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Global Challenges, Global Solutions

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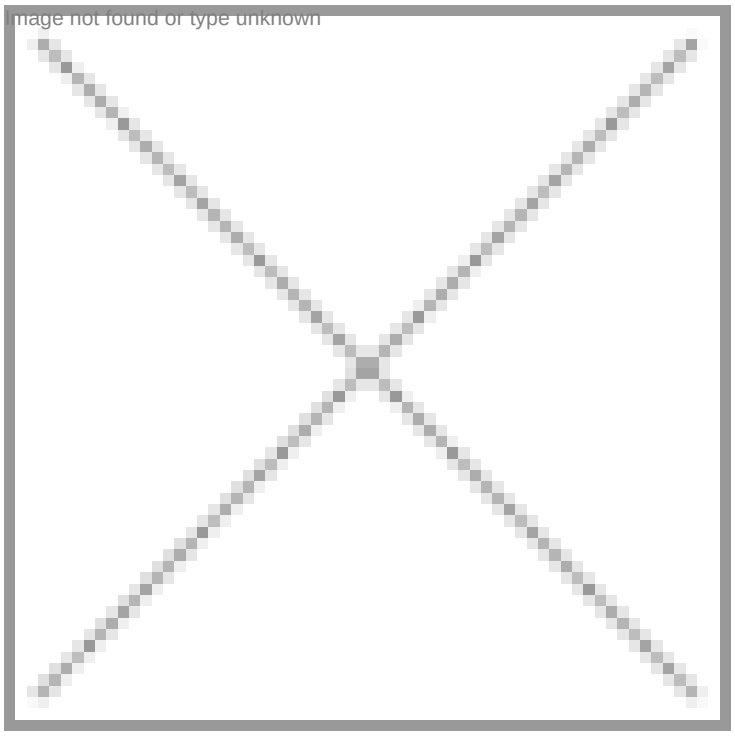
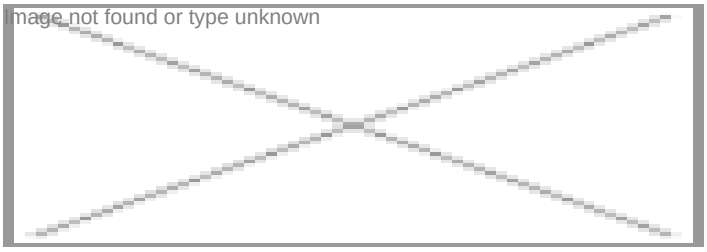


The biotech industry is becoming more competitive and is rapidly expanding beyond its borders. The industry is still dominated by the US sector and the relatively younger companies in Europe and Asia have some significant challenges ahead. They, however, have the benefit of learning from the US industry and have the ability to tap into resources and strengths from around the world, in what is rapidly becoming a truly global industry, says Beyond Borders, the Global Biotechnology Report 2005 of Ernst & Young



"We see a bright future for biotech globally. There are already 290 approved biotech drugs and 55 more are awaiting regulatory approval. And the biotech industry's R&D spend is 50 percent more than that of the pharma sector," emphasized Ernst & Young (E&Y) partner, Utkarsh Palnitkar, while announcing the highlights of the report at a crowded auditorium at the BIO convention in Philadelphia on June 21.

The globalizing nature of the industry is evident from the fact that nearly half of the publicly traded 641 biotech companies are now outside the US, the cradle of the industry. There were 59 initial public offerings (IPOs) by biotech companies worldwide in 2004, including India's first one by Biocon.

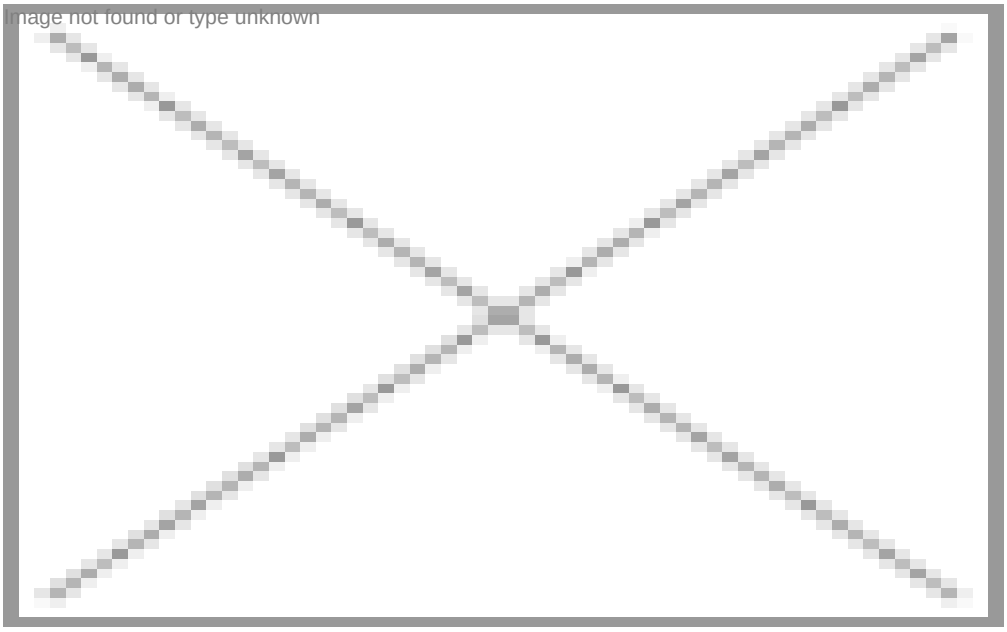
Biotech entrepreneurs are finding new ways to raise capital. For example, there were 350 biotech companies in Germany. At least 35 of them disappeared last year, majority of them becoming insolvent. However, 30 new biotech companies were

