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MANUFACTURING OUTSOURCING IN THE MEDICAL DEVICE INDUSTRY: AN OVERVIEW OF THE PROCESS AND KEY LEGAL ISSUES

In today's increasingly competitive global economy, medical device companies are continually seeking ways to drive down production costs while at the same time improve quality and accelerate time-to-market. Outsourcing the manufacturing and assembly of medical devices or components thereof to a third party – whether onshore or offshore – may serve as an efficient and cost-effective way to achieve these goals. While outsourcing is by no means a new concept for the medical device industry, its scope, and the types of outsourcing being used, have increased in the last couple of years.

The Buzz

Notwithstanding the negative perception that offshore outsourcing means the loss of U.S.-based jobs, offshoring continues to be identified by medical device companies as a method to reduce costs and overhead. Many companies have found, however, that the benefits of offshoring are greater when labor-intensive processes are involved (rather than highly automated ones). Offshore transactions require additional attention to a number of contract issues, including (a) due diligence around security and compliance, (b) intellectual property, attachment and ownership rights under local law and (c) business continuity options.

Increased regulatory oversight have also lead to a heightened emphasis on quality and control in manufacturing offshoring. The supplier's understanding of, and willingness and ability to comply with, existing and new applicable laws and regulations, as well as the customer's existing and new protocols and SOPs, are emerging as critical down-selection criteria in most manufacturing outsourcing transactions.

The Process

Navigating the outsourcing process can often be daunting. It is important to understand the process time line, as well as the key issues and pitfalls that arise at each stage of the process, in order to facilitate a

successful transaction. The process typically can be broken down into three phases: (1) the prenegotiation phase, (2) the negotiation and contracting phase and (3) the post-contract phase. From a leverage standpoint, it is critical to have a clear understanding of how much time each phase may require, while taking into account how long the customer has to complete each phase.

The prenegotiation phase typically begins with the identification of an outsourcing opportunity and continues to down-selection of the preferred supplier or the commencement of contract negotiations. During this early phase, the customer should be focusing on (a) defining success criteria (as determined by its key objectives, such as cost savings or high quality), (b) defining requirements and specifications, (c) establishing performance criteria (e.g., output requirements and delivery dates) and (d) performing due diligence (e.g., site visits and reference checks).

The negotiation and contracting phase involves the actual creation, review and fine-tuning of the contract documents. The customer can enhance its negotiation leverage during this phase by ensuring that it has other options, either through extending time lines or pursuing other supplier alternatives.

Critical milestones of the post-contract phase include transition commencement and completion, and go-live and contract governance implementation. Key success drivers for this phase include putting in place effective task and deliverable tracking systems, aligning customer and supplier teams (so that project managers are able to communicate directly with both teams) and establishing a flexible change of control process.

Key Legal Issues

Any outsourcing transaction gives rise to many issues for the legal, business and technical teams to consider. Some of the key legal issues are set forth below.

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Due Diligence: Prior to entering into any outsourcing transaction, typical due diligence includes (a) assessment of the potential outsourcing supplier or suppliers (through site visits and examination of references), (b) review of the customer's existing contracts for similar services (Do any contracts need to be terminated? Is there a termination fee?) and (c) review of any third-party agreements for technology or services that may need to be accessed or used by the supplier (Are any consents necessary?).

Scope of Services: The output that the outsourcer is responsible for delivering, as well as the necessary documentation surrounding the manufacturing process, should be clearly described in an exhibit to the agreement. Simply stating that the output will meet the applicable specifications is often not enough in the regulated medical device industry. The contract should clearly state how the supplier will comply with the customer's SOPs (including testing and documenting compliance) at each step of the manufacturing, storage and delivery processes. In addition, the contract should specify whether the outsourcer will source all subcomponents or whether the customer will be responsible for sourcing certain subcomponents and having them delivered to the outsourcer for inclusion in the end product. Finally, the customer should retain the right to audit all services and products at each phase of the manufacturing, storage and delivery processes.

Performance Standards: The "scope of services" exhibit deals with what is being

delivered. The performance standards cover when and how the products are to be delivered. For example, the contract should specify the percentage of the quantity ordered (or the forecast) that must be delivered to a specific site upon delivery of a purchase order. The performance standards may also include a service level for handling rush requests.

Manufacturing Locations: All manufacturing outsourcing agreements should expressly state that all outsourcer sites must be compliant with applicable FDA registration, listing and manufacturing regulatory requirements. The sites should also be subject to periodic audits by the customer and will be subject to unannounced inspections by the FDA and/or other regulatory authorities. In addition, the company should have the right to approve any changes to an outsourcer site as well as any site relocation. For offshore deals, the company may want to consider what would happen in the event that doing business in a certain country becomes undesirable. Are there any relocation or termination options?

