PRACTICAL LAW

Key Negotiating Points in Academic IP Licenses

by David M. McIntosh, Melissa S. Rones, and Sameer Desai, Ropes & Gray LLP, with Practical Law Intellectual Property & Technology

Status: Law stated as of 30 Dec 2022 | Jurisdiction: United States

This document is published by Practical Law and can be found at: **us.practicallaw.tr.com/w-037-7643** Request a free trial and demonstration at: **us.practicallaw.tr.com/practical-law**

An Article discussing issues unique to intellectual property (IP) license negotiations with universities and other academic research institutions. It outlines potential solutions for commercial entities seeking to license IP from academic institutions.

A license under intellectual property (IP) developed at an academic institution can be among a company's most critical assets. Since the passage of the Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-212 (Bayh-Dole Act), licensing of IP discovered in academic research labs has produced more than 11,000 new startup companies, more than 4.2 million jobs, and more than \$1.3 trillion in U.S. economic growth (see Gabrielle Athanasia, The Legacy of Bayh-Dole's Success on U.S. Global Competitiveness Today (2022)). The Bayh-Dole Act allows academic institutions to retain title to and license inventions arising from federally sponsored research. However, the Act's restrictions on institutions, the institution's academic, non-profit mission, and each institution's incentives and interests often create unique licensing structures that may seem off-market to lawyers more familiar with negotiating IP license agreements with commercial entities.

Unlike commercial companies, most academic institutions face legal constraints and obligations under both the Bayh-Dole Act as the recipient of government grant funding and tax regulations that pertain to their non-profit status and their use of tax-exempt bonds to finance their facilities' construction. They also generally have an interest in expanding the public's access to knowledge and information and fostering broad use of university research results. To further this, academic institutions generally seek to establish a balance between financial interests, the public good, and academic research, both at their own institution and more broadly.

This Article describes issues for licensees that are unique to academic licensing and potential solutions that lawyers representing commercial licensees may propose to address those issues for the benefit of their licensee client. It is written from the licensee's perspective, and although it presents approaches some academic licensors

may find acceptable in some contexts, each transaction is different, and each institution has different concerns and approaches to the various issues.

While the approaches and solutions this Article suggests may help bridge the gap for some issues and in some negotiations, any particular academic technology transfer office may not consider them market or standard. However, they are approaches that the authors, based on their decades of experience, believe may be acceptable to some academic institutions in the right context and so may be worth exploring in negotiations.

For a sample academic license agreement drafted with licensee-favorable terms, see Standard Document, Patent License Agreement (University Licensor, Pro-Licensee).

License Grant

License Scope

IP and technology licensed under academic license agreements typically include:

- Inventions covered by patents or patent applications (see Licensed Patents).
- Related technical information (see Licensed Know-How).
- · Tangible research materials (see Materials).

The license grant is generally limited in scope to certain licensed products or processes (see Licensed Products).

Licensed Patents

Universities usually seek to define Licensed Patents tightly to avoid disputes regarding the licensed IP's scope. Most typically, the term Licensed Patents refers to a schedule



of patents, patent applications, and invention disclosures (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Licensed Patents). With this structure, the licensee should ensure that the definition captures all patent rights that share common priority with the identified patent applications and patents.

Where a license agreement results from an earlier sponsored research agreement, the licensee also wants to ensure that the Licensed Patents definition captures all inventions that were made in the course of the sponsored research that the licensee funded.

Licensed Know-How

A licensee should seek to ensure that the Licensed Know-How definition:

- Clearly references any important technical information, perhaps by reference to a list on a schedule to the agreement.
- Captures any other non-public information developed at the academic institution:
 - under the inventor's direction; and
 - necessary for the practice of the licensed patents or licensed products' development, manufacture, or commercialization.

(See, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Licensed Know-How.)

