Administration of Technology Licenses

HANS H. FEINDT, *Chief, Monitoring and Enforcement Branch, Office of Technology Transfer, National Institutes of Health, U.S.A*

ABSTRACT

The National Institutes of Health Office of Technology Transfer (NIH OTT) administers technology licenses for the NIH, generating substantial royalties (in the millions of dollars). Although this revenue flow is important, the NIH OTTs principal mission is the timely introduction of new products and technologies into the marketplace to ensure that the fruits of NIH research and development are made commercially available to serve the greater public good. The NIH OTT utilizes six types of technology licenses:

- commercial evaluation licenses (also known as options)
- patent commercialization licenses (either exclusive or nonexclusive)
- nonexclusive patent licenses (for internal use)
- biological materials licenses
- software licenses

The NIH OTT insists that licenses are drafted with well-defined financial terms and clearly delineated reporting obligations, so that both parties to the license (NIH as licensor and, for example, a biotech firm as licensee) understand their respective obligations. The NIH OTT seeks to build cooperative relationships with its licensees in order to facilitate problem solving discussions, resolve outstanding issues, and identify possible opportunities for advancing commercialization of products and/or services. As a best practices licensor, the NIH OTT carefully manages license administration by monitoring commercial development performance benchmarks, reviewing sales reports, and enforcing other license obligations. The office will also, if necessary, impose sanctions in license enforcement and implement procedures for dealing with infringement of its patents. The policies, protocols, and procedures of the NIH OTT have broad applicability to both developed and developing countries; scientists, administrators, technology managers, intellectual property professionals, and even attorneys can learn from the NIH OTT, a good example of an office operating effectively, efficiently, and profitably by employing best practices.

1. INTRODUCTION

The National Institutes of Health Office of Technology Transfer (NIH OTT) strives to fulfill its mission of transferring technology to improve public health not only by licensing to commercial enterprises but also by working with and licensing to institutions serving disadvantaged populations in the United States and abroad. The administration of technology licenses is an important part of this process. License administration focuses on the licensee's obligations to the licensor, such as periodic royalty payments and reports. In fiscal year 2005, the NIH collected over US$98 million in royalties from 750 licenses (out of a total portfolio of over 1400 licenses). Royalties from commercial products made up nearly US$77 million of this amount.

Describing the different types of licenses used by NIH to carry out its technology transfer program, this chapter explains the procedures for ensuring that licensees meet their obligations. It provides an overview of the tools used to administer large numbers of technology licenses and offers advice on how to monitor commercial-development

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performance benchmarks, review sales reports, and enforce other license obligations. This chapter also discusses the use of amendments in license administration, sanctions in license enforcement, and suggests procedures to follow when nonlicensed companies infringe on patented technology. The policies and practices of the NIH OTT aim to further develop scientific discoveries that may lead to commercial products that improve public health. This overview of license administration at NIH seeks to provide guidance for others who are considering establishing and operating their own programs for administering technology licenses.

2. TYPES OF TECHNOLOGY LICENSES

Technology licenses include commercial evaluation licenses (also known as options), exclusive and nonexclusive patent commercialization licenses, nonexclusive patent licenses for internal use, biological materials licenses for commercial sale, biological materials licenses for internal use, software licenses for commercial sale, and software licenses for internal use. Financial terms and reporting obligations vary with the type of license. Table 1 shows which obligations are typically included for each type of license. Regardless of the type, licenses should be written with well-defined financial terms and reporting obligations that both parties understand. This section briefly describes each type of NIH license; a more detailed discussion about the various types of technology licenses can be found elsewhere in this *Handbook*.[1]

Commercial evaluation licenses (also known as options) are useful for companies to explore the value or appropriateness of a new technology for a limited time without committing the financial and other resources required by a standard exclusive or nonexclusive patent license. Appropriately, these agreements have smaller financial terms and are for a short duration. If the licensee finds the technology meets their needs, then the parties will generally negotiate a new exclusive or nonexclusive patent commercialization license.

Patent commercialization licenses provide licensees with rights to patented technology or inventions described in patent applications that have been filed. An *exclusive patent commercialization license* provides a single licensee the right to practice and exclude others from practicing the technology for a period of time limited by the term of the patent. In most fields of commercial endeavor, an exclusive license provides a significant competitive advantage to the licensee and, therefore, the potential for a large financial return. Consequently, the royalty obligations and financial terms in such licenses are generally quite substantial. With exclusive licenses, the licensor also has a higher level of expectation that the licensee will diligently meet the performance milestones agreed to in the license.

