

Tips For Biotechnology In-Licensing

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Take a look at the life sciences industry these days and one can see that most start-up technology is licensed-in or developed through sponsored research arrangements with built-in licensing provisions. The danger for many companies who license-in these technologies is that they fall into the not-so-glorious traps of intellectual property licensing. Although these traps may not cause damage to the company on day one, they could be extremely harmful to the future of the product and the life sciences company as a whole.

Tip #1: Understand the difference between products, services, technology, and intellectual property rights.

Products, services, technology and intellectual property rights are distinct. For example, a product could be a medical device, a therapeutic drug, or diagnostic kit, and a service could relate to bioinformatics processing, gene targeting, or diagnostic testing. Any of these may consist of or utilize one or more technologies. A technology is the physical embodiment such as material, compound, design, substance, or program, or an innovative method such as a process, procedure, technique, or other know-how. Each technology has associated intellectual property rights, whether they be patent, trade secret, copyright, or trademark (in the case of bioinformatics, certain database rights may also be applicable depending on the country).

Patent rights enable the holder of such rights to prevent others from making, having made, selling, offering for sale, using, or importing the technology, either alone or as embodied in, or utilized to produce, a product or service. Trade secret

rights enable holders to prevent others from misappropriating a holder's secrets that have value in the particular trade. Copyrights prevent others from copying a holder's expressions of his ideas. Note that this is distinct from protecting the idea itself, which cannot be protected by copyright. Finally, trademarks prevent others from using a particular mark in connection with a product that would create a likelihood of confusion with the holder's product.

Tip #2: Identify the product(s) and determine the applicable commercialization strategy.

Before negotiating any license agreement for a particular technology or intellectual property right, the first step should be to identify the potential product(s). Venture capitalists and corporate venture arms will agree that too many start-up companies get caught up in their technology, instead of focusing on the commercial product(s) enabled by the technology. Without a viable product, regardless of the value of the science itself, the technology loses its commercial viability.

Next, companies need to determine their commercialization strategy. Does the company plan to develop a product itself by building a manufacturing and distribution force, does it plan to utilize a downstream licensing strategy to enable others to commercialize the technology, or does it plan to have a combination strategy and outsource certain aspects of the commercialization (i.e., partner with contract manufacturers or third-party distributors). In the former case of a go-to-market approach, take the time to understand the product and what technology or technologies will comprise it. For example, if multiple

technologies are required, especially if they are licensed from different sources, negotiating royalty stacking provisions to keep the royalty costs low is going to be important.

Tip #3: Look beyond patents.

Patents are critical because of their strategic "blocking" potential. They enable companies to prevent others from practicing the patented technology, and can be tactically used to drive licensing revenue from potential infringers. However, if a company's commercialization strategy is not a licensing strategy, but a go-to-market strategy, then obtaining patent rights alone, without the transfer of the technologies and the license of other associated intellectual property rights, may not be adequate to develop and commercialize the technology or product.

For example, despite the disclosure and enabling requirements in a patent filing, the practical know-how gained from actually practicing the subject invention of the patent can be essential for conducting further research on or fully exploiting the technology. Moreover, reports, manuals, disclosures, documentation, guidelines, and other information developed during the research process may be quite useful for later research or commercialization. Not to have a physical material or the right to utilize it (or even worse, to utilize it without obtaining the rights to do so), could be detrimental to a company. Research and

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development rarely go as planned, and referencing past mistakes or using alternative paths could be very important in future research. Moreover, certain unpatented technologies that can be kept trade secrets and are difficult or impossible to reverse engineer or recompose, can provide a competitive advantage to others in the field.

Accordingly, companies should expand the focus of the license beyond patent rights to ensure that in the license, or in a separate material transfer agreement, the technologies, including materials and know-how, needed for further development and commercialization are physically obtained along with adequate licenses to associated intellectual property rights. Licensees should also be forward thinking and negotiate to include improvements to the technology or new technologies developed that relate to the product. If the licensor retains the right to conduct future research, given recent rulings, this retention needs to be explicit in an exclusive license. More importantly, the licensee should include technologies resulting from such research as part of the license agreement.

Companies should also make sure that the intellectual property rights are those that exist now or arise in the future. For example, there should be no doubt that the licensee obtains patent rights that issue from a pending patent application. In addition, know-how and invention disclosures may include patentable subject matter that the licensor may not have recognized, and additional claims may be able to be made. Accordingly, if possible, especially in a broad exclusive license, obtain control of the patent prosecution.

Tip #4: Separate the license grant and duration of patent rights from other intellectual property rights.

