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Business Development

Published online: 20 February 2007, doi:10.1038/bioent916

Becoming an American company: a holistic approach to decision making

Pradip K Banerjee[1]
Pradip K. Banerjee is chairman & CEO of The Banerjee Group, 141 Christopher Drive, Princeton, New Jersey 08540, USA. Previously he was the president and CEO of the University City Science Center in Philadelphia, PA. E-mail:e-mail: pbanerjee@patmedia.net

For most biotech companies, the US market represents their best avenue to financial success. For non-US companies, that might mean opening a subsidiary, and that's a move that requires careful planning.

Every day, in laboratories and research institutes around the world, new drugs and interventions are moving closer to fruition. But getting these promising products to markets—especially to the US market—has never been more difficult. Some fundamental business drivers have remained unchanged and a few new macroeconomic factors have come into play, providing both challenges and opportunities for biotech companies deciding if and when to set up a US location.

- The US market remains the most attractive destination for all life sciences companies, which makes approval by the US Food and Drug Administration (FDA) the most important milestone for most biotech companies.
- Despite a decade of harmonization efforts, the requirements, the protocols and processes for FDA approvals are still substantially different from that of other regulatory authorities.
- Emergence of India and China as viable, low-cost areas for drug discovery and development further complicates the decision making regarding geographic expansion into the US.
- Emergence of 'born-global' companies adds a new dimension to the biotech landscape. Unlike traditional companies, which start their operations locally and expand slowly into exports, becoming multinational and global later, born-global companies establish global operations from the very start. These companies come mainly from countries with advanced scientific research bases and small local markets, such as Israel, Australia, Denmark and Sweden.
- Emergence of 'soft landing' platform organizations can ease the entry into the US by offering a comprehensive package of management services, capital and appropriate facilities to fast forward the product development cycles.

(Box 1).

These issues inevitably raise the questions "When is the best time for a non-US company to set up a US base?" and "What is the best way of establishing a US presence?" Like most questions of this kind, the answer is "It depends." It depends on what the company does, its objectives and strategy, the nature of its portfolio and its country of origin. Because most biotech companies are in the R&D stage, this discussion will focus on companies at that stage. These companies must consider the value drivers and cost consequences of their desire to have access to the US market and have the context of the entire process of drug development as part of a global execution strategy.

Value drivers for geographic expansion

There are various reasons that a biotech company would consider expanding beyond their borders. Productivity improvement—getting the highest output per dollar—speed of innovation, and increasing the commercial value of their R&D are the primary reasons for considering moving or expanding into the US. Other reasons are:

Accessing talent.

Geographic expansion may provide talent that the company needs but has no easy access to. The San Francisco and Boston areas, for example, claim significant talent in biotech and software engineering. On the other hand,

the Philadelphia area, where there is a high concentration of pharmaceutical companies, offers a large pool of people trained in drug development. The cost of talent will depend on supply and demand in the area. Costs are high in places like San Francisco and Boston, whereas they are more affordable in Philadelphia, North Carolina and Houston.

Sustaining its position in intellectual property.

Geographic expansion may change the company's approach to innovating from a reliance on alliances to a more balanced emphasis on internal innovation. Scientists within biotech clusters may become more innovative through information sharing and competition.

Lowering cost.

Whereas expanding into developing countries, such as India, China or Eastern Europe, can have cost advantages, the coordinated execution of a plan for product approval in the US along with execution in places like India and China can result in higher value creation through faster FDA approval and lower overall cost.

Accessing technology.

Geographic expansion may improve access to technology through alliances —by facilitating the identification of opportunities, deal making and post-deal management—through internalizing technology, as staff become more connected with the external community, leading to more information exchange. In addition, geographic expansion may improve the ability to innovate or anticipate and prepare for technology innovation as the staff becomes better informed.

Accessing financing.

Venture capitalists in the US have the most experience in investing in biotech companies as well as experience in managing the growth of these companies. Public markets in the US are also the most experienced in dealing with biotech companies. Although life sciences financing in Europe and Asia has grown greatly over the last decade, it is still advantageous to tap into the US capital markets, as it offers a hedge against market cycles in other countries.