Nonexclusive patent commercialization licenses give patent rights for technology to multiple licensees. These may be for a limited time or for the term of the patent. Such licenses are often given when the patent technology has the potential to significantly benefit the broader public. By providing such technology to multiple licensees entry into the marketplace will be accelerated. Royalty obligations imposed on nonexclusive patent commercialization licensees vary widely, depending on the nature of the technology.

Nonexclusive patent licenses for internal use provide a licensee with access to a patented technology that may be useful as a tool or process but is not itself a marketable product.

In the biotechnology field, ***biological materials licenses*** provide licensees with access to nonpatented materials or biological constructs that were prepared at great effort and expense and that may be available only from the laboratories that made them. Nonexclusive biological materials licenses for internal use provide a licensee with access to unpatented technology that is unique or difficult to replicate without significant expense. This saves the licensee time in its commercial development efforts. Biological materials licenses for commercial sale promote the wider use of unique materials or biological constructs in the research and commercial development community.

Similar to biological materials licenses, ***software licenses*** provide licensees with access to nonpatented software that may only be available from the laboratories that developed them. As shown

Table 1: Typical License Obligations

Financial Terms and Other Obligations Found in Technology Licenses	Types of Technology Licenses					
	Evaluation	Exclusive patent for commercial use	Nonexclusive patent for commercial use	Nonexclusive patent for internal use	Biological materials for commercial sale	Biological materials for internal use
License execution fees	+	+	+	+	+	+
Annual (minimum annual) royalties	±	+	+	±	+	±
Past patent-prosecution fees	–	+	±	–	–	–
Ongoing patent-prosecution and patent-maintenance fees	–	+	±	–	–	–
Annual, periodic, or final reports on commercial development or research progress	+	+	+	±	±	±
Report of performance benchmark achievement	–	+	+	–	+	–
Performance benchmark royalties	–	+	+	–	–	–
Report of first commercial sale	–	+	+	–	+	–
Annual, periodic, or final reports on sales and earned royalties due	–	+	+	–	+	–
Earned royalties on product sales	–	+	+	–	+	–
Report of sublicensing activity	–	+	–	–	–	–
Report of sublicensing considerations and royalties due	–	+	–	–	–	–
Sublicensing royalties	–	+	–	–	–	–
License renewal or term extension fees	–	–	±	+	+	+

Key: + = Generally in license.
± = May or may not be in license.
– = Generally not in license.

in Table 1, the financial terms and obligations found in such licenses vary depending on the type of license.

NIH has used most of these license types to expand the transfer of technologies—specifically those for neglected diseases or that meet public health needs—to public and private institutions in developing countries.

3. TASKS OF THE LICENSOR

To administer, monitor, and enforce technology licenses requires the licensor to follow-up on the execution of a license agreement. The licensee has agreed to fulfill various financial terms and reporting obligations in exchange for the right to practice a licensed technology for a limited period of time. Regular reminders may be needed to ensure that they fulfill these obligations throughout the term of the license.

The licensor should monitor compliance with royalty payment and reporting obligations during the license term, and reports submitted by licensees should be carefully reviewed on an ongoing basis. Routine correspondence with licensees about these matters is usually handled through invoices, form letters, and e-mail. However, license administrators will sometimes need to invest considerable investigative time and practice skillful communication to understand the activities of the licensee and determine which actions should be undertaken to remedy any noncompliance. A cooperative approach that engages the appropriate licensee contact in problem solving is generally best. Such discussions will resolve most issues and also provide feedback that may be useful for future technology license negotiations. Utilizing these contacts also may allow the licensor to direct the licensee to financial, technical, and other resources that will help the licensee move its commercialization efforts forward.

Most tasks performed in the administration, monitoring, and enforcement of technology licenses typically flow out of the financial terms and reporting obligations described in Table 1. The more-routine license administration tasks include:

- arranging for shipment of licensed materials to the licensee
- invoicing licensees for royalty payment obligations specified in the license
- recording royalty payments
- verifying that the amount paid is correct
- distributing royalty receipts
- requesting overdue royalty payments through reminder notices
- requesting overdue reports through reminder notices
- notifying licensees of license expiration

Other license administration tasks related to monitoring and enforcement include:

- checking the accuracy of sales and earned royalty reports
- collecting overdue or underpaid royalties and imposing additional royalties for late payment
- reviewing progress reports against performance benchmarks
- tracking and recording achieved-performance benchmarks so that associated royalty payments are invoiced at the proper time
- contacting licensees about license noncompliance issues
- amending licenses to extend them, modify benchmark schedules or other license terms, or correct errors in the original license
- preparing and reviewing patent expense reports that support the billing for patent expense reimbursement

4. TOOLS FOR LICENSE ADMINISTRATION, MONITORING, AND ENFORCEMENT

4.1 *Licensee contacts*

One of the most important tools for effectively administering, monitoring, and enforcing licenses is the list of licensee contacts. If contact information for royalty and reporting obligations is not available when the license is executed, it should be obtained immediately after. The list could include contacts in business development, legal affairs, licensing, finance, and research. The

names of senior-level executives should also be included. Ideally, full names, titles, mailing addresses, phone numbers, and e-mail addresses should be recorded for each contact. The contact list should be periodically reviewed and updated. These contacts are extremely important for beginning discussions about royalty payments and other noncompliance issues that may develop. Without a contact list, valuable time can be wasted trying to identify the appropriate contact.