Academic licensors are often willing to be more liberal with the Licensed Know-How definition than they are with the Licensed Patents definition because they typically insist that the license granted under licensed know-how be non-exclusive (see Exclusivity). As with licensed patents, however, it is likely that the academic licensor wants to limit the definition to know-how existing as of the agreement's effective date to avoid sweeping in improvements (see Improvements).

Materials

Universities may seek to define Materials being licensed as both:

- Those materials the academic licensor provided to the licensee (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Materials).
- Derivatives or modifications of those materials the licensee creates.

This may be entirely fair where the tangible materials are valuable and the parties anticipate that the licensee needs them for use in the licensed products. However, the licensee should consider whether the license agreement's economic terms should be adjusted if the licensed products make use of derivative materials but do not infringe any of the licensor's licensed patents.

Licensed Products

Licensees should be aware of definitions of royalty-bearing Licensed Products that define this term by reference to Licensed Know-How instead of only by reference to Licensed Patents and Materials. Doing so can significantly expand the scope of royalty-bearing products in a manner that may subject a larger universe of products to payment obligations. This is particularly true in a situation where an unpatented product constitutes a licensed product because it uses (or was developed using) licensed know-how that has since been published or otherwise becomes widely known.

Licensees should also watch for circularity in this definition and the Licensed Patents definition. It is not unusual to see Licensed Products defined as any product that is covered by a Licensed Patent and Licensed Patents defined as all patent rights that cover a Licensed Product, leaving both definitions ambiguous.

Exclusivity

Academic license agreements may include both an exclusive license under licensed patents and non-exclusive license under licensed know-how. If tangible research materials are licensed, academic licensors sometimes grant an exclusive license, but it is usually a negotiated, case-specific point.

Outside specific contexts where the parties consider licensed know-how to have a great deal of commercial value relative to the licensed patents, academic licensors often balk at granting exclusive know-how licenses. This is because protecting the secrecy of information can be seen as contrary to their mission as an academic research center, where researchers both within the academic licensor and across institutions typically freely share information. Because of this, academic licensors often feel that granting an exclusive know-how license is extremely challenging.

Licensed tangible materials are usually easier to control than intangible know-how. Academic licensors therefore are often more willing to consider granting exclusive licenses with respect to materials, often subject to certain reserved rights (see University Reservation of Rights).

Sublicenses

Permitted Sublicensing

A commercial licensee usually wants to include language that permits it to grant sublicenses through multiple tiers, without obtaining the academic licensor's prior consent. Academic licensors often want to have consent rights (perhaps not unreasonably withheld) to assure that the sublicensee is a reputable party with the capability to pursue the research and satisfactorily commercialize and make public the research. Academic licensors sometimes do yield here, subject to requirements that the sublicense include certain minimum terms designed to insulate the licensor from liability and give it visibility into the sublicensee's activities, but this can often be a point of contention. However, often academic licensors remain steadfastly unwilling to permit sublicensing to a sublicensee sight unseen, regardless of the contractual provisions binding the sublicensee.

Where this issue persists, another solution may be to define a category of sublicenses that do not require licensor approval (such as sublicenses to service providers and sublicenses to companies of a certain size or type).

Mandatory Sublicensing

It may come as a surprise to lawyers unfamiliar with academic licensing, but a mandatory sublicensing provision is not uncommon (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 2.2(b)). Mandatory sublicensing serves the academic licensor's mission to make its technology available for the public benefit to the greatest extent possible, which includes unmet market needs, such as underserved geographies, populations, and indications.

If the provision cannot be stricken entirely, a commercial licensee's best approach may be to try to limit its scope to:

- Require any third party seeking a sublicense to negotiate directly with the licensee.
- Avoid or limit the scenarios under which the academic licensor can directly license any third party in the licensee's field.

University Reservation of Rights

An academic licensor typically insists on reserving the right to practice and use the licensed patents for non-commercial academic research and educational purposes (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 2.3). A licensee may seek to clarify that non-commercial research does not include research sponsored by for-profit companies, but often academic institutions do not agree to this limitation.

Government Rights

Where a US government grant funded the research leading to a licensed invention, the academic licensor is required by statute to reserve rights for the US government (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 2.4).