Challenges with geographic expansion

The advantages of global R&D come with several challenges. For one thing, there may be communication barriers. These can exist in two forms:

- Differences in time zones and work hours can make it difficult to communicate in real time.
- Different levels of technical skills and different standards of measurement between countries will impair smooth communication. Often there is misunderstanding of what is being said and what was understood.

In addition, different countries may have different policies and implementation levels of intellectual property rights. As a result, companies in countries with strong laws are reluctant to share critical technology with their own R&D centers located in other countries. This can work in reverse for companies originating in countries with weak intellectual property rights who then might want to make strategic alliances with US companies.

Embargos and government policies can hinder technical collaboration. In the post 9-11 world, it has become more difficult to exchange R&D work on biological products across international boundaries. Material transfer across international borders requires extensive customs clearance procedures adding to timelines and costs.

Geographic expansion may cost more than other alternatives, because of, for example, up-front cost (for facility, real estate) and operating cost (labor), though costs vary depending on specific locations (local real estate market, cost index, government incentives).

Global coordination of R&D is a management challenge. Creating a cohesive network of coordinated R&D centers requires dedicated efforts from top management, human resources department and R&D staff. However, the greater effort required for managing geographically dispersed sites may be offset by less management effort required for recruiting and retaining talent.

New sites may have a unique culture under the local influence, which might be in conflict with the culture at the home base. Coexistence of two cultures may cause organizational problems, whereas imposing one over the other may stifle innovative spirit.

Finally, integrating organizations at dispersed locations requires significant effort and cost. Integration of technology at multiple sites may incur extra technical and personnel cost and may prove difficult. Novel technologies developed or used in new sites may not be easily leveraged by other sites. Management and coordination of projects across disperse locations can be inefficient. Communication and information sharing across sites may be exceedingly difficult. Therefore, organization knowledge capital may not be effectively leveraged. Conflicts may arise regarding investment priority among facilities, and as a result, the efficiency of current R&D operation can be severely undermined.

A decision framework and a suggested process

For this discussion of a decision framework, the countries of origins can be grouped into four categories:

- Companies originating in Western European countries with competitive, patent-protected products, which FDA will consider a new drug (Group A).
- Companies originating in Japan (Group B).
- Companies originating in India and to some extent in China (Group C).
- Born-global companies irrespective of the country of their origin (Group D).

Western European companies have competitive, patent-protected products, which FDA will consider a new drug and on the whole. In addition, they are generally familiar with FDA regulations, have access to infrastructures and facilities that are good manufacturing practice (GMP), good laboratory practice (GLP) and good clinical practice (GCP) compliant in their local countries, are comfortable in doing business in English and have fewer cultural barriers to doing business in the US. The cost of doing business in these countries is generally not much different than that in the US.

In contrast, companies from Japan, which also have patent-protected products that the FDA will consider a new drug, have significant language and cultural barriers and generally do not have good access to FDA-approved facilities and infrastructures.

Companies from India, and to a lesser extent, China, have some unique opportunities today. In India, there are plenty of FDA approved GMP, GLP and GCP facilities with trained people available at a significantly lower cost than in the US. Several large pharmaceutical companies are now setting up their own R&D facilities in India and China.

Born-global companies offer a new paradigm for biotech companies today irrespective of their country of origin. This approach offers an opportunity to combine the best intellectual properties from the US and the country of origin and to take advantage of global financial markets, government incentives and rapid global product development. To be an effective born-global company, several intrinsic characteristics need to be in place (Box 2).

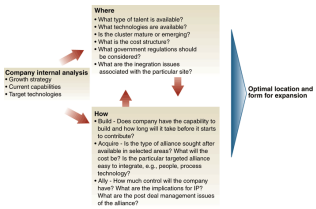
Companies in Western Europe, India and China have the most flexibility in their decisions regarding the timing and nature of their expansion into the US. European countries enjoy the advantage of availability of FDA-standard facilities and service providers in their own countries especially those in the western EU.

Beyond those considerations are others specific for each country of origin (Table 1).

