

Maximizing The Value Of License Agreements

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Introduction

Biopharmaceutical companies and not-for-profit (academic) research institutions have become increasingly adept at structuring license and related collaboration agreements. Year 2006 was the most active year on record in nearly two decades with 1,615 licensing deals valued at \$42.7 billion (see Figure 1). But there has been a shift in strategy by the large pharmaceutical companies, who continue to lose patent protection on blockbuster products including Lipitor, Plavix, and Seroquel. This has compelled these companies to shift their dealmaking, licensing efforts and dollars to later stage assets to bolster their pipelines.

In recent years, there has been a gradual increase in research collaborations, co-promotion and marketing agreements and royalty monetizations. In fact, these transactions have outpaced licensing deal activity every year over the past three years (see Figure 2). Royalty monetizations in particular have risen sharply in both volume and value with the sector experiencing a 40 percent CAGR (cumulative annual growth rate) from 2001 through 2012.¹

However, the partnering landscape has become more pressured, competitive and complex in terms of deal structure. Life sciences licensing professionals have learned to value, price, and craft

agreements appropriate to their commercial potential and inherent risks (including, proof of clinical relevance, regulatory, competition, intellectual property, and pricing/reimbursement). But licensing professionals, and the attorneys that support them, need to structure agreements that reflect the goals and objectives of the parties involved today and well into the future. In today's market nothing is standard. In fact, it is often boilerplate language or lack of common sense terms that can derail or hinder the use of licensed assets and influence their long-term value. Flexibility, access, clarity and protection are critical when negotiating license agreements.

Building a Valuable Agreement

Flexibility to Share Information

Biopharmaceutical license agreements are increasingly being used to support financing transactions. While confidentiality provisions are standard and customary parts of the agreement, both parties should have the right to share critical pieces of the agreement under confidentiality, with a potential acquirer or investor. This may include license terms, royalty and audit reports. Each is used to assess the underlying value of the intellectual property.

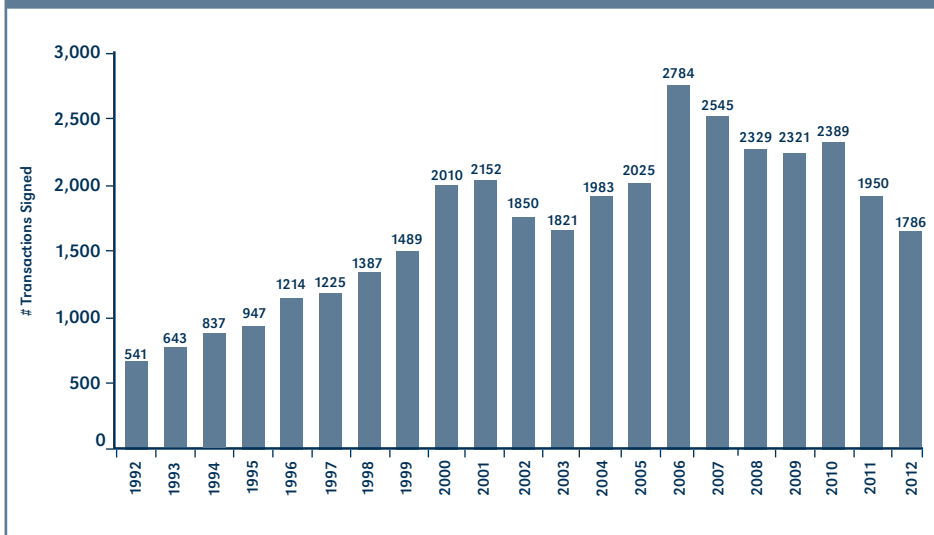
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Figure 1. Biopharmaceutical Licenses Signed—Last Twenty Years



