Licensing Biotechnology Inventions

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ABSTRACT

After providing an overview of licensing in the field of biotechnology, the chapter carefully examines the key components of a license agreement, particularly in relation to the field's unique concerns. The chapter raises a number of issues that licensors and licensees should consider when negotiating patent license agreements. It offers precise definitions of key terms, points out areas of the agreement that merit special attention (including the relative merits of exclusive and nonexclusive licensing), considers the difficult question of how to determine a patent's value (especially when the patent is being used for screening purposes), and gives much-needed attention to the complexities of confidentiality agreements, especially those involving academic research institutions. To make negotiations easier and more realistic, the incentives for licensors and licensees are discussed, as are some of the finer points of development collaboration. In addition, the author offers some advice about how to define patent misuse, offering some helpful suggestions about what to do should things go bad. The goal of this chapter, however, is to ensure that agreements succeed.

1. BIOTECH LICENSING OVERVIEW

The issues raised in licensing patents are similar to those raised when prosecuting and enforcing biotech patents. In the case of licensing, however, the process is somewhat of an art, and the characteristics of the biotech industry are the artist's tools. No other industry requires so much time and so much money to market a product. Indeed, biotech patent applications typically are filed, and biotech patent licenses typically are executed, well before commercial goals are even in sight. This is particularly true for inventions with important medical applications that involve a drug or a diagnostic that will travel an extraordinarily long road before being manufactured commercially and used clinically. Even for inventions that are not related to medicine, extraordinary amounts of money are likely to change hands long before commercial goals are reached, if they ever are. Often, patent licenses play a key role in the development of biotech inventions.

Indeed, the likelihood of successfully commercializing any medical application embodied in a patent is a battle against the odds. According to an article by Henry Grabowski, professor of economics at Duke University, less than 1% of compounds examined in preclinical studies makes it into human testing, and only 20% of the compounds entering clinical trials survives and gains marketing approval.[1] Thus, less than one-fourth of 1% of newly developed compounds makes it to market. Once the product achieves marketing approval the task does not get much easier. The product will face enormous pressures from competition and will have significant difficulties establishing an infrastructure to manufacture and commercialize the drug product.

This is not to say that a biotech patent license needs to address all of these issues in detail. That would be impossible. These issues are raised to

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suggest some of the ways biotech patent licenses differ from patent licenses in other industries. Moreover, knowing that a biotech invention is unlikely to succeed should heighten the license drafter's sensitivity to the kinds of reasons permitted for terminating the agreement, as well as what the impact of that termination would be. Other industry characteristics that the license drafter should keep in mind include:

- long, costly lead times to market that can result in limited patent life remaining after commercialization
- process of discovery, proof, and development into a product that requires a synergy of complex operations
- very high risks combined with high (often deferred) reward

2. KEY COMPONENTS OF THE LICENSE

Given the inherent complexities, in terms of business and science, of biotech patent licensing, it is easy to forget that a biotech patent license is merely a contract. All of the basic principles of contract law apply. The license drafter must take a step back from business terms and scientific subject matter to consider how the document will stand up to questions of enforceability, breach, and so forth.

A patent license, like other contracts, is enforceable in a legal action seeking either (a) damages for the aggrieved party in an amount corresponding to the benefit of the bargain that was breached; or (b) equitable (injunctive) relief giving the aggrieved party the benefit of its bargain. To withstand the scrutiny that a license will face, particularly if there is legal action for breach of contract or patent infringement, the licensing document should be precise and written in complete, clear sentences without errors in grammar, use, or syntax that could make interpretation difficult. Above all, the license should use terminology consistently (as is true for a patent claim) and avoid using different words for the same thing or using the same word to indicate different things.

Completeness and clarity are important goals, but some ambiguity is unavoidable. The parties need to use good judgment in tolerating ambiguities that cannot be resolved at the contracting stage.

The license document governs the parties' rights over a substantial period of time during which unforeseen events very likely will occur. The license cannot address explicitly all of the possibilities.

During the negotiations, it is important to consider, along with their consequences, events that are unlikely to occur. However, attention to these unlikely events can easily consume a disproportionate amount of time and effort and can sidetrack progress toward agreement on core issues. Thus, care should be taken to devote an amount of attention that is proportional to the potential cost or benefit associated with such an unlikely event. Keep in mind that alternate ways of mitigating the risks may be equally appropriate. For example, excessively negotiating over the division of risks and liabilities, and trying to structure the language of the agreement accordingly, may be less efficient than agreeing on insurance coverage to address those risks. This chapter will review some key components of the license to identify issues that recur during the negotiation and enforcement of biotech patent license rights.

2.1 *Background*

The background section of a license agreement identifies the factual predicates (or basis) for the license, including the parties, the effective date, and the parties' motivations and expectations. Definitions of critical terms may also appear in the background section.

Certain types of problems commonly arise when drafting this section. One type involves the identification of participants. Because corporate structure can be extremely fluid in the biotech industry—companies are acquired and spun off, and they frequently collaborate—and because small companies may have key personnel whose participation in product development is more important than the other assets of the licensee, careful attention must be paid to the identification of the party who is obligated to perform under the contract. The parties would be wise to consider the following questions:

- Does the obligation carry over to *affiliates*?

- Is the term *affiliates* defined in a way that meets expectations about who the other party should be? Does the term include a well-capitalized corporation that can be expected to survive other less well-capitalized affiliates?
- Could a competitor be defined as party to the license through its affiliation with another company that is more directly involved in your negotiation? (For example, does the definition of *parties* include companies that could sell to your customers or to the customers of your affiliates?)
- Should the flow of confidential information be restricted to certain affiliates in the family?
- Is a competitor company a shareholder in the licensor?
- Does a competitor company have a right of refusal in the commercialization of certain technologies or in certain territories based on previous agreements?

