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Companies providing contract services to the life science industry face significant liability exposure from the work they perform, especially when maintaining custody of client property. From the perspective of the vendor and the customer, this publication examines the complex issues that arise as a result of working on or taking possession of the property of clients for a fee.

Everyday, clients entrust valuable components, such as Active Pharmaceutical Ingredient (API), other raw material ingredients, finished goods awaiting packaging, and packaging materials, to vendor organizations they retain to perform a variety of services, such as manufacturing, processing, packaging, sterilization, and distribution of finished goods. Not unexpectedly, property losses have occurred through just about every stage of the supply chain, some with the potential to cripple the client's commercial product supply, research projects, or clinical trials.

Property losses commonly find their origins in a mechanical or human error, the end result of which is out-of-specification material, damaged goods, or destroyed goods. While, at first, the cause of the loss might not be readily apparent, what is known is that the product is no longer usable for its intended purpose.

Importantly, it should be noted that in many instances, contracts between the parties are often written in favor of the contract service provider (the vendor), wherein no liability is accepted for damage that

the big questions

- › When a loss occurs, who is responsible for the damages?
- › Is the issue contractually addressed with sufficient specificity?
- › Does the liable party possess insurance that will provide adequate protection?

occurs to client property while in their possession. Commonly, the liability of the vendor will be limited to a percentage of their service fee, but nothing else. While the client should understand this limit of liability when executing the agreement, there



is usually enough dispute as to critical facts to allow for a move into the legal system – litigation or the threat of litigation. As a result, the parties often seek a negotiated resolution of the matter – a settlement – or they take their dispute into arbitration or litigation. If properly written, insurance clauses are typically triggered and the matter ends up being resolved with some form of insurer participation.

There are four important areas of insurance that a contract service provider/vendor needs to consider in managing its insurance portfolio: General Liability; Products/Completed Operations; Errors & Omissions; and Property insurance. It is critical that the first three liability policies work in harmony.

Some of the questions that a vendor's legal counsel or risk advisor should seek to address proactively when securing insurance coverage include: Which type of policy will cover loss to a client's property in a vendor's possession? Under

what circumstances and conditions will such policy respond or not respond (exclusions)? How will the policy respond and to what amount of liability?

Most General Liability, Products Liability, and Errors & Omissions insurance policies specifically exclude damage to property in the insured's (i.e. vendor's) care, custody, or control. They may also exclude damage to "your" property or "your work" or include caveats to cover, such as: a requirement that property damage be "physical damage" to tangible property; a professional services exclusion; the exclusion of loss from government proceedings or the failure to maintain licenses; and a number of equally onerous clauses intended to severely limit the insured's ability to recover from their insurance policy.

This can prove very frustrating to the vendor since client property is susceptible to loss in a variety of different ways when in their possession, including but not limited to: facility-related problems; accidental damage during processing; or errors by the professionals performing the work. The potential losses that can be claimed by the client can include: replacement cost of the property itself; cost associated with the loss of use of the product; the lost sales that may be incurred (actual and future if loss of market share is asserted); cost of clinical trials that are delayed or discontinued; and the extra expenses incurred to resume operations. Obviously, claims resulting from any one of these issues will be fact and case specific to the operations of the customer at the time of the loss. All of these events and categories of damage impact multiple types of insurance policies within a portfolio of coverages.

So, what happens when the unfortunate occurs and the vendor causes a property loss for its client? Management asks, "don't we have insurance for that?" And, your response . . . "well, maybe" – is not the response that management wants to hear!

Often management on both sides are surprised by inadequate insurance policy terms and conditions after it is too late to do anything about it.

But, the reality is the client has damaged property, and not all losses will be deemed to constitute a covered first party property insurance claim. Significantly, property insurance policies are designed to cover “accidents” and the damage resulting from the physical peril (fire explosion, flood). This form of coverage is not usually intended to cover human error that causes a loss that is not directly associated with the covered perils (though favorable language can be included to address this issue in part).

Often, property coverage does not provide adequate limits whether the policy is placed by the vendor or by the customer. In those instances where the limits are sufficient, exclusions and liability limitations set a high bar to cross in order to trigger coverage for even the most common causes of loss to sensitive property, such as contamination, spoilage, or change in temperature. The language contained in some of the leading property insurance policies specifically excludes “errors in process or manufacture” or “any loss or damage during manufacture, processing, testing, or otherwise being worked upon.” The result? The customer has damaged property and potentially faces a downstream loss. Their property insurance policy may not have been written to cover such supply chain exposures (even if it is a result of a covered peril), and even if their policy does provide such coverage, the above limitations almost always come into play, as they do for any property insurance policy that may be maintained by the contract service firm itself. This is why it is critical to understand the limits of your property insurance coverage and to make sure that this policy is integrated properly with the rest of your insurance coverage portfolio! When property insurance fails to cover the

loss, the customer is likely to make a claim against the contract service firm for damages, which then becomes a liability issue of the vendor and its liability insurer. That being said, it is a rare instance when the vendor does not have to shoulder all or at least a portion of the liability for the loss that has occurred, whether because of a desire to maintain the client relationship, or based on the pre-agreed contractual terms.

Best Practice Solutions

So, what should you do to protect your company or client in the future, should such a loss occur?

