

Suggested Guidelines for Releasing Intellectual Property Rights to Faculty Inventors

Scott Elmer and Christopher D. McKinney, DA, MBA, CLP

Scott Elmer is director, Office of Technology Licensing, at St. Jude Children's Research Hospital in Memphis, Tennessee. Christopher D. McKinney, DA, MBA, CLP, is associate vice president, technology transfer and economic development at Georgia Health Sciences University in Augusta, Georgia.

In 1980 the Bayh-Dole Act provided a set of rules for federal grant recipients to elect to retain ownership of inventions made with federal funding. Since the advent of this act, most U.S. universities and academic research institutions that receive federal grant funding have established technology transfer offices within their organization or as part of a separate affiliated research foundation. Each year these offices are responsible for reviewing thousands of invention disclosures and deciding, on behalf of their organization, whether to elect to retain ownership and invest in pursuing patent protection for these inventions.

Many of these disclosures are pursued, but a large portion are abandoned for a variety of reasons. In addition, many of those cases that are initially pursued will be abandoned sometime after a patent application is filed based on further developments or changed circumstances. In most cases, inventors concur with the decision to abandon their invention.

Occasionally, however, an inventor will disagree with an abandonment decision and seek the right to pursue an invention on his or her own. In these cases, having a clear efficient process for releasing intellectual property (IP) rights is important. Releasing IP rights to inventors creates an opportunity for development of a technology that would otherwise be abandoned.

In order to facilitate and promote the efficient release of IP rights to inventors, the following guidelines are suggested. These guidelines are intended to help AUTM member institutions develop customized policies and procedures for releasing IP rights that are

compatible with their institutional mission and culture.

Considerations Prior to Release of IP to the Inventor(s)

Several issues must be addressed prior to the release of rights to an inventor. The inventor, TTO, and institution each play an important role in this process. The issues involved and roles each of these parties plays in the process leading up to the release of IP rights are described below.

Inventor Role

The integrity of the IP release process depends on full disclosure from the inventor. Inventors should be required to fully disclose their invention to the technology transfer office (TTO). This includes providing a detailed description of the invention, its utility, a list of funding sources used, any materials obtained from third parties, and any interest expressed by third parties.

Full disclosure is needed for the TTO to evaluate the invention. If an inventor fails to disclose everything about his or her invention that he or she knows, the TTO is placed at a disadvantage. Such failure can taint a release decision and lead to claims that an inventor intentionally withheld information to hide the true value of his or her invention (see, e.g., *Fenn v. Yale Univ.*, 393 F. Supp. 2d 133, 141-42 (D. Conn. 2004), *aff'd*, 184 Fed. Appx. 21 (2d Cir. 2006)). To make sure this disclosure requirement is met, the IP release agreement should include a representation from the inventor that he or she has fully disclosed his or her invention and all third-party interest of which he or she is aware.

Inventors should also be expected to disclose their inventions well before any publication or other public disclosure that could affect patentability. Such public disclosures can place unreasonable time pressure on the invention evaluation process. If the inventor does not provide sufficient time for the prerequisite steps required before IP rights can be released, he or she should expect that his or her ability to obtain an IP release may be compromised or that he or she may be expected to pay for accelerating the process in some way (e.g., reimbursement for an urgent provisional filing).

Technology Transfer Office Role

The process of releasing IP rights to an inventor begins with an evaluation of his or her invention by the TTO. This evaluation is critical since it determines whether the institution pursues or abandons the invention. The quality of invention evaluations is expected to vary among offices based on the time and resources they have to devote to this activity. At a minimum, this evaluation should involve an assessment of the patentability, marketability, and potential value of an invention.

It should be noted that the frequency of requests from inventors for the release of IP rights may act as a bellwether for the quality of invention evaluations performed by the TTO. A low frequency of IP release requests suggests that inventors are confident in the institutional evaluation process and decisions based thereon. On the other hand, a high frequency of IP release requests suggests a lack of confidence by inventors in the evaluation process and indicates that the quality of such evaluations may need to be improved.

Once an invention evaluation is completed, a decision of whether to pursue or abandon the invention needs to be made. The maker of this decision is expected to vary among institutions, with some granting this authority to the TTO and others leaving this decision to a committee or management executive, such as the vice president for research. Regardless of who the decision maker is, procedures should be in place at each institution that allows this decision to be made soon after the invention evaluation is completed.

Once a decision is made to abandon an invention, the TTO should consider a few additional matters before releasing IP rights to an inventor.