Terms such as net sales, net profits, and licensed product will likely appear and need to be defined in the background section. The following list presents a few of those terms and some notes on how they are likely to be treated:

- **Net Sales.** Includes deductions from gross sales before figuring royalty. Typical exclusions from net sales can include transportation costs, returns, bad debt, actual trade, quantity or cash discounts, broker's/agent's commissions, credits or allowances made or given on account of rejects or returns, and so on.
- **Net Profits.** Can be used instead of net sales but can be problematic as a basis for calculating royalty because profit figures can vary tremendously depending on accounting practices.
- **Licensed Product(s)**. Identifies the product(s) whose sales constitute the royalty base. Include(s) any product covered by the licensed patents, or any product made by a method covered by the licensed patents. The scope of licensed products should be limited by field in accordance with the license grant.
- **Licensed Patent.** Usually includes particular patents identified by number. Problems may arise over patents issuing on applications that are continuations, divisionals, foreign counterparts, reissues, reexaminations, and continuations-in-part of known patents. Another issue is whether the license covers all of the licensor's patents that could ever be used in conjunction with the technology of the licensed patent. For example, the licensee may want to license "*all patents covering a licensed product.*" Such a definition is unclear, because the applicability of other licensor patents would depend entirely on what embodiment(s) the licensee chose to practice. For an academic institution with wide-ranging patent positions in many fields, this type of open-ended license is likely to raise problems and should be avoided. An even worse definition would sweep in "*all patents necessary to practice the licensed invention.*" In addition to the problem of not knowing exactly what embodiments the licensee will practice (and therefore not knowing which patents are being licensed), this definition is circular when combined with the standard definition of *licensed products*: products licensed are those covered by the licensed patents, and the licensed patents are those necessary to make, use, or sell the licensed product. Further, this definition is problematic because it implies a license to patents belonging to third parties. Finally, a license to "improvements" can raise problems (see also sections 2.5 and 5. below).

Seemingly innocuous definitions in the background section of the license agreement may decide key issues, including the scope of the license and the nature of the parties.

2.2 *Grant*

The grant section of a license establishes whether the license is exclusive to the licensee or whether others (including the licensor) may practice the invention. The grant section establishes limitations on the grant, such as restrictions on the technical

or commercial fields or on the geographical areas within which the license may be practiced. The grant section may set out rights to sublicense or assign, or it may say that there are no such rights under the license.

The right to allow sublicensing or a prohibition on sublicensing should be explicit, as should be a right to assign or a prohibition on assigning. A party can retain some level of control on future events by using provisions allowing for the assignment of the license only with the consent of that party. The licensor should be aware that withholding the right to sublicense or even to assign does not guarantee that the nature and character of the licensee will remain constant. In one case, a very large player in HIV diagnostics purchased controlling stock in a relatively minor player that had a license under a key patent from a third party licensor, with no right to assign or sublicense. The licensor's intent in making the license personal to the minor company was to avoid competition from a large competitor. By purchasing controlling stock in the small licensee, the large competitor frustrated the licensor's purpose (*Institut Pasteur v. Cambridge Biotech Corp.*).[2]

In certain cases, it may be desirable to allow an assignment of interests without consent when a significant change in control occurs (for example, a merger or acquisition of a party) provided that the surviving entity assumes all of the obligations and benefits of the merged/acquired party. This can be advantageous to a corporate entity considering merger or spinout scenarios because it can simplify such transactions. This may be acceptable when a licensor is more concerned about income and less concerned about who is paying (and getting access to the license) and what future research/development interactions may arise with a partner.

Biotech licenses frequently are limited to specific medical indications, treatment modalities (for example, route of administration) or diagnostic formats (for example, screening versus confirmatory diagnosis). One reason for this might be that the technology is in a very early stage and substantial resources are needed to commercialize the technology, even in one limited field. Many biotech inventions feature basic ideas or technologies that may be used for a number of different medical indications, and the licensor may seek to increase its chances of success by establishing different licensees in different fields, particularly if no one licensee is likely to have the resources or interest to give top priority to all fields. Examples of such basic or *platform* technologies include viral constructs to deliver genes to a patient for gene therapy, diagnostic formats, and methods of screening.

Another reason the parties may prefer to negotiate a license with a limited field of use is to tailor the field of use to the strength of the licensee. Even large pharmaceutical companies generally specialize to some degree in certain medical indications. One may have made a strategic decision to invest in cystic fibrosis therapies; another may favor clotting disorders. A company with ongoing research projects related to both indications may decide to prove the technology in one area first before trying it in a second.

For these and many other good reasons, the licensor may want to license a number of companies exclusively, but in different fields. Some cautions are appropriate. Some biotech patent claims define the invention functionally (for example, by molecular mechanism). While claim language that relies heavily on functional limitations should generally be avoided, if possible, or supplemented with narrower claims that avoid descriptions of events at the molecular level (for reasons explained elsewhere in these materials), such functional language does have a place in patent claims when there is no other way to broadly express the inventive contribution. That does not mean that similar functional expressions are suitable to define license fields. No matter how certain scientists are about the molecular mechanisms, nature has a way of foiling neat pigeonholes. Functional limitations in patent claims can cause problems for patent claim interpretation and validity.[3] When it comes to licensing, functional descriptions in fields of use can be the seeds of a major disaster, in effect granting the same rights to multiple licensees, each of which was thought to have a distinct field. For example, it might seem safe to license a broad patent on administration of substance X exclusively in each of two fields (say, protection

of central nervous system neurons and relaxation of blood vessels) thought to be distinct when the two licenses were executed. Should the data indicate that the substance helps glaucoma patients both by relaxing blood vessels to reduce intraocular pressure and by protecting the retinal ganglion from damage due to hypoxia, then which licensee is authorized to treat glaucoma may become a hot topic of dispute. The point is simply that fields of use typically should be defined according to medical indications so that licensees are less likely to trip over each other.

One problem with licenses limited to treating certain medical indications concerns so-called off-label uses. If the license is limited to a particular one of several uses of a patented drug, the licensee will want to consider procedures that can be put in place in the contract to prevent, or at least limit, the extent of overlapping sales by the products of other licensees. The licensee should also consider ways to avoid a possible charge of infringement if it allows its products to be sold for other uses. Even careful labeling of the drug for use in the licensed field does not ensure that doctors will not prescribe it for off-label uses, or that the product from the licensee will not be used outside the licensee's field.

Licensors may also grant multiple exclusive licenses based on geographic territory. The advantages to the licensor include: having access to multiple research and development partners, (thus tapping additional expertise as well as ameliorating the risk of a single development partner), allowing the selection of a partner with particular sales/marketing expertise in that geographic area, and allowing the selection of a partner with regulatory agency experience in a particular territory.

A note of caution about the decision to grant multiple licenses, whether exclusive in a field or nonexclusive: it is important to establish a financial incentive for at least one party to defend the patent. A licensor who is not prepared or able to spend the money and effort to defend its patent is well advised not to establish a nonexclusive licensing program. Nonexclusive licensees rarely, if ever, have an incentive to defend the patent, which leaves enforcement solely to the licensor. If the licensor lacks the resources, or will be unwilling to enforce the patent for some other reason, its licensing program may stall at the starting gate. Believing the patent will not be enforced, potential licensees may have no incentive to accept fair license terms.