4.2 *Filing system*

A well-organized system for filing and retrieving documents, reports, correspondence, and other information related to a specific license is as important as licensee contacts. Depending on how things are organized, several different files may be needed to address and keep track of different aspects of license administration. For example, a file used only for archiving the original, executed license agreement may be set up. Another "working" file may be set up for daily use in filing, reviewing, and retrieving a reference copy of the license and any correspondence associated with the license. If a computer network and systems are available, the filing system may be set up electronically by scanning and converting all correspondence and license agreements into image files (for example, Adobe Acrobat® pdf files) that can be easily stored, searched, and retrieved. It is essential, of course, for any such system to be maintained.

4.3 *Tracking system for license terms and due dates*

To effectively administer license agreements, collect royalties that are due, and monitor and enforce license obligations, the licensor must have a reliable system to record and track the financial terms, performance milestones/benchmarks, reporting obligations, amounts due, due dates, invoice or overdue notice deadlines, payments receipts, and royalty payment distributions for individual licenses.

The greater the number of licenses, the more important it is to use a computerized database for license administration. At the NIH Office of Technology Transfer, the database has been essential for monitoring, recording and updating contact lists, tracking due dates for financial terms, recording the amount of royalty payments received, tracking the due dates of performance benchmarks, recording the receipt of reporting obligations, recording completion dates for performance milestones/benchmarks, and so forth.

Ideally, the database should be designed to meet the needs of the entire technology transfer office. The NIH database consists of an integrated system of interactive modules that handle data about people (contacts), companies, inventions, invention marketing, patent prosecution, patent annuity payments, license applications, license royalty payment obligations, royalty receipts, license reporting obligations, and so forth. Queries can be made about the data, and a variety of report types can be generated. The database sends reminder e-mails to individuals in the office and allows routine form letters and reports to be prepared, edited, and printed. The database also allows comments to be recorded and the attachment of externally generated electronic files (such as scanned copies of licenses and correspondence or e-mails) to specific records in the database. These features help to maintain a historical record of each invention and license.

4.4 *Technology transfer office Web site*

The NIH Office of Technology Transfer recently reorganized and updated its Web site[2] in order to answer licensees' questions about license obligations and provide potential license applicants with information. A menu bar on the Web site provides links to licensing and royalties information; examples of Forms and Model Agreements; FAQs (frequently asked questions) about royalty payments, reporting obligations, and other license matters; and contact information. By providing links to technologies currently available for licensing, the Web site helps market those technologies. Finally, neglected disease technologies available for licensing can be shared via the web.[3]

4.5 *Royalty payment obligations*

When a license is fully executed, several royalty payments will often be due. These may include: (1) a license execution royalty payment, (2) a prorated minimum annual royalty payment, and,

for patent licenses, (3) a royalty payment for past patent prosecution costs. Typically, these payments are mailed to the licensee with individual invoices that state the license number, the type of royalty payment due, the amount due, the due date, and instructions for where the payment should be mailed. The database is used to record when payments are received and to alert license administrators when payments become due or are overdue.

When royalty payments become 30 days overdue, a first overdue notice is mailed to the licensee. If there is no response within two weeks, it is often useful to contact the licensee to verify that the contact information is correct and determine why payment has not been made. If payment is not received within 60 days after the due date, a final notice is mailed out. This notice informs the licensee that failure to pay may result in license termination. If payment is not received within 90 days of the due date, a license administrator contacts the licensee to determine why payment was not made and to discuss possible sanctions that may be imposed if payment is not received within a short period of time (see below).

4.6 *Sales and earned royalties reporting*

Licenses for the development and/or sale of commercial products usually require periodic sales reports and the earned royalty due. These reports may be annual, semiannual, or quarterly, depending on the product type and anticipated sales volume. Net sales figures quantitatively measure a license's performance and are the basis for calculating the earned royalties due. Licenses prescribe in some detail the deductions allowed from the gross sales for calculating the net sales figure. However, ambiguities or misunderstandings often arise. Recognizing such issues early, when smaller amounts of money are involved, usually makes resolving them easier for both parties. If sales and earned royalty reports are not provided with the earned royalty payments submitted by the licensee, the licensee should be reminded of its obligation to provide them, and a short-term deadline should be established for submitting the reports.

