2013 ISSUE 1 A POINT OF VIEW ON INDUSTRY ISSUES

LIFE SCIENCES POV℠

Working with International Suppliers: Sound Contracts Minimize Risk

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Consider the following hypothetical scenario:
ABC Inc., an American-based pharmaceutical company, hires XYZ LLC, an Indian-based contract manufacturer, to produce a drug for sale in the United States. Once the drug is on the market, however, a series of consumer complaints indicates that it is defective. While ABC is deemed primarily liable for these injuries, it appears to have the legal right to recover from XYZ, which is at fault for the problem. However, enforcing a judgment against XYZ may be quite difficult in either an American or Indian court. The attendant costs and difficulties will only be magnified if the Food and Drug Administration (FDA) requires ABC to recall the defective drug, or if ABC voluntarily issues a recall notice.

Today's global economy means that many companies rely upon foreign-based suppliers. This type of business has inherent risks, which can be substantially reduced by a well-defined contract. This issue of *Life Sciences POV*℠ is designed to help organizations evaluate their exposure and implement measures to protect themselves against potentially complex and costly litigation.

EVALUATING INSURANCE COVERAGE

The first step in evaluating organizational exposure is to understand what the current insurance policy does and does not cover. Ask the insurer or broker about foreign business considerations, as well as policy limits and exclusions. If the existing policy cannot meet today's global sourcing needs, consider adjusting the coverage to help ensure that overseas events do not result in major losses.

In addition, before finalizing any business plans, ask an insurance representative who specializes in the life sciences industry to review the proposed agreement, assess potential coverage under existing policies and determine whether a new type of insurance is needed. This step is especially important if the proposed deal involves indemnifying another entity, a provision often included in overseas manufacturing contracts, as discussed in the sidebar on page 2.

USING CONTRACTS TO MANAGE RISK

A contract is more than a legal document: it is also a tool for conducting business. A detailed, negotiated, scrutinized contract has several advantages over a form purchase agreement with generic language attempting to limit liability and allocate various risks. First of all, the process of negotiating the agreement may reveal risk issues that otherwise may go unnoticed. Also, a contract addressing all aspects of the relationship with the supplier will enable both parties to structure their relationship in ways that advance strategic business goals. Finally, a fully negotiated contract that specifically allocates risk and liability makes enforcement simpler and more predictable, while a purchase order lacking contractual detail could result in prolonged litigation and unanticipated judicial remedies.

During the negotiation process, every aspect of the proposed business arrangement should be evaluated from different perspectives. In addition to securing legal review, ensure that the contract is examined by regulatory, clinical and other departments for potentially damaging provisions.

DRAFTING A COMPREHENSIVE CONTRACT

The following provisions, among others, should be included in contracts between purchasers and overseas suppliers:

Duties of the parties. Contracts should expressly allocate responsibility for every aspect of the business relationship. For example, the contract between ABC Inc. and XYZ LLC should address, among other issues, which party is responsible for

- developing the manufacturing process
- designing packaging and storage materials
- determining label content
- paying the upfront costs for raw materials
- securing FDA or other relevant regulatory approval
- shipping the product
- ensuring compliance with current good manufacturing processes and other applicable regulatory requirements, potentially including the right of ABC Inc. or government agencies to inspect XYZ's facilities on a routine basis
- reporting adverse events or quality problems to the FDA or other regulatory authorities

Insurance Considerations for Indemnification Clauses

Contracts containing indemnification clauses, especially with foreign business partners, can have a wide range of insurance implications. The following questions can help clarify fundamental contractual and coverage issues, reducing the potential for future misunderstanding and litigation:

- Does the indemnification clause require the organization to insure contractual obligees?
- Does the current insurance policy provide this coverage, and if so, are there any limitations or exclusions?
- Are the insurance policy's indemnification and defense limits adequate to meet the needs of both the organization and the indemnitee?
- If the indemnitor is a foreign corporation, is it possible to file a claim and collect under its foreign policy, or is it advisable to request domestic coverage for the partner's indemnification obligation?
- Has organizational leadership consulted with a qualified life sciences insurance professional and a lawyer with international contract experience for specific guidance and advice?

