

A photograph of a pond with numerous green lily pads floating on the water. A single pink lotus flower is in bloom in the lower center of the frame. The water is dark and reflects the surrounding environment.

Emerging Focus

The Asia-Pacific Perspective

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B iotechnology continues to grow rapidly in the Asia-Pacific, as companies and governments across the region focus on this emerging sector. The Asian sector's top-line revenues increased by an estimated 46 percent compared to 2004. However, as in other parts of the world, growth stemmed largely from the success of a few big companies. In Australia, strong performance by CSL, the sector's largest company, boosted the country's biotech revenues by an astounding 64 percent, and allowed Australian and Asian biotech to reach a remarkable milestone—aggregate profitability. In other countries, leading stars continued to show strong growth. But for many smaller companies in the region, challenges abound—the lack of experienced venture capital (VC) and increasing competition from new patent protections and foreign companies.

Asian governments are making biotechnology a top strategic priority, recognizing the industry's tremendous growth potential and strategic importance. For Asian countries, the focus on biotech stems from several underlying trends. The first of these is economic liberalization. In the '80s and '90s, China and India started to liberalize their massive economies, enacting policies to encourage deregulation, privatization, and international trade. As they opened their borders, both countries have had to boost intellectual property (IP) protections. Inevitably, these measures increased competition for domestic industries, and countries are looking for areas where they might have a competitive advantage. India's prior patent laws had spawned a thriving generics industry, and these firms are now scrambling to find a competitive toehold under the new rules. Japan, an economy that has sometimes been accused of using regulations as “non-tariff-barriers” to shield its domestic economy, now is enacting regulatory reform to expose its sleepy drug industry to foreign competition.

Asian governments also see biotech as a natural fit because it is a technology-based industry with tremendous growth potential. Over several decades, several East Asian economies, including Japan, Taiwan,

Singapore, and South Korea, experienced rapid growth by developing competitive strengths in high-technology industries. But in recent years, many of these sectors have seen shrinking margins due to commoditization and intense price competition. Biotechnology is viewed as the next big thing—an industry with tremendous growth potential in the decades ahead. While the strategy is risky—developing biotech products is a long, expensive proposition with no guarantee of success—the industry has much higher profit potential and creates high-education, high-wage jobs.

The ingredients for a thriving biotechnology industry are no secret. Successful locations in the West have prospered from a combination of strong university research, experienced VC and management, a highly educated labor force, physical infrastructure such as specialized real estate, and laws that support technology transfer. To varying degrees, Asian governments' strategic plans aim to replicate these success factors. But, while biotech in the West took three decades to come of age, companies in the Asia-Pacific face the all-too-real prospect of looming foreign competition in the near term. They will need to accelerate development, creating unique solutions that reflect their own particular strengths and challenges. In an increasingly competitive environment, executives and policymakers are looking for focused strategies and competitive niches.

Competitive niches

Today's biotechnology industry is extraordinarily diverse, encompassing numerous technologies, platforms, and industry segments, and Asian countries are well placed to be competitive in several key areas.

Contract research/manufacturing:

Research and manufacturing services are a growth sector that many Asian countries are targeting. Western drug development companies face tremendous pricing pressure in their home markets and need ways to reduce costs and increase returns for their investors and shareholders.

Asia-Pacific biotechnology at a glance		
	2005	% change
Public company data, U.S.\$		
Revenues (\$m)	3,002	46%
R&D expense (\$m)	312	23%
Net income (\$m)	7	-108%
Number of employees	12,490	-7%
Number of companies		
Public companies	139	6%
Private companies	577	4%
Public and private companies	716	5%

Source: Ernst & Young
Numbers may appear inconsistent because of rounding
2005 data shows most recent financial data available from companies as of January 2006, and includes some estimation for companies whose data could not be obtained

The Asia-Pacific region has long served as a hub for low-cost manufacturing, with countries such as Taiwan, Hong Kong, and Korea producing everything from toys to semiconductors. More recently, China and India are transforming Western industries through outsourcing manufacturing and services. The same labor costs that facilitated each of those transitions are at play in the biotech sector—savings from outsourcing research or manufacturing to Asia can range from 50 to 80 percent.

Biotech, however, has a key difference from most other industries. It is one of the most heavily regulated industries in the world, and companies must meet stringent requirements at every phase, from designing and conducting clinical trials to manufacturing finished products. To compete in this arena, Asian countries will have to raise their regulatory regimes to global standards. For instance, China has been actively boosting its enforcement of regulations covering good manufacturing practices (GMP), good selling practices (GSP), and good laboratory practices (GLP).