It is important to make distinct license grants for each of the different intellectual property rights. The “bundle of rights” associated with patents is different from those for copyrights, trade secrets, or

trademarks. For example, granting “patent” rights in a bioinformatics invention—the right to make, have made, use, sell, offer for sale, and import—is not adequate to enable you to modify, adapt, or create derivative works of the copyrighted technology. Moreover, patents may be limited to certain territories, but trade secrets may be worldwide. Furthermore, the length of the term covering patents rights typically lasts for the remainder of the applicable patent terms, but you can usually negotiate for a longer license to copyrights, trade secrets, and trademarks. This becomes even more important when you can base your royalty term (discussed below) on the patent term, and get a royalty-free remainder to the other intellectual property rights.

Tip #5: Make sure to get the intellectual property rights you need.

Licensees should craft the grant language consistent with their business and product strategy and recognize that broader rights may come at an unnecessary cost. For example, if a company plans to manufacture products outside the United States, but sell them only in the United States, then they should not pay for the worldwide commercialization rights, but just license and pay for foreign manufacturing and domestic distribution rights. Alternatively, assuming the company’s focus is on breast cancer, but can negotiate an oncology field-of-use, the broader grant may be worthwhile if the company can “flip” the rights it does not intend to use itself (i.e., sublicense them to third parties for a profit). In such case, the ability to sublicense, including through “multiple tiers,” would be important. Companies should also consider negotiating a right of first refusal or option for additional fields-of-use or territories so that the license can expand as the company broadens its business focus.

Depending on the importance of the technology to the product and whether the intellectual property rights are subject to existing

licenses, exclusivity may be key. However, if negotiating exclusivity becomes difficult, companies can use territories and fields-of-use to narrow the exclusivity to fit their business needs, yet provide some comfort to the licensor. Furthermore, if the company intends to conduct research, make sure that purpose is explicitly granted and define which parties own and have rights to the technology and associated intellectual property rights resulting from the research. Remember that rights rather than ownership is important. Many universities want to maintain ownership because it provides them with recognition (i.e., they can count the number of patents registered with the USPTO).

Tip #6: Think about the company’s corporate future.

Companies should not forget about the need to transfer and assign intellectual property rights in the event of a buy-out or merger with another entity. Particularly, the assignment provision should at least allow for assignment without consent in the event of a significant stock or asset acquisition, or corporate merger. Any restrictions in the license grant section (e.g., non-transferable) should not conflict with the assignment provision usually found in the miscellaneous section (e.g., non-transferable except as otherwise provided in the assignment provision).

Tip #7: Read the definitions.

Companies negotiating license agreements need to recognize that defined terms in a contract do not necessarily take on their ordinary meaning. As defined terms, they can be broader or narrower depending on how the parties wish to use the specific term. For example, many standard definitions of patent rights include patent continuations (applications that have the same disclosure as the earlier filed parent application and claim the benefit of the filing date of the earlier parent application), divisions (applications with claims that were divided out of the original patent application because of the USPTO’s restriction

requirement that the original application only relate to one invention) and reissues (patents issued for the same invention for the remainder of the original patent term when mistakes or inadvertent errors were made in the original patent), but may not include continuations-in-part (applications based on the parent application disclosure plus an additional invention disclosure) or all foreign counterparts. Also, as mentioned in Tip #3, the definition of intellectual property rights should not be limited to patent rights, but should include copyrights, trade secrets, and trademarks. For bioinformatics technology, the inclusion of database rights in the definition is critical.

Patent licenses are usually structured to cover “licensed products,” where license products are “products” claimed in the licensed patents or would infringe the licensed patents. However, it is important to include the concept of “services,” particularly if they are directly or indirectly part of the commercialization strategy. Moreover, the definition should also include products or services derived from trade secrets, and not just claimed in the patents.

Clear definitions of products and technologies are important. Do not use circular definitions by identifying products or technologies by their trademarks. Descriptions taken from patent applications or invention disclosures may be more appropriate. However, be careful that the definitions are not too limiting and cover the products and technologies intended to be commercialized.

Tip #7: Don't get bogged down negotiating a low royalty rate.

Inexperienced negotiators tend to fall into the trap of focusing almost entirely on the royalty rate—trying to keep it as low as possible. For many emerging companies, that focus is misplaced.

For starters, royalties may be structured differently for different technologies. For example, a company may make money as a service provider performing outsourced diagnostic or screening assays on

certain compounds or substances. Such services may utilize a method covered under a licensed patent. At the same time, it may sell to third parties the diagnostic or screening product that is covered under the licensed patent. Accordingly, if its margins are higher on the services side, it may want and can afford to negotiate a higher royalty rate on services revenues in exchange for a lower royalty rate on product revenues. Alternatively, if one revenue source is larger than the other, a company can advantageously give-up a higher royalty rate on the smaller revenue source, in exchange for a lower royalty on the higher revenue source.

