

# **Patent Issues Facing Universities**

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## **ABSTRACT**

Establishing an environment where faculty publications flourish while also ensuring that the university's intellectual property rights are properly maintained represents a challenge for the university research administrator. This article provides guidance on how to facilitate both of these fundamental goals in the context of four key issues affecting university patent interests: the risks publications can pose to patent rights; the impact of the CREATE Act on collaborative research endeavors; special considerations for patents resulting from government-sponsored research; and the importance of laboratory notebooks in documenting the date of an invention.

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In managing and overseeing the development of a university's patent portfolio, research administrators and technology transfer professionals typically face an arduous challenge in coordinating and reconciling the often differing interests of the university's researchers and administrators. On the one hand, university researchers place a heavy emphasis on garnering publication in scholarly, professional, or industry journals, which can bolster a university researcher's efforts toward receiving tenure or elevating their standing in their field of study. Given the importance of significant research results and the rush by university researchers to quickly disseminate relevant findings to interested colleagues in the scientific community, a researcher's first concern may not be about protecting the underlying intellectual property stemming from the research result. On the other hand, university officials often expend a substantial amount of resources in fostering studies conducted by university researchers. In addition to expending monies to fund a project, a university also dedicates additional overhead such as laboratory space and manpower. While the university is undoubtedly motivated by altruistic motivations in supporting certain research proposals, including its interest in making inventions available under conditions

that will promote their effective development and utilization in the public interest, it still hopes for a return on its investment to compensate for funds spent.

A university's return on its investment can best be maximized by properly leveraging available intellectual property protections, whether patent, copyright, trademark or trade secrets, all of which require proper adherence to legal guidelines. It is this delicate balance between the university researcher's objective to publish and the university's additional objective to protect that places the research administrator in the often inevitable—and unenviable—position of bridging the gap between these two interests.

Although these two goals are not inherently incompatible, careful coordination and management is necessary to ensure the university's proprietary intellectual property rights are not unnecessarily compromised by a university researcher's premature decision to disseminate research results to cohorts. Often, the greatest obstacle preventing a research administrator from accomplishing this tenuous balance is a tendency by researchers to disregard administrators' reminders of proper legal procedures and protocol as an impediment to furthering the "scientific process." Recognizing the difficulties faced by university research administrators and other technology transfer professionals in properly educating researchers about the university's interest in protecting its intellectual property rights, yet not encumbering a researcher's desire to share results, this article expounds upon a number of tips and pointers that can guide a research administrator's efforts.

### **RESEARCHER'S PUBLICATIONS AND HOW THEY CAN LEAD TO LOSS OF PATENTABILITY<sup>1</sup>**

A university research administrator must be wary of how a university researcher's efforts to publish research results can lead to a potential loss of patent rights if the research administrator fails to monitor the researcher's publication efforts very carefully. In academia, the axiom "publish or perish" has long guided researchers, and faculty at many universities are under discernible pressure to publish research findings or risk losing funding or the opportunity to obtain tenure. But while producing timely research results is a necessity, the rush to announce or publish findings can sometimes cause unforeseen problems in protecting a researcher's intellectual property rights, particularly patents.

The consequences are especially severe—and immediate—in regard to patent applications filed abroad. Most patent offices outside the United States require "absolute novelty" in deciding whether to issue a patent. That means that the invention must not be previously known to the public, has not been sold or offered for sale (publicly or secretly), and has not been made available to the public anywhere in the world in any way prior to the filing date. If an invention is not "absolutely novel," a patent will not be granted in most countries. Conversely, the U.S. does not require absolute novelty under its patent laws. Instead, an inventor is given a "novelty grace period" that gives an inventor up to one year to file a patent application after any publication, sale, or other act that places the invention in the public domain.

How does this affect a researcher's everyday work? Suppose your researcher is asked to give a presentation at his or her annual industry conference. While the invitation is undoubtedly a great honor and an opportunity for recognition, as he or she speaks at the podium, the unwary researcher could be ruining any chance to procure international patent rights for the university. Most foreign jurisdictions would deem an oral presentation as sufficient disclosure to trigger the absolute novelty

bar. While under U.S. law a researcher has up to one year to file a patent application after the public disclosure, the very same researcher would likely surrender international patent rights by the time he or she finished the presentation.

U.S. patent laws provide their own pitfalls, in particular the “printed publication bar,” which gives an inventor up to one year to file a patent application after publishing a description of his or her finding.<sup>2</sup> The “printed publication bar” is based on the postulate that once an invention is in the public domain for a given amount of time, it belongs to the public and can no longer be patented. A failure to file a patent application within one year will result in the permanent loss of the inventor’s patent rights for the given invention.<sup>3</sup>

The critical question is this: what defines a “printed publication”? Generally, a reference will be classified as such if it has been made sufficiently accessible to the public. Certainly, a journal or magazine meets this standard, but courts have interpreted the term far more broadly than the traditional notion of publishing an article in a periodical. A researcher who is not careful can easily start the clock that can trigger the “printed publication bar” without even being aware of doing so.