Indeed, situations justifying nonexclusive licenses as a purposeful strategy from the outset (as opposed to a basis for settling legal actions) are rare. One such exceptional situation was a license to a family of the early patents on manipulating genetic material—Stanford University's so-called Cohen/Boyer patents on gene splicing. Stanford sought to make this technology available throughout the industry under nonexclusive licenses. This strategy was highly successful, in part because the license fee was fixed very low, but perhaps also because it was the first of its kind. Companies were willing to accept the first such license, but they soon drew the line and refused to spend money for nonexclusive licenses to later patents from other licensors, complaining that their fragile commercial beginnings would be substantially jeopardized by the multiple royalty burdens imposed by licenses for such broad-based patents. Of course, when dealing with federally funded or co-owned inventions, political considerations may rule out exclusive licensing, even if exclusive licensing represents the best business strategy.

2.3 *Fixed payments, royalties, or both?*

Nearly every license negotiation involves a tradeoff between risks taken for a large sum in the future (for example, getting a percentage of sales) and the more-certain enjoyment of a smaller, upfront sum. This choice is particularly significant in biotechnology, where both the upside potential and the risk are enormous. Licensees may wish to save the upside for themselves and not share it. On the other hand, they face substantial expenditures for commercializing the technology, and they may not want to add to their cash-flow burden in the near term, particularly in view of the low probability that a marketable product will result from the technology. From the licensor's standpoint it may be hard to accept the idea that someone else stands to realize more from developing and commercializing an idea than those who originated it and obtained patents.

Royalties are typically calculated as a percentage of a royalty base (such as net sales). Where the license is exclusive (and therefore the licensor gives up the opportunity to commercialize the invention itself or through other parties) the agreement typically provides minimum annual royalties, or at least reversion to nonexclusivity if a minimum royalty is not paid in a given period of time. The problem with the latter provision is that the licensor can no longer grant an exclusive license to another party, so long as the original licensee retains any license rights. Thus, diligence provisions, coupled with a complete reversion right for failure to meet those provisions, are desirable to ensure that a technology moves through the development stage, either with another partner or alone.

In return for an exclusive license, the licensor should place contractual requirements to ensure that the licensee exerts sufficient efforts to commercialize the invention. In addition to rather vague efforts requirements, such as "reasonable efforts" or similar language, the licensor should consider easily measurable requirements, such as minimum sales amounts or clinical achievement milestones. Conversely, if the licensor requires a minimum annual payment, the licensee may want to specify that the minimum annual fee is in lieu of best (or other) efforts, so the licensee retains the exclusive rights by paying the annual minimum fee, even if it sits on the technology and develops a competing product.

Milestones at which additional fixed payments may be due from the licensee (for example, selection of a clinical candidate, initiation of a clinical trial, completion of a satisfactory clinical trial, and filing of a nondisclosure agreement) provide a convenient middle ground for the risk/reward trade-off. The licensee with commercialization rights should be able to obtain additional financing at that milestone. Moreover, some of the risk of project failure at the clinical-trial stage is shifted to the licensor, justifying higher payments than would have been due at the license signing date. Other common milestones that indicate progress in accordance with the business plan and that are likely to bring funds to the licensee include U.S. Food and Drug Administration (FDA) marketing approval, the execution of an agreement with a marketing partner or some other collaborator, the first commercial sale, and/or the creation of a joint venture.

A common licensee complaint in the biotech field is royalty stacking, which is the need to pay royalties to multiple parties for commercializing a single product. For instance, a pharmaceutical company that screens a combinatorial chemistry library for compounds that bind to and block a particular neuronal receptor might owe royalties to the various owners of patents covering the library, the general screening assay, the isolated receptor, a cDNA encoding the receptor, and an expressed sequence tag (EST) derived from the cDNA (if the EST patent claim is written in open-ended *"comprising"* language). Stanford University met with success in its Cohen/Boyer patent license program, in part because Stanford University was the first with a broad biotech patent. Afterward, biotech companies were heard increasingly to say that they would not pay multiple royalties for a single product.

One compromise on stacking is to permit an offset to royalties up to but not more than some percentage (say, .5%) of the nominal royalty, if the accumulated nominal royalties add up to more than a set percentage of sales. In effect, the licensor is funding one-half of the cost of obtaining licenses under additional patents.

2.4 *Confidentiality*

Depending on the extent to which the parties exchange confidential information and biological materials, confidentiality provisions can be extremely important in the agreement. In some cases, patent protection may be narrowly limited to biological material that is not reproducible, and that alone is important confidential information, at least until the patent issues.[4] In such cases, the applicant may decide to abandon allowed but extremely narrow claims instead of making available the key biological deposits required for those claims to be issued.

Nucleic acid and amino acid sequence information is another type of confidential information. With modern sequencing technologies, however, such information arguably becomes

nonconfidential when materials become available in a form pure enough to sequence easily.

In any confidentiality provision, it is important to spell out how long each type of information and materials remains confidential under the agreement, the disposition of written information and materials when no longer needed, and ownership of inventions made when the recipient makes authorized use of the materials and information internally.

One particularly important implication of confidentiality provisions is that they hinder a party's freedom to look for another partner should the collaboration fail. Having been "contaminated" by the first partner's confidential information, a licensor or licensee may be unattractive to future partners who are risk averse and do not want to have to deal with the possibility of a legal action for "misappropriation" of that information.

One solution is to limit the time period of confidentiality and to provide (in a sort of prenuptial agreement) an understanding that if certain milestones are not reached, the parties may collaborate with others on the same subject matter. Of course, such an understanding does not amount to a license under improvements that one or both parties may have made during the collaboration using confidential information. If the agreement does not specify who owns such improvements, there may need to be inordinate emphasis on murky and contentious ownership and inventorship issues related to improvements that are made after the license is executed.

2.5 *Enforcement against infringers*

As with payment terms, the decision about which party shoulders the burdens and realizes the benefits from enforcing the licensed patent against infringers often involves allocating the risks and rewards of the overall success of the venture. The party standing to make the most money from the operation typically wants (and should have) the right to enforce the patent against infringers. Litigation strategy (particularly settlement) of expensive and protracted patent infringement actions should be guided by proper business incentives and not by an entity on the financial sidelines of the litigation. For example, it is undesirable to have a licensee who can maintain unreasonable positions in patent enforcement litigation when the licensor is paying for the litigation, directly or indirectly (for example, with an offset to royalties that is carried forward to future years when it exceeds current-year royalties due). To the extent that the license provides a total offset to royalties, the licensor is, in effect, partially financing litigation it doesn't control, which is a very frustrating position to be in. Even deferral (as opposed to permanent offset) of guaranteed minimum royalties increases the licensor's risk, because if the patent is struck down or narrowed, those deferred royalties probably will never get paid.

