The Metropolitan
Corporate Counsel®

National Edition www.metrocorpcounsel.com

Volume 23, No. 2 February 2015

Life Sciences: Protecting the Crown Jewels

Important strategies for licensors of intellectual property

Lori M. Waldron

Sills Cummis & Gross P.C.

An innovator or owner of patent rights or other technology in the life sciences arena is often unable, because of lack of financial or other resources, to develop or commercialize a pharmaceutical product covered by such intellectual property rights. In these cases, the innovator/owner (the licensor) will frequently out-license the invention to a third party (the licensee) for development and commercialization by such licensee. The resulting license agreement can be a complicated document. In this article, I will address some of the important licensing considerations that a licensor should take into account before executing a license agreement.

Consider the Exclusivity v. Non-exclusivity of the License Grant

An initial consideration in a license agreement is whether the license grant will be exclusive or non-exclusive to the licensee. If the license grant is exclusive, then the licensor typically agrees not to grant a license to any third party. If the license grant is non-exclusive, then the licensor typically is permitted to grant further licenses to third parties. Even in an exclusive license, however, the licensor may want to retain certain rights for itself. For instance, the licensor may want to preserve for itself the right to enter into certain geographical markets or fields of use. The parties should be very clear in the license agreement as to whether or not the licensor is permitted to exercise any R&D, commercialization or other rights during the term of the license agreement.

Lori M. Waldron

Whether a license is exclusive or non-exclusive will set the tone for the associated rights and obligations of the parties set forth in the remainder of the license agreement. For example, an exclusive licensee is usually subject to "diligence" obligations, requiring it to exploit the licensed technology in order to maintain the license grant; a non-exclusive licensee is usually subject to limited or no such obligations. Also, an exclusive licensee usually has more rights than a non-exclusive licensee with respect to the prosecution, maintenance, defense and enforcement of patent rights.

Also Consider the Scope of the "Field of Use" and "Territory"

Other important initial considerations in the license agreement are the scope of the licensed field of use and the scope of the licensed territory. A "field of use" defines the field in which the licensee may exercise the licensed rights and may take one of many forms. For example, the field of use may be all encompassing ("any and all fields and applications"), may be limited to only therapeutic or only diagnostic products, may be limited to only biologics or only small molecule products, or may be limited to a specific medical indication (e.g., cardiac indications). Especially in the case of an exclusive license (and based on the nature of the licensee), it is sometimes better for the licensor to limit the field of use. Then the licensor would be permitted to grant subsequent rights to other parties in the non-licensed fields. Alternatively, if the field of use is broad, the licensor should require that the licensee actually exercise its rights in certain specified fields in order to maintain such rights. If the licensee fails to exercise its rights in a specified field of use within a certain period of time, the licensor's remedies could include the right to terminate the license agreement in its entirety, the right to terminate the license agreement with respect to one or more specific fields and/or the right to convert an exclusive license grant in such field to a non-exclusive grant.

Considerations regarding the "territory" are very similar to the considerations regarding the field of use. Often, in order to maintain an exclusive worldwide territory grant, the licensee is required to exploit the licensed technology in specified countries. For example, the licensee may be required to develop and commercialize a product covered by the licensed technology (licensed products) in the United States and at least one other "major market country" (e.g., Japan, France, Germany, Italy, Spain and the United Kingdom). Again, the licensor's remedies for the licensee's failure to satisfy this obligation could be similar to the remedies set forth above for field of use.

Maximize the Royalty Payments

Pursuant to the terms of the license agreement, the licensee will most likely be required to pay to the licensor a royalty based on sales of licensed products. Although the determination of the amount of royalty is in large part a business decision and takes into consideration, among other things, the scope and strength of the licensed patent and other intellectual property rights, the breadth of the field of use and territory, whether the licensed product is a therapeutic product (typically a higher

Lori M. Waldron, *a member of Sills Cummis & Gross P.C., focuses her practice on the representation of both emerging growth and well-established public and private companies in sophisticated business transactions, with a particular focus on the life sciences and biotech industries. The views and opinions expressed in this article are those of the author and do not necessarily reflect those of Sills Cummis & Gross P.C.*

Please email the author at lwaldron@sillscummis.com with questions about this article.

royalty rate) or a diagnostic product, and whether the license grant is exclusive or non-exclusive, there are many important legal nuances that the licensee could and should consider. One such nuance is the calculation of "net sales."

