Biotech Licensing: Key Principles for Building Successful Licenses and Collaborations Between China and the West

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China's biotechnology sector, fueled by government funding and talented scientists with a desire to innovate, is growing rapidly. These new entrepreneurs include Chinese nationals who have been trained in the West and who have returned home – the so-called "sea turtles"– to establish new China-based biotechnology companies, as well as Chinese scientists who establish US-based companies with substantial operations in China.

In either case, many of these new China-based biotechnology companies will establish relationships with traditional Western biotechnology or pharmaceutical companies. Increasingly, these relationships go far beyond a Chinese contract research organization (CRO) performing services for a large Western pharmaceutical company. We have already seen the first crop of biotechnology innovations originate in whole or in part from work performed in China; and innovation will certainly increase.

If you are one of these scientists and entrepreneurs performing innovative biotechnology work in China, you may wonder how to create the legal framework around your technology transactions that will protect your innovations and grow the value of your company. This article will briefly explain eight principles of biotechnology transactions that you want to understand and implement before you sign your next licensing, collaboration, manufacturing or services agreement.

1. New Intellectual Property: Carefully Identify And Allocate Rights.

Next to scientific innovation itself, establishing solid intellectual property rights – typically patents – drives the creation of value in the biotechnology industry. A patent is a powerful tool: it gives the owner (or exclusive licensee) of the patent the right to prevent others from practicing the patented invention. For example, if you possess the exclusive rights to a United States patent covering a new chemical compound, no one else can lawfully make, use, sell, offer for sale or import that compound in the United States without your permission.1

Patent rights are deeply ingrained in Western business. In the United States, for example, the modern patent system was authorized by the Constitution, which in 1787 gave to Congress the right "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."2 In Europe as in the United States, biotechnology and pharmaceutical companies create value by obtaining patents on their innovative com-

pounds, formulations and manufacturing methodology.

Given the power and history of patent rights in the West, vigorously negotiating and carefully documenting rights to new intellectual property is essential in every biotechnology transaction that involves the possibility of new inventive work. This is a complex topic with many traps for the unwary, but here are a few key points.

In the United States, an invention is owned by the inventor unless a contract provides otherwise. 3 Thus, if your company signs a contract that permits the other party to perform inventive work in the United States, and if the contract does not assign (or license) those inventions to your company, your company will not own (or have rights to) the United States patent rights claiming those inventions. If the inventive work results in a block-buster new drug that was discovered using your company's technology, your company could suffer an unnecessary and devastating loss of value.

Even in an agreement that was intended to assign new inventions to your company, poorly drafted terms can lead to disputes and a loss of rights you thought your company had secured. Consider this example of unintended consequences.

Many agreements provide that each company owns all inventions "related to" its own technology. But what happens if an invention "relates" to both company's technologies? The result could be that the companies jointly own the new invention. In the U.S., each joint owner can use and exploit a joint invention – including granting licenses to one or more third parties – without permission from the other joint owner. If this occurs with an invention critical to your company's business model – such as a patented new method of producing vaccines – your company will lose substantial value.

Finally, be wary of definitions. Licensing and collaboration agreements often rely on terms that are defined, in many cases, by reference to a series of other defined terms. This "hall of mirrors" approach to drafting agreements can make many of their provisions difficult to understand. In connection with categories of intellectual property, however, it is essential to draft and understand each defined term. You may encounter an agreement, for example, that uses a term like "Collaboration IP," which sounds like it refers only to inventions jointly created by your company (the "Licensor") and the other party (the "Licensee"). If the definition of "Collaboration IP," however, includes inventions related to improvements to "Licensor's IP," which in turn is defined to include all inventions related to "Licensor's Technology," which is defined to include "all inventions related to Compound [X]," then in fact the term "Collaboration IP" could include all inventions related to your company's "Compound [X]" – even if your company is the sole inventor.

The brief outline above is only the tip of the iceberg. Provisions related to defining and allocating rights to new inventions and intellectual property demand close attention, creative negotiation, and careful drafting. Only in this way can you create trust with the other party while preserving and growing your own company's value.

2. Exclusivity: When "Freedom-To-Operate" Is Not Enough.

The right to practice a patented invention can be transferred from one party to another by a license grant, which can be exclusive, co-exclusive or non-exclusive. Understanding which type of license you need can be critical to your company's ability to create value.