One solution is to allow the licensee commercializing the invention to control litigation and to defer some portion (not all) of the royalties due each year, down to some minimum amount that is due no matter what legal expenses the licensee incurs. The offset ceases when the licensee's legal expenses in a given royalty period fall below a certain level. A variation on this theme allows the licensee to deduct a certain percentage of legal expenses due in a given year. If the total royalties owed in the year are less than the amount of that deduction, the question is whether any legal expenses from that year can be carried forward to reduce royalties in future years. While the fact patterns and license provisions vary tremendously, it is generally a good idea to set up the license so that the licensee will experience at least some significant nonrecoverable legal expenses and thus will have an appropriate economic incentive (litigation cost) to conduct and/or settle the litigation efficiently.

On the other side of the table, the licensor who wants to reduce or eliminate any risk of litigation expense should understand that its valuable patent property is at risk. It may make sense for the licensor to at least partially fund and fully control the litigation, as a strategy for avoiding an inept defense of the patent by the licensee. This is particularly true if the patent represents an important asset for the licensor in the form of income from other sources, such as royalties from other licensees or increased licensor profits due to the licensor's enhanced market position under the patent outside the licensee's field. Moreover, to

give a licensee responsibility to fund and control litigation, with no offset or deferral of royalty payments, may deprive the licensee of the resources and incentive to defend the patent properly.

One important incentive for the licensee is exclusivity under the patent, at least in one important field. In general, only an exclusive licensee has a strong interest in maintaining the patent. A nonexclusive licensee is likely to face competition with or without the patent. Moreover, as far as the nonexclusive licensee is concerned, a royalty is owed so long as the patent is valid, yet the validity of the patent does not give the licensee a significantly better market position. In some cases, the nonexclusive licensee may have a substantial incentive to invalidate the patent, so it is unwise to place such a licensee in control of patent enforcement. Indeed, nonexclusive licensees lack standing to enforce the licensed patent, so even if the parties want the nonexclusive licensee to enforce the patent, the infringement action will probably be brought in the licensor's name (*Ortho Pharmaceutical Corp. v. Genetics Institute*).[5] Moreover, even when the licensee is the enforcing party, the licensor may be a necessary party under the Federal Rules of Civil Procedure, so the accused infringer can force the licensor to be joined in the action.

In sum, when negotiating the terms of patent enforcement, one should keep an eye on the business incentives that are created. Obviously, these questions depend on the context of a given license, such as the relative financial strength of the parties and their relative interest in maintaining the patent.

2.6 *Term and termination*

As with most licenses, the biotechnology license will often have a term that coincides with the patent term. Also, the right to premature termination for material breach typically includes a grace period for correcting the breach after notice.

One common provision is that a bankruptcy filing by either party constitutes termination. It is unlikely, however, that courts will uphold such provisions when the licensee declares bankruptcy under chapter 11. This is because the license is viewed as an executory contract under 11 U.S.C. § 365, with substantial performance remaining due on both sides (*Institut Pasteur v. Cambridge Biotech Corp*).[6] Therefore, the trustee in bankruptcy has the option to assume the rights and obligations under the license.

3. INCENTIVES FOR LICENSING

As with any contract negotiation, it is important to know how the deal will benefit both parties. Without knowing both parties' incentives, it is difficult to negotiate effectively.

Biotech patent owners grant licenses for a number of reasons:

- to trade long-term risk and the possibility of substantial income for the certainty of a, perhaps more modest, short-term payoff
- to obtain development and marketing assistance beyond the owner's abilities
- to obtain clinical development for applications of academic discoveries
- to obtain funding for further research
- to exploit areas that would not be developed in-house by the patent owner
- to enhance reputation in a field by collaborating with a well-known company

In granting licenses, the owner is exposed to several risks:

- adding a competitor if the product is in an area the licensor already exploits
- having to depend on the choice of the licensee to realize the value of the discovery (if the licensee fails, the opportunity may be lost)
- having to share profit in the long run if the invention succeeds
- losing control over information that could be kept secret if development were done in-house

The licensee takes a license for any of several reasons, such as:

- to ensure freedom to use a product line
- to obtain exclusivity for a product line
- to become current quickly without the cost of internal research

- to gain access to technology from a leader
- to gain access to trained personnel

In exchange, of course, the licensee:

- adds to costs and reduces profit margin
- undertakes potential liabilities associated with long-term confidentiality agreements
- undertakes a long-term obligation to share internal financial information with the licensee

Understanding the balance of pros and cons in a given situation is critical for assessing how much the opposite party will be willing to pay and what other terms are critical for them. Not surprisingly, the balance the parties strike will be different in different licensing contexts.

4. DEVELOPMENT COLLABORATION

Usually a great deal of work with uncertain success remains to be done between the time the license is signed and the date that the biotech product reaches the market. Unless that work is carried out entirely by the licensor or handed off entirely to another entity, collaboration will be necessary. The licensor has made the initial discoveries and knows their nature and promise best. The licensee, however, generally is best equipped to develop those discoveries further to the point of marketability. The synergies achieved by combining these disparate strengths are the rationale for the collaboration of licensee and licensor, at least in theory. Such collaborations, however, often raise additional licensing issues.

4.1 *Confidentiality in the context of collaboration*

We have already discussed some of the confidentiality issues raised in nearly all biotech-licensing situations. Where there is a genuine collaboration, in which employees of each company share ideas and information, confidentiality provisions become even more important.

Confidentiality provisions in a collaborative license should address several points. First, they should forbid any use or disclosure of confidential information by the recipient for any purpose other than the furtherance of duties under the collaboration. Second, if each party brings existing expertise (and confidential information) to the collaboration, the agreement should be two way, with each party disclosing and receiving information solely pursuant to confidentiality provisions. Third, it is important not to give either party an excuse to create a confidentiality obligation for information that was never intended to be confidential. To avoid doing so, it helps to identify in the background section of the license agreement the technical expertise of each party and the technical nature of each party's expected contribution. This information may also be helpful for sorting out inventorship.

While the following points apply generally to confidentiality agreements, they take on particular significance when the information at issue is disclosed as part of a long-term mutual exchange of information and skill. In effect, nonemployees are given the type of information and access to information usually reserved for employees. These long-term exchanges make the confidentiality issues extremely important.

4.1.1 *The nature of confidential information*

Put simply, any information that gives a commercial advantage over those not possessing the information can be a trade secret. The authors know of no meaningful distinctions between *trade secret* versus *proprietary* versus *confidential* information. Regardless of the label used, information that is valuable and obtained as part of a confidential relationship is in theory protectable. The ability to recreate information by combining numerous public sources does not necessarily establish that the information was readily available to those outside the confidential relationship. The standard for considering information confidential is not nearly so high as it is for nonobviousness, and analysis akin to a patent obviousness test has no place in determining whether something is confidential. Items of commercial value, such as customer and vendor lists, price lists, and selection of certain specific combinations of steps out of a large number of known alternative ways of approaching each step, may in some cases be

protected. Typical exceptions to confidentiality include information that has been

- published
- independently developed by the recipient of the information (sometimes limited to information developed before receipt of the confidential information)
- independently learned by the recipient from a third party not obligated to the disclosing party
- ordered to be disclosed by a judicial- or regulatory-body process (subject to notice and best efforts to oppose such a process)

It makes sense to put the burden on the recipient of the information for invoking one of these exceptions. They should document the factual basis for the exception and notify the disclosing party before the recipient's disclosure or use of the information. The key is to avoid letting these exceptions become after-the-fact justification for improper disclosure or use.