The US government also imposes certain requirements on inventions resulting from federally funded research and development, including that any exclusive licensee substantially manufacture in the US all products embodying or produced by using the invention for sale in the US (35 U.S.C. § 209(b)). To the extent that manufacture outside of the US is important to the licensee, the licensee may seek to add language requiring the academic licensor to seek a waiver to the domestic manufacturing requirement at the licensee's request.

Improvements

Licensees often seek to have the licensed patents and licensed know-how include improvements of the inventions claimed by the licensed patents that may be made at the academic institution after the parties sign the license agreement.

Although this is a common feature in commercial licenses, it can be a vexing request for academic institutions for many reasons, including that:

- Granting a license to all improvements to licensed technology made at the academic institution encumbers potential future inventions made by the academic institution's faculty therefore impeding their ability to attract new funding and stifling their ability to conduct new research, contrary to the academic licensor's mission.
- As non-profits, academic institutions must receive fair value for property granted to for-profit organizations, often limiting the ability for academic licensors to grant rights under future improvements for no additional consideration.

For these reasons, a licensee is likely to find obtaining a broad license to future improvements unobtainable. Nonetheless, a licensee may consider proposing one of the following more limited alternate approaches.

Narrow Definition of Improvements

A licensee may seek to limit the improvements definition to inventions made:

- By or under the supervision of the principal investigator who is the inventor of the licensed patents. This avoids encumbering other faculty members.
- Within a certain limited number of years after the license agreement's effective date. This avoids a perpetual encumbrance on the principal investigator.

The definition may be further limited to inventions that either:

- Are dominated by the existing licensed patents, that is, inventions that cannot be practiced without infringing the agreement's licensed patents.
- Claim the composition, manufacture, or use of existing materials, if any.

Narrowing the definition in this way may allow the academic licensor to conclude that the improvements do not have any independent value and therefore it can license the improvements without seeking any additional economic consideration.

Option to License Improvements

A licensee may seek an option to negotiate for a license of improvements, either in the license agreement itself or in parallel under another agreement (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 3).

A licensee often can enter into a sponsored research agreement with the academic licensor at the same time as the license agreement under which the licensee obtains an option to negotiate an exclusive license under any resulting inventions. For a sample sponsored research agreement, see Standard Document, Sponsored Research Agreement (Pro-Sponsoring Party).

If it exercises the option, the licensee may seek to amend the existing license agreement to incorporate the new inventions, perhaps for some additional upfront consideration, but without stacking royalties or milestone payments.

Diligence Obligations

In commercial licenses, often the only diligence requirement a licensee may have is to use commercially reasonable efforts (typically a defined term) to bring a licensed product to the market. In contrast, to honor their

obligation to see their technologies made available to the public, academic licensors often require a series of rigorous diligence milestones that a licensee must achieve to avoid creating a right for the academic licensor to either terminate the license or make it non-exclusive. Given the stakes, the parties typically heavily negotiate these diligence milestones.

To mitigate the risk of termination or loss of exclusivity posed by an academic licensor's proposed diligence milestones, a licensee may try one or more of the following strategies:

- Express the licensee's obligation as an obligation to use commercially reasonable efforts to achieve each diligence milestone, rather than a flat obligation.
 (See, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 4.1.) Commercially reasonable efforts is often a defined term that provides the licensee with flexibility to devote those efforts that any reasonable company devotes to meet diligence milestones, taking into account all relevant factors.
- Provide for a mechanism to extend the timeline for the various diligence milestones. Another option is not to condition the achievement of the diligence milestone with any sort of performance standard, but to create an opportunity or even obligation for extensions at the licensee's request. (See, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 4.3). Whether the academic licensor agrees to an obligation to extend milestone deadlines is heavily negotiated and often depends on the proposal by the licensee as to what requirements are needed to show the academic licensor why the extension is necessary.
- Negotiate to have only near-term diligence milestones that are more likely to be within the licensee's control and avoid committing to achieve long term milestones by any particular date. By their nature, the risk of missing long-term product development milestones, such as a deadline for achieving regulatory approval, is much greater than the risk of missing shorter-term milestones, like filing an investigational new drug application (IND) or initiating IND-enabling toxicology studies.