Exclusivity is a simple but important concept: it determines whether one company, two companies, or many companies, have the right to practice a patented invention.

Your company first needs to determine, from a business perspective, whether a particular transaction should convey exclusive rights, or something less than exclusive rights.

Under a non-exclusive patent license, for example, the licensee will obtain "freedom to operate" under that patent – i.e., the right to practice the invention – while the licensor retains the right to practice the invention itself and to grant licenses to a potentially limitless number of other parties. In many cases, a non-exclusive license is an appropriate choice, such as for a platform technology that is widely applicable to many different products. However, in the United States a non-exclusive licensee does not have the right, on its own, to bring a lawsuit against an alleged infringer.4 Thus, the non-exclusive licensor (and possibly all other licensees) may be required to join in a lawsuit.

All other things being equal, an exclusive license will cost more for the licensee to obtain and yield greater revenue to the licensor. An exclusive license, however, usually carries with it other terms that a potential licensee should carefully consider, including: obligations to "diligently" develop the licensed technology, sometimes

with minimum annual royalties due; the right to control patent prosecution, usually including the obligation to pay prosecution costs; and the right to control lawsuits to enforce the patent rights against alleged infringers, and to recover most or all of the proceeds from such litigation. Thus, an exclusive license, with all of its costs and burdens, is not always appropriate.

Finally, co-exclusive license grants are often seen between collaboration partners for new inventions created under the collaboration but owned solely by one of the partners. A co-exclusive license enables both of the collaboration partners to practice the invention, usually for the sole purpose of furthering the collaboration.

Regardless of whether you are granting or receiving a license, knowing when to structure it as an exclusive, non-exclusive or co-exclusive license is a critical part of developing your business strategy.

3. Territorial Divisions: Consider Options And Rights-Of-First-Refusal.

A license can grant "worldwide" rights or rights to a single country – and anything in between.

For example, in many cases a Chinese company will grant a Western biotechnology company worldwide rights, minus China (or minus a list of specific Asian countries). Retaining rights to China (or Asia) may make sense if the Chinese company would like to develop a commercial sales force in China (or Asia), or if it believes a different company would have more success in China (or Asia) than either the licensor or licensee.

When dividing up territory, however, there are other possible approaches and considerations.

If at the time you do your deal, for example, it is unclear whether a particular country should be included, you may wish to structure an option or right-of-first refusal to the country. In the example noted above, the Chinese company can grant the Western biotechnology country an option to acquire the Chinese (or Asian) territory. An option, if exercised, usually requires the payment of an additional fee (similar to an upfront fee). An option, once exercised, may also require the other company to meet certain diligence requirements to commercialize the technology in the newly-acquired territory. Also, an option can expire after a certain number of years.

Another alternative is similar: a right-of-first refusal. With this approach, the Chinese company in the example above would agree not to license out the rights to China (or Asia) to any third party without first giving the Western biotech company an opportunity to do the deal on terms that, on the whole, are at least as favorable to the Chinese biotech company. This structure provides the Western biotech company the opportunity to control additional rights, which it may find attractive. It may also create a competitive bidding environment that will enable the Chinese biotech company to obtain better terms. The disadvantage, however, is that it can be difficult to negotiate a deal with a third party if the third party knows that its terms will be presented to the original licensee who may have a substantial period of time (typically at least thirty days) to exercise its rights, further delaying any potential deal.

The option and the right-of-first-refusal approaches, however, provide flexibility when you consider whether to grant "worldwide" rights, or something less.

4. Joint Steering Committees: Create Rules That Build Trust And Efficiency.

Most collaborations have a "joint steering committee" that governs major decisions regarding the collaboration, such as selecting a drug candidate to advance into further development or clinical testing. Sometimes subcommittees are also created for handling specific issues, such as patent prosecution, finance, regulatory and other matters.

Each party identifies members for each committee, and the committees usually meet periodically, and make decisions – usually by vote – within their area of responsibility.

But what if the committee members disagree?

Although the parties usually hope to achieve consensus, that is not realistic over a long-term collaboration. An agreement that requires consensus before a committee can act – such as a decision to advance a candidate into a Phase 1 clinical trial – can create paralysis. And the alternative of sending a disagreement to an arbitrator for resolution of the "dispute" can create tension, delay, extra cost and may put the decision in the hands of someone ill-equipped to understand the scientific, regulatory or business considerations that should drive a prudent decision.