- For European companies, the decision to set up a US site depends on the nature of the company it desires to become after FDA approval of their first product. If the company plans to be a fully integrated pharmaceutical company, then it makes sense to open a US office once the first product nears FDA approval. If, on the other hand, the goal is to go to market with a pharmaceutical partner, then it is not necessary to ever open a US office. A US office would allow a company to expand its portfolio through collaboration with academic or other US biotech companies. In this case locating the company in a cluster region with a high degree of pharma/biotech resources available would be optimal.
- For Japanese companies, it makes sense to tie-up with a soft-landing partner as early as possible and grow the business both in the US and in the home base for both research and product development, and financing. Once the products are in late-stage clinical development and the company desires to become a fully integrated pharmaceutical company, the company should consider opening an independent operation possibly near the location of the soft-landing partner's sites.
- Companies from India and China, today, have very similar options to their European counterparts. However, the stage of overall scientific research is not broad or deep enough yet in these countries. Therefore it makes more sense for companies in these countries to establish high-level academic collaborations early on and at late-stage development, have a US business development/marketing office. It is expected that the most cost-efficient process for these companies for manufacturing and development would be through their home base.
- Born-global companies need to establish a US presence as early as possible. Soft-landing partnership in a life science cluster region is the most convenient way to achieve strategic goals for these companies.

Figure 1 outlines a sample process driven by a thorough analysis of the strategy, capability and the method of choice to arrive at a location decision for these companies. Companies should (i) conduct a thorough analysis of their growth strategy, technology and capabilities needed from the US expansion; (ii) create a cost and resource model and understand various clusters and soft-landing facilities in the US to determine the region that offers the best match for the company; (iii) conduct this analysis in conjunction with an analysis of the various modalities for setting up a new location-build, buy or partner/alliance in the US.

Figure 1: A process for geographic expansion and site location decisions



Final analysis

The US still remains the ultimate prize for market success for biotech and pharmaceutical companies, making it necessary for most biotech companies to have a US location at some point in their life cycle. Biotech companies have more options and ways to access the US market today than ever before due to several macroeconomic factors in play. But to do so, companies need to analyze thoroughly who they are, given where they are coming from, and how far they can go before having to set up a US base of operations. This needs to tie in with financing strategy and a clear understanding of their endgame—whether to become a fully integrated pharmaceutical company or go to market through a pharmaceutical company partnership.

In today's world it is also necessary to understand the opportunity for creating a cost efficient—speed model through leveraging another global node in low-cost countries. The future is no longer what it used to be. So, think clearly, plan holistically, start small and scale quickly to capture the ultimate prize—the US market.

Box 1: Soft-landing platforms

Soft-landing platform organizations integrate capabilities under a single management process to provide:

- Hands-on management services, not just advice.
- Specialized facilities.
- Financing/ venture capital.
- A network with high-quality research institutions.
- Ability to find people with FDA and pharmaceutical experience.

These organizations have experience in dealing with non-US companies, understand different corporate organizations, can help create international partnerships and find capital, and provide hands-on management for all aspects of these companies' US operations all under one umbrella. An example of such an organization is the University City Science Center in Philadelphia, which is located next to the University of Pennsylvania, with over 1.7 million square feet of space in a research park, two lab incubators, a management services company and venture capital fund, all under corporate management with several international strategic partnerships in place.

Box 2: Born-global company's core competencies

Flexible and adaptive organization. These organizations consists of managers with previous work experiences in multiple countries with different business environments. They are able to quickly adapt to changes in business environments.

Global culture. This culture is marked by sensitivity to other national cultures and cultural awareness of foreign cultures.

Global strategy. A global strategy based on their origins. Companies from emerging countries tend to have a cost leadership strategy as they try to exploit the cost advantages of operating from a developing country. Companies from developed countries tend to focus on the superior performance of their products rather than on cost advantages which is more prevalent in strategies from companies originating from low cost base countries (Group C).

Financial planning. Capability to raise capital from around the world based on the costs and availability.

Human resources and staffing. Attract the best talent from all over the world.

Information technology and systems. Invest in the best computer network technology to enable their staff to coordinate their activities around the clock.

Table 1: Decision framework for geographic expansion in a global context

	Discovery/pre-IND	Early clinical	Late clinical
Group A. Western European	Seek alliance with Group C companies	Establish US business development and alliance office	US contract research organization/pharma partner/US business development and marketing office
Group B. Japanese	Establish US soft-landing partnership	Establish US soft-landing partnership	Establish US pharma and soft-landing partnership
Group C. China and India	Seek US academic research partners	Establish US soft-landing partnership	Establish US soft-landing partnership
Group D. Born global	Establish US research partnership	Establish US soft-landing partnership	US marketing/business development office