Going global in R&D

Economics and politics are making offshoring an increasingly attractive option for biobusinesses

Gregory Mankiw, a Harvard University (Cambridge, MA, USA) economist and Chairman of the US Council of Economic Advisors, told reporters in February that "Outsourcing is a growing phenomenon, but it's something that we should realize is probably a plus for the economy in the long run." Adding that he believes that moving jobs overseas is "a good thing" because it expands free trade, which in turn benefits the global economy, Mankiw's comments brought the long-simmering issue of skilled jobs moving offshore to a boil in the USA during what is euphemistically called a "jobless recovery". In spite of a growing stock market, millions of workers remain unemployed, which has brought greater scrutiny to offshoring as a potentially harmful practice to American workers.

Two years ago, the Forrester Report (www.forrester.com) predicted that the number of US jobs moving offshore would grow from 400,000 to about 3.3 million by 2015, accounting for US\$136 billion in wages. "How many of these are bioscience related is unclear," said Merrilea Mayo, Director of the Government–University–Industry Research Roundtable at the National Academy of Sciences (Washington, DC, USA). A fact sheet produced by the US National Academy of Sciences also noted that "fundamentally, there has been a significant increase in the quantity of science and engineering capacity around the globe." India now has 700,000 postgraduates and graduate students in the biosciences and engineering, as well as 170 biotech companies; China's rate of graduating scientists and engineers is growing at about 36.5% a year and these workers earn about one-tenth of what a researcher receives in the USA. Indeed, Mayo noted about a year ago that the trend of jobs moving overseas seems to coincide with high unemployment

Please pass your test tube on...

rates among scientists and engineers. Talk of "a great sucking sound of jobs going southward," which US presidential candidate H. Ross Perot warned of a decade ago, is being revived, said Mayo, who remained pessimistic about the positive effects of offshoring on both the domestic and global economies. "When jobs here are lost, that might benefit the stockholder and the company, but it really doesn't help the workers," she said, adding, "When a job leaves, is it replaced?"

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Offshoring is expected to grow from 30–40% a year over the next five years, according to McKinsey & Company, a worldwide business consultancy. Top destinations include Ireland, India, Canada, Singapore, Israel and China—all countries with a pool of well-educated English speakers. Stories of biotech companies opening up offshore laboratories to cut costs, such as Discovery Partners International and ChemBridge Corporation (both in San Diego, CA, USA), are becoming everyday news while fast-growing new businesses in the destination countries, such as Clinigene International (a clinical trials company in Bangalore, India), hope to cash in on the trend. Large pharmaceutical companies are also increasingly relocating some operations offshore, albeit much more quietly to avoid negative publicity.

While debate continues about whether offshoring is good for the domestic economy, there is also no consensus among economists as to whether it will ultimately benefit all or just some. The debate is nothing if not polarized: those discussing the "dark side of free trade" (Herbert, *The New York Times*, 20 February 2004, pA25) are concerned about the economic effects on workers at home. They are in turn called "protectionists" by those proclaiming "the bright side of sending jobs overseas" (Porter, *The New York Times*, 15 February 2004, section 4, p3), who see themselves as champions of the free-market economy. Accompanying the debate is an increasing number of bills floated in US state legislatures seeking to ban offshore outsourcing. Even announcements such as that of Eli Lilly and Company (Indianapolis, IN, USA) to add 2,000–3,000 jobs this year are no longer simply good news for Americans, because about one-half of Lilly's workforce is located abroad and many new recruits are likely to be added overseas. More often, companies simply fire domestic employees and hire abroad.

Offshoring is not just an American problem. Recently, UK Trades Union Congress President Roger Lyons called on British business to explain why offshoring is best for Britain (4NI, www.4ni.co.uk, 20 January 2004). He and many unions believe that companies are being lured offshore by "aggressive marketing" from offshore providers and business consultants. Indeed, statements such as McKinsey's predictions are accompanied by encouragement to relocate R&D operations. The McKinsey Global Institute (San Francisco, CA, USA), which describes itself as an independent research group within the firm, released a White Paper in August 2003 in which it argues that offshoring R&D is a "win-win" proposition for both sides—meaning companies and workers overseas (McKinsey & Company, 2003, *Offshoring: is it a Win-Win Game?* McKinsey Global Institute, San Francisco, CA, USA). In fact, the benefits of offshoring for companies cannot be ignored: the reduction of labour costs results in savings of at least 45–55% and an opportunity to drive revenue growth, the report states. It calculates that every dollar of labour cost moved offshore creates US\$1.45–1.47 globally: US\$1.12–1.14 to the USA and

33 cents to the hosting country. "Moving R&D offshore, and not consolidation in the pharmaceutical industry, is the only real long-term solution to cutting costs," McKinsey consultant Jay Rao noted. "It is inevitable."

Consulting Resources Corporation (CRC), a consulting firm in Lexington (MA, USA), also released its own report in December 2003 echoing McKinsey's conclusions. The combination of decreasing pressure on drug pricing and rising costs of R&D points to offshoring as a solution. "US manufacturing has held R&D spending to a level equal to about 3% of sales; drug industry spending on R&D has doubled from 9% in the 1970s to twice that percentage today," commented CRC's President Roger Shamel. "Obviously, things can't continue in this direction without negatively impacting industry profitability." He maintained that until now, offshoring has been underused because of "management myopia" but the first companies to jump on the bandwagon will have a competitive advantage. CRC's analysis suggests that moving R&D operations offshore might reduce the putative cost of developing a new drug in the USA from the current cost of between

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US\$700 million and US\$1 billion down to US\$250 million, if clinical trials can also be moved offshore. Changing international intellectual property laws, the growth of the Internet, lower-cost telecommunications and large educated English-speaking populations are further enabling such moves. Both Shamel and Rao therefore predict that pharmaceutical companies are more likely than biotech companies to move operations overseas, and they might be right: numerous companies, including GlaxoSmithKline (Uxbridge, UK), Novartis (Basel, Switzerland), Eli Lilly and Chugai (Tokyo, Japan) have already established a presence in Singapore, and biotech companies are following.