First, the TTO should determine if there are any third-party interests in the invention that need to be addressed. These interests may arise from funding or materials obtained from a third party that were used to conceive and/or reduce the invention to practice. The TTO needs to determine if these interests create any restrictions or impediments to the IP release process. Also, the TTO needs to make the inventor aware of any obligations to these third parties that he or she will be responsible for if IP rights are released to them.

The most common third-party interest associated with academic research is the interest of the U.S. government based on grant funding. These interests are set forth in the Bayh-Dole Act (35 U.S.C. sec 202-212). According to 35 U.S.C. sec. 202(c)(7)(A), an institution cannot assign its rights to a government-funded invention to an inventor without the approval of the funding agency. An explanation of the process for requesting government approval of assignment of invention rights to the inventor can be found at <https://s-edison.info.nih.gov/iEdison/InventorWaiver.jsp>. Important deadlines for effectively acquiring and retaining ownership of a government-funded invention are summarized in the table below.

Action	Deadline	Rule
Reporting invention to federal agency	Within two months of inventor disclosure	37 C.F.R. 401.14(c)(1)
Electing to retain title or not	Within two years of reporting invention or earlier if statutory bar is in effect	37 C.F.R. 401.14(c)(2)
Filing an initial patent application	Within one year of electing title or earlier if statutory bar is in effect	37 C.F.R. 401.14(c)(3)
Foreign patent filings	Within 10 months of original patent filing (assuming foreign filing license granted)	37 C.F.R. 401.14(c)(3)
Utilization reporting	On request of the funding agency, but no more frequently than annually	37 C.F.R. 401.14(h)

The TTO should also consider filing a provisional application to protect the invention prior to release of IP rights. This has a number of benefits that may offset its cost:

- If the invention is federally funded it is necessary to file a provisional for the institution to effectively elect title. If the institution does not file a provisional application for a federally funded invention in the allotted time then ownership in the invention reverts to the federal government. In that case the inventor would have to deal directly with the federal government to obtain a release of rights and the institution would have no further interest in the invention.
- It creates a priority filing date and avoids prior-art concerns related to impending public disclosures by the inventor or his or her competitors.

- It buys time (one year) for the release process to take place and for the inventor to take over responsibility before any further filings are needed to protect the invention.
- A provisional filing builds good faith with the inventor by providing some concrete support for his or her effort.
- The provisional application can be used to define the scope of rights to be released to the inventor. Although not required, including claims in the provisional is recommended to help clarify the scope of the rights to be released and to create a basis for an inventorship determination (see below). Without a provisional it may be difficult to define the scope of rights to be released; a situation that can lead to future disputes with the inventor.
- The provisional can be used to help determine or verify inventorship.
- The process may reveal deficiencies or weaknesses in the invention that may not otherwise be recognized.
- Preparing a provisional application will help educate the inventor on the patent process.

Given its central role in the process, the TTO is also the logical party to develop an institution policy and procedure for the release of IP rights if it does not already have one. The TTO is also in the best position to periodically review this policy and procedure and recommend changes based on prior experience or changes within the institution or of technology transfer norms.

Institution Role

The institution controls the staffing and resources of the TTO. Its primary obligation in this regard is to make sure that the TTO is adequately staffed and resourced so that it can evaluate new invention disclosures and existing patent families in a timely manner.

The institution also plays a role in the decision to abandon IP so that it is available to release to the inventor. The institution may give its TTO the authority to make IP abandonment and release decisions, in which case its only obligation is to make sure the TTO has sufficient resources for this activity. Alternatively, the institution may require these decisions to be made by a committee or other body outside of the TTO. If this is the case, then the institution should make sure that the process is not unduly burdensome and allows abandonment and release decisions to be made in a timely manner.

Finally the institution should, through its TTO, create and approve a clear policy and procedure for the release of IP rights to inventors if it does not already have one. Such a policy and procedure will help guide all participants in the process and ensure inventors that they will be treated fairly and uniformly. Considering their significant stake in the process, any policy for releasing IP rights should be approved by the faculty as representatives of prospective inventors.

The Timing of the Release

TTOs and their institutions should commit to complete the process of evaluating an invention and releasing IP rights between three to six months after the inventor has fully disclosed his or her invention to the TTO. More time may be needed for disclosures that are premature, complex, or outside the expertise of the TTO; while less time may be needed for disclosures that are relatively simple or in a field that the TTO is very familiar with. As noted above, a provisional application may be filed to provide sufficient time for the TTO to adequately evaluate a disclosure and avoid prior-art concerns. Timing should not usually be an issue when the release occurs after the initial patent application filing as both the TTO and inventor should be aware of upcoming filing and fee deadlines.