4.1.2 *Duration of obligation from time of disclosure*

What is, or will be, the value of the lifetime of the information? Information that is about to be published will be confidential for only a short time. On the other hand, biological materials that cannot be duplicated may retain value indefinitely. It is important to be realistic about the length of time, so as not to provide a wide-open opportunity for a dispute on this subject.

Of course, there should be no obligation to maintain confidence for information that has been published or otherwise made public. This principle is easily stated, but not easily applied, because the typical fact pattern does not involve a wholesale publication of all information on a given topic. Instead, the information may dribble out over time in many publications, and a unified knowledge of the entire process, from start to finish, may continue to be valuable business information that is not generally available to competitors or other members of the public without a great deal of work.

4.1.3 *Survival of obligation*

Parties may be bound to maintain confidence for at least some period after the collaboration ends (so long as the information still qualifies as confidential information), and this obligation may affect the parties' ability to work on the subject matter alone or with others. The confidentiality obligation therefore creates a disincentive to terminate the collaboration because the parties' freedom to develop the technology separately is in doubt. This doesn't mean one has to avoid post-collaboration confidentiality obligations. In fact, the client may want such obligations to protect its own information.

4.1.4 *Recordkeeping for confidentiality*

Often the agreement requires the disclosing party to label information as confidential, if that party wishes it to be treated as such. Because of the proof issues raised about the content of the information disclosed, information disclosed orally with no written record before or after the disclosure generally is not treated as confidential. In this situation, the one making oral disclosures of confidential information has the burden of following up with a written disclosure. That procedure may seem unnecessarily cumbersome, but the alternative is to seek protection of orally disclosed information, which entails the burden of proving in detail the nature and full content of the information disclosed (along with the confidentiality of that information). Thus, sound business practice dictates making a record of the disclosure. A requirement to put a legend on the written disclosures is useful, but it should not apply when the nature of the information and the context of the disclosure make clear that the parties' understanding is that the information is confidential.

4.2 *Ownership of inventions resulting from collaboration*

Deciding who owns inventions is the hardest part of any collaboration negotiation. Without a contractual arrangement, ownership will depend on inventorship. Inventorship decisions can be contentious, and the law can be difficult to apply to individual facts. Therefore, consider

avoiding the standard solution, for which each side owns its inventions and joint inventions are jointly owned. One option is to put ownership of all inventions in the field of the collaboration in a single party, with the other party having exclusivity in its field. Alternatively, ownership can be divided by field or geography. The parties' inability to agree on these issues may indicate that they want to keep open their option to compete and that the collaboration is not really a long-term arrangement. The inability to agree on ownership issues may reflect an inability to decide at an early stage about the relative sharing of risk and reward that is implicit in every license. A party may want to share in the ultimate success of the venture, even though the party's near-term contributions (capital plus IP plus commitment to use resources) are not commensurate with the other party's contribution.

Finally, ownership of an invention at the time the invention was made can determine whether commonly owned patents or inventions are prior art under 35 U.S.C. § 102(e), (f) and (g) as those sections are applied through § 103. A well-thought-out collaboration agreement should address ownership in a way that will minimize or avoid serious prior-art problems arising from inventions and patent applications that the parties bring to the collaboration. This issue had been quite a thorn in the side of biotech-patent license drafters for many years. Fortunately, however, with the passage of the Cooperative Research and Technology Enhancement (CREATE) Act in December 2004, the scope of common ownership was expanded. The existence of prior art under 35 U.S.C. § 102(e), (f) and (g) does not preclude patentability where the related inventions were made pursuant to a joint research agreement (in addition to the already existing safe harbors under 35 U.S.C. § 103[c]). New terms in the amendment, such as *joint-research agreement,* are certain to go through some interpretive growing pains. Still, it is interesting to note that the CREATE Act was pushed in large part by the biotech industry. This change recognizes the realities of collaborative practices in the biotech industry.

4.3 *Collaborators' rights to practice and sublicense*

An exclusive license is presumed to prevent even the licensor from practicing the invention. If the licensor intends to practice the invention, even in a narrow field, the license must explicitly reserve or grant that right.

In the United States, each joint owner may practice the invention without authorization from the other owner(s), and the licensor/owner need not account to other owners (35 U.S.C. § 262). In the absence of an agreement, therefore, joint owners can compete with each other. Indeed, a prospective licensee may force the owners to compete each other. Also, by definition, neither joint owner can unilaterally grant an exclusive license, because the other owner and the other owner's licensees are free to practice the invention.

Japan and Europe also permit each owner to practice the invention, but the countries differ from the United States when it comes to licensing. A licensee of a European or Japanese patent position must have authorization from all owners in order to practice the invention. If your business plan calls for licensing overseas, and your co-owner's plan calls for practicing the invention on his or her own, you should obtain the co-owner's agreement that you can license for both parties.

5. LICENSING FROM ACADEMIC INSTITUTIONS

Academic institutions pose special licensing issues. Part of the academic mission is to make worthwhile technology available to the public, particularly medical technology. Of course, money helps to do that, but other factors are equally, if not more, important. The licensee's stability, competence, incentive, and willingness to use its resources, technical expertise, and business skill to achieve this end are critical to the academic licensor's goal of bringing the invention to the public. Another factor in achieving this goal is the relationship between the licensee and the investigator. Cooperation between the parties increases the chances that the licensee will be able to develop clinical applications of the invention.

Many academic research institutions depend heavily on federal government funding. In comparison, licensing revenue is relatively minor. Under the terms of most government research grants, the licensing of inventions made with grant funding is controlled to some degree by the government. The key tool for control is legislation known as the Bayh-Dole Act.[7] The terms of the research grant typically follow that legislation, providing that the recipient of the grant (usually the academic institution as the grantee under the grant) must retain title, so that the government can regain title if certain conditions are not met. These conditions include a requirement that the academic institution or its licensee make reasonable progress toward commercialization of inventions resulting from funded research. Also, the government must have advance notice of the abandonment of patent applications in time to take over ownership and prosecution of those applications. In either case (failure to make progress or abandonment of the application), the government may take over. The government also has a royalty free, paid-up license to practice the invention—for example, to use such medical inventions as vaccines for military personnel.