Higher royalty rates may also be negotiated if those royalties are tied to net, rather than gross, revenues. In an ideal world, a company would want to deduct its direct and indirect costs from net revenues. However, more realistically, the negotiated definition of net revenues deducts taxes and bad debts, and sometimes freight costs and sales commissions. A big expense worth focusing on, especially for a licensee of early stage technologies, relates to the prosecution, maintenance, defense and enforcement (and, ideally, commercialization) of intellectual property rights licensed under the agreement, including reasonable attorney's fees. Although licensors dislike agreeing to these expense carve-outs, licensees can argue that the costs associated with prosecuting, maintaining, and defending intellectual property rights should come out of the “revenue pie,” rather than just the licensees share, especially when licensors, notably universities, provide no representations, warranties, or indemnification with respect to the intellectual property rights. Without such an expense deduction, a licensee can get caught in the red spending millions of dollars defending an infringement action while still paying royalties to the licensor.

Licensees should make sure that royalties are based on amounts it receives as opposed to amounts it invoices to customers. Also, there

should be no royalties on the value of sample products distributed for marketing or business development purposes. Note that licensors may pay particular attention to transfers such as these, especially if they feel such transfers were made in exchange for non-cash consideration that should be included as royalty earning revenue.

Structuring higher royalties can also be a way to minimize risk. If a licensee exchanges a higher royalty rate for nominal or eliminated upfront payments, its downside is reduced. This may be especially important if the company is thinly capitalized or needs to use its existing funds on further research or clinical trials. A solid negotiating tactic if the royalty rate looks a little scary is to build in stacking provisions that reduce the rate in the event multiple royalties need to be paid out. In the example above, this would be the case if the diagnostic product includes technologies from multiple licensors, or if the product was a kit that includes products from multiple distributors.

As alluded to earlier, another negotiating tactic is to tie royalties to the patent term, rather than a trade secret term that could be much longer. This is especially important where products have strong trademarks that can maintain their strength in the marketplace long after generics have hit the shelves. Moreover, if patents do not issue or are held invalid, they should be excluded from the definition of licensed products on which the royalties are based. Note, however, that a skilled licensor will make sure to get some value for its trade secrets, and recognize that products almost always outlive their patents.

Tip #8: Think about the downside.

Attorneys earn their fees in license negotiation by forcing clients to think about the downside. Although getting the deal done may be a high priority, too many companies fail to address the “what if things go wrong” scenario. For a company with only one product, the downside

may just be closing up shop. But for a company with multiple technologies or products, limiting the downside and shielding those other profit centers is critical. One way to do this is to obtain the right to terminate the license for convenience or in the event certain milestones are not obtained. An even better approach is to have the license convert to non-exclusive in the event milestone payments are due but go unpaid. This creates an automatic remedy favorable to the licensee because it saves it from a potential breach of contract. A company can try to negotiate for an exclusivity “buy-back” if circumstances change for the better, but this assumes that the licensor has not licensed to anyone else during that time.

Indemnification can be a significant issue for a company with more than one technology or product. An infringement or product liability suit could drain the company of all of its capital and subject its other intellectual property to sale in bankruptcy, ruining it and the success of its other products. Some kind of limited indemnification or intellectual

property and product liability insurance is critical. Also, creative entity structuring may be a good solution by using the “corporate veil” of affiliated, but separate corporations or limited liability companies to shield the technology and associated intellectual property rights.

Although licensors, especially universities, are wary of warranties or indemnifications, it is critical for licensees to ensure that the licensor represents and warrants that it has the rights to grant the license, and at the very least, that it is not aware of any claims of infringement or actions to invalidate the patents. Due diligence is also important and should include getting comfortable with the chain of title, including original inventor assignments.

Conclusion

As early stage biotechnology companies try, almost desperately at times, to obtain funding or strike their first pharmaceutical deal, their intellectual property can make or break it. For a start-up company, experienced management and a mar-

ketable product (rather than a pure technology focus) are key. However, a company will not succeed without a strong intellectual property portfolio. To even be considered for a deal with pharmaceutical companies requires great comfort that the intellectual property associated with the technology will protect their multi-million dollar investment in the product.

A poorly drafted license to the intellectual property in that portfolio could quash any hopes of such a deal or capital infusion. Take the time to negotiate the right license to put your company in a position of securing technology and intellectual property in a fashion that gives comfort to your potential investors and downstream licensees. Be sure that the company’s lawyer is not the type who “kills the deal.” Skilled legal counsel who know intellectual property, the life sciences industry, and win-win negotiation can do so in a way that help your license agreement and business along, rather than hinder them.