The Scope of the Release

It is important to clearly define the invention that is being released so that it can be distinguished from subsequent related inventions. The inventor needs to understand that rights being released to him or her cover only the present invention and not future related inventions or improvements to the present invention that may be subsequently conceived as research continues.

An invention is most clearly defined by the claims of the patent application. Therefore, having a patent application prepared, with claims, is the best way to define the scope of an invention to be released. If a patent application is not prepared, then a written invention disclosure from the inventor is likely to be the best available way to define the scope of the released invention. If an invention disclosure is used to determine the scope of released rights, then it should be scrutinized to make sure that it includes sufficient detail to serve this purpose.

The Institution's Financial Interest in a Released Invention

Determining what financial interest an institution should have in a released invention is a balancing act between competing interests. On one hand is the inventor. From his or her perspective, financial obligations to the institution may diminish his or her interest in taking an invention over. Such obligations may also seem unreasonable considering that the institution has decided not to support (or continue to support) his or her invention based on an assessment that it is not valuable enough to pursue. Certainly an institution cannot have much expectation for financial return for an invention they have decided to abandon.

On the other hand is the institution. From the institution's perspective, there may be considerable concern about releasing an invention at an early stage. Since evaluations of invention disclosures are speculative by nature, the TTO may worry that the invention, while a long shot, could become a home run. These concerns are tempered if the institution retains some financial interest in the invention. The institution may also feel that it is reasonable to recover any patent expenses they have incurred in supporting the invention as well as receive some fair return for supporting the inventor, his or her research, and the TTO's evaluation of the invention if it turns out to be a financial success.

Similarly, institutions that have a policy of liberally sharing royalties with an inventor when the institution bears all of the upfront costs may feel that it is likewise fair that the inventor share some of the royalties they receive from released inventions. Finally, the institution may worry that if the inventor has no financial obligation they may be more inclined to sandbag or game the system to obtain a release for an invention he or she feels may be very valuable.

Considering the low probability of financial return, an institution may decide to relinquish all financial interest in a released invention. The good will engendered by such a gesture may ultimately be worth more than any retained financial interest. However, this approach creates the risk that the institution may lose out on substantial revenue and appear incompetent in the event that a released invention becomes a financial home run.

Having the institution retain a modest financial interest in a released invention, or a

more substantial interest above a significant threshold of return, is a safer approach. Some level of continuing financial interest in a released invention does appear warranted given the resources institutions contribute prior to release. However, institutions are cautioned to keep such an interest relatively low, or limited to return after a significant threshold, to avoid any deterrence effect it may have on the inventor. After all, one goal of the institution is to commercialize its research whether or not the commercialization is spearheaded by the institution or the inventor.

To avoid burdening the inventor at the early stages of development where cash and resources are at a premium, the institution's financial interest should only be triggered after the invention has generated enough income to compensate for any out-of-pocket expenses the inventor has incurred; i.e., after it has generated net income for the inventor. At this point it would be reasonable for the institution to receive some portion of net income. Alternatively, the institution may allow net income to reach some substantial threshold amount before triggering a sharing obligation. Such a threshold recognizes that inventors and their licensees may still struggle financially for some time after net income has been achieved. Such a threshold may also lessen any deterrence effect this interest may have on the inventor.

Inventors may be tempted to minimize the financial obligations to their institution by transferring rights in a subject invention to a third party, such as a startup company controlled by the inventor, for little or no compensation. To avoid this, the release agreement should create a fiduciary obligation on the part of the inventor to seek fair market value for the transfer of rights in the invention to any third party.

It may be reasonable for an institution to initially seek a higher share of net income until its sunk patent costs are recovered. However, for the sake of simplicity a fixed share of net income is recommended.

Each institution should decide what exact share of net income is reasonable for a released invention. However, a share between 25 percent and 50 percent of the inventor's normal share of net income for inventions pursued by the institution is recommended. For example, if the inventor is entitled to a 30 percent share of net income received by the institution from his or her inventions, then it would be considered reasonable for

the institution to receive a 7.5 to 15 percent share for a released invention. Relating the institutional share for a released invention to the inventor's share for a retained invention creates a symmetry that may help justify the institutional share.

Avoiding Negative Consequences From Release

While the release of abandoned IP rights poses a low risk, these risks should be mitigated by placing the following conditions on the release.

Retained License for Institutional Use

The institution should retain the right, for itself and other nonprofits, to practice the released invention for research, education, and patient care. This will prohibit the inventor from using released IP rights to block or tax normal nonprofit activities.

Liability Protection

Inventors should be willing to indemnify, defend, and hold their institution harmless from any liability that might arise from the development and commercialization of a released invention. Institutions may also require the inventor or their licensee to carry insurance to make sure he or she can meet these obligations, especially once the invention reaches the commercial market.