...she's eager to take it.

Some, however, take a dim view of the recommendations and forecasts of business consultants. Ron Hira, Assistant Professor of Public Policy at the Rochester Institute of Technology (Rochester, NY, USA), maintains that there is a potential conflict of interest in companies that "predict" business trends and then consult with businesses to make them happen. "These are the same companies that are selling offshore consulting services—it's self-serving," Hira said of McKinsey and CRC. Whether or not the trend should be encouraged, it is indisputable that "everyone is trying to attract biotechnology," said Bruce Mackler, a regulatory affairs specialist at Heller Ehrman White & McAuliffe, a law firm in San Francisco (CA, USA). The winners so far seem to be Ireland, Puerto Rico and Singapore, all of which have instituted a range of incentives to draw big biobusiness to their shores.

Singapore started a US\$2 billion biotech initiative in 2000, which includes tax incentives and liberal laws to attract foreign pharmaceutical companies and biotech start-ups as well as scores of world-class scientists from around the globe. The country is trying to make biomedical research a foundation of the Singaporean economy. In addition, it has liberal laws on stem-cell research; a group of international researchers has therefore chosen Singapore as the site of ES Cell International to commercialize human stem-cell research, which cannot be done in the USA or most European countries. The first phase of its seven-building life-sciences park, Biopolis, opened last October, and will eventually house 2,000 researchers. Further north, South Korea is also gaining a reputation as a mecca for Asian biotech, with more than 300 biotech start-ups. The nation recently attracted world attention when two of its scientists demonstrated that embryonic stem cells can be derived from cloned human embryos.

For the past 40 years, Puerto Rico has proven to be a powerful magnet for pharmaceutical manufacturing. More recently, it is also growing as a centre for biotech, at least in part because of a strong history of manufacturing, a well-trained workforce and powerful government incentives. As a US territory, it offers both the advantages of home and the benefits of

offshore investment, which continue to make it extremely attractive to US, European and Asian companies in spite of the phasing out of a tax law particularly favourable to business. And although Puerto Rico shares the same labour laws as the USA, wages are about 20–30% lower than on the mainland.

In addition, the government has earmarked biotech for fast growth. It has a newly established clinical trials initiative, a new disease registry and biotech incubator sites in development. Companies with a strong presence on the island, such as Amgen (Thousand Oaks, CA, USA) and Abbott Laboratories (Abbott Park, IL, USA), are investing millions in professional development to recruit and train native scientists and businesspeople. In the past 18 months, the island has attracted more than US\$2 billion in biotech investment, including a US\$800 million plant for Amgen to produce erythropoietin and the arthritis drug Enbrel, a US\$450 million plant for Lilly, a US\$350 million Abbott facility to produce its antibody drug for rheumatoid arthritis, Humira (adalimumab), and a US\$103 million plant for Pfizer (New York, NY, USA). There is also a strong US Food and Drug Administration (FDA) presence in Puerto Rico, which gives it a powerful competitive advantage, as FDA compliance is an absolute imperative for successful overseas manufacturing. "Cheaper is not better if it doesn't meet US regulatory standards," Mackler commented. At present, 16 of the 20 top-selling drugs in the USA are produced on the island.

Ireland recently managed to draw Wyeth (Madison, NJ, USA) to its shores with incentives and a growing biotech environment; the company is now building a US\$1–2 billion plant in Dublin, which it says will become the world's largest biopharmaceutical campus. Last year alone, the government supported the establishment of 61 new start-ups with a €75 million investment.

Bruce Jenett, Co-chair of the Life Science & Technology group at Heller Ehrman, does not see these events as indicative of a vast move of bioscience R&D, as information technology did before, although he does concede that India and China are gaining importance for clinical trials and manufacturing. "Pharma and biotech have always conducted

business globally," he said. Emerging companies—before and after initial public offerings—might see some cost advantage in going overseas, but he does not expect to see mass offshore migration.

More movement might also be expected from Europe to the USA to conduct clinical trials as a result of a directive adopted by the European Union (EU) in May 2003, said Mackler. European companies now have to follow stricter regulatory rules for initiating clinical trials, similar to those in the USA, which could encourage European-based firms to conduct studies where the regulations are well defined, rather than be the first to try out new EU regulations. Indeed, biotech companies such as BresaGen (Thebarton, SA, Australia) and PPL Therapeutics (Roslin, UK) have already added operations in the USA.

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Whether or not offshoring represents a crisis for US- and UK-based scientists, it is imperative for their governments to gauge what is happening when many companies might be in the planning stage of moving, Mayo said. "Now is the time to take action to keep business at home, not later." One clue that something is not right is the high rate of unemployment in the USA for scientists and engineers, which is much higher than for doctors and the college educated, she said.

"The real question here is not whether offshore outsourcing is good or bad, because it is already happening and will continue to accelerate," said Hira. "The issue is how we can find effective ways to mitigate its significant negative impacts. Rather than just calling the displacement of workers 'painful' and 'an inevitable part of reality,' it is necessary to address the real losses—human, economic and innovation—that we will experience from it," said Hira. "In the end, free trade must also be fair trade," said Mayo.

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