Vaccines: Asian countries are creating competitive niches in the vaccine space by developing vaccines at more affordable prices. Using pioneering technologies and efficient production methods, companies such as China's Sinovac Biotech and India's Bharat Biotech have successfully developed vaccines for diseases such as hepatitis A and B

at prices that are a fraction of Western prices. Western companies are already recognizing that the region will play an increasingly important role in the global vaccine market and are making investments and forming alliances with Asian companies.

Generics/biogenics: Generics is a rapidly growing segment. Several blockbusters are scheduled to go off patent soon, and 2005 was pharma's biggest patent-expiration year ever, with an estimated \$23 billion worth of products losing protection. As some early biotech products go off patent, the prospect of generic biologics is equally tantalizing. Regulatory pathways are not well defined in the West, but as these issues are resolved in the years ahead, follow-on biologic products could be a lucrative growth segment. Some Asian countries are well positioned to take advantage of these changes. India, for instance, has long had a thriving generics industry because of its permissive IP laws, and Indian firms already are gearing up for the coming boom in generics.

IT/bioinformatics: Given their traditional strengths in information technology (IT), many Asian countries are well positioned to be competitive in segments within the growing convergence between IT and biotechnology, and several governments and companies are making key investments in the segment. For instance, Malaysia is leveraging cutting-edge infrastructure developed for its Multimedia Super Corridor project (MSC), originally launched in 1995 to boost the IT sector, for the needs of biotech and bioinformatics companies. Taiwan is exploring ways to integrate its strengths in IT to benefit its burgeoning biotechnology strengths. In India, companies such as Strand Genomics and Tata Consultancy Services (TCS) are already playing an active role in the country's bioinformatics sector.

Traditional strengths: Some Asian countries also are well situated to leverage more traditional assets. Malaysia, for instance, is trying to leverage its biodiversity. Traditional Chinese Medicine (TCM) gives China a vast pool of untapped active compounds, which—combined with modern drug discovery tools

such as high-throughput screening—could accelerate the commercialization of new therapeutics. Western companies are already paying attention.

Recently, India, Brazil, Peru, and other developing countries banded together to try to win an amendment to the World Trade Organization's (WTO's) Agreement on Trade-Related Aspects on Intellectual Property Rights that would compel patent holders to disclose the origin of their patents and share revenues when patents are based on genetic plant material or traditional knowledge from developing countries. Clearly, there is much at stake, and such traditional assets represent significant growth opportunities.

Disinvested technologies: Asian countries have achieved some success by focusing on technologies that may be temporarily out of favor in the West. When the United States severely curtailed federal funding for stem cell research, Asian locations such as Korea and Singapore continued to invest in the segment. Korea's program suffered a highly visible setback last year, when several breakthroughs by a leading scientist were revealed to be based on falsified data, but companies in Korea and other Asian countries continue to focus on the segment.

While stem cells have been controversial in parts of the West for ethical reasons, the field of gene therapy fell out of favor because of development hurdles. However, Chinese companies have persevered and are successfully bringing products to market.

Leveraging growth

Asia's history as a manufacturing hub for numerous industries has followed a similar pattern—the migration to higher-value, higher-margin activities over time. While many Asian countries started out producing low-margin, easily commoditized goods, they invariably developed the skills and confidence to transition to more valuable activities. In the early '90s, Japan moved from being a producer of economy cars to a serious player in the luxury sedan market. Recently, Korean companies have made a similar transition, leveraging existing strengths in consumer

electronics manufacturing by becoming powerhouses of cutting-edge design.

There is good reason to think that Asia's biotechnology companies would follow a similar path. While outsourced manufacturing and research represent cash cows in the near future, many companies will inevitably seek to move from the fee-for-service model to the more lucrative, though more risky, innovation model. Foreign competition and patent protections are pushing Asian companies to become more innovative. It follows that they will seek to maximize their revenues from new drugs by pursuing sales in other markets. In the next article, Dr. K.V. Subramaniam presents a plausible scenario that India could follow to make this transition, moving from outsourced services to generic and innovative products, and finally to a globally competitive industry.

The transition will not be easy, as companies will need to pursue clinical development strategies for regulatory approval in other countries. Companies that are relatively inexperienced in developing novel medicines will need to learn how to innovate, and will need to identify sources of funding for R&D.

Friends in need

The year 2005 was marked by tremendous activity on the biotech deals front, and Asia-Pacific was no exception. In an environment of rapid change, companies formed alliances to further their strategies and accelerate growth. In China, a big driver of deal activity was access to domestic markets. Some of the year's deals also illustrated the potential for Asian companies to go global and transition to higher-value activities.

Looking ahead

Ultimately, a booming Asia-Pacific biotechnology industry will raise living standards in the region, creating bigger markets for Western drugs. And more innovative companies in Asia will mean a greater supply of life-saving medicines for patients around the world. ■

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