In addition to the government's residual rights, certain other provisions are generally essential in an academic license. First and foremost, the inventors must retain the right to publish, although the licensee often is given the right to review manuscripts to identify potential inventions prior to submission or publication of the manuscript. In addition, the academic institution will require indemnification and insurance covering legal actions (for example, workers' compensation, commercial general liability, umbrella liability, product liability, or personal injury) growing out of development activities, sometimes naming the licensor as an insured party. There should, however, be flexibility in the insurance requirements depending on local regulations and customary business practices in the territory.

Many academic inventions are early stage and based on work that will be or has been published. Thus, confidential information generally is not a long-term asset. In an academic context, the value of the license to the licensee lies in the patents, and the value of the patents depends on:

- the likelihood of getting broad coverage from early-stage patent applications that will dominate later improvements
- the likelihood of getting patents on narrow improvements after the original work has been published
- recognition that the licensee is free to use unpatented, published work without a license
- the licensee's ability to obtain an option to license improvements under reasonable terms

6. PATENT MISUSE

Patent misuse is a defense to patent infringement. In asserting this defense, the accused infringer takes the position that the patent owner has misused its government-granted monopoly, thereby forfeiting the right to enforce that monopoly in a patent infringement action (*C.R. Bard, Inc. v. M3 Systems, Inc.*[8]). A body of case law has evolved to address the application of this doctrine to patent licensing practices, and in 1988, the Patent Misuse Reform Act[9] was enacted to amend 35 U.S.C. § 271 (d) regarding certain aspects of patent misuse.

Unenforceability due to misuse does not call into question the inventor's entitlement to a patent under the provisions of 35 U.S.C. It is distinguished from a defense of invalidity, which would require proof that the U.S. Patent and Trademark Office (PTO) was not empowered to grant the patent because the invention application did not meet the statutory requirements for patentability.

Most often, resolution of misuse issues involves a balancing of the inherent tension between patent law and antitrust law. To establish a claim of patent misuse, it must be shown that the patent owner misused its government-granted right, or in other words, used the patent to improperly extend its power in the marketplace. Patent-misuse analysis is acknowledged to be somewhat convoluted, due in part to its close interplay with antitrust analysis, which makes it susceptible to

contemporary societal/regulatory pressures at the moment of analysis, and also in that often such analyses are particularly fact specific, leading to narrowly applicable analyses. Historically, certain activities were considered *per se* patent misuse. Other activities, such as those governed by 35 U.S.C. § 271(d), were evaluated under a "rule of reason" analysis similar to that in antitrust analysis. (*Virginia Panel Corp. v. MacPanel Co*.[10]).

It is now abundantly clear that the mere existence of a patent right does not establish market power in the antitrust sense and that certain licensing provisions that were once thought to unfairly extend the patent monopoly do not constitute patent misuse, per se. Rather, the courts require a factual analysis (a rule of reason) of whether the patent owner possessed market power, and the patent is simply one factor in that analysis. The Supreme Court dealt with an allegation that a patentee misused its patent by tying sales of a patented printhead and ink container to sales of unpatented ink in *Illinois Tool Works, Inc. et al. v. Independent Ink, Inc.*[11] The court held that a patent does not necessarily confer market power upon the patentee in every case involving a tying arrangement. The plaintiff seeking a finding of illegal tying and monopolization in violation of the Sherman Act must prove that the patentee has market power in the tying product.

The United States Court of Appeals for the Federal Circuit relied on the *Illinois Tool Works* decision when it recently held that various Monsanto marketing practices for sales of seeds resistant to its Roundup® pesticide did not constitute patent misuse (*Monsanto Co. v. Scruggs et al.*[12]). The facts in that case involved a complex marketing scheme that included flexibility to react to FDA approval of competitive products.

CSU, LLC, et al. v. Xerox Corporation[13] raised the basic issue of whether a refusal to license is anticompetitive activity under § 2 of the Sherman Act (15 U.S.C. § 2). CSU brought an antitrust action charging that Xerox had engaged in anticompetitive behavior when it tried to monopolize markets for sales and service of Xerox high-volume copiers and printers. Xerox counterclaimed for patent infringement, and CSU raised a misuse defense. The Kansas District Court denied Xerox's motions for summary judgment, in part based on the conclusion that CSU may have a valid defense of misuse (*In re Indep. Serv. Orgs. Antitrust Litig.*[14] and *In re Indep. Serv. Orgs. Antitrust Litig.*[15]). The Federal Circuit, however, ultimately supported the notion that although a patentee's right to exclude is not without limits, a unilateral refusal to sell or license a patent does not exceed the scope of the patent grant and does not rise to patent misuse (*CSU LLC, et al. v. Xerox*[16]).

A per se rule on whether refusal to license always (or never) amounts to misuse seems unlikely. Such a rule would eviscerate the patent system and exceed judicial authority to compel patent owners to license in all situations. On the other hand, it seems artificial to ignore a patent owner's licensing activities (or lack of them) when viewing the overall picture of monopolization. The practitioner is left to exercise judgment in the vast middle ground.

One interesting aspect of the CSU case involves the accused monopolist's state of mind (*"intent"*). In concluding that it must take evidence on the misuse issue, the Kansas District Court expressly declined to follow the Federal Circuit's subjective intent standard for evaluating misuse. The Kansas District Court also refused to adopt a per se rule on the ground that refusal to license violates the Sherman Act. This trend away from per se rules has been going on for a long time (*Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*[17]).

Another example of potential patent misuse is a license requiring royalty payments after expiration of the patent of the licensed technology. Case law that has not been explicitly overruled holds that such license agreements are illegal and unenforceable and are per se misuse (*Brulotte v. Thys Co.*[18]; *Scheiber v. Dolby Laboratories, Inc*.[19]). Conditioning a license grant upon the payment of royalties on unpatented products has also been found to be a per se wrong (*Zenith Radio Corp. v. Hazeltine Research, Inc*.[20]). Another example is charging royalties twice (*PSC v. Symbol Tech.*[21]). This example was analyzed under a rule-of-reason analysis. It is open to question whether any

such license arrangement will be misuse, per se (that is, without an analysis of market power).

