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*Fourth Quarter 2004*

EXECUTIVE  
**AGENDA**

IDEAS *and* INSIGHTS *for* BUSINESS LEADERS



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# VERTICAL VIEW

EXECUTIVE AGENDA

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## Pharma Explores Uncharted Territory

*As the tectonic plates beneath the pharma industry shift, many companies are looking for sturdier ground. They are discovering that a trip offshore can be more rewarding than they thought.*

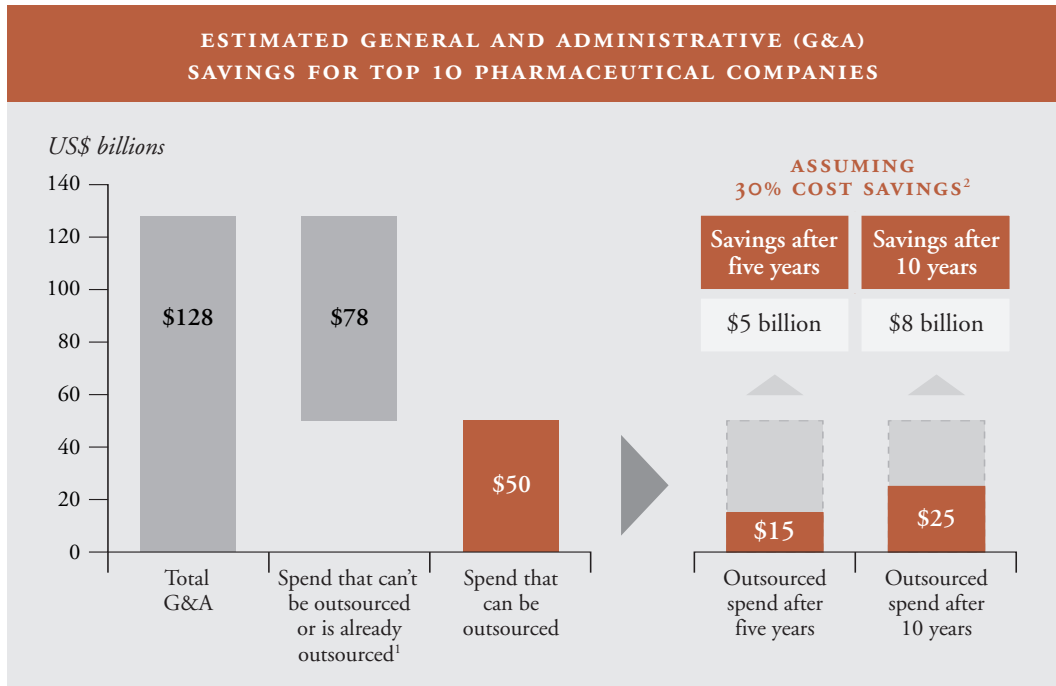
The story of Sir Alexander Fleming's chance discovery of penicillin after returning from vacation to a pile of dirty petri dishes is among the greatest eureka moments of the 20th century. That millions of saved lives can be traced back to a single defining moment is the stuff of legend. Duplicating Fleming's discovery in a thousand different ways is what pharma companies do best.

But the industry dynamics are changing, unmistakable in the reams of key indicators that show a steady downward slope from 2003 to 2008. Blockbuster drug launches will drop from 14 to just four, drugs accounting for US\$72 billion in sales today will be off patent by 2008, and the annual number of new drug launches will be nearly halved, dropping from 60 to just 34 in the same period.

There is no panacea for these challenges, but pharmaceutical companies must be open to possible solutions, which partly lie in cost control and improved productivity—neither of which have been top priorities during the blockbuster-drug era. If it is any consolation, pharma is not alone. Other industries have faced similar pressures, and many of the world's leading companies emerged stronger as a result. Many did it by restructuring the focus and scope of their internal operations and effectively employing global outsourcing, the umbrella term for both traditional outsourcing and offshoring.

