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Intellectual Property Strategy and Best Practices in China and India Life Sciences Business Transactions

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This paper is based on a presentation made at the Asia America Multitechnology Association (**"AAMA"**) Conference on October 8, 2004. Intellectual property (**"IP"**) strategy and practices are examined in the context of the currently most common business transactions in drug discovery, manufacturing and drug sales:

- research and testing services in China and India;
- manufacturing services in China and India; and
- product sales transactions in the U.S., China and India.

In 2003, U.S. pharmaceutical and biotechnology companies invested about $33.2 billion in research and development activities, amounting to about 18% of the total sales of their products. The pre-tax cost of discovering, developing and bringing to market a new drug increased from about $500 million in 1990 to about $880 million in 2003. Further, the time to market has lengthened due to greater regulatory approval requirements and because of slow enrollment of patients in clinical studies in the U.S. and Europe. The increased costs and slow enrollment is leading to greater research and development (**"R&D"**) activities being conducted outside of U.S. and Europe.

Up to a 50% cost savings may be possible on certain drug discovery services in India. However, these lower costs must be balanced against potential risks to the business from inadequate intellectual property protection. Cultural differences are also a factor. For example, China is a civil law country and does not have a history of private property ownership. Nevertheless, a business can take certain practical measures to protect its IP in business transactions in China and India. The measures depend on the specific business activity, the stage of development in the drug discovery process and the relevance of the final product to the local population where the research is done.

Research and Testing Services in China and India:
Drug discovery research and testing services being done in China and India for U.S. companies include pre-clinical and Food and Drug Administration (**"FDA"**) Phase I clinical trials. Phase II and Phase III clinical studies are also currently being done. However, they are few in number since the FDA requires a "representative" sample of patients across cultures in these studies rather than the homogenous group of individuals available in China and India, and because the disease patterns of the population in China and India differ from those of the Western population.

Research and testing services can be provided either by a wholly-owned subsidiary of the U.S. company or by an independent contractor of the U.S. company. Eli Lilly, Pfizer, Aventis, Novo Nordisk, GlaxoSmithKline, Merck, Johnson and Johnson and others, for example, have established R&D subsidiaries in India to control costs and compress the development time. An advantage of having a subsidiary is that the U.S. company has more practical control over performance and IP protection. A disadvantage is that the parent also must pay for the infrastructure costs of the subsidiary. Regardless of the model being followed, there must be a services agreement between the U.S. company and the service provider.

The research and testing services produce data, processes, methods, and other confidential information that may not yet be patentable, but that needs to be protected. Further, the ownership of the results must be assigned to the U.S. company. The U.S. company can address these issues by agreements and business practices as discussed below.

The IP risk in research and testing services may be mitigated by the early stage of drug discovery. Since the drug target must still be tested in clinical studies that are expensive and carry a large likelihood of failure, the early stage data is not as valuable as later stage data. Moreover, the IP risk also depends on the therapeutic area under investigation, *i.e.*, if the services and results relate to a product that has

a market in Asia, then the IP risks are higher. For example, HIV is not geographically limited and presents a growing problem in Asia, especially China and India. Therefore, HIV related activities in China and India carry a higher IP risk. In contrast, certain cancers prevalent in the U.S. and Europe have a much lower occurrence in Asia, therefore, research activities related to these therapeutic areas carry a reduced IP risk.

As a practical way to reduce IP risk, it is important to select a trustworthy business partner in China or India. This applies both to selecting an independent service provider and the management team of a subsidiary. Each prospective business partner should be carefully checked on the basis of its track record in both IP protection and contract performance (quality and timing of deliverables) in prior agreements, on their internal physical, electronic and other security controls for protecting IP and confidential information and on corporate IP policy and practices. A trusted partner should have a clearly communicated policy on protecting IP and its actions must be consistent with the policy.

