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Feature Article

***GEN Review* BIO 2008: Tips for Doing Business in China and India**

Risks, IP, Opportunities, and Approaches Are Morphing at Breakneck Speed

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The wild, wild west is heading east, according to a “BIO 2008” session of the same name. It’s a catchy title but it is also true. Both India and China have enormous potential markets, growing middle classes, great needs, good talent, and still-emerging regulatory systems. There are enormous similarities.

There are also enormous differences. The question, noted Murali Prahalad, Ph.D., vp, molecular biology essentials, [Invitrogen](#), is “how do you put India and China in context?” The risks, IP, opportunities, and approaches are all “morphing at breakneck speed,” he said.

One of the biggest changes rippling throughout both cultures is the development of intellectual property within the country. The situation is akin to that of Japan and Korea a few decades ago, and industries now are acknowledging that “both India and China are far more complex—and radically different—than many first believed.” Rather than developing novel intellectual property in the West and defending it from the East, “India and China are developing IP themselves, foreshadowing where the new centers of innovation will be,” Dr. Prahalad pointed out.

The result is not just new approaches but new challenges that push innovation in wide areas. For example, a population in which vast numbers of people live on less than \$2 per day—as many do in China and India—requires price points “1/100th that of Western models. You have to create vastly different price points to compete.”

Differences in the infrastructure such as poor temperature control and different distribution networks also force companies to find new solutions that often have wider benefits. Consequently, “this is the ideal epicenter for innovation,” Dr. Prahalad said, because such constraints force novel thinking.

China

The result, according to Tony Chen, partner in the Shanghai offices of Jones Day ([www.jonesday.com](#)), is that China will soon grant more patents than any other nation, and that most of the top-20 pharmaceutical firms will conduct R&D in China. “Shanghai will have as many biotechs as San Diego,” he predicted. As yet, though, “you don’t see huge deals in China.”

There is a perception that trade secrets are hard to keep in China, Chen noted, adding that the situation is

improving. “When local companies have a stake in the game, there’s more effort in enforcement, even in China,” he elaborated.

[Hùyà BioScience International](#) has a four-year presence in China, sourcing development-stage compounds, according to Jan Tuttleman, Ph.D., vp of marketing. “We focus on pre-IND through Phase I or II, working with Chinese partners to codevelop the projects and have the right of first refusal from 15 biotech parks.”

Of the Chinese, she opined, “They’re great at drug development and preclinical work but they don’t have the clinical expertise” that is needed for FDA approval. She positioned the collaborations as a win-win situation for both parties, providing new compounds to Hùyà and experience with good lab practice and good clinical practice for the Chinese firms.

FDA feedback has been positive, and although the trials are redone in the U.S. because of good manufacturing process issues, Hùyà still saves 6–12 months per step, Dr. Tuttleman pointed out.

Many companies choose not to file patents in China, feeling that they wouldn’t be successfully defended. There are justifiable fears of patent hijacking, patent invalidation, loss of trade secrets, and no term extensions.

Historically, China has operated, not by rule of law but by the concept of *guanxi*—personal connections—and the concept of intellectual property is a relatively recent introduction. Laws and courts are still evolving, and *guanxi* is still a vital ingredient. The darker, corrupt elements, unfortunately, are still functional. Now, even with Chinese patents, enforcement can be an issue because—particularly at Chinese universities—the patents are often poorly written.

Chen said that progress is being made in patent enforcement as evidenced by the burgeoning number of lawsuits. In China, intellectual property litigation has grown from about 6,000 cases in 2001 to about 14,000 cases in 2006 and nearly 18,000 cases in 2007.

“Of those,” Chen said, “4,041 were patent cases. Most are between Chinese parties, but about three percent were between Chinese and foreign companies. Cases are increasing at double-digit rates,” he added. Regarding outcomes, “the Chinese courts and patent office don’t always agree,” he pointed out, and the court has granted some significant damages.

It is a fact that Chinese patent regulations differ significantly from those in Europe or North America. For example, in China the patent is awarded to the first to file and originality isn’t required, Chen emphasized.

There is also a question of who should own the IP. Logically, the Western parent company wants to own the patent, but ownership affects tax rates. So, Chen explained, granting the patent to the local entity—a subsidiary, perhaps—can lower the tax rate on that entity from 25% to 15%. “So, let the Chinese entity have some IP,” Chen advised, “but be diligent about assignment.”

India

India has some large advantages over China. Thanks to a long-time British presence in India, English is widely spoken, Indian law is based in English common law, and the concepts of the rule of law and of intellectual property are broadly acknowledged.

“Piracy is not that pervasive in India,” according to Nishith Desai, J.D., managing partner of [Nishith Desai Associates](#). India is also a strong advocate against what it calls “bio-piracy.” And, he added, “university and pharmaceutical cooperation is increasing.”

Collaborations are also expanding among biotech companies. Shyam Bishen, Ph.D., vp of corporate development for [Nishith Desai Associates](#), noted many collaborations among leading Indian and international firms, including Ranbaxy’s own out-licensing endeavors.

“India,” Dr. Bishen commented, “is strong in science, hits, lead development, preclinical development, and synthetic chemistry. It is weak in biology for target identification and validation,” but it is quickly developing competence in clinical development.

India enacted intellectual property protection for pharmaceuticals some years ago and is compliant with the World Trade Organization’s Trade-Related Aspects of Intellectual Property Rights, although some harmonization issues remain. For example, India IP law doesn’t provide for work-for-hire, except in the sense of actual employment, and also lacks the notion of data exclusivity.

The government is working to increase awareness of both process and product patents as vital ingredients of R&D programs. India, for example, granted 131 patents in 2000 and 686 in 2007. One of India’s current endeavors, Desai remarked, is to coordinate administrative and judicial mechanisms.

“Unlike China, India has a strong court system. It is very independent of politics and big business,” he continued. “Often a company can get an injunction one day, but litigation may take 10 to 15 years, and damages awards like those in the U.S. don’t happen.” For legal remedies, foreign companies have a choice of their own or Indian jurisdictions, Desai said. Whether foreign-owned Indian subsidiaries may apply foreign laws to resolve disputes, however, remains unresolved.

Because of the long delays and the current lack of coordination, “most Indians prefer to arbitrate disputes,” Desai said. Be aware, though, that “foreign judgments are not enforceable in India, so you’d better have an arbitration clause in your contract,” he advised. He also recommended that employment contracts include strong nondisclosure agreements and noncompete and nonsolicitation clauses. Trade secrets, he emphasized, are best protected by contract.

Although both India and China are going through growing pains now as they make the changes vital to growing their own biopharma industries and attracting international capital and know-how, both still have a way to go. They are making progress, however, and certainly merit careful consideration as a part of global companies’ long-term strategies.

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