In this article, we explore the current state of the pharmaceutical industry, the significant benefits that global outsourcing could provide and the imperative to develop a strategy now.

Figure 1: Globally Outsourcing Non-Core Functions Offers Significant Savings Potential



<sup>1</sup>Conservatively assumes that 20% of addressable spend has already been acted upon.

<sup>2</sup>The cost savings from global outsourcing have been estimated to be 30% based on wage-rate differences.

Source: A.T. Kearney

### A NEW EUREKA MOMENT

Yes, global sales of prescription pharmaceuticals alone are about US\$400 billion a year. But in the past decade, the cost of bringing a new drug to market has more than doubled, and is approaching US\$1 billion. To manage these costs and foster growth, pharmaceutical companies are exploring a host of strategies. A long list of mergers and acquisitions, including the 2003 Pfizer-Pharmacia deal, grabbed headlines and underscored one of the industry's more popular tactics. Another favored approach currently is partnering with biotech firms and universities to co-develop or in-license

(buying the rights to) innovative products.

The pharmaceutical industry has not been anxious to dive into the offshore waters, although a few companies have been wading deeper: AstraZeneca, Novartis, GlaxoSmith-Kline (GSK) and Wyeth. Indeed, the pharmaceutical giants have been in the hot offshore markets such as India and China for years, but concerns about risk and quality have limited the scope of activity. Considerable opportunity remains untapped.

Outsourcing back-office functions cuts costs. For proof, look no further than the financial services industry. Many financial institutions outsource 30 to 50 percent of

their general and administrative processes and operating activities (HR, IT, finance), resulting in estimated savings of more than US\$30 billion across the industry each year. Now consider the pharma industry, which is roughly where the financial services industry was a decade ago. The top 10 global pharma companies spend about US\$127 billion on general and administrative functions, of which about US\$50 billion could be targeted for global outsourcing. By assuming that 30 to 50 percent of this spend will be outsourced over five to 10 years and with conservative savings estimates pegged at 30 percent, this translates into US\$5 to US\$8 billion in annual cost reduction (*see figure 1*).

#### THE WIDENING WINDOW OF OPPORTUNITY

Outsourcing back-office functions is just the starting point. With costs reaching 15 to 20 percent of sales, sending R&D offshore offers significant savings. Although pharmaceutical companies will have to forge their own path in this area, the territory isn't as uncharted as it may seem. In fact, 20 percent of Fortune 500 companies already have R&D facilities in India. GE, Delphi and GM are all there. GE has its second largest R&D facility in Bangalore. With an investment of US\$60 million and 1,600 researchers, GE plans to add another 800 researchers. So far, the center has filed for 95 patents in just the past three years.

Pharmaceutical executives confess to being uneasy about sending any functions offshore, let alone R&D. In our interviews,

we heard an array of perceived risks associated with global outsourcing, particularly regarding business continuity and tolerance for mistakes. "Misreading, losing or misentering one piece of data could result in a multibillion dollar lawsuit," explained one pharma executive. "We have a very low threshold for error, added Joe McCracken, senior vice president at Genentech. "We have to do everything right and we are in a hurry."

Another fear in executive circles is in intellectual property (IP) protection. In the United States and the larger international community, intellectual property regulations focus on both the process of making the drug and its formulation. Until now, intellectual property rights in India focused only on process, leaving the door open for local companies to reverse engineer generic drugs in a way that would infringe on U.S. patent laws. International companies that operated there demanded reassurance from their Indian partners that, despite national legislation, they would adhere to stricter international codes. Still, such hazards precluded many pharmaceutical companies from even considering the market.