A federal district court addressed the issue of whether a license requiring reach through royalties to products (for example, drugs), discovered using patented screening tools, constitutes patent misuse in *Bayer A.G. v. Housey Pharmaceuticals, Inc.*,[22] affirmed on other grounds,[23] further proceedings on other grounds,[24] affirmed by the Court of Appeals of the Federal Circuit.[25] Bayer first alleged that misuse arose because the license contemplated royalties on products and activities not covered in the licensed patents by claims relating to screening. As Housey offered alternative compensation structures to licensees, for example, lum-sum payment, royalty based on discovered-product sales, or royalty based on licensee's total R&D expenditure (the selection of which was explicitly stated in the agreement as the "most appropriate" and "convenient" approach), the district court found that Housey did not "condition" the license on products/activities outside the patent, and therefore there was no misuse. Bayer next alleged that misuse arose because the agreement imposed a requirement of royalty payments beyond the term of the patent, which was a per se misuse under Brulotte. The district court, also finding no misuse by Housey on this issue, held that collection of royalties after expiration of a patent was not per se misuse. The district court reasoned that a patentee can charge a royalty for practicing an invention prior to the expiration of the patent covering the invention and that payment for such can be postponed beyond the expiration date of that patent. Whether the payment is for pre- versus post-patent expiration use appeared to be determinative to the district court. Thus, agreement language explicitly delineating that payment is "time-shifted" for the convenience of the parties, and is not for post-patent expiration use, seems to be an important factor in this district court's analysis of patent misuse.

In sum, it remains risky for a patentee that has external (nonpatent) market power to engage in the above licensing practices, but it is likely that the rule-of-reason analysis will be required to find misuse.

7. SPONSORED RESEARCH

Sponsored research, for example, at an academic institution, should not be viewed as a typical collaboration but as a special case. The sponsor will nearly always want exclusivity over the fruits of the research, regardless of inventorship. Also, disputes about confidential information may arise should the sponsor want to establish a competitive advantage by maintaining confidence, at least until a patent application is filed, and maybe for some time thereafter. The researcher will want freedom to obtain future funding from others, given that current funding will be limited in amount and duration. If the researcher is an academic, he or she will want the freedom to publish without interference, though he or she may be willing to delay publication for a short period to give the sponsor an opportunity to prepare and file a patent application. In a highly competitive field, however, even a month can give another laboratory a chance to scoop the researcher in print. The researcher is unlikely to cede any control over the content of his or her publication, with the exception of information that originated with the sponsor.

The extent to which the issues discussed above will present serious problems for any given sponsored research arrangement depends on specific circumstances, particularly the extent and duration of the funding. A researcher whose entire operation is funded to a substantial extent by a single sponsor obviously will have fewer problems with such issues as the right to collaborate with other companies. Ideally, a sponsor desires a representation and warrant from the researcher that no confidential information of a third party or proprietary material or process of a third party is utilized in the sponsored research. In reality, particularly with the multiple funding scenarios from both institutional and government sources, such representation and warrants cannot be made.

Maintaining the confidentiality of sponsors' confidential information can also be a challenge. Some institutions may not allow some of their researchers to be a party to confidentiality agreements. In such instances, it is necessary to identify the specific researchers (in addition to the principal investigator) and what their exposure

to confidential information will likely be. Mechanisms for protecting information should be carefully considered. Representations and warrants that the materials will not be used other than as agreed and that the materials will specifically not be analyzed or reverse engineered, may also be appropriate.

One common problem when drafting a sponsored research agreement in an academic setting is the "mobility of funding" culture. Typically, a principal investigator has the freedom to move his or her operation, funding and all, to another institution. If the sponsor wants to remain with a particular investigator should the investigator move from one institution to another, the agreement must be clear on this point. Otherwise, if the principal investigator moves, the sponsor could be left in the position of being obligated to fund other researchers at the original institution. One solution is to clearly state that the sponsor's funding obligation terminates if certain named individuals (usually just the principal investigator and perhaps one or two others) cease employment. The sponsor then has the freedom to decide whether to continue funding the project elsewhere.

Another problem arises from the culture of authorship and even ownership of technology as discretionary privileges to be controlled by the principal investigator. It is common for a principal investigator to assume that he or she has the right to determine the inventorship and content of a patent application, just as he or she has the power to control content and authorship of journal publications. Obviously, these decisions must instead be controlled by inventorship law, patent prosecution strategy, and the sponsored research contract. For these reasons, the sponsor may want to control the prosecution of patent applications arising from the research.

A similar problem arises from multiple grants for a single laboratory. Investigators are used to deciding to some degree how grant funds will be allocated among a number of projects. Here again, the agreement should contain a carefully drafted statement of the work and the field of the research, coupled with clear entitlement to exclusivity in the investigator's work in the field.

8. LICENSING TOOLS FOR DRUG SCREENING AND DEVELOPMENT

Even biotech discoveries that are too fundamental to support a patent claiming a clinical therapeutic or diagnostic use may support a patent on screening. Driven by the rapid increase in knowledge about molecular (including DNA) bases for diseases, coupled with automated equipment for synthesis, screening, and analysis, the interest in rational drug design and screening has exploded. Indeed, licensing inventions featuring drug screening and development are all the rage.

8.1 *The computer software component*

The computer software developed in connection with rational drug design and screening can be protected by patent, copyright, and/or trade secret. The particular form of protection will depend upon the ability to reverse engineer the software, and/or the effect upon the company of making the software public, as will happen in connection with patent protection. No matter what form(s) of protection are selected, the license agreement will include several elements that are unique to the software environment.

For example, various limitations upon the use of the software, and the availability of the software (in source code or object code form) need be addressed. Further, will the licensee, if he or she is able to obtain source code, be permitted to modify and improve the software, and if so, which of the improvements, if any, will flow back to the licensor? Will the use of the software be limited to a particular database, CPU, physical location, number of users, simultaneous users, and/or application?

If the license is for object code only, will the licensee insist, as well he or she might, that the source code be placed in escrow in case computer software bugs develop that are not corrected by the licensor? (The nature of the escrow agreement, and who shall hold the escrow, is typically the subject of yet another agreement.)

If software is provided, will it be subject to a maintenance agreement, that is, an agreement by which the licensor submits to providing improvements, fixing problems if they develop in the software code, and in return receiving an annual

maintenance fee? If maintenance is provided but not taken by the licensee, will the licensor disclaim all responsibility for operation of the software after a fixed period of time, for example, one year?

If the software being provided is experimental software and there is a software bug, the licensor will likely limit his or her liability to either a return of any monies paid or to using reasonable efforts to correct the code. On the other hand, most academic institutions provide software code "as is," without any obligation on the institution's part to provide any further help. (As a result, there is often a consulting arrangement with the developer of the code to aid in fixing problems or improving the code, if improvements are allowed under the license agreement.)

One should also consider the distinction between providing the software code, the technology, and the license to develop similar functionality under a patent license. With respect to the latter, no technology may be transferred at all, only the license to use the technology as covered by the patent claims. The provision of technology invokes many of the elements noted above with regard to protecting the technology being transferred.