The accuracy of reported sales figures can be verified in several ways. Comparison to prior period sales figures will show whether product sales are growing or declining and at what rate. Company press releases, annual reports, filings with governmental securities agencies (such as the U.S. Securities and Exchange Commission SEC), stock analysts' reports, marketing reports, news stories, and so forth, are other resources that can be studied to verify reported sales figures. Many of these sources are available on the Internet. When the reported sales figures seem inconsistent with data from other sources, the licensee should be asked to explain the discrepancies. If the license includes provisions for auditing the company's sales to verify the figures reported for the licensed product, this may be the time to conduct an audit.

4.7 *Commercial development or research progress reports*

Most technology licenses require periodic reports describing the progress of research, commercialization, or product development. These reports serve several purposes:

- they verify that the licensee is using the licensed technology or product
- they demonstrate, for commercialization licenses, that an effort is being made to bring the licensed technology or product to market
- they provide verification that a license benchmark or milestone was achieved and when

Moreover, when benchmarks or milestones have associated royalty payments, the reports alert the license administrator to invoice the licensee for a royalty payment. If a licensee fails to provide these reports, the licensee should be contacted and reminded of their obligations. A short-term deadline should be set for the licensee to submit the report.

Progress reports should be carefully reviewed and compared to the commercial development plan and the benchmarks or milestones described in the license. Are initial expectations being met? If not, why not? Are the problems technical? Are they due to insufficient financial resources? Regulatory issues? Has the company lost focus in

its desire to commercialize the product? Are there other issues not mentioned in the report? Getting answers to these questions usually requires contacting the licensee for additional information. Once these answers are obtained, a decision can be made about what actions to pursue with the licensee. (See the sections "Amendments to license agreements" and "Sanctions for noncompliance" for examples.)

4.8 *Patent prosecution and maintenance cost reimbursement*

Patent claims should match the commercial goals of licensees. Since IP protection normally precedes licensing, those responsible for licensing inventions need to monitor patent prosecution to ensure that the goals pursued by patent agents and attorneys align with those of the licensees.

Patent licenses often include the reimbursement of past patent prosecution costs incurred by the licensor for a licensed technology as a financial obligation. The licensee may also agree to pay ongoing (future) patent prosecution and maintenance costs. Periodically, these costs need to be carefully tracked, documented, and billed to licensees. Patents are usually not assigned in technology licenses, so control of patent prosecution most often resides with the licensor and not the licensee. Like all legal fees, patent prosecution costs can quickly get out of control without careful monitoring. Seeking timely reimbursements of patent costs incurred by the licensor is an important part of license administration.

Occasionally, an applicant for a technology license may want to manage patent prosecution and be billed directly for the costs incurred. In this case, special oversight is needed to ensure that the licensor's interests are protected.

5. AMENDMENTS TO LICENSE AGREEMENTS

The outcome of an effort to commercially develop a new technology is often difficult to predict because of technological, regulatory, financial, patent, and business issues. Licensees usually set timelines for meeting performance benchmarks or milestones with a best-case scenario in mind. Not surprisingly, delays are common. When a company is demonstrating diligence but has encountered unexpected delays that have a reasonable chance of being overcome, the appropriate action may be simply to amend the license to update the benchmark or milestone schedule. Such amendments reflect mutually agreeable changes in the expectations of licensor and licensee. But when the company's issues appear insurmountable, it may be better to terminate the license. Other considerations may lead to different approaches to such situations, but a successful conclusion will be based on establishing and maintaining good communications between the license administrator and the licensee.

License term extensions are normally simple modifications of a license that indicate the satisfaction of both sides in the existing agreement and a desire to continue the agreement. Sometimes, term extension amendments also include changes to other terms or obligations. For example, minimum annual royalties may be raised or lowered to reflect the current institutional costs of administering the agreement and the costs associated with the amendment process, or to better capture the value of the invention for the extended time period.

Financial hardship, changes in the cost structure of doing work, opportunity costs, or priority changes can make licensees want to change the financial terms of technology license agreements. Like most tangible assets, licensed IP assets depreciate with time (due to the shrinking of the exclusivity period, changing marketplace interests, and the degree to which the technology provides a competitive advantage over the industry's standard technology). While it is not a good idea to set rules for changing financial terms, an effort to weight influencing factors can be useful. The licensor might weigh such factors as the probability of getting paid, the probability of relicensing the technology (if the license is terminated), the present value of a payment reduction, and the costs involved. Consistently administering this amendment process will also prevent opportunistic changes in licenses that are not linked to appropriate needs.