A better alternative, in many cases, will be to identify which party will have "final say" over decisions. In some cases, this may change as the collaboration progresses

through product development. It may make sense, for example, for the smaller biotech company whose technology is being developed to control decisions about early R&D work, such as identifying potential drug candidates. When the same drug progresses into human clinical trials, however, the larger and more experienced party may control decisions.

The time to resolve disputes over which party controls which decisions is during the negotiation of the collaboration agreement – not during the collaboration!

5. Due Diligence Obligations: Understand The Limits Of "Commercially Reasonable" Or "Best Efforts" Standards, And Consider Alternatives.

Most exclusive licenses require the licensee to exert some form of "diligence" in developing and commercializing the licensed technology. Often, the licensee is required to use "commercially reasonable efforts" or "best efforts," which can be defined at length in the agreement and in U.S. case law. Enforcing these obligations, however, can be difficult, expensive and time consuming – and the results are uncertain.

In an attempt to create an objective diligence standard, "commercially reasonable" is sometimes further defined as the efforts of "similarly situated" biotechnology company. These provisions can list numerous factors to be used in determining whether the licensee's efforts are "commercially reasonable," including the quality and scope of patent protection available for the product or technology, regulatory hurdles, market size, projected profitability, and even the presence of competitive products within the licensee's portfolio.

But do these provisions, which are often heavily negotiated, provide clear and enforceable obligations? If you are the licensee, can you be certain you have met your obligations? If you are the licensor, can you establish with certainty that the licensee has "materially breached" its diligence obligations? In many cases, the answer to all of these questions is "no."

If a licensing relationship goes well and a product is successfully launched and sold, these questions never arise. If, however, a product is delayed or abandoned, a dispute about whether the delay or abandonment was "commercially reasonable" can lead the licensor to attempt to terminate the contract on the ground that the licensee failed to meet its diligence obligations. The result can be a costly dispute with the potential to keep a product in limbo for years.

Alternatives exist for these diligence standards. For example, if the licensee is required to pay minimum annual royalties starting several years after signing, the licensee will be motivated to commercialize the product before the minimum royalties become due. Payment of the minimum royalties can, in effect, force the licensee to either succeed or give back the asset to the licensor – without litigation.

The minimum royalty approach can either be combined with "commercially reasonable efforts" diligence standards or replace them. In either case, the advantage is that the payment obligation is clear and objective; either the minimum royalties are paid, or they are not.

Another alternative to consider is objective diligence milestones. If the licensee is required to launch at least one licensed product in at least one country, for example, it will usually be clear whether or not the licensee has complied or is in breach. This approach, too, can be combined with traditional "commercially reasonable efforts" standards, as well as with minimum royalties.

Regardless of whether your company is imposing diligence obligations or complying with them, consider carefully whether they are realistic and clear.

6. Representations And Warranties: Know When To Use A "Knowledge Qualified" Representation.

Representations and warranties are usually grouped together and even intertwined into a single sentence, but they are distinct concepts.5 A factual representation (but not a warranty) can be absolute, or it can be "knowledge qualified" – meaning that the party representing a fact to be true does so only "to its knowledge" or "to the best of its knowledge."

Knowing when to insist on or accept a knowledge-qualified representation is important, because the breach of a representation can give the other party the right to rescind the entire agreement. However, if a representation is knowledge-qualified, any dispute over its breach is likely to require invasive and potentially expensive discovery into what the allegedly breaching party knew at the time the transaction was signed.

One representation that is often knowledge-qualified is a statement that the practice of a particular technology does not (as of the effective date of the agreement) breach any intellectual property right held by a third party. Often this fact cannot be known for certain,

especially if the representation is intended to encompass worldwide rights. As a result, parties who agree to this representation often insert the qualifier "to the best of [licensor's] knowledge."

This may seem like a reasonable compromise, but it can have unforeseen consequences if a dispute later arises over the accuracy of this knowledge-qualified non-infringement representation. Determining whether the licensor breached this representation – i.e., whether the licensor did in fact know that its technology infringed a third party's intellectual property – requires discovery into what facts the licensor knew on or before the date the agreement was signed. Pertinent facts may be contained in opinions obtained from patent counsel, which may be subject to the attorney-client privilege. Unless waived, that privilege can preclude disclosure of the legal opinions to the licensee.