But next year new legislation will standardize the country's IP laws, bringing them in line with those of the international community. Although skepticism will no doubt linger until the legislation is fully tested and enforced, the shift is encouraging. AstraZeneca is already aboard. "We are investing in India because of its vibrant science and because we anticipated the adoption of meaningful intellectual property

rights and total abidance to the patent regime in 2005,” said Sir Tom McKillop, CEO of AstraZeneca, pointing to the legislation as a key factor in the company’s increasing presence in India.<sup>1</sup>

The legislation will also encourage established Indian pharma companies to focus more aggressively on sales to U.S.- and EU-based companies. Each year, India graduates 122,000 chemists and chemical engineers many of whom, until now, have worked to reverse engineer drugs. Finding ways to keep both these employees and manufacturing plants busy will become a top priority for domestic companies.

#### MORE THAN MONEY

Global outsourcing can also improve quality and access to talent. Many firms are investing in India because the capabilities and expertise in the pool of the scientists are on par with the highest international standards. AstraZeneca recently built a state-of-the-art research facility in Bangalore dedicated to finding a new treatment for tuberculosis (*see figure 2*). It is also investing another US\$30 million over the next five years for laboratory equipment and operations costs. “Our investment here in Bangalore is definitely not based on cost because the cost of doing research is mainly a small part of the total global research and development efforts,” proclaims Sir McKillop. “The only reason for opting for India is the quality of scientists.”

Think of the prospects in India. In performing clinical trials, companies are able to take advantage of a larger population base

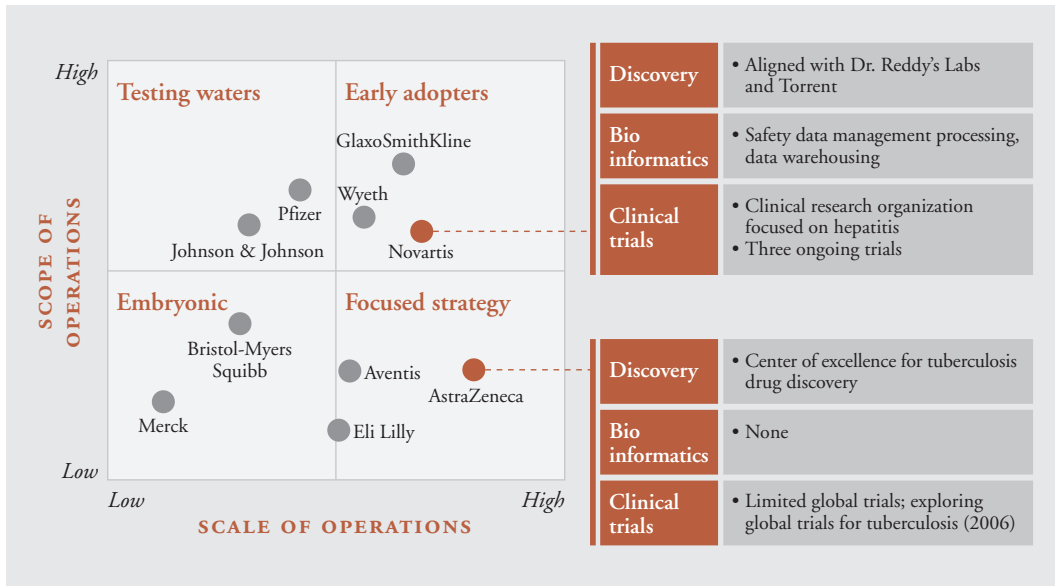
and diverse pool of currently untreated patients, both of which significantly speeds trial time. Low-per patient costs are also an advantage. Clin Tec International, for example, reports that recruiting 200 patients in the United States for a one year study would take about three to six months. In India, Clin Tec claims it slashed this time in half. The time required for data analysis is also significantly shorter, from six to 10 weeks in India versus up to four months in the United States. The estimated cost savings can reach 50 to 60 percent.

Some pharmaceutical companies are opting to partner with or outsource to third-party providers, such as Ranbaxy, Dr. Reddy’s Labs and Sun Pharma, while others are setting up captive operations. GlaxoSmithKline, for example has entered into a five-year R&D agreement with Indian-based Ranbaxy for drug discovery.