Payments

Net Sales

The Net Sales definition directly determines the calculation of revenue based on which royalties are

paid and is intended to match the amount a licensee, its affiliates, and sublicensees receive for the sale of goods, less discounts, rebates, bad debts, and other amounts that should fairly be deducted when measuring top-line sales revenue. Academic licensors are often suspicious of deductions in the Net Sales definition, as the more that is subtracted, the less the academic licensor receives in royalties.

Licensees often seek to add language to Net Sales definitions accounting for the sale of so-called combination products, which are products sold for a single price that combine two or more products, one that uses the IP licensed from the academic licensor and one or more that do not. The most common solution adjusts net sales of the combination product by multiplying it with a fraction of A/A+B, where A is the licensed product's average price when sold separately and B is the price of the other product in the combination (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Net Sales). Other fractions are used if either A or B are not sold separately.

Large companies often strongly prefer to use their own Net Sales definition in their license agreements, arguing that they must calculate Net Sales the same way across all their products and that it is impossible for them to agree to any definition that deviates from their standard practice. Because of this, a licensee that anticipates one day sublicensing to a larger company may want to consider adding language that allows a qualified sublicensee to use its own customary Net Sales definition.

Universities can be skeptical of this request and may insist that any replacement definition:

- · Be consistent with:
 - the definition the sublicensee uses in other similar license agreements; and
 - the sublicensee's publicly reported financial statements.
- Not have more than a *de minimis* adverse effect on the amounts to be paid the academic licensor.

Royalties and Anti-Stacking Provisions

Royalty stacking occurs when, after the license agreement is signed, the licensee determines that it must:

- Obtain a license from a third party under additional IP that is necessary or useful to exploit the licensed products.
- Pay the third-party licensor royalties in consideration for that license, on top of the royalties due under the

license agreement with the academic licensor, thereby "stacking" the royalties.

To mitigate this financial risk, licensees often propose to add a provision to the license agreement allowing the licensee to offset a percentage (typically 50%) of the amount of royalties paid to a third party in consideration of a future license against royalties due to the academic licensor under the license agreement (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 5.5(c)).

Whether the third-party license must only be under necessary patent rights, or can include other reasonably useful IP, and to what extent the payments may be deducted are heavily negotiated and case specific.

These offsets are often capped, so that the royalty due to the academic licensor cannot be reduced by more than a certain percentage (usually 50%), typically referred to as a royalty floor.

Sublicensing Revenue Share

Provisions requiring the licensee to share with the academic licensor amounts the licensee receives in consideration for a sublicense are often the most heavily negotiated provisions in an academic license agreement (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 5.7 and Sublicensing Revenue).

Universities seek these provisions to capture a share of the value that the licensee receives from sublicensing its license from the academic licensor. Licensees often strongly resist these provisions because they are viewed as siphoning sublicensing consideration that would otherwise be used for developing the licensed products, thereby reducing a licensee's ability to defray the cost of development through the use of strategic partnerships involving sublicenses. If the definition of sublicense revenue to be shared is too broad, it can also give the academic licensor a share of consideration paid by the sublicensee for the licensee's own intellectual property (that is, not the academic licensor's IP).