It is very important, therefore, for a savvy research administrator to carefully monitor the exact date a university researcher publishes an article and also have a solid understanding of what additional actions can trigger the “printed publication bar” and its one-year deadline for filing a patent application. If a research administrator is not careful and is unaware that a researcher has initiated certain actions that trigger the start of the one-year clock, he or she runs the risk that the university will suffer a loss of U.S. patent rights if an application is not filed within the ensuing one-year period.

To the unwary research administrator, the “printed publication bar” to patentability may appear to be an easy administrative task to quantify and track. A research administrator may fall into the trap of believing that rigorous monitoring of the researcher’s publication dates alone will suffice in avoiding the “printed publication bar.” While monitoring a researcher’s publication dates and making the appropriate filings with the patent office within one year will likely protect the university’s intellectual property interests, there are in actuality a plethora of additional activities a researcher may undertake that may qualify as a “printed publication” and inadvertently trigger application of the “printed publication bar.”

Various courts have interpreted the term “printed publication” far more broadly than the traditional notion of simply publishing an article in a periodical.<sup>4</sup> Generally, a reference will be classified a “printed publication” if it has been made sufficiently accessible to the public. *Id.* In deciding whether a reference is a “printed publication,” most U.S. courts have focused on the public’s accessibility to the reference and the means used to disseminate the reference.<sup>5</sup> For a research administrator, this means that many other actions in addition to journal publications could potentially qualify as a “printed publication” and start the one-year countdown. The most overlooked and most common scenarios occur in the context of dissertations and industry conferences.

For example, most universities require researchers and aspiring Ph.D. candidates to submit a thesis or a dissertation that elucidates their research findings. While the submission of a thesis is considered standard operating procedure, the simple submission of the required thesis or dissertation may lead to triggering the “printed publication bar,” and prevent the university and researcher from obtaining proper patent protection.

In one well-known case, *In Re Hall*, the Federal Circuit considered whether a **single** thesis submitted by a doctoral student to the university and subsequently indexed, catalogued and placed on the shelves of the university library, qualified as a “printed publication.”<sup>6</sup> The student’s catalogued thesis was readily accessible to any member of the public via the library catalog system.<sup>7</sup> Even though there was only one copy of the student’s thesis in the university library, and even though the student’s thesis was not made available anywhere else nor published in any periodical, the Court deemed the thesis a “printed publication,” and the student was barred from obtaining a patent because he filed a patent application more than a year after his thesis was made available to the public. *Id.* The court focused on the fact that the catalogued thesis was “sufficiently accessible” that anyone with an interest in the subject matter could find the thesis by exercising reasonable diligence. *Id.*

The implications of *In Re Hall* for a research administrator are clear. If a researcher independently submits a dissertation or thesis to the university library without the research administrator’s knowledge, and the dissertation or thesis subsequently becomes available to the public, the one-year deadline for filing a patent application has already begun. If the research administrator is not aware of the researcher’s actions and does not learn of the cataloguing until a year later, the university will lose its right to any patent that could have otherwise been obtained from the publicly accessible dissertation. To avoid such a scenario, efforts should be made by the research administrator to educate researchers and graduate students about this issue and, if feasible, to work with the graduate school and the university library to monitor submissions of theses and dissertations.

In addition to monitoring researcher dissertations and journal submissions when attempting to avoid the “printed publication bar,” research administrators and other technology transfer professionals also need to be cognizant of a researcher’s actions at industry conferences, especially given recent court decisions that have expanded the definition of “printed publication” even more broadly than in the past. In *In Re Klopfenstein*, the Federal Circuit considered whether an inventor’s use of a slide presentation at an industry conference was sufficient to trigger the “printed publication bar.”<sup>8</sup> The inventor had given a presentation at the conference and posted the presentation slides onto poster boards. The printed slide presentation was displayed for only two and one-half days during the conference, but no copies of the presentation were handed out, and the presentation was never catalogued or indexed in any library or database. *Id.* Even though the inventor’s presentation was never distributed to the public or indexed and placed in a database, the court nonetheless deemed the posted patent slides a “printed publication.” *Id.* Given the inventor had made no effort to prevent the audience from copying the presentation and given the large number of people skilled in the art who viewed the presentation, the poster boards were considered sufficiently accessible to the public to qualify as a “printed publication” and start the one-year clock for submitting a patent application. *Id.*

The implications of *In Re Klopfenstein* are important for universities. The researcher should inform the appropriate administrator or technology transfer office of the researcher’s plans to present at an industry conference well in advance. This will allow the administrator to review and amend the presentation as necessary or implement additional protective measures, such as those mentioned in *In Re Klopfenstein* (“license agreements, non-disclosure agreements, anti-copying software or even a simple disclaimer informing the viewing public that no copying of the information will be permitted”). *Id.* By implementing these measures, the university may be able to avoid needlessly extinguishing its patent rights.