Regulatory Requirements: The regulatory framework for medical device companies requires that both the customer and the supplier understand the specific regulatory requirements applicable to the outsourcing transaction at hand. A key part of the negotiations will involve determining which laws the customer will be responsible for monitoring and complying with, which ones will be the responsibility of the supplier, and how the costs will be allocated for changes required by new laws (including different interpretations of existing ones). Questions to consider include: (a) Which company will be responsible for interpreting FDA and other governmental regulations related to the testing, manufacture, marketing, labeling and distribution of medical devices? (b) If the customer retains responsibility for interpreting such industry-specific laws, how will the supplier implement them? Will the customer provide specifications, guidelines or protocols, and/or conduct periodic audits? (c) How will Sarbanes-Oxley compliance be handled? What are the supplier's responsibilities? A key issue on which the customer's auditors will want comfort is the ability of the supplier to provide SAS 70 reports if and when required.

Termination Rights: A key point of leverage is the right to terminate the outsourcing contract. In addition to the typical termination-for-breach rights, the customer may wish to consider including termination rights for noncompliance with applicable laws and regulations, for repeatedly missing performance requirements, and upon the occurrence of certain unforeseen events.

Exit Rights: Another critical part of the outsourcing contract is the section that outlines the mechanics for unwinding the relationship. These provisions are particularly important from a business continuity perspective. If the relationship sours, what are each party's rights to the facilities? The products? The underlying technologies, processes and intellectual property? The supplier's employees? In all events, the supplier should be required to provide ongoing and termination-related assistance for a period of time so that the customer is able to transition in-house or to another supplier in an orderly manner.

Business Continuity: As part of due diligence, the customer should consider what its alternatives are if the supplier does not or is not able to perform. Are there other sources available? Does the supplier have back-up or secondary sites? The customer may wish to consider including step-in or joint-management procedures to be instituted upon the occurrence of certain events.

Pricing: As one would expect, the pricing provisions of the outsourcing contract are typically the most negotiated and receive the most attention from the business team. Key questions to consider when drafting pricing provisions include: (a) Is there a right to withhold disputed amounts or amounts for products that the customer believes are substandard? (b) Are there adjustment mechanisms for increased/decreased volumes (and are the adjustment mechanisms subject to any minimums or maximums)? (c) How will inflation and (if applicable) currency risk be handled? (d) How is responsibility for taxes allocated? (e) What are the invoicing and payment procedures? (f) What are the customer's audit rights?

Conclusion

The critical role the manufacturing outsourcer plays in the customer's business requires that the customer's team negotiating the outsourcing contract be knowledgeable not only about the company's business and current and future requirements, but also about such issues as regulatory compliance, taxation, business continuity, and audit and risk management. A thorough and flexible contract should facilitate a good working relationship between the medical device company and its manufacturing outsourcing partner, as well as clearly describe the mechanics for unwinding the relationship if and when necessary.

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KEEPING WATCH: THE FDA'S NEW DRUG WATCH PROGRAM

In the wake of well-publicized and aggressively litigated claims regarding Cox-2 inhibitors, diet drugs and other pharmaceutical products, the FDA became the target of criticism from the public, industry analysts and elected officials. Among the criticisms were complaints that the FDA had become too close with the manufacturers it regulates and that it did not sufficiently warn the public about certain products' post-approval adverse events or emerging signs of potential injury. Primarily to address the latter concern, the FDA announced in May 2005 that it would initiate "Drug Watch," an Internet-based drug safety reporting systems to publicize emerging safety information about drugs. This article discusses (1) the Drug Watch program and how it will work (2) the response to the FDA's announcement and (3) what pharmaceutical manufacturers can do to monitor and respond to Drug Watch concerns.

The FDA's Drug Watch Program

According to the FDA, the Drug Watch program and website are intended to identify drugs for which the agency is "actively evaluating early safety signals." Inclusion on the site means that safety information beyond what was known at the initial approval stage has been compiled, and that the FDA believes the public should be aware of the information as it becomes available, rather than after the FDA has completed its evaluation. The FDA cautions that inclusion on the Drug Watch list means that the agency has not yet made a final judgment about the drug's safety.

The FDA explained that the types of emerging information that would cause a drug to be considered for posting on the Drug Watch site are (1) newly observed, and serious, adverse events; (2) significant emerging risks that might be associated with, and thus need to be avoided by, a particular patient segment; and (3) recommendations of important risk-minimization procedures, such as blood tests while on the drug, put forth in response to the emerging information. Each posting will include an FDA disclaimer stating that the information reflects preliminary analyses only and that the agency has not reached a final conclusion about the drug or the information.

The FDA established a Drug Safety Oversight Board with responsibility for, among other things, managing the Drug Watch program. The Board includes individuals from various offices of the FDA's Center for Drug Evaluation and Research, from other FDA and government offices, and possibly from consumer and patient representatives. The FDA has promised that the Board will not include people directly involved in the drug approval or safety review process, and it will not waive Board members' conflicts of interest. The Board's deliberations will not normally be disclosed.

The FDA intends to notify manufacturers shortly before information sheets about their products are posted on the Drug Watch website. Likewise, the FDA intends to remove drugs from the Drug Watch website promptly once safety issues are resolved. It is not clear, however, what the exact time frames will be. Pharmaceutical manufacturers will not have the chance to review or comment to the FDA on the information before it is posted, although they may comment and/or request changes to the FDA after the posting and make other public comments.

