

Buyer Beware: Important “Supply” Issues For Life Science Companies

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Very often, a biotech or other life sciences company will need to purchase materials or products from a third party vendor. This arrangement could be in connection with the company’s clinical testing/R&D or in connection with the company’s commercial supply of its product. In any event, and regardless of whether the arrangement relates to development of a product or an already commercialized product, the parties typically enter into a Supply Agreement. This provides the life sciences company with a constant supply of sourcing of the materials or products without having to continuously negotiate contract terms. In addition to traditional purchase order terms, such as those relating to pricing, quality and delivery, a prudent life sciences company should be aware of the benefits and disadvantages of other common (or uncommon) Supply Agreement provisions. In this article I will address several of these provisions and propose some terms that are favorable to the life sciences company purchaser.

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Exclusivity From Both Perspectives

There are two components to an “exclusivity” commitment – purchaser exclusivity and supplier exclusivity. With respect to purchaser exclusivity, the purchaser agrees, for some period of time, to buy *all* of its requirements for the particular material or product from the supplier. This type of commitment on the part of the purchaser should include a pricing structure that compensates the purchaser for its agreement to forego buying the materials or products from a third party. If the purchaser agrees to this exclusivity, it takes on a heightened risk that the supplier will fail to comply with its supply obligations and that the purchaser will not have a readily accessible back-up supplier. (See *Failure to Supply* below.) The Supply Agreement could provide that if the supplier breaches its 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 non-exclusive arrangement.

The flip-side of the “exclusivity” commitment is analogous to a supplier non-compete provision. The supplier agrees not to supply the same (or similar) materials or products to a competitor of the purchaser or, more broadly, to any third party. Of course, the scope of this exclusivity arrangement would have to be negotiated. When several potential suppliers are courting the purchaser, the purchaser often has added leverage and success including such an exclusivity provision in the Supply Agreement. In any case, the Supply Agreement should clearly state that in no event may the supplier use the purchaser’s information, materials, technology or other confidential information in connection with services provided by the supplier for any third party.

Think Outside Of The Box For Pricing And Purchase Quantity Requirements

Instead of the most basic “flat fee per unit” purchase price arrangement, the parties could implement one or more of the various other pricing arrangements. These arrangements include volume discounts (to motivate the purchaser to increase its quantity of purchased items), price adjustments based on fluctuations in cost of goods or some other indicator (though this results in uncertainty for both parties and could include a floor and a cap on the adjustments), revenue-sharing (the supplier receives additional compensation from the purchaser after the product is sold in exchange for a lower

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initial purchase price) and cost-sharing (the purchaser bears a portion of some of the supplier's production expenses, again in exchange for a lower initial purchase price).

With respect to purchase quantity requirements, a Supply Agreement often includes a minimum amount that the purchaser must buy in a given quarterly, annual or other period. If the Supply Agreement includes this requirement, the purchaser should consider a provision stating that a purchase "overage" in one period would be applied to the minimum requirement in future periods or that purchase "underages" would be permitted a certain predetermined number of times before the purchaser would be penalized. Also, although it is fair that the purchaser be bound by its short-term forecasts, longer term forecasts should be provided to the supplier for informational purposes but should not be binding on the purchaser.

Failure To Supply

If, for whatever reason, a supplier breaches its supply obligation (a supply failure or even a supply delay), the purchaser may suffer serious ramifications. This is particularly true in the case where the purchaser has agreed to use the supplier on an exclusive basis. The Supply Agreement should include one or more provisions to protect the purchaser in this scenario. For example, the supplier could be assessed with daily monetary penalties for its breach. Additionally, even in an exclusive arrangement, the purchaser should be permitted to purchase from a second source under certain breach 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. The Supply Agreement could (and should) include a non-exclusive, 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.

"Preferred Customer" Protections

In the event of a non-exclusive arrangement where the supplier is supplying the same or similar material or product to a third party, the purchaser should consider including a "most

favorable 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 non-financial material terms) of the Supply Agreement would be reduced and/or otherwise adjusted to conform to the more favorable terms. Another advantageous protection is a provision stating 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 resources to the purchaser.

Ownership Could Be Complicated

Each party to a Supply Agreement should continue to own all of its "background" technology and information – the information and technology that the party owns before the start of the supply arrangement or that the party develops at a later time, independent of the other party. Obstacles arise, however, when a new invention is discovered or created during the course of the supply arrangement. An example would be that, while performing supply services for the purchaser, the supplier develops an improvement to its 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 non-exclusive, 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 new invention in connection with its supply of materials or products to the purchaser's competitors.

Ownership of a new invention is even more complicated when the invention is developed jointly by both the supplier and the purchaser. Typically, under U.S.

patent law, unless the parties otherwise agree, co-inventors (in this case, the supplier and the purchaser) each generally have the separate independent right to commercialize jointly-owned inventions. In this scenario, the purchaser may require some payment or other compensation from the supplier in exchange for the purchaser granting full ownership to the supplier. Such a grant should still include a grant-back license to the purchaser, as described above.

Force Majeure Clauses – Not Just Boilerplate

Most Supply Agreements include a "force majeure" provision. This provision, sometimes also referred to as an "Act of God" clause, 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. Although a *force majeure* provision is often considered to be contract boilerplate, 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 attempt to exclude certain economic events (e.g., a stock market crash) and should 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.

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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 life sciences company purchaser is better able to maximize this important asset.