formed in 2004 and not one of them was helped by venture capitalists.

"Biotech is the innovation engine of the economy. Small companies account for nearly two-thirds of the drugs in the pipeline," commented E&Y's Americas leader Mike Hildreth.

Here is an extract from the introduction of Beyond Borders:

"As the biotechnology sector matures and brings products to market, it is rapidly evolving, restructuring and recombining in response to unique challenges and opportunities. With biotech spreading across the globe, and strong progress in Asia, companies are no longer constrained to look for resources close to home. Increasingly, the answers to challenges are being found at the global level, as obstacles in one region are overcome by leveraging strengths and capabilities in another part of the world.



Driven by the forces of competition, pricing pressure and funding challenges, the biotech sector is moving beyond borders on multiple fronts-locating activities around the world, and expanding aggressively into new industries and products.

The pressure on drug prices is relentless and will only increase in years ahead. In Europe, some countries are already imposing a so-called "fourth hurdle" on top of the existing approval process, adding cost effectiveness to the criteria of safety, efficacy and quality.

Following the lead of the UK, Germany established IQWiG in 2004, a new institute to advise the country's healthcare system about which treatments should be funded. In the US, Dr Mark McClellan, the new administrator of the Centers for Medicare and Medicaid Services has indicated support for such cost-benefit considerations. Pricing pressures will increase over time, as many industrialized nations grapple with budgetary constraints and aging populations.

In this environment, companies need to find ways to increase the efficiency and productivity of drug development-put simply, they need to do more with less. Even as scientific progress brings exciting new cures to the clinic, the industry needs to control the cost of drug development, now estimated at $800 million per new drug. It's a daunting challenge, and while there are no easy answers, solutions are emerging.

One potential solution lies in scientific advancements. With the advent of personalized medicine, companies may use increasingly focused clinical trials to drive down developmental costs and reduce the time to approval.

A second solution is to harness biotech's growing global strengths. For several years, drug development companies have used alliances to focus on what they do best, while leveraging the strengths of partners for the rest. Examples abound, from the specialty pharma model that some biotechs have adopted, to the extended enterprise concept that many big pharmas pursue.

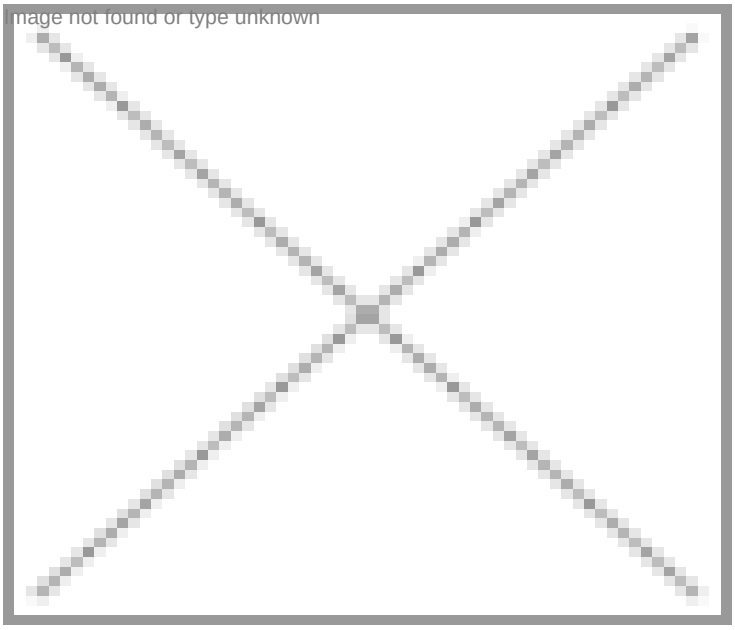
Now, with China and India improving their regulatory systems, we are starting to see these trends go global in a big way. In recent years, both countries have boosted intellectual (IP) property protection, and with the passage of India's Patents Law in early 2005, the world's two largest markets allow for patenting of drugs.