1. HealthCare Royalty Partners.

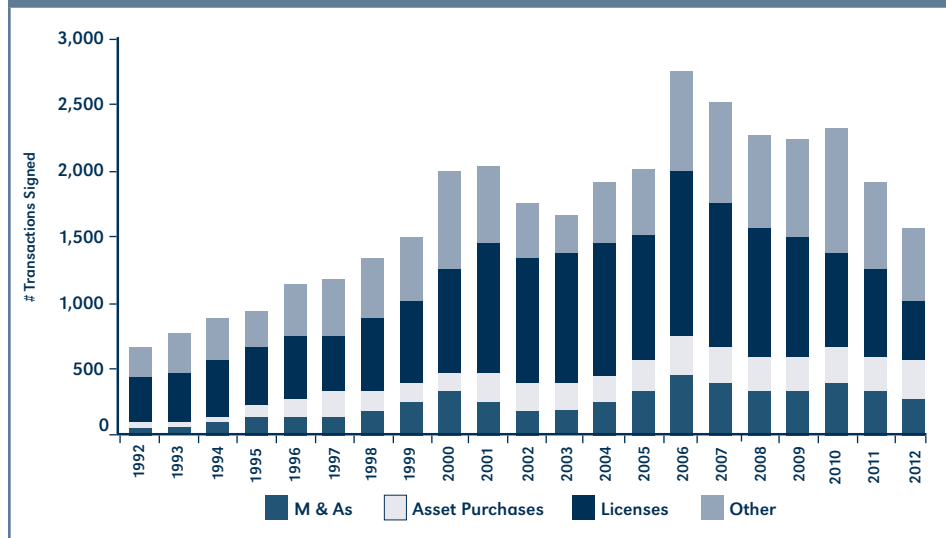
Access to Critical Pieces of Information

A license for commercialized technology is one of a licensor's most important assets. But without access to key pieces of information during the development and commercial stages it is difficult to monitor and ultimately value the license. In the development stage, it is important not only to be able to validate how things are progressing but, at the most basic level, that the product is actually being developed. Once the product is on the market, a licensor should be able to validate the calculation of the royalty rate and estimated payments. Royalty reports by product and geography; audit rights (before and after the first commercial sale) and reports; regulatory information (annual report, 10-K, 10-Q); and license communications will give a licensor the tools to do this and are indispensable parts of a well-crafted license agreement.

For each licensed product, the reports should include:

- The number of licensed products constituting sales;
- Gross consideration invoiced, billed, or received for sales;
- Qualifying costs, listed by category of cost, for the calculation of gross to net sales;
- Net sales;
- Gross amount of any payments and other consideration received by the licensee from sublicensees and the amount of any allowable deductions permitted under the license in terms of sublicense revenue sharing;
- Royalties, fees, and other payments owed to the licensor, listed by category;
- Calculations for any applicable currency conversions;
- A model royalty report (as an appendix or attachment).

Figure 2. Biopharmaceutical Deals By Type—Last Twenty Years



Clarity of Payment Terms & Obligations

Uncertainty reduces the value of any asset. It's the "ifs, and or buts" in license agreements that make it hard to decipher how much money is due and when; what seems clear to those who hammer out the deal can often be confusing years later. At a minimum, the license should clearly specify the royalty rate (including what products are covered by the licensed patent rights), how it is calculated, when it will be paid and for how long. Clarity is critical when assessing how much the asset is worth.

The royalty base definition should anticipate different, relevant situations including:

- Trade channels (*i.e.* will the licensee sell directly, through distributors, and/or trading companies and how will royalties be calculated);
- Product distribution schemes, including *dosage vs. bulk form*;
- Less than arm's length transactions;
- Bundled products (*i.e.* licensed product with other products);
- Combination products with multiple active ingredients.

Royalty Term: It is important to look at not only the patents to be licensed, but the underlying value of what is being transferred as part of the agreement. Leaving the know-how or other components unaccounted for can leave the innovator empty handed

after delivering significant value. Historically, a customary and standard royalty term was “last to expire” of the patent rights. However, in the world of generic competition and biosimilars, it may be no longer appropriate, reasonable, or necessary for licensors to limit the royalty term to the last to expire of the licensed patent rights.