In particular, a licensee should seek to exclude from the sublicense revenue definition the following:

- Royalties, profit share payments, and other amounts received from a sublicensee based on the licensed product's net sales. Without this exclusion, an academic licensor receives two forms of payment on a sublicensee's net sales:
 - the royalty and sales milestone payments that the academic licensor receives on the sublicensee's net sales; and

- a share of the royalty or profit share or sales milestone payment that the licensee receives from the sublicensee for the same net sale.
- Payments made to fund the licensee's research, development, manufacture or, if applicable, commercialization of the licensed product. Licensees often enter into sublicenses to help finance the costs of development. If the licensee had to share these funds, it decreases the funding available to further the licensed products' development. A licensee should also consider that:
 - the academic licensor wants to ensure that this exclusion does not apply to an upfront payment or milestone payment, even though the licensee may also use those payments to fund development;
 - any exclusion for these types of payments is sufficiently defined so that it does not swallow the entire concept of a sublicensing revenue share; and
 - related to the point above, it is more controversial from the academic licensor's perspective to exclude payments made to reimburse the licensee for activities conducted **before** the sublicense is executed because a large part (or all) of the consideration the sublicensee pays to the licensee may be categorized as a reimbursement.
- Amounts the licensee receives in consideration for its equity. Universities often seek to clarify that any amounts the licensee receives for its equity in excess of fair market value should be considered sublicense revenue. This is a fair request in concept, but if accepted, the licensee should seek to clarify that fair market value may include a premium over and above the equity's trading value, which is common.
- Amounts received under a sublicense agreement in consideration for licenses under IP other than the academic licensor's IP licensed under the license agreement. Sublicense agreements often grant the sublicensee a bundle of IP rights, including:
 - the academic licensor's IP rights licensed to the licensee under the license agreement;
 - IP rights developed by the licensee; and
 - IP rights in-licensed or acquired from third parties.

The licensee may argue that in these cases it would not be fair for it to pay the academic licensor the same percentage of sublicense revenue as it would if the academic licensor's IP rights were the only IP rights being sublicensed. If the parties agree that allocation is appropriate, they should consider including a mechanism to efficiently arbitrate disagreements

regarding the proper allocation, as this has often been the subject of dispute. The academic licensor may also seek a floor to provide certainty that the value attributable to its IP is not less than a negotiated percentage of the total value.

Some academic licensors refuse to permit any allocation of sublicense revenue on the basis that allowing allocation invites dispute. They typically instead settle for a lower sharing percentage with no possible allocation. If the academic licensor takes this approach, the licensee must consider whether the negotiated percentage reflects that trade-off.

Consideration received due to a change of control
of the licensee. Some academic licensors may seek to
treat a change of control separately, perhaps attaching
a flat or graduated fee to this event. Where this occurs,
it is always a heavily negotiated business term.

Patent Matters

Patent Prosecution

Academic licensors generally insist on controlling patent prosecution and require licensees to cover patent costs (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Sections 6.1 and 6.2). This is typical in academic licensing and at odds with the norm in commercial licensing where the party paying patent costs usually controls prosecution. In our experience, however, an academic licensor's counsel often takes significant direction from the licensee's counsel.

In cases where the licensed field is sufficiently narrow to permit more than one licensee, a licensee may propose to pay only a pro rata share of patent costs along with any other commercial licenses the academic licensor grants to the same licensed patents to third parties in different fields.

Enforcement

An academic licensor sometimes agrees for the licensee to have the first right to enforce the licensed patents in the case of infringement by a third party's exploitation of a product or process competitive with the licensed product in the field.

Joinder

Licensees receiving a license from a public academic licensor must carefully consider the implications of the public academic licensor's sovereign immunity.

In *Gensetix, Inc. v. Board of Regents of University of Texas System*, the University of Texas (UT) asserted its sovereign immunity to avoid joining a lawsuit that Gensetix, UT's exclusive licensee, sought to bring against Baylor College of Medicine enforcing the licensed patents (966 F.3d 1316 (Fed. Cir. 2020)). In that case, the Federal Circuit ruled that UT was not compelled to join the lawsuit against Baylor, even though UT was an indispensable party to the litigation and had agreed to cooperate in any lawsuit brought by Gensetix to enforce the licensed patents. The Federal Circuit allowed Gensetix's lawsuit to continue without UT as a party based on its view of the relative hardship of the alternative and their determination that the defendant was not at risk of multiple suits, which may not always be the case in all contexts.