8.2 *Controlling the reagents used to screen*

The reagents used for screening typically are protectable trade secrets. For example, monoclonal antibodies, specific peptide fragments or DNA fragments, and cellular components that are used in a screen may not be publicly known or available. When licensing others to perform the screen, the agreement should be clear that the license is limited (for example, in time or in the number of compounds that can be screened) and that the materials are to be returned when that license has run out. At least, the license should provide (as do software licenses) that the reagents can only be used in limited ways (for example, on the premises in certain types of screen formats) and can be duplicated only to provide a secure backup in case the primary reagent is lost or damaged. The reagents (or their derivatives) should not be duplicated and used in additional screens at other sites or by other companies. In cases where the PTO is unlikely to grant broad protection, this type of contractual protection may be the only meaningful protection available.

8.3 *Valuation of screening patents*

Assessing the value of screening patents poses special issues. Because screening patents specifically focus on research activities and do not cover commercial products or manufacturing processes, and, indeed, by their nature are practiced before any product is identified—much less ready to market—traditional valuation techniques (discounted stream of sales over time) may be inappropriate.

One way to evaluate screening patents is to estimate the amount of research expense saved by licensing the screen from outside rather than engaging in an in-house project. Another way is to consider the screen in view of its proportion to the total R&D budget or to the appropriate program or screening budget. As discussed below, however, other factors come into play.

8.3.1 *Concerns about screening preissuance*

Since in the United States there can be no infringement until the patent issues, screening preissuance cannot give rise to damages absent an issued patent having claims covering the screening.[26] However, the American Inventors Protection Act[27] provides provisional rights. If the application is published, a resulting patent will include the right to a reasonable royalty for the period between the date of publication and the date of grant, if: (1) notice of the published application is provided, and (2) the patent claims are substantially identical to the claims of the published application. Given the ordinary course of at least two years pendency for biotech patent applications, the potential licensee should evaluate the likely duration of its screening project to determine how long, if at all, screening will continue after patent issuance.

8.3.2 *Damages for unlicensed use*

For screening that is likely to be conducted after issuance, the question remains of how much to pay for a license. Of course, the licensor would like to have a percentage of sales of drugs discovered

using the screen, but there is no reason to believe that measure is common in the industry, or that it would be used by a court in fixing "reasonable" royalty damages for infringement. More typically, screening assays will produce a royalty based on the length and intensity of use and the noninfringing alternative screens available. Thus, a screen used occasionally to confirm results of a noninfringing screen would be compensated at a much lower rate than a screen so well accepted that it is effectively required to get approval for human clinical trials.

Finally, use of a screen to generate data for submission to the FDA may not constitute infringement at all. It may be difficult for many reasons to obtain suitable value when licensing screening technologies.

8.3.3 *Compositions used for screening*

In general, licenses of patents covering compositions used for screening are subject to the same considerations as those discussed above. To take into account the situation in which the reagents may have some other, more valuable use, the license should restrict use of the reagents to screening (for example, as a field of use) and should explicitly exclude clinical uses.

9. CONCLUSION

Licensing of biotech inventions requires special considerations and specialized license drafting with clear provisions that unambiguously detail the obligations of the licensors and licensees. In large part, this attention is needed because of the nature of biotech inventions and the risks and uncertainty that are integral to the biotech business. For example, development of an invention into a product requires a synergy of complex operations. Hence, the biotech invention may be unlikely to succeed, or may entail long, costly lead times to market, resulting in limited patent life remaining after commercialization. Such high risks are combined with high (often deferred) rewards. Therefore, licenses are structured to reflect this risk/reward reality of the biotech business. Key considerations include: fees and royalties, royalty stack ceilings, fields of use, setting milestones, mergers and acquisitions, exclusivity of licenses, patent maintenance, patent enforcement, confidentiality, patent misuse, and issues relating to collaborations. Notwithstanding this rather daunting list of considerations, there are many incentives that drive successful licensing of biotech inventions.

For the ***licensor***, incentives include obtaining:

- development and marketing assistance beyond the owner's abilities
- clinical development for applications of academic discoveries
- funding for further research
- assistance in areas that would otherwise not be developed

For the ***licensee***, incentives include:

- ensuring freedom to use a product line
- obtaining exclusivity for a product line
- becoming current quickly without the cost of internal research
- gaining access to technology from a leader and accessing or developing trained personnel

Hence, by balancing the inherent risks and potential rewards, properly structured biotech licenses serve to coherently actualize the incentives of licensors and licensees, such that all parties are winners, and biotech R&D advances toward commercialization for the benefit of all. ■

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1 Gradowski H. 2002. Patents, Innovation and Access to New Pharmaceuticals, July. *J. Int. Econ. Law* 5(4):849-860.

2 104 F.3d 489 (1st Cir. 1987)

3 See also, in this *Handbook*, chapter 4.2 by C Nottenburg.

4 If those in the art cannot duplicate the material based on a written description and public starting materials, then patent law requires that the material be deposited with a public depository. Absent publication of a foreign patent or issuance of the U.S. patent, however, this deposited material is probably not available to the public, and it remains valuable confidential information.

5 52 F.3d 1026, 34 USPQ2d 1444 (Fed. Cir. 1995).

6 104 F.3d 489, 41 USPQ2d 1503 (1st Cir. 1987).

7 PL96-517 (1980); see 35 U.S.C. § 200 and following.

8 157 F.3d 1340, 1372 (Fed. Cir. 1998).

9 (PL 100-73, 102 Stat. 4674 (H.R. 4972).

10 133 F.3d 860 (Fed. Cir 1997).

11 126 S. Ct. 1281, 547 (US ____ 2006).

12 (Fed Cir. Slip op., August 16, 2006; 01-1532; 05-1120; 05-1121).

13 203 F.3d 1322 (Fed. Cir. 2000).

14 964 F. Supp. 1454 (D. Kan. 1997).

15 964 F. Supp. 1469 (D. Kan. 1997).

16 203 F.3d 1322, 1328 (Fed. Cir. 2000).

17 114 F.3d 1547, 42 USPQ 2d 1737 (Fed. Cir. 1997).

18 379 U.S. 29 (1964).

19 63 USPQ 2d 1404 (7th Cir. 2002).

20 395 U.S. 100 (1969).

21 26 F. Supp. 2d 505 (WDNY1998).

22 228 F. Supp. 2d 467 (D. Del. 2002).

23 340 F.3d 1367 (Fed. Cir. 2003).

24 386 F. Supp. 2d. 578, 582 (D. Del. 2005).

25 (Fed. Cir., August 4, 2006) (Slip op.)

26 We ignore for the moment the question of whether use of a screen patented in the United States to identify a compound renders the importation or use of the compound in the United States infringement of the screening patent under 35 U.S.C. § 271(g).

27 PL 106-113. Enacted 29 November 1999.