrected the "obvious to try" standard as a way to show that a patent was invalid based on obviousness. In *KSR v. Teleflex*, the Supreme Court rejected the Federal Circuit's "rigid approach" which required that to find a patent invalid as obvious the prior art had to provide a "teaching, suggestion, or motivation" to make the invention. The basis for this decision was that the results of ordinary innovation are not the subject of exclusive rights under patent laws, and the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. The *KSR* decision has led to a number of challenges to API patents by generic drug companies based on the "obvious to try" standard, including compound patents as well as patents covering stereoisomers and salts.

In 2009, the Federal Circuit followed *KSR* in reinvigorating the "obvious to try" standard in two life sciences cases. The Federal Circuit said that most inventions that are obvious are also "obvious to try" with two exceptions: first, an invention would not have been "obvious to try" when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art; second, an invention is not "obvious to try" where vague prior art does not guide an inventor toward a particular solution. There have been at least seven Hatch-Waxman cases since the *KSR* decision challenging compound patents and four challenging patents covering stereoisomers and salts. In *Takeda v. Alphapharm*, the Federal Circuit held that the obviousness of a chemical compound is determined by whether it would have been obvious to modify a "lead" prior art compound. In the stereoisomer cases, the Federal Circuit has held that difficulty in separating enantiomers without undue experimentation and the unpredictability of activities of stereoisomers favor nonobviousness. In the cases involving salts, prior art suggesting that "any and all" salts would work favors obviousness, even if the properties of a particular salt were unpredictable. However, unexpected properties can still support nonobviousness where prior art does not narrow the possible salt forms.

Cutting Edge Patent Issues Affecting Pharma/Biotech: Method of Treatment Claims and the Changing Written Description and Utility Requirements

Daniel L. Reisner, Partner, Kaye Scholer

Method of treatment patents are less respected by the courts than compound patents. Today the courts have a much less favorable view towards pharma companies than they did 10 or 20 years ago. The courts have changed the written description and utility requirements for determining whether method of treatment claims are valid. Recently, the Federal Circuit invalidated the '318 patent claiming that utility was not demonstrated. This patent claimed that it was possible to treat Alzheimer's disease with galanthamine based on six scientific papers. The patent specification proposed testing to determine the accuracy of the hypothesis. No animal testing was presented in the case, but it is clear that testing need not be conducted by the inventor. The Federal Circuit's finding appears to be inconsistent with prior cases such as *Burroughs Wellcome Co. v. Barr Labs., Inc.* In that case, the Federal Circuit held the inventor conceived of the idea of using AZT as a treatment for AIDS even though it assumed for purposes of defendants' summary judgment motion that there was no reasonable scientific basis to believe AZT would be an effective treatment for AIDS until the human clinical trials demonstrated effectiveness.

In *Ariad Pharm., Inc. v. Eli Lilly and Co.*, the Federal Circuit Court recently declared that the '516 patent covering three classes of molecules potentially capable of reducing NF-KB activity in cells was invalid based on lack of utility. The Federal Circuit Court's primary criticism was that "the '516 discloses no working or even prophetic examples of methods that reduce NF-KB activity, and no completed syntheses of any of the molecules prophesized to be capable of reducing NF-KB activity." For one class of molecule, the specification did propose example structures, but the Court said "this disclosure is not so much an 'example' as it is a mere mention of a desired outcome." The Court is in the process of reconsidering the written description requirement and its scope and purpose. In a separate case (*Bilski*), the Federal Circuit Court held that a patent claiming methods for calibrating the proper dosage of thiopurine drugs was valid based on a 'definitive test' that a process is patent-eligible if : (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. The Supreme Court granted certiorari to *Bilski* and is considering what constitutes patentable subject matter including whether the Federal Circuit Court's "definitive test" is consistent with Congressional intent.