Take for example a license that ties specifically to one cell line. The licensee ultimately changes cell lines but still uses the additional art and know-how transferred as part of the deal. Unless the license requires payment for the “know-how,” the licensor will receive no royalties. By defining the components of the value as broadly as possible, a licensor can maximize the long-term value of the asset.

Royalty Stacking: To preserve the long-term value of the license, licensors should avoid royalty stacking or bundled discounts. The royalty rate (and base) should be a unit or percentage of net sales. If royalty reductions and other discounts are essential, an absolute floor or minimum royalty rate should be specified in the agreement. If the royalty rate was initially set based on the perceived need for additional licenses, stacking language can be incorporated to account for the change. For example, the stacking royalty can be structured to not start until a defined number of additional licenses are executed and paid. The agreement should state that there are no stacking penalties when additional licenses come from affiliates of the licensee or where cross licensing is used. Stacking provisions should also exclude third party licenses that have already been taken by the licensee.

Sublicense Revenue Sharing: License agreements will regularly delineate payments from sublicensees that are considered gross sublicensing revenues (“GSR”). However, there is no customary or standard language for GSR sharing obligations or a set of generally agreed to deductions or exemptions for GSR. This makes it difficult for a licensor to define and justify their valuation expectations for sublicense revenue sharing. Licensors of embryonic technology for example are now allowing for decreased tiers or ratchets of GSR based on how much the licensee has contributed to the value of the product since the agreement was signed. This helps specify and use development milestones and diligence obligations as the basis for tiered or ratchet reductions of the shared GSR percentage in the agreement.

Standard categories of payments that are excluded and/or deducted from GSR, and not eligible for sharing include:

- Royalties paid to licensee, if licensee is obligated to pay licensor a royalty directly (pass-through);
- Amount received to fund or reimburse licensee’s prospective (future) R&D activities;
- Amount received by licensee to fund prospective (future) R&D activities by licensor;
- Amount received for the manufacture and supply of licensed products including licensed products for clinical trials;
- Equity investments in the licensee by a sub-licensee up to the amount of the fair market value of the equity purchased on the date of the investment;
- Loan proceeds paid to the licensee by a sub-licensee in an arm’s length, full recourse debt financing, to the extent that such loan is not forgiven.

Reversion/Termination Rights: While every license agreement is drafted when the parties expect success, a licensor should negotiate a reciprocal right to terminate under certain adverse conditions, including conditions of significant product underperformance. It is also essential to regain all of the rights owned prior to the agreement, such as ownership of the intellectual property, data generated by the licensee (and its affiliates and sublicensees) and regulatory approvals, upon termination of the license.

If the intellectual property is sublicensed or may be sublicensed in the future, the agreement should specify the sublicensees’ rights in the event of termination. This can be accomplished in a few ways. The licensee’s rights to the intellectual property can be granted to the sublicensees or the sublicensees can be provided preferential rights to access the licensed patent rights. As simple example, a licensee is paying a 3 percent royalty and the sublicensee a 6 percent royalty on net sales of the intellectual property. Assignment of the sublicense to the licensor would net the licensor twice the royalty rate on the intellectual property over an assignment of the license to the sublicensee.

Protection of the Intellectual Property

Bankruptcy protection clauses are a critical component of a license agreement. Product liability claims and unanticipated changes in the market can prompt bankruptcy reorganization but the stakes change depending on which party files. Several potential scenarios should be addressed in the license agreement including:

The Licensor Goes Bankrupt

A licensee will typically want the license to continue even if the licensor goes bankrupt. Licensees are generally protected in this scenario assuming there are no anti-assignment right provisions in the agreement on the part of the licensor. They can elect to retain their license rights even if the contract is rejected in bankruptcy court. However, this protection is not available under foreign bankruptcy laws. If the licensor is a non-U.S. entity, the licensee should have the right to terminate either for cause or for the licensor's bankruptcy. The parties should also mutually agree that the intellectual property is subject to Section 365(n) of the Bankruptcy Code.