In addition to amendments, other changes can be made to existing agreements to increase

the chance that a technology will be successfully developed. Some areas that may need to be addressed include:

- changing the field(s) of use
- permitting the licensee to seek a patent term extension
- eliminating or adding certain technologies from or to a license
- allowing the licensee to seek sublicensing agreements
- allowing the licensee to take on patent-prosecution responsibilities

Many of these issues may be more appropriately handled by licensing personnel than by license administrators. However, the latter should understand the ongoing development of the technology so that they know when deviation from the original agreement is warranted.

6. SANCTIONS FOR NONCOMPLIANCE

When a technology transfer office has a large portfolio of inventions and technologies available for licensing, companies often will return to license additional technologies. This gives the licensor an opportunity to obtain some leverage for collecting late or underpaid royalties due on existing licenses with that applicant. The licensor may put on hold the execution or negotiation of new agreements until the licensee has fully paid any outstanding royalty obligations under existing licenses. All that is needed to use this sanction well is effective communication between license administrators and licensing personnel.

The threat of terminating a license due to a licensee's defaulting on the material obligations of a license is an important tool for enforcing compliance. However, license termination procedures are usually not undertaken until the licensee has been given (1) several written notices describing the obligation(s) in default and (2) an opportunity to respond. If no satisfactory response is forthcoming, a written 90-day notice of license termination is given as the final step. If the licensee's response is still unacceptable after 90 days have passed, a final letter of termination is sent to the licensee.

Although other intermediate sanctions may be desirable, they are frequently unavailable. The licensor's only choice then is to threaten license termination in order to recapture the technology for relicensing. However, when a licensee's breach causes a license to be terminated, license administrators should not forgive any outstanding financial obligations that predate the effective date of the license termination. Unpaid license financial obligations—such as minimum annual royalties, reimbursable patent costs, execution fees, and others—should be identified when a license is terminated, and serious efforts should be made to collect the monies owed. When a license expires, the licensor should conduct a similar review to capture any lost or missed milestone payments, patent-prosecution costs, minimum annual royalties, or other royalties.

One of the hallmarks of a successful technology transfer program is maximizing the collection of license financial obligations. Technology transfer programs that operate as part of a government agency may have that government's power to enforce debt collection, while nongovernmental technology transfer programs may have to rely on the courts for enforcement.

7. LICENSE EXPIRATION

At license expiration and during the ongoing monitoring of active licenses, license administrators can provide helpful feedback about the terms and structure of license agreements to those who negotiate them. Likewise, the performance of licensees can be assessed during the term of a license and when it expires. Delays in development, ambiguous license terms, and failures to address license issues that may require an amendment during the term of a license are good examples of what can be identified from monitoring and expiration reviews. Capturing this knowledge and sharing nonconfidential information about best practices with other organizations can help build a knowledge base that continuously improves the technology licensing process.

8. PATENT INFRINGEMENT

One enforcement task that does not flow out of existing license financial terms and reporting obligations is the pursuit of suspected patent infringers. When a company has not licensed a patented technology but is infringing a patent owned by the licensor, legal action should be undertaken. The first step is to notify the infringing company by letter that they are infringing and should immediately cease to do so. The company usually receives an offer at that time to license the technology in order to avoid legal action against the company by the patent holder. Follow-up may require negotiating a license agreement or, if the license is refused, additional legal action by the licensor.

9. CONCLUSION

Administering technology licenses gives a TTO an opportunity to monitor and participate in an invention's development and commercialization. A successful effort requires good organization, good tools, diligent attention to detail, and the persistence to engage licensees in dialogue when license obligations are not being met. While many technology transfer organizations focus most of their time and effort on negotiating license terms, the overall success of a TTO also requires allocating resources and time to license administration, monitoring, and enforcement. Thorough, consistent follow-up with licensees will ensure that the licensor and inventors financially benefit. The licensee may also benefit from the discipline of an attentive partner and access to the knowledge and experience of the licensing office. Above all, effective license administration ensures that economic development and the public good are well served by the timely introduction of new products and technologies in the marketplace. ■

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HANS H. FEINDT, *Chief, Monitoring and Enforcement Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd, Suite 325, Rockville, MD, 20852, U.S.A. feindth@mail.nih.gov*

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1 See Section 11 in this *Handbook* which contains a number of related chapters.

2 www.ott.nih.gov.

3 www.ott.nih.gov/licensing_royalties/NegDis_ovrvw.html.