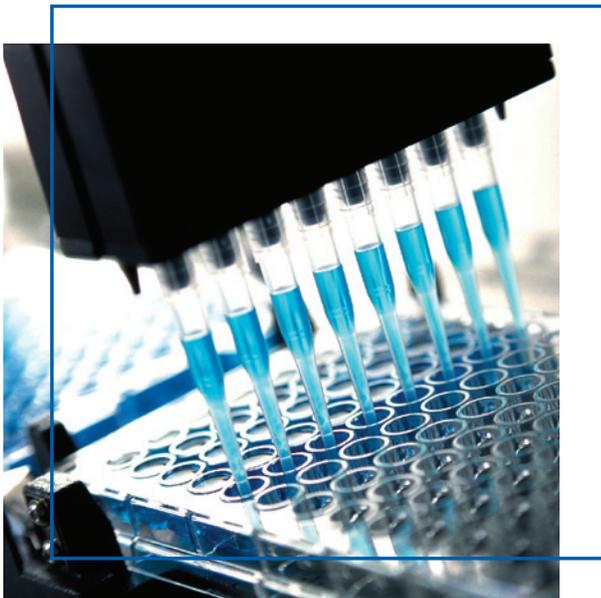
- First and foremost, the company should ask its insurance broker to assist it with a full scale review of its coverage, including hypothetical situation testing, to determine how its insurance program will likely respond to such a loss.

protect your company

- Understand the limits of your property insurance coverage.
 - Ask your broker to conduct a full-scale review of coverage.
 - Establish a game plan to fill coverage gaps.
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- Ask how the insurer intends to allocate loss among the policies based on different hypothetical situations. To the extent that you cannot connect the insurer’s intent to the actual policy language, a game plan must be established to negotiate with company insurer’s in order to fill coverage gaps so that the company’s insurance program

meets its expectations. To be fair, remember that not all losses will be insurable regardless of how many gaps may have been closed. But – you will know in advance what is and what is not likely to be covered, and you can set up reserves and/or negotiate client contracts armed with knowledge of your vulnerabilities.

- > Think about where the claim would need to go based upon what caused the loss and the type of damage being claimed. Realizing as the vendor, that such claims might potentially impact all three types of liability coverage, we think it is critical to attempt to place these coverages with the same insurer whenever possible. Property that is damaged because of a leak in the roof while awaiting processing or while in finished goods storage should be treated as a General Liability Property Damage Claim, so long as the coverage issues above have been properly addressed. Correspondingly, a premises-related loss should be treated under the GL policy designed to cover



exposures of the premises/operations. If properly written, the loss associated with loss of use of property may also be claimed and will follow the underlying Property Damage claim, thus being covered as a General Liability loss. Often, insurers will attempt to treat Property Damage Loss as a covered item under a professional liability insurance policy (E&O). There are many pitfalls with this approach. For example, the requirement that the loss be triggered by a “Wrongful Act” as defined by a typical Professional Liability policy, leaves other damage situations potentially uncovered. The typical retention within a Professional Liability policy is often quite high. The payment of a Property Damage/Loss of Use claim under an E&O policy will erode the limits available for what often is the largest portion of Loss — Loss of profits, Loss of Sales, Costs of running a Clinical trial, and so on.

- > Property that is damaged by the vendor during the process of manufacturing or processing should be treated as a Products/Completed Work Property Damage (assuming it is unrelated to a facility problem), as would the loss of use that may flow from the underlying damage. Products policies should properly define “Your Product” and “Your Work.” When written properly, the in-process exposure should fall squarely into this coverage, subject in part to the limits of liability portion of the client/vendor contract. Again, as is the case with a General Liability policy, Care, Custody and Control exclusions along with Professional Services exclusions must be removed or modified.
- > Errors & Omissions coverage should come into play for the component of the Property Damage loss that constitutes down-stream “Financial Injury,” such as lost sales, loss margin, or the cost of

a halted clinical trial. The largest catastrophe that a contract service firm is likely to confront as a result of possessing client property, aside from the complete destruction of a facility, is regulatory non-compliance during some period of time when the client's property was in the vendor's possession. It goes without saying that policies with a Governmental Exclusion or Failure to Maintain License exclusion are also huge problems. These exclusions will be called upon by the insurers for most events related to government regulatory issues (FDA, EMEA, etc).

- > Since a component of damage that may be claimed by a customer experiencing a property loss will be for the actual fees that were paid for the service, it is important to realize that most E&O policies exclude "cost of contract" or "return of fees." This coverage can be negotiated with some insurance companies, as can coverage for the portion of damages related to any performance delay that may have occurred, which also is a commonly excluded issue.

Summary

There are different levels of coverage that can be negotiated for several of the most common causes of loss to sensitive property while in the Care, Custody and Control of a third party vendor. **Scattered within every Liability and Property insurance program are numerous exclusions that serve to avoid claims related to Property Damage.** Among the areas to review:

Common Property Insurance Limitations

- > Mechanical Breakdown, Change in Temperature, Error in Process, Failure to Maintain Equipment, Spoilage, Contamination, Acts or Decisions/ Governmental Body – i.e. Regulatory Shutdown



Common Liability Insurance Limitations

- > Damage to Impaired Property or Property Not Physically Injured, Property Entrusted to You for Safekeeping, Property on Your Premises for Purposes of Performing Operations on Such Property, Damage to Your Product, Damage to Your Work

A suite of liability insurance policies may be secured and customized to meet specific operational and financial situations.

Conner Strong & Buckelew knows both business and science. We believe in innovation and opportunity and most of all protecting your greatest assets. For more information on our risk management solutions for the life science and technology industry, please contact us at 1-877-861-3220.

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