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Five Traps For The Unwary Licensee

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Licensors and licensees enter into agreements with each other all the time with respect to the commercialization of products covered by patent rights or other technology. These agreements can take many forms, including "pure" license grants, R&D collaborations and joint venture arrangements. Some of these agreements are not very complicated and others are packed with thorny issues. However, regardless of the structure or complexity of the transaction, some common traps persist. In this article I will address some of these traps and propose ways for a careful licensee to sidestep them.

Trap 1: Avoid Disputes Over Whether The Licensee Is Diligent

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/or commercialization of a product covered by the licensed rights. Typically, 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 licensee will define the phrase as narrowly as possible to match its specific circumstances. For example, the license agreement could provide that the requirement for the licensee to use "commercially reasonable efforts" means, more specifically, that the licensee must use efforts and resources that are consistent with those that would be used by a company in a *similar position* as the licensee and with respect to a product at a *similar stage of development or product life*. In this way, the licensee (if it is a small company with an early-stage product) would not be held to a standard that would apply to a larger company with more financial resources or to a more mature product. As another example, the language could state that the licensee's required level of effort must take into account the amount of available patent protection or the existence of competitive products in the marketplace. Additionally, different diligence standards could apply with respect to different jurisdictions.

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Of course, even with a licensee-friendly definition of "commercially reasonable efforts" in place, a licensor could always argue that the licensee nonetheless has failed to attain the requisite level of conduct. In order to avoid this argument, a licensee could pre-negotiate a minimum dollar spend "safe harbor." Pursuant to this type of safe harbor, if a licensee spends a certain amount of money with respect to the subject product during a particular time period (e.g., during a calendar year), then the licensee would automatically be deemed to have satisfied its diligence obligation with respect to such period, regardless of the specific activities performed by it. Even better, the license agreement could provide that money spent by the licensee in excess of the safe harbor with respect to a particular period could be carried forward and applied as a safe harbor credit for a future period or periods.

Trap 2: Do Not Fail To Think Ahead – Provide For Royalty "Stacking"

In order to successfully develop and commercialize a product, a licensee often needs or desires to in-license inventions or technologies from several sources. However, multiple royalties owed to multiple licensors could be expensive and, in some cases, so cost prohibitive that actual commercialization of the product would be difficult. A cautious licensee should plan ahead, even if it does not know up front the nature or cost of any additional licenses that it may

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need or desire to obtain, and include a royalty "stacking" provision in the license agreement. Pursuant to such a provision, the licensee would be permitted to offset royalties paid by the licensee to one licensor against the royalties owed by the licensee to another licensor, thus reducing the aggregate royalty burden. Licensors are often willing to agree to such a provision based on the theory that the value of the end product will increase as more technology is added. The amount of the typical offset differs depending on the circumstances and is usually subject to a royalty "floor" below which an individual royalty may not fall.

Trap 3: Do Not Tie A Milestone Payment To An Event That Does Not Increase The Value Of The Licensed Technology

Many license agreements include a provision pursuant to which the licensee must pay the licensor one or more milestone payments upon achievement of certain events. The core concept is that as the potential product progresses through the various stages of research, development and commercialization, the risk associated with obtaining a viable product decreases and, thus, the value of the licensed patents or technology increases. Typical milestone triggers for a pharmaceutical product include identification of a lead compound, commencement of animal studies, filing of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (or filing of a comparable or equivalent application in a foreign country), commencement of clinical trials and product approval. In each case, a milestone payment should correlate directly to an event that reduces the risk and increases the value of the product or potential product.

When occurrence of a milestone event is tied to one or more of the various clinical developmental stages of a potential product, the licensee should attempt to draft the language so that the payment is not owed upon *completion* of a particular stage – but rather upon *commencement* of the next stage. For example, it is usually better to provide for the occurrence of a milestone event upon the "first dosing of the first patient in a Phase III clinical trial" than to provide for the occurrence of a milestone event upon "completion of a Phase II clinical trial." Although the completion of the Phase II clinical trial and the commencement of the Phase III clinical trial may occur within a very short period of time of each other (in which case the distinction would not be as meaningful), it is quite possible that the licensee would complete its Phase II clinical trial but not be satisfied with the results. Instead of moving forward to a Phase III trial, the licensee may opt to conduct another Phase II trial or, perhaps, end its R&D with respect to the particular product entirely. In either of these latter scenarios, it would be unfortunate for the licensee to be contractually required to pay a milestone payment to the licensor. An alternative approach for the licensee would be to tie the occurrence of the milestone event to completion of the Phase II clinical trial, but to provide that specific successful trial results must be obtained in order for the milestone payment obligation to be triggered.

Trap 4: Be Sure To Preserve The Right For A Sublicensee To "Go Direct" If Necessary

In the event that a license grant is sublicensable, the licensee will want to avoid the need to renegotiate any license terms with the licensor if and when the licensee desires to sublicense its rights. Thus, the licensee should take steps in advance to include provisions in the license agreement that are typically required by sublicensees prior to executing a sublicense agreement. One such provision is the right of the sublicensee to continue to exercise its sublicensed rights even if the underlying license agreement between the licensor and the licensee/sublicensor is terminated. It could be disastrous for a sublicensee if its sublicense grant is terminated because, for example, the licensee/sublicensor breached the underlying license agreement and the licensor terminated such agreement (and the corresponding sublicense). As a condition to its execution of a sublicense agreement, a far-sighted sublicensee will require an upfront agreement from the licensor that the sublicensee may continue to exercise its rights pursuant to a license grant directly from the licensor in the event of such a termination. Thus, the license agreement should include terms requiring the licensor to continue the license grant to the sublicensee in such a scenario and to provide the sublicensee with reasonable assurances or acknowledgments with respect thereto upon execution by the sublicensee of the sublicense agreement.

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Trap 5: Do Not Allow Patent Expenses To Run Out Of Control

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 a portion of such amounts. The licensee should ensure that it has some control over the magnitude of the costs. In the absence of such control, the licensor would have no motivation to keep costs in check – since the licensee would be bearing the expense. Ideally, the license agreement should provide that the licensee has input into where (which jurisdictions) the licensor will prosecute and maintain patents. The agreement should also 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.