
Pharma Supply Agreement Considerations During COVID-19

In addition to the tragic loss of life and the sobering shut down of the U.S. economy, the COVID-19 pandemic has caused some other not-so-obvious devastating effects.

One of these is the destructive impact of the pandemic on the global pharmaceutical drug supply chain. As a result of COVID-19, public access to certain life-saving and life-improving drugs has been hindered or, in some cases, even temporarily halted.

The purpose of this article is to note some important supply agreement terms that a prudent pharmaceutical company decision maker should consider, especially in light of the new COVID-19 landscape. These concepts apply whether the pharmaceutical company is purchasing a finished product or application programming interface, components or other materials.

Exclusivity and Supply Failure

In negotiating a supply agreement, a pharmaceutical company may agree to purchase all of its requirements for the particular material or product from the supplier. If the pharmaceutical company purchaser agrees to this exclusivity, it takes on a heightened risk that if the supplier fails to comply with its supply obligations, the purchaser would not have any access to the material or product. To combat this problem, the negotiator for the pharmaceutical company should consider the following:

Provide that if the supplier breaches any of its material supply obligations (as they relate to quantity, quality, timing or otherwise), then, in addition to termination and other rights, the purchaser would receive a downward purchase price adjustment and/or have the right to convert the exclusive arrangement into a nonexclusive arrangement.



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Provide that the purchaser be permitted to qualify and purchase the material or product from a second source under certain breach or other scenarios. Complications arise if this second source needs to use technology owned or controlled by the original supplier in order to supply the identical materials or products to the now at-risk purchaser.

In this case, the supply agreement could (and should) include a nonexclusive, perpetual, irrevocable, royalty-free license in favor of the purchaser and its second source manufacturer to manufacture and supply the materials or products for the purchaser, even after termination of the supply agreement.

Nonexclusive Arrangements and Preferred Customer Protection

In the event of a nonexclusive arrangement where the supplier is supplying the same or similar material or product to a third party, the negotiator for the pharmaceutical company should consider the following:

Include a most-favored-customer provision. Such a provision provides that, notwithstanding the terms described in the supply agreement, in the event that the supplier provides a third party with the same or similar items on more favorable terms, the financial terms (and perhaps nonfinancial material terms) of the supply agreement would automatically be reduced and/or otherwise adjusted to conform to the more favorable terms.

Provide that if the supplier only has sufficient time or materials to satisfy its obligations to the purchaser or a third party purchaser, the supplier would allocate its time and materials to the purchaser first.

Ownership Could Be Complicated

Whether the supply agreement is exclusive or nonexclusive, obstacles arise when a new invention is discovered or created during the course of the supply arrangement. The invention could be an improvement to an existing technology or, alternatively, could be a new invention.

Improvements

An example would be that, while performing supply services for the pharmaceutical company purchaser, the supplier develops an improvement to its own manufacturing process. In this scenario, the supplier and the purchaser would have competing interests. The supplier would argue that it should own the invention, as it relates directly to its background technology (i.e., the manufacturing process). The purchaser, on the other hand, would argue that the invention was developed on its dime (i.e., the purchaser paid the supplier for the underlying materials or products).

If the purchaser agrees to allow the supplier to maintain ownership of the invention (since the purchaser is not in the supply business), it should obtain from the supplier a nonexclusive, perpetual, irrevocable, royalty-free license to use the invention for the purchaser's supply purposes, even after termination of the supply agreement.

The purchaser should also attempt to restrict the supplier's ability to use the improvement in connection with its supply of materials or products to the purchaser's competitors. In the event that the invention is an improvement to the pharmaceutical company's product, the pharmaceutical company should own the invention, especially in light of the fact that the supplier would have no use for an improvement where it does not own the underlying technology.

New Inventions

Ownership of a new invention that is not an improvement to the supplier's manufacturing process or the pharmaceutical company's product is more complicated. The parties typically divvy up (or share) ownership and use of the invention based on expectations regarding the type and use of the potential invention.

Force Majeure Clauses – Not Just Boilerplate

Most supply agreements include a force majeure provision. This act-of-God provision typically releases a party from its requirement to fulfill an obligation because of an extraordinary event or circumstance that is beyond the control of such party. Force majeure are now being invoked frequently as a consequence of the COVID-19 pandemic.

Although a force majeure provision is often considered to be contract boilerplate, pharmaceutical company purchasers should give these provisions careful consideration, as more often they are applied against the purchaser when the supplier is unable to fulfill its supply obligations. The purchaser should review the list of possible force majeure events and always exclude events that are caused by the supplier's negligence or misconduct.

The clause should provide that the supplier is relieved of its obligation for only so long as the force majeure event continues and the supplier should be required to provide the purchaser with prompt notice of any actual or foreseeable force majeure event and with periodic updates. The supplier should also be required to use reasonable efforts, at its own expense, to remediate the force majeure event. If the force majeure event persists for a certain period of time, the purchaser should have the right to terminate the supply agreement.

Conclusion

Although supply agreements could be complicated documents, a successful supply arrangement can be a significant asset for each of the parties. By understanding the unique issues and concerns that arise when analyzing and negotiating a supply agreement, the pharmaceutical company purchaser is better able to maximize this important asset, even when faced with a pandemic.