Public Response

Public reaction has been mixed since the FDA announced the Drug Watch program in May 2005. The Pharmaceutical Research and Manufacturers Association cautioned that "regulatory decisions and communications [should] be based on sound science and reflect carefully considered judgments regarding both benefit and risk," raising the concern that patients might stop taking needed prescription drugs if they discover

that the drugs prescribed by their doctors are on the Drug Watch list.

Echoing that concern, the Academy of Managed Care Pharmacy supported the Drug Watch effort, but suggested that the FDA clearly advise patients that they should not stop taking any medications without first speaking with their doctors. The Academy also recommended that the FDA state explicitly that inclusion on the Drug Watch list does not create a legal cause of action if a patient suffers harm from use of a listed drug.

Consumer and patient advocates stated that the Drug Safety Oversight Board (and, presumably, the Drug Watch program) is a "cruel hoax" that is "unlikely to make any difference." Others allowed that the creation of the Board is a good first step toward enhancing public information but does not go far enough.

From an operational standpoint, the FDA's temporary Drug Watch website has been criticized as being difficult to navigate and confusing. Likewise, there has been confusion between Drug Watch and the FDA's similarly named, but different, MedWatch program.

Recommendations for Pharmaceutical Manufacturers

It is fully expected that the Drug Watch program as proposed by the FDA in May 2005 will go into effect, although aspects may be modified from the original proposal. Pharmaceutical manufacturers can take these steps to be prepared:

First, have an efficient and robust mechanism in place for reviewing and

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EVENTS, SPEECHES & ARTICLES

MORGAN LEWIS SPONSORED LIFE SCIENCES EVENTS

Temple University and PA BIO Breakfast Forum
*The Real Deal: Perspectives on Funding Early State
Biotechnology Companies*
Manya S. Deehr, Chairperson - November 15, 2005, Philadelphia

**American Conference Institute 10th Annual Drug and
Medical Device Litigation Conference**
December 12-14, 2005, New York

New York Biotechnology Association Annual Meeting
April 17-18, 2006, New York

LIFE SCIENCES SPEECHES & ARTICLES

Intellectual Property

ACI 6th Annual Maximizing Pharmaceutical Patent Life Cycles
*How Have Hatch-Waxman Reforms Changed the Patent End
Game? The Industry Response*
Brian P. Murphy
October 17, 2005, New York

Pharmaceuticals/Biotechnology/Medical Devices

**American Conference Institute 10th Annual Drug and
Medical Device Litigation Conference**
*Preparing for Plaintiffs' Latest Theories and Claims:
In-House and Outside Perspectives*
James D. Pagliaro
December 13, 2005, New York

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processing adverse event reports regularly and quickly, and identifying trends. A company should try to be as “real time” knowledgeable and similarly oriented to the FDA’s Drug Safety Oversight Board so as not to be taken by surprise by an emerging safety focus or trend identified by the Board.

Second, establish internal procedures and contacts so that response and reaction will be prompt and organized. These procedures should include designating people responsible for regularly viewing the Drug Watch site and appointing a quick response team, which will be tasked with responding to any posting on the Drug Watch site. (A manufacturer may want to have more than one quick-response team, depending on the number of products that could potentially be included in the program or the different therapeutic areas and specialties involved.) The quick-response team must be given the authority necessary to respond rapidly and appropriately to a posting on the Drug Watch site, including the authority to draft and disseminate a public statement, communicate with the FDA and the public, respond to professionals’ and patients’ inquiries, place announcements in national publications and, in extreme cases, begin legal or even product recall action. The

quick-response team should include personnel from the medical, safety, regulatory, legal, government relations and communications areas. To avoid creating any misimpression, personnel from sales, marketing or advertising should not be on the quick-response team.

Third, marketing, sales, advertising and public relations personnel should be trained and kept current about the Drug Watch program and cautioned that the FDA does not consider a drug’s appearance or nonappearance on the Drug Watch list to constitute substantial evidence or clinical experience sufficient to support a comparative safety or effectiveness claim. Thus, it should be made clear that claims should not be made that Manufacturer X’s product is safer than Manufacturer Y’s product because Y’s is on the Drug Watch list and X’s is not.

Fourth, manufacturers should be prepared to respond to questions about a product’s posting on the Drug Watch website. In today’s legal environment, it must be expected that plaintiffs’ attorneys will be monitoring the website regularly and using it as a potential source for generating lawsuits. As such, a pharmaceutical manufacturer’s conduct *after* a posting will likely

come under scrutiny. Appearance and impressions may mean a lot. For example, if a manufacturer responds by modifying, detailing or suspending direct-to-consumer advertising for the product until the safety issue is resolved and the product is removed from the Drug Watch site, it may be harder for a plaintiff’s attorney to argue successfully to a jury that it was “business as usual” and “all they cared about was sales.”

Conclusion

The Drug Watch program will significantly alter public perception of drug safety. Pharmaceutical manufacturers must be prepared to assess and monitor their products’ safety issues within this new model of public and regulatory information-sharing. Consideration should be given to internal processes to evaluate and respond to having one’s product included on the Drug Watch list, and to recognizing the litigation and liability implications.

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