Warranties and remedy for breach. The contract should specify any warranties provided by the parties, and what the remedy is for breach of such warranties. XYZ may warrant, for example, that its products will conform to the terms of the agreement and governing U.S. laws and regulations. The contract also can limit the remedy for a breach of this warranty by stating that in the event of a manufacturing problem, XYZ owes ABC only a refund of the money paid for that specific batch of defective drugs.

The parties also may consider a provision allowing for liquidated damages (i.e., a set or easily ascertainable recompense) in the event of a material breach. A stipulation for liquidated damages may thus obviate the need for a lengthy and expensive trial to determine the amount owed by the liable party.

Dispute resolution mechanisms. Contracts can specify such key legal points as what law is to be applied in interpreting the contract, whether potential disputes will be settled by arbitration or judicial proceedings, how costs are to be allocated and where disputes can be adjudicated. Contracts can also provide for a more informal dispute resolution mechanism, such as a neutral third-party examiner with authority to determine whether XYZ's goods conform to the contract's specifications.

Establishing a dispute resolution mechanism is of particular importance when dealing with a foreign company, which may not be subject to legal process in the United States. The Hague Service Convention, an international treaty signed by many but not all countries, provides a method for obtaining jurisdiction over foreign individuals and corporations. However, even in those nations that are party to the treaty, enforcement of its provisions can be challenging for other reasons, such as cost and delay. It may be advisable to have a foreign company waive its Hague Convention rights in this respect or agree outright that it can be sued in the United States.

Indemnity clauses. An indemnity clause allows a contracting party to shift the costs of a claim or lawsuit onto the other party, if that is where the fault lies. This type of clause is essential whenever there is a possibility that the other party's negligence or product defect could subject one's own company to liability. In general, it is wise to specify the types of fault covered by this provision, such as manufacturing or design defects. Many contracts include reciprocal indemnity clauses, which are generally intended to ensure that neither party will be held liable for the actions of the other. These provisions should also address other issues, such as which party is entitled to direct and control the litigation, and whether one party has the authority to settle the case on behalf of the other.

These clauses should not be entered into lightly, as illustrated by a recent case in which a foreign drug manufacturer agreed to indemnify its American supplier for any injuries resulting from the use of its drug. Years later, a verdict was entered against both parties, divided between the two. However, due to the indemnity clause, the manufacturer was obliged to pay the whole amount, including damages that the jury had assessed against the supplier. (For more information, see the sidebar at left.)

Insurance coverage. Especially in situations involving potentially large exposure, consider requiring the other party to obtain an insurance policy that names one's own company as an additional insured. This is an especially important consideration when the contracting party is based in a country whose laws make it potentially difficult to obtain or enforce a monetary judgment.

Recall of defective products. Any contract for the provision of goods or components should address the issue of product recall. As recalls are often very costly, the parties should decide who will bear the expense in varying circumstances – for instance, if the recall is based on a design flaw rather than a manufacturing flaw. The contract also should specify whether one or both of the parties can authorize a voluntary recall, if one is deemed necessary.

Note that recalls are usually not covered under general commercial or product liability policies. Therefore, after assessing the potential risks and costs of a recall, consider obtaining a special "recall policy." For maximum security, either request that the other party purchase such a policy and name one's own company as an additional insured, or self-insure with the understanding that losses will be paid out of pocket.

Contracting with international suppliers can help life sciences companies expand production and boost profits. However, it is essential to understand and address the associated liability exposures. By negotiating a comprehensive, carefully reviewed contract with the supplier and discussing the risks with one's insurer, organizations can minimize the prospect of catastrophic loss, even in the event of a product defect or similar occurrence.

(**Note:** A future edition of *Life Sciences POV*℠ will focus on insurance and risk transfer techniques to mitigate exposure associated with foreign vendors/suppliers.)

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