The amount of royalty owed by the licensee is normally calculated by multiplying the royalty rate by the amount of sales of the licensed products. The royalty rate does not need to be a flat rate and could be graduated, for example, with a rate change as sales increase. In determining the "sales" portion of the royalty calculation, it is more advantageous to the licensor that sales be based on amounts *invoiced* (as opposed to amounts *received*) by the licensee, thus keeping the risk of bad debt (i.e., a sales amount is *invoiced* but not actually *received* by the licensee) with the licensee. Also, although "net sales" (as opposed to "gross sales") is the usual royalty base, the licensor should restrict the deductions taken into account to determine such net sales. For example, although the "net sales" calculation frequently includes deductions from gross sales for governmental taxes and charges, customer credits and rebates, and transportation, storage and insurance expenses, the licensor should avoid less typical deductions such as sales commissions owed by the licensee or a catch-all deduction for "other reasonable deductions."

Ensure That the Inventions Are Fully Exploited

Once a licensor licenses its invention to a third party in an exclusive license arrangement, the licensor will lose much control over the day-to-day use of the technology. It is imperative that the licensor requires the licensee to actually exploit the technology in a timely manner and devote sufficient time, money and resource to such exploitation. Almost all exclusive patent or technology license agreements contain a "diligence" provision requiring the licensee to employ certain efforts with respect to the research, development and commercialization of licensed products. Generally, the diligence requirement provides that the licensee must use "commercially reasonable efforts" to advance the product through the pipeline and sale process. However, the meaning of "commercially reasonable efforts" is not precise and the two parties to the contract could interpret the phrase, and the corresponding diligence requirement, quite differently.

A prudent licensor defines the diligence requirement more exactly. Ideally, the diligence requirement would be accompanied by diligence milestones, contractually obligating the licensee to reach certain developmental, regulatory or sales milestones by certain target dates or to spend a certain dollar amount on the licensed product in a given time period. Additionally, different diligence standards could apply with respect to different jurisdictions. If the licensee fails to meet its target, the licensor would be entitled to one or more remedies such as a financial payment from the licensee or a right of termination.

Maintain Control over Patent Prosecution

In an exclusive patent license arrangement, the licensee usually pays for the costs associated with patent prosecution and maintenance. Even in a non-exclusive arrangement, the licensee could be required to pay for a portion of such amounts. Though the licensor bears some or all of the patent prosecution and maintenance expenses, the licensor should ensure that it ultimately has control. Ideally, the license agreement should provide that the licensor controls the prosecution and maintenance, perhaps with counsel reasonably acceptable to the licensee. The licensor could allow the licensee to provide input into where (which jurisdictions) the licensor will prosecute and maintain the patents. However, the licensor should have the final say as to the scope and jurisdiction of the patent filings. In order to address a licensee's concern that it would be required to pay for expenses in jurisdictions where the licensee does not deem patent coverage to be necessary or desirable, the license agreement could provide that the licensee may notify the licensor that the licensee will not pay the patent costs in a particular jurisdiction – in which case the licensee would probably lose its license rights (or at least its exclusivity, in the case of an exclusive license grant) with respect to such jurisdiction.

Carefully Consider Termination Provisions

A license agreement includes customary termination provisions. For example, each party usually has the right to terminate the agreement in the case of an uncured material breach by the other party. Additionally, the licensee typically has the right to terminate the license agreement for convenience (without cause) following some notice period (e.g., 90 days). Following termination of the license agreement, the licensor may want to either resume R&D or commercialization efforts on its own or re-license the technology to another suitable third party. In order to avoid the need to duplicate efforts (and expenditures) of the first licensee, the licensor should give careful consideration to the termination provisions in the license agreement. Ideally, if the licensee terminates the license agreement for convenience (i.e., the licensee walks away from the technology) or the licensor terminates the license agreement because of an uncured material breach by the licensee, the licensee would be required to automatically assign to the licensor, for no additional consideration or for some agreed upon payment, all of the results, know-how and intellectual property generated by or on behalf of the licensee under the license agreement and all regulatory files, regulatory approvals and other rights related to the licensed product. Thus, the licensor or its new licensee would be able to capitalize on the past work performed by the licensee, expedite timelines and reduce expense.

* * *

All or some of the points described above could be very important to a licensor. Although the interrelation of these and various other provisions in a license agreement are complex, by understanding the unique issues and concerns that arise when analyzing and negotiating a license agreement, the licensor is better able to protect its invention and ultimately increase its profit.