Western countries are already conducting research and development activities in the two countries, but many remain cautious about expanding research alliances to include more sharing of IP. Enforcement remains a big challenge, but if China and India demonstrate solid progress on this front, western companies should have no good reason to hold back, and many reasons to jump in-the cost savings could be tremendous.

Less heralded, but equally significant, is the city-state of Singapore. With a long tradition of openness to trade and

investments in technology, Singapore is on its way to achieving its Biopolis vision-the goal of becoming a world-class hub for biomedical manufacturing. Several of the world's biggest biotech and pharma companies have located facilities in Singapore, and others have announced plans to do so.

While outsourcing has revolutionized industries in the West, from IT to financial services, the issue remains politically charged and was very visible in the 2004 US presidential elections. Any concerns about the outward migration of drug R &D should be outweighed by the huge benefit to western economies from lower drug development costs. In the drug pricing debate, analysts have long argued that the US subsidizes the cost of drug development for the rest of the world, since the absence of widespread price controls in the US market means that American consumers and taxpayers underwrite the lion's share of R&D. Now, as biotech and pharma develop extended enterprises on a global scale, the rest of the world could contribute in kind, by helping lower the cost of drug development.



Countries around the world are competing fiercely to attract and develop biotech activity. To some extent, this is driven by improving Asian regulatory systems, which increases location options for the rapidly expanding sector. The industry's maturation and growth potential have also attracted the attention of national and regional governments across the world. From Malaysia to Michigan, governments are developing strategic plans with ambitious goals for growing biotech.

One consequence of this aggressive competition is the "don't fence me in" factor. Companies are no longer constrained by the limitations of their local markets and can look for solutions in other parts of the world. This is most evident in the areas of stem cell and therapeutic cloning research.

This increasing competition between regions could also help address one of the industry's most pressing issues-the dearth of early-stage capital. Though the global industry raised a whopping $21.2 billion in 2004, funding for early-stage development (the infamous funding "gap") remains a challenge for many, and a consistent theme across the globe. Across Asia, governments are setting up funds for their early-stage companies. In the US, several state governments are using tobacco settlement money for seed funds targeted at the industry.

In addition, biotech companies are moving beyond geographic borders through alliances, mergers and acquisitions. The number of cross-border alliances grew from 421 in 2003 to 480 in 2004, a 14 percent increase. European companies in particular, went global in their search for partners, accounting for half of all cross-border alliances in 2004.

Exporting Revolution

As biotech companies search for ways to increase the efficiency and productivity, it may be reassuring to note the sector's long history of creating efficiency gains through scientific advances. It is no exaggeration that biotechnology produced a revolution in drug development, as a series of breakthrough technologies took the 160-year-old pharmaceutical industry and reinvented it. High throughput screening revolutionized the process of target identification. The development of DNA sequencing machines by PE Biosystems (now Applied Biosystems) shaved years off the mapping of the human genome, and changed forever the fields of genomics and proteomics. The invention of monoclonal antibodies transformed the diagnostic industry, and after some hiccups along the way, is bringing to market revolutionary new treatments for diseases such as cancer. The field of pharmacogenomics, just starting to bear fruit, will change medicine as we know it by transforming the one-size-fits-all drugs of yesterday into the targeted therapies of tomorrow.

Extraordinary achievements such as these overshadow that most of what we have seen so far is the application of biotechnology to just one existing industry. The word biotechnology is often used to describe what is, in fact, the health biotechnology sector. But the term literally refers to a set of biologically-based techniques that could be applied to a wide range of industries.

With the introduction of the first genetically modified (GM) crops in mid-1990s, the global area of biotech crops has increased by double-digit growth rates, growing 20 percent in 2004 alone. Biotech crops are now being cultivated in 18 countries, with R&D conducted in another 45 countries.

Similarly industrial biotechnology has the potential to shake up another long-standing sector-chemicals and industrial manufacturing. Industrial biotech is being driven by new varieties of enzymes, which are protein catalysts that step up chemical reactions in cells. Biotechnology is making numbers work, by creating GM enzymes so that existing production processes do not have to be altered.

Second Wave

The first wave of biotech products was recombinant proteins, based on recombinant DNA technologies. More recently, the second major wave of biotech products, therapies based on monoclonal antibodies (MABs), is reaching critical mass. Several of the product approvals in 2004, including Humira, Remicade, and Campath are MABs. Personalized medicine is emerging as well, with tremendous potential to improve health care. Drugs such as Gleevec and Herceptin have already been developed on the premise of targeting specific genotypes. The widely anticipated approval of NitroMed's BilDil could bring the first drug targeted to a specific demographic group."