Speaking at conferences is what researchers do; the challenge facing the research administrator is to make sure that the proper steps have been taken beforehand to protect the researcher's ideas. For example, conferences usually require speakers to submit abstracts detailing proposed topics of conversation. Often, conference moderators will post this abstract on a Web site or distribute it to conference attendees, all without the researcher's knowledge or explicit permission. Either of these actions may be enough to trigger either the "absolute novelty bar" or start the clock running for the "printed publication bar," and prevent the university from obtaining certain patent rights. The best way to prevent such a scenario is to maintain maximum control over the dissemination of the researcher's invention at all times. Do not assume that others will treat the disclosure of the researcher's work as confidential and proprietary.

The safest course is to be proactive. Do not put the university's patent rights in jeopardy by waiting until after research results are published or disclosed to file a patent application. File a sufficiently descriptive patent application (either a provisional patent application or a regular utility patent application) in the U.S. before publicly disclosing the invention, whether the disclosure occurs via a periodical, an industry conference, an Internet abstract, or even posting research results on a poster board outside your office. Filing a U.S. patent application before disclosure establishes a priority filing date and protects the researcher's idea both domestically and, with subsequent foreign filing, abroad as well.

Protecting patent rights can be as valuable to the researcher and the university, or more so, than meeting publishing requirements. With foresight and planning, along with open dialogue with the researchers, a research administrator can severely mitigate the risk of inadvertently triggering the "printed publication" and "absolute novelty" bars, and properly protect both the university's and the researcher's interests.

## THE IMPACT OF THE CREATE ACT ON UNIVERSITY RESEARCH ENDEAVORS

In the U.S., a patent may not be obtained if it contains only obvious differences from the prior art.<sup>9</sup> An invention will be deemed "obvious" and not patentable if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art to which the subject matter pertains. *Id.* Prior art can take many forms, including past research efforts created by the same research team or by different research teams, so sharing information with another party could potentially obviate the possibility of garnering a patent via an obviousness rejection.<sup>10</sup>

The Cooperative Research and Technology Enhancement Act (the "CREATE Act") was enacted in March 2004 in an effort to promote collaborative research among universities and industry. Before enactment of the CREATE Act, only subject matter that was commonly owned by the same individual, company, or university was entitled to exclusion from being asserted as prior art against new inventions made by that same entity. In other words, before the CREATE Act, so long as the subject matter involved the same inventors, all working for the same entity, a patent applicant could escape an obviousness rejection under the patent statute. What the patent statute failed to address, however, were inventions developed by research teams working together with researcher teams from one or more *different* universities or corporations. This gap in the law proved problematic by discouraging collaborative efforts among different universities and corporations based on the tangible fear of triggering an obviousness rejection. Nowhere was this concern more

apparent than in the controversial decision reached by the Federal Court of Appeals in *OddzOn Products, Inc. v. Just Toys, Inc.*<sup>11</sup>

Decided in 1997, in *OddzOn* the Federal Circuit found that confidential and proprietary information derived from a collaborative research partner from a different entity or university than the inventor could be considered prior art and could serve as evidence of obviousness against any patents made by the collaborating parties.<sup>12</sup> As a result of the *OddzOn* decision, even when structured research relationships were involved, the simple exchange of information between research teams from different universities could create an obstacle to patentability via an obviousness rejection. There simply was no exclusion for researchers working for different employers collaborating under a joint research venture. Faced with the possible loss of otherwise viable patent rights, the *OddzOn* decision had a severe chilling effect on universities contemplating sharing certain research findings with other research entities.

Recognizing the negative effects of the *OddzOn* decision, the CREATE Act sought to remedy the aforementioned adverse possible repercussions. Legislatively preempting *OddzOn*, the CREATE Act provides that patentability will no longer be prevented when the patent is a result of research conducted between more than one different entity pursuant to a joint research agreement, so long as that agreement meets the following three requirements: (i) the joint research agreement must be in effect on or before the date the claimed invention was made; (ii) the claimed invention must be made as a result of activities undertaken within the scope of the joint research agreement; and (iii) the patent application must disclose or be amended to disclose the names of the parties to the joint research agreement.<sup>13</sup> For universities adhering to the requirements of the CREATE Act, the dangers of triggering an obviousness rejection by virtue of sharing information with other research facilities are severely diminished.