The agreement with the trusted partner or subsidiary should be such that a U.S. court would enforce it, but also address certain local law provisions, particularly those relating to IP ownership assignments. The agreement also needs to include confidentiality provisions. The U.S. company needs to make sure it owns the results even when the service provider is its wholly-owned subsidiary. These obligations must also flow down into agreements with the service provider's employees and subcontractors. The use of subcontractors should be minimized since each additional tier of development makes ownership issues more difficult to manage. At a minimum, the agreement should also include a non-compete provision, an audit provision (when, under what circumstances, and the extent to which the U.S. company can inspect the operations in China or India), and make the service provider liable for the actions of its employees and contractors. In addition, where feasible, the most practical method for protecting IP may be to restrict access to different steps of a process and use the audit provision to ensure that only authorized personnel have access to the IP.

Contractual requirements for obtaining ownership differ for contractors and employees. A subsidiary is treated as an independent contractor not an "employee." Unless these requirements are met, the U.S. company may not own the results of the work even if it paid for them. The following chart summarizes ownership assignment requirements in China, India and the U.S. for both employee and independent contractor relationships. The factors in the columns from left to right address these issues:

(1) whether a written assignment made prior to the completion of the results is effective or if a second written assignment is needed after completion of the results;

(2) the geographical scope of the assignment;

(3) if there is any obligation to exercise the rights assigned; and

(4) the duration or time period of the assignment.

Employee		**Contractor**			
		Following Completion of Work (1)	**Geographical Scope** (2)	**Obligation to Exercise** (3)	**Duration** (4)
China	Copyright – Yes	Not Required	Worldwide	Not Required	Perpetual
	Patent – No unless assigned in writing	Not Required	Worldwide	Not Required	Perpetual
India	Copyright – Yes	Yes	India only unless world-wide is expressly stated	Must be exercised within one year unless otherwise agreed in writing	5 years unless otherwise agreed in writing
	Patent – No unless assigned in writing	Patent – Recommended	Patent – Worldwide but recommend that this be expressly stated	Patent – No	Perpetual
U.S.	Copyright – Yes	Not Required	Worldwide	Not required	Perpetual
	Patent – No unless assigned in writing	Not Required	Worldwide	Not required	Perpetual

India's assignment requirements are materially different from those in the U.S. and China. Bioinformatics R&D, which tends to be protected by both copyright and patent laws is of particular concern, because of the Indian copyright law requirements. Assignment requirements in China are more like the U.S. requirements. The U.S. company must assure that the contractor's agreements with its employees and subcontractors also have the proper assignment provisions.

The scope of patent protection in India will be expanded to include life sciences products on January 1, 2005 under TRIPS (Trade-Related Aspects of Intellectual Property Rights). Products and processes will then both be eligible for patent protection. There is no judicial protection until a patent is issued. U.S. companies are not likely to see any increased patent protection in India for some time. The number and inexperience of patent examiners and the inexperience of India's judicial system to deal with patent conflicts over products will delay the practical impact of these changes. This change may not have meaningful effect until the "equal dignity" rule takes effect in India for biotech products as it has for software. Respect for the IP of others seems to increase when local businesses and individuals understand the value of patent protection in the local market to provide a competitive advantage for the products they create or to protect their customers in service agreements.

In China, the Regulations of the People's Republic of China on Technology Import and Export Administration became effective January 1, 2002. These regulations cover patent assignment and licensing, patent application right assignment, technology know-how assignment and licensing, and technical service and other means of technology transfer. These regulations should provide greater protection for life sciences intellectual property, however, their enforcement remains an issue.

While the best practice is to try to prevent an IP problem, the most practical remedy is to stop patent infringement or a breach of the agreement through injunctive relief. Contracts at all levels should provide for injunctive relief to increase the likelihood of a court ordering such relief. Injunctive relief for a contractual breach (as opposed to infringement of statutory patent protection) is not certain in China and is difficult to obtain in India. The IP risk should be evaluated in terms of how can infringement be proven and against whom the remedy can be obtained. Further, the governmental agencies whose cooperation will be needed in obtaining injunctive relief should also be identified.