On the clinical trial side, the pharmaceutical giant has also set up in-house capabilities for clinical research with plans to conduct four trials in India in 2004, focusing on diseases common in India. Pfizer recently doubled its clinical research investment in India to roughly US\$13 million. GSK is also ramping up its offshore clinical trials from 10 percent of global trials to 30 percent by 2005. “We do about 60,000 patients in total trials each year—so the saving per person if you switch, say, 20,000 of those patients to India is in excess of US\$10,000 per patient. So that’s a savings of US\$200 million right there,” explains Jean-Pierre Garnier, CEO of GSK, in a recent interview

<sup>1</sup> “India Was Chosen for TB Research for the Quality of Scientists,” *www.pharmabiz.com*, 11 June 2003.

Figure 2: *Pharmaceutical Companies in India*



Source: A.T. Kearney

with *BusinessWeek*.<sup>2</sup> Novartis, Pfizer, Sanofi and Eli Lilly are also conducting clinical trials in India.

Reflecting this increased activity, patent applications have soared from 4,000 in 1995 to almost 15,000 in 2003.<sup>3</sup> The market for clinical research is still developing, but the capabilities exist and experience is becoming more solid. In fact, estimates indicate that sharp segment growth could mean that clinical research in India will account for as much as 20 percent of the global revenues by 2010. And because the wage rates are lower, companies can apply more people to a problem, allowing them to solve it that much faster.

### GETTING FROM HERE TO THERE

Pharmaceutical companies are taking a variety of approaches to global outsourcing; how and at what pace they're traveling is different across the board. As drugmakers explore their options, they're quick to discover that in outsourcing R&D functions, there are no cookie-cutter answers. However, they can adopt common strategies and tailor them as needed.

**Learn from the leaders.** In describing GE's global outsourcing activities, John McCarthy, a researcher with Forrester Research, declared, "What GE does today, the rest of the world will be doing two years from now."<sup>4</sup> Being a fast follower to leading

<sup>2</sup> "It's a Perfect Storm for Drugmakers," *BusinessWeek.com*, 4 October 2004.

<sup>3</sup> "India, the World's R&D Hot Spot," *Asia Times*, 18 August 2004.

<sup>4</sup> "GE Plans to Sell Call-Center Unit Based in India," *Wall Street Journal*, 17 September 2004.

## VERTICAL VIEW

Figure 3: Business Model Should Reflect a Company's Risk-and-Return Profile

	PROS	CONS	SAMPLE FUNCTIONS
<b>CAPTIVE</b>	<ul style="list-style-type: none"> <li>• Maximum control</li> <li>• Process consistency</li> <li>• Protection of intellectual property</li> </ul>	<ul style="list-style-type: none"> <li>• Lower cost savings</li> <li>• Higher capital outlays</li> <li>• Increased start-up time</li> </ul>	<ul style="list-style-type: none"> <li>• Research</li> <li>• Clinical development</li> <li>• High-touch customer services</li> </ul>
<b>ALLIANCES AND JOINT VENTURES</b>	<ul style="list-style-type: none"> <li>• Lower business risk and investment</li> <li>• Maintain process control</li> <li>• Accelerated time to market</li> </ul>	<ul style="list-style-type: none"> <li>• Greater management and contractual complexities</li> <li>• Effort to transfer skills to partner</li> <li>• High capital investment</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical trials</li> <li>• Chemical-process development</li> <li>• Manufacturing</li> </ul>
<b>OUTSOURCE</b>	<ul style="list-style-type: none"> <li>• Higher cost savings</li> <li>• Maximum speed and accelerated benefits</li> <li>• Increased flexibility</li> <li>• Minimal capital investment</li> </ul>	<ul style="list-style-type: none"> <li>• Less control of processes and output</li> <li>• Risk of negative public reaction to job losses</li> <li>• Less protection of intellectual property</li> </ul>	<ul style="list-style-type: none"> <li>• IT</li> <li>• Accounts receivable and payable</li> <li>• Payroll</li> </ul>

Source: A.T. Kearney

companies is a solid strategy; despite losing a brief time edge, companies get the benefit of hard-won experience, without the costs of the leaders' mistakes. In developing global outsourcing strategies, including how to handle critical R&D functions, pharmaceutical companies have a host of companies to learn from. It's important to follow not just what the leaders did, but how they did it. In all success stories, company executives made a strategic commitment to send operations offshore, drew upon the global talent pool and made all necessary investments to carry the plan through.