In light of this, licensees should consider asking public academic licensors to waive their sovereign immunity for the purpose of permitting a licensee to maintain standing in actions in federal court or federal administrative proceedings to enforce or defend the licensed patents. In our experience, however, public universities are often hesitant to do so despite the *Gensetix* decision (and many have a policy forbidding it), and this is a developing area of practice.

Confidentiality

It is important for a licensee to consider what kind of information it is sharing with the academic licensor and that information's sensitivity. In most cases, a licensee shares royalty reports and progress reports. Depending on the stage the research is in, this information may be highly sensitive, and it is important to put strict restrictions on what the academic licensor may do with this information.

An academic licensor usually insists on preserving its right to publish research results (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 7.4). Publication of research results is a critical function for any academic institution.

Representations and Warranties

As non-profit institutions with limited income, academic institutions are often unwilling to put their endowments at risk and generally seek to severely limit their exposure to liability. Accordingly, academic licensors typically are willing to make far fewer representations and warranties than commercial licensors. That said, academic licensors are often willing to make basic representations about:

- The licensor's authority to enter into the license agreement.
- · Lack of conflicts with other agreements.
- Title to licensed IP (sometimes knowledge qualified).

Well-negotiated representations and warranties are often case-specific and reflect core assumptions vital to the transaction.

Indemnification; Liability

Academic licensors are often unwilling to indemnify a licensee, even for third-party claims arising from its breach of the license agreement, and this is often non-negotiable. Public universities are often prohibited by law from providing indemnification.

Academic licensors also often look to have limited exceptions, if any, from the consequential damages waiver (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 9.4).

Term and Termination

Termination for Material Breach

Academic license agreements are nearly always terminable by the licensor if the licensee materially breaches the agreement and fails to cure the breach within a certain cure period (see, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 10.2(b)). A licensee should consider seeking a provision that tolls the cure period for the duration of any dispute between the parties as to whether the licensee is, in fact, in material breach of its diligence obligations.

Sublicense Continuance

A license agreement may provide that on the agreement's termination all sublicense agreements automatically terminate. Licensees often seek to add language that provides that on termination any sublicense granted to a third party remains in effect as a direct license from the academic licensor or obligating the academic licensor to grant a direct license to a sublicensee. (See, for example, Standard Document, Patent License Agreement (University Licensor, Pro-Licensee): Section 10.3(a).)

In response, academic licensors may reasonably argue that they did not agree to a license with whoever the sublicensee is and therefore cannot be forced to enter

into a direct license with that new party. From the licensee's perspective, however, it is often difficult to attract sublicense partners without giving the sublicensee assurance that its sublicense survives even if the licensee defaults under the license agreement and loses its rights.

In our experience, academic licensors often acquiesce to a licensee's demands on this point. Academic licensors typically insist on language that clarifies that in this event, the academic licensor does not:

- Take on any obligation to the sublicensee beyond its obligations set out in the license agreement.
- Have any obligation to enter into a direct license with a sublicensee who is in breach of the sublicense agreement with the academic licensor's original licensee.

A licensee should also clarify that in this event the consideration the university licensor receives under its direct license with the sublicensee is the same as what the licensor receives under the license agreement as a result of the sublicensee's exploitation of the licensed technology had the license agreement not been terminated. In other words, the academic licensor should not be entitled to the same amounts that the sublicense agreement required the sublicensee to pay the original licensee because those amounts may have been in consideration for more than just the academic licensor's sublicensed IP.

About Practical Law

Practical Law provides legal know-how that gives lawyers a better starting point. Our expert team of attorney editors creates and maintains thousands of up-to-date, practical resources across all major practice areas. We go beyond primary law and traditional legal research to give you the resources needed to practice more efficiently, improve client service and add more value.

If you are not currently a subscriber, we invite you to take a trial of our online services at legalsolutions.com/practical-law. For more information or to schedule training, call 1-800-733-2889 or e-mail referenceattorneys@tr.com.