The U.S. company should not expect any significant monetary recovery in either China or India. It takes about 4-7 years for a suit to be heard in China and longer in India and the dollar amount of any monetary damages is small. For example, Article 25 of China's Anti-Unfair Competition Law, issued in 1995, permits the relevant control and inspection authority to award up to $25,000 for misappropriating trade secrets. Thus, monetary remedies do not provide a meaningful deterrent.

Manufacturing Services in China and India:
Manufacturing service providers in Asia are almost always independent contractors rather than subsidiaries. There are over 60 FDA approved manufacturing plants in India, primarily for bulk drugs.

There is a greater IP risk in manufacturing services. At this stage, the drug is either on the market or data for regulatory approval is available. Patents are more likely to have been issued at this stage of the drug discovery process. A U.S. company will need to have patents issued in the country of manufacturing to protect manufacturing rights as well as the composition of the results. The IP risk also depends on the incidence of the type of disease in the local market.

The recommended practices under **Research and Testing Services** on selecting a trustworthy partner and the need for confidentiality and ownership assignment provisions in agreements are also applicable to manufacturing services. The injunctive relief strategy for enforcement is also equally applicable. The injunctive relief remedy can clearly be sought when statutory patent protection has been implemented. While the manufacturing services agreement should provide for injunctive relief, this remedy is less likely to be available for a breach of contract of a confidentiality or other provision.

There will be a TRIPS dispute mechanism available after January 1, 2005 if no local legal remedy is available but it remains to be seen if this remedy will have any practical effect. It is important to note that a patent must be issued in the country to have this potential remedy available.

Product Sales:
This addresses IP protection for life sciences products currently being sold in the U.S. from China or India or sold into those countries from the U.S. The import flow of products is currently much more in the direction of to the U.S. The primary products being sold from India into the U.S. are generic drugs which are a growing presence in the U.S. market and other markets. This is a $16 billion-$17 billion market in the U.S. Indian companies had 4% of the

market share in 2003 and this market share is expected to grow to 10% by 2008. In 2003, Indian companies filed 119 DMFs (drug master files) or 30% of the total DMFs with the FDA, and 73 (20% of the total) abbreviated new drug applications. A smaller but growing market in the U.S. is traditional medicines from both India and China primarily for the overseas (U.S.) Chinese and Indian population.

There are very few U.S. drug products being sold in China or India because the pricing economics do not work. In 2003, China's pharmaceutical drug market was valued at only about $6 billion, with the over-the-counter drug market accounting for about $1.2 billion. While IP protection in these countries is a consideration, the pricing for most U.S. products is too high for the China or India markets.

The U.S. has strong patent protection for life sciences products. Indian generic manufacturers (such as Reddy Labs and Ranbaxy) are savvy about the U.S. patent system and are aggressively testing it. Rather than waiting for a U.S. patent to expire, they are trying to create non-infringing generics or find ways to invalidate patents on the basis of prior art or other factors. They are also savvy about the FDA process for generics, particularly for 180-day market exclusivity. U.S. pharmas are trying to make their patents stronger in response to the India generics challenge.

A U.S. company trying to protect its products in Asia must have patents issued in China or India. Under TRIPS, this will protect against infringement in the territory as well as restrict exports from the territory into countries where there is no patent protection. Strong U.S. import protection against patent infringement helps protect U.S. pharmas from imports into the U.S. market.

Conclusion:
Selecting a trusted partner in China or India with the right IP practices and security infrastructure is a practical means of protecting IP. Injunctive relief rather than damages is the most realistic legal remedy in China or India. A patent protecting the product or process must be issued in these countries in order for the U.S. company to seek injunctive relief for patent infringement. Injunctive relief is more readily available for patent infringement than breach of contract. While doing business in China or India has IP risks, the risks need to be weighed against the economic benefits. A practical IP strategy and set of best practices can reduce the risk.

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