Thus, a seemingly reasonable knowledge-qualified representation presents risks for both parties. For the licensee, who is relying on the representation and will probably have the burden of proof in a dispute, it may be impossible to prove that the licensor knew its technology infringed if the only proof of that knowledge is contained in privileged attorney-client communications. For the licensor, too, there is risk. The licensee may succeed in overcoming the attorney-client privilege and expose not only the licensor's knowledge of infringement, but also other aspects of the legal opinion that may be harmful to the licensor – such as statements that could undermine the licensor's own intellectual property.

While knowledge-qualified representations can be an appropriate and reasonable approach, they carry with them hidden risks if there is a dispute.

7. Indemnity Provisions: Beware Of Unforeseen Consequences.

In most circumstances, if a party breaches an agreement it can be found liable to the non-breaching party for damages. In most instances, it is possible to estimate what those damages might be, or to contractually limit them. Contractual liability limits, however, often do not apply to a party's indemnity obligations, which can be difficult to estimate and virtually unlimited. Consequently, an indemnity claim can destroy a company.

An indemnity obligation requires a party to "hold harmless" the other party from a lawsuit initiated by a third party. One example of this could be a product's liability lawsuit against a licensee that arises from material supplied by the licensor. The licensor may not even be a party to the lawsuit, which might be filed in a country where the licensor has no facilities or personnel, and under local laws with which the licensor has no familiarity. But, if the licensor has agreed to indemnify the licensee, then the licensor is exposed to the possibility of a severe and adverse judgment for which it will be contractually liable.

Because indemnity provisions can trigger damaging and unforeseen obligations (or, from the other point of view, provide critical protection), these provisions – often stuck at the end of a long agreement and potentially overlooked – should be given careful attention and negotiated thoughtfully.

Usually a party will only have indemnity obligations for certain types of lawsuits. By limiting the types of suits that will trigger an indemnity obligation, risk can be reduced. For example, if a party indemnifies for suits arising only from a breach of its representations and warranties, that limitation may preclude indemnity for a products liability case if the product was supplied in compliance with the terms of the agreement.

Though often considered to be boring "boilerplate" provisions, indemnity sections can have devastating consequences.

8. Term Sheets: Negotiate Financial Term Based On Risk Allocation.

Most licensing transactions begin with a term sheet. A term sheet is usually two or three pages outlining the key elements of the transaction, commonly including the licensed intellectual property, exclusivity, territory, diligence obligations, and the financial terms. Consider, however, whether other provisions that materially effect risk allocation – such as representations, warranties and indemnity obligations – should also be outlined at the term sheet stage.

For example, if a licensor is going to be required to represent that its technology does not infringe any other intellectual property and to indemnify the licensee if it is sued for infringement, those provisions could alter the economics of the deal. As noted above, indemnity obligations are often excluded from any liability cap, and can be potentially very costly.

If a licensee insists on being indemnified, a licensor may want to demand higher financial terms that correspond to the likelihood of the licensee being sued. In the case

of licensing a pharmaceutical product that is in early-stage development, a lawsuit is probably more likely to occur only after the product is launched for sale (and probably shortly after product launch). In that circumstance, it may be prudent for a licensor to demand a higher royalty payment, at least in the first year or two when a suit is most likely, while the upfront and milestone payments that occur pre-launch need not be raised.

It is preferable to negotiate all of these key risk allocation and financial terms at the term sheet stage, rather than have a deal fall apart only after considerable time and money has been spent drafting a full, definitive license agreement.

Conclusion

The principles discussed above are only a few of the most important provisions in a license or collaboration agreement. There is no "typical" deal, and each transaction should be analyzed, negotiated and drafted with care.

References

1. Title 35, United States Code § 271(a)
2. United States Constitution, Art. I, Sec. 8.
3. Laws of jurisdictions other than the United States are often different. This article will confine itself to rights under United States patents and U.S. laws.
4. Intellectual Prop. Dev., Inc. v TCI Cablevision of Cal., Inc., 248 F3d 1333, 1345 (Fed. Cir. 2001).
5. A "warranty" is a promise that some fact or circumstance will exist in the future – for example, that a product will be manufactured in compliance with specifications and will not be adulterated or misbranded. A properly drafted "representation," however, concerns a state of facts that exist at the time the agreement is entered into – that the licensor owns the licensed patents, for example. See 3-23 Milgrim on Licensing, §23.00.