Complying With Third-Party Obligations

Any third-party obligations associated with the released invention that continues after the release date should be transferred to the inventor. This may include reporting obligations, such as submitting annual utilization reports to the National Institutes of Health for federally funded inventions, as well as the obligation to share income with private research sponsors.

Other Obligations of the Inventor

An inventor may also be expected to fulfill the following obligations with respect to a released invention.

Reporting

Inventors may be expected provide the TTO with a periodic report on the progress of development and commercialization of a released invention. Such a report should normally only be required once a year and no more frequently than twice a year. Inventors should also be required to notify the TTO at least 60 days in advance of the abandonment of a released invention. This would allow the TTO to re-evaluate the invention to see if circumstances at that time might cause it to revisit its earlier abandonment decision.

Relinquishing the Standard Share of Institution Income

Since the inventor is acquiring ownership, he or she has the predominant financial stake in the released invention. In addition, for a released invention, any income the institution receives will come from the inventor. Under these circumstances, it does not make sense for the inventor to receive a portion of income derived from the released invention that he or she pays to the institution. Therefore, the inventor should be expected to relinquish his or her right to the standard share of net income received by the institution that is apportioned to inventors.

Diligence

The process of releasing IP rights utilizes resources that are precious to a TTO. To justify the use of these resources, it is reasonable to impose modest diligence obligations on inventors for released inventions. Such diligence commitments should protect the institution's remaining interest in a released invention and be commensurate with the level of resources devoted by the institution to the release process that would not have otherwise been utilized. Evaluations that are normally conducted for invention disclosures should not be taken into account, even though they contribute to the release process.

However, actions taken solely to facilitate the release process, such as negotiation of a release agreement or filing of a provisional application, should be considered.

For example, if a provisional application is filed to facilitate release of IP rights (see below) then it may be reasonable to require the inventor to commit to the filing of a corresponding regular U.S. application before the provisional expires. A commitment like this should only discourage those who are not serious about pursuing their invention.

Continued Development of Released Invention at Institution

Once an invention has been released to an inventor, its continued development at the institution raises a few concerns. First, the inventor's enhanced financial interest may create a bias toward research that could improve or otherwise add value to a released invention. Thus, continued development may be perceived as a conflict-of-interest issue for the inventor.

Second, continued development can lead to additional related inventions and/or improvements to the subject invention. The institution would own these additional related inventions and/or improvements, but the inventor may need access to these inventions as a practical matter to effectively develop his or her original released invention. Negotiating rights for access to these additional inventions with the inventor can be tricky especially if (i) the inventor expects the institution to give him or her favorable treatment in view of the prior release and/or (ii) other parties express interest in these additional inventions. Also, the inventor may contend that the additional inventions are included in the original release of rights, especially if the scope of the release (see above) is not clearly defined.

To avoid these concerns, prohibiting continued development or research related to a released invention is recommended. However, if this is not possible then steps should be taken to mitigate these concerns. Any research projects proposed by an inventor that are related to his or her released invention should be vetted by the institution to make sure that they are justified on their scientific merit. Further, the TTO should discuss with the inventor how additional related inventions and/or improvements that arise from the project will be handled.

Multiple Inventors

Each co-inventor has an individual, equal, and undivided interest in his or her invention. Therefore, it is not possible to release IP rights to one co-inventor without affecting the rights of the other co-inventors. In view of this, whenever multiple inventors are involved, IP rights should be released collectively to all named inventors. Thereafter, the inventors may decide how to proceed amongst themselves.

If co-inventors are from different institutions, then each institution will have an ownership interest in the invention. In this case, the decision to release of IP rights and the actual release process should be coordinated between the institutions.

Conclusion

From time to time, institutions are faced with the prospect of releasing their rights when they decide to abandon an invention that the inventor(s) are interested in continuing to pursue on their own. When this happens it is important for the institution to have a policy and procedure in place that allows for the efficient release of rights under terms that are fair to all involved. Unfortunately, due to the general rarity of this occurrence and somewhat difficult issues that must be addressed, institutions may defer the development of such policies and procedures until an immediate need exists. This can lead to significant delays and frustration on the part of the inventors and institutional representatives involved in the process when it happens.

These guidelines, and the associated template release agreement (<http://www.autm.net/AM/Template.cfm?Section=TechTransferResources&Template=/CM/ContentDisplay.cfm&ContentID=7337>), are designed to help and encourage institutions to proactively develop policies and procedures for releasing invention rights based on their own unique circumstances. With such advance planning and consideration, releasing invention rights to inventors can be a smooth and efficient process benefitting all parties involved.