**Find the best opportunities.** Executives must identify functions within their organization that would benefit from global outsourcing. The next step is to determine the

scale, or the size and commitment level, then the scope, or breadth, of functions.

**Manage complexity.** Managing complexity, both in terms of the functions being outsourced and the maturity level of the supply market is critical. In other words, companies should begin with relatively less complex functions in mature markets. As the supply market matures, it can take on increasingly complex functions. Other areas, such as Eastern Europe are building their R&D capabilities, but India's outsourcing market is evolving at a remarkable rate. Indian-based Matrix Laboratories, a bulk drugmaker, grew its outsourcing business fivefold in one year. After clinching deals with Pfizer, AstraZeneca and Bristol-Myers Squibb for contract research, Biocon has upped its staff of

scientists from 25 to 300. As these companies continue to grow and gain experience, the risk for international pharmaceutical companies to broker deals or enter into partnerships with them will decline significantly. Similarly, as pharmaceutical companies gain outsourcing experience, supplier management will become more focused, scale will become significantly broader and outsourcing will become an integral part of the company's business strategy and operating model.

**Choose the best business model.**

Companies can also manage complexity by choosing an appropriate outsourcing model. As figure 3 illustrates, there are pros and cons of each, leaving companies to assess the level of risk they're willing to take on given the potential benefits.<sup>5</sup> Key consid-

erations include the company's need for control, time to benefits and investment thresholds. Most pharmaceutical companies will adopt a mix of models, and change the combination as they gain experience.

**NOT IF, BUT WHEN**

The pharmaceutical industry is at an inflection point where global outsourcing is fast becoming a reality; it's not a matter of "if," but "when." For companies beginning to seize these opportunities, the benefits are clear. For others, the luxury of waiting is ending. The timeworn adage that says prevention is the best medicine is applicable. While pharmaceutical companies help soothe the world's ills, they must also take steps to ensure their own long-term health. ■

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**CONSULTING AUTHORS**

*Chris Paddison is a vice president and leader of A.T. Kearney's global healthcare practice. Based in Dallas, Chris has international consulting experience focused on the pharmaceutical, medical device and consumer industries. His expertise is in strategy, research and development, and corporate transformations. He can be reached at [chris.paddison@atkearney.com](mailto:chris.paddison@atkearney.com).*

*Chris White is a vice president in A.T. Kearney's healthcare practice and is based in Boston. Over the past 18 years, Chris has worked with pharmaceutical companies to improve growth and profitability by addressing a broad range of topics, including product life-cycle management, portfolio management and marketing effectiveness. He can be reached at [chris.white@atkearney.com](mailto:chris.white@atkearney.com).*

*Carol Cruickshank is a principal with A.T. Kearney's healthcare practice and is based in Toronto. She has more than 10 years of experience in serving healthcare insurers, and pharmaceutical and biotech clients. Carol's areas of expertise include channel strategy, large-scale transformation, margin improvement and global outsourcing opportunities. She can be reached at [carol.cruickshank@atkearney.com](mailto:carol.cruickshank@atkearney.com).*

<sup>5</sup> For more information, see also, "The Outsourcing Shuffle," in *Executive Agenda*, third quarter, 2003.

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A.T. Kearney, Inc.  
Marketing & Communications  
222 West Adams Street  
Chicago, Illinois 60606 U.S.A.  
1 312 648 0111  
fax: 1 312 223 6759  
email: [insight@atkearney.com](mailto:insight@atkearney.com)  
[www.atkearney.com](http://www.atkearney.com)

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