The Licensee Goes Bankrupt

Patent license agreements are not typically assumed or assigned by a trustee unless the patent owner gives permission. If the licensor's objective is to retain control of the intellectual property, an assignment provision should be incorporated into the agreement which states that the licensee cannot assign the agreement without approval from the licensor. This approval can be qualified with specific language (*i.e.* will not be unreasonably withheld, delayed, or conditioned). The provision can also specify that the licensee is unable to assign the agreement to a competitor of the licensor.

The Licensee Becomes Insolvent

A licensor with a potentially bankrupt licensee may want or need to terminate the license agreement if the licensee becomes insolvent. But with no effective "*ipso facto*" clause, a licensor must rely on other contractual methods to terminate the license agreement prior to bankruptcy. For example, the licensor may be able to terminate the agreement if the licensee pledges its assets used for performance under the agreement; but, only for the benefit of creditors, fails to make timely payments under the agreement, or takes actions that may indicate impending financial difficulty.

Other Legal Considerations

Security Interests

Licensors and licensees can further protect their

intellectual property by using security interests. A security interest can be crafted to include rights that arise under a license agreement including the right to exploit the intellectual property without liability for infringement. For example, a licensor can take a security interest in a license agreement and the proceeds to secure the licensor's interest in the licensee's performance. A licensee can also take a security interest in the licensed patents to secure their right to practice under the patents without infringement.

While a security interest will not guarantee ownership of the intellectual property upon bankruptcy, it may place the party ahead of unsecured creditors. It may also prevent a trustee from assuming and assigning the license to a third party. A licensee with a security interest in the licensed patents may be able to acquire the patents instead of electing to continue under the license.

Ownership Interests and Enforcement Rights

For not-for-profit research institutions in particular, there are two additional legal considerations that must be considered: perfecting their ownership rights in inventions; and structuring agreements in a manner that is consistent with their enforcement activities.

The U.S. Supreme Court recently reminded us that patent ownership vests with inventors.² Not-for-profit research institutions require (by policy and/or contract) that faculty and staff assign work-related inventions to the institution. But affirmative steps are necessary to ensure that all inventors assign their patent rights to their institutional employers at the time they make and disclose their inventions. In cases where investigators are from different laboratories or institutions, not-for-profits may need to take additional action to ensure all inventors affirmatively assign.

Patent enforcement activities vary by institution. Some institutions are directly involved with licensees in times of enforcement litigation while others are involved to the extent required by licensees and the courts. However, even licensors who have assigned all their substantial rights to the licensee, may be required to participate in the litigation process. For further protection, licensors can add in patent enforcement clauses including no right to sue or enforce; ability to enforce depending on actions of exclusive licensees; obligation to join litigation if exclusive licensees seek to enforce; and sole right to enforce.

2. *Stanford Junior Univ. v. Roche Molecular Sys.*, 131 S. Ct. 2188, 2195 (2011)

Conclusion

Dealmaking is an essential element of the biopharmaceutical business model and licensing is critical to product development. The baseline economic terms in these agreements are important in terms of measuring and realizing the value of intellectual property, but it is in negotiating the numerous key terms of the agreement that the full range of value, such as the “know-how” value of the intellectual property, can be exploited. Experience has shown that clarity and at-

tention to licensing terms will ease the due diligence process and simplify future transactions but, most importantly, preserve the intended value of the deal in the myriad circumstances that will inevitably occur following the execution of the agreement. The time to optimize a license agreement is prior to signing, when the only certainty is the inability to predict the future. Attention to these key terms will reduce restrictions on the ability to respond to adverse situations, and will help a licensor better navigate the uncharted waters ahead. ■