However, the party invoking CREATE agrees that the patent is only enforceable if it is not enforced separately from the earlier patent that is being disqualified as prior art by CREATE. More particularly, the owner of the rejected application must: (a) waive the right to separately enforce the patent; (b) agree that the patents shall be enforceable only during the period that the patents are not separately enforced; and (c) agree that the waiver is binding upon the owner, its successors, or assigns.<sup>14</sup> On the other hand, the owner of the “disqualified” patent is not bound by a terminal disclaimer made by the party invoking CREATE and, thus, it would appear that the owner of the “disqualified” patent could unilaterally render the other party’s patent unenforceable by enforcing the “disqualified” patent separately.

What follows is an example provided by the Patent Office to show how the CREATE provisions are applied:

- Company A and University B have a joint research agreement (“JRA”) in place prior to invention X’. Professor BB from University B communicates invention X to Company A. University B files a patent application on invention X on November 12, 2004.
- Company A files an application disclosing and claiming invention X’, an obvious variant of invention X, on December 13, 2004.
- University B retains ownership of invention X and Company A retains ownership of invention X’.
- Company A files an information disclosure statement citing the University B’s patent application of invention X.

- The Patent Office Examiner makes a rejection of the claims of invention X' under 35 USC 103(a) as being obvious in view of the application of invention X.
- Company A properly invokes the prior art disqualification under 35 U.S.C. 103(c) as amended by the CREATE Act.
- The Examiner makes an obvious double patenting rejection of the claims of invention X' in view of the claims of invention X.
- Company A files a proper terminal disclaimer under new 37 CFR 1.321(d) to overcome the double patenting rejection (note: there is a common enforcement of the patents requirement in addition to a common term requirement).
- The Examiner may allow the application of invention X, assuming no other issues need to be resolved in the application.<sup>15</sup>

A university research administrator needs to be careful in defining the "scope" of the subject matter covered by a joint research agreement. The broader the definition, the decreased the likelihood that new inventions arising out of the collaboration may be deemed outside the scope of the joint research agreement, and therefore not protected from the prior art exception proffered by the CREATE Act. So a university research administrator should carefully consider all possible subject matter when defining the scope of work covered under a proposed joint research agreement, to prevent falling outside the auspices of the CREATE Act's protection against a possible obviousness rejection.

### **SPECIAL CONSIDERATIONS FOR PATENTS SPONSORED WITH GOVERNMENT FUNDS**

The use of government funds opens up a whole other set of concerns for universities concerned with protecting their patent rights. When a university research project is either fully or partially funded by government funds, research administrators and other technology transfer professionals need to be well versed in the requirements of the Bayh-Dole Act.<sup>16</sup> Implemented in 1980, the Bayh-Dole Act (hereafter the "Act") permits small businesses and nonprofit institutions, including applicable universities, to retain title to inventions made using federal funds.<sup>17</sup> The Act was enacted to further federal policy of "using the patent system to promote the utilization of inventions arising from federally supported research or development and to promote collaboration between commercial concerns and nonprofit organizations, including universities." *Id.*

For a research administrator managing a research project funded with federal funds, the Act and its many implications are important to consider. First, the Act applies to any inventions "made" by the university research team during the term of the contract with the government. It is important to note that the term "made" has a broad scope and is defined in the Act as anything "conceived or first actually reduced to practice in the performance of work under the contract."<sup>18</sup> Thus, it is important to recognize that the Act applies not only to inventions that are created during the term of the contract, but also to inventions that are conceived *prior* to the contract but reduced to practice during the term of the contract. This corollary applies even if the government is not the sole source of funding for either conception or reduction to practice. Consequently, tracking when an invention is conceived and when it is reduced to practice is of vital importance. The research administrator must make careful annotations whether a particular invention is covered by the Act, because the invention will be bound by the Act's requirement for the duration of its patent term.

When an invention is covered by the Act, the most important requirement to keep in mind is that the university must take certain steps to retain title to the intellectual property funded by federal funds.<sup>19</sup> Obtaining title to the patent is not automatic. *The Act requires a researcher to timely identify any inventions made with federal funds and to notify the federal government whether it elects to retain title to the invention.*<sup>20</sup> A failure to strictly comply with the requirements of the Act can result in the title being transferred to the federal government, and the university being left with nothing to show for its research efforts. *Id.* For example, in one recent case the federal government forced an inventor using federal funds to transfer title of a patent to the government because the inventor failed to properly and timely inform the federal government of an invention developed with federal funds.<sup>21</sup> In addition, a failure by the university to perfect title of inventions created with federal funds can prevent the university from even enforcing the patent against possible infringers in certain circumstances.<sup>22</sup> Any lack of diligence on the part of the research administrator to strictly comply with the requirements of the Act may result in loss of patent title to the government of a technology the university could otherwise license or use for itself. Research administrators must carefully keep abreast of their researchers' discoveries, and promptly report any such discoveries to the appropriate government agent as soon as possible so as to not risk losing the benefit of the discovery.

Additional provisions in the Act could also severely encumber a university's patent rights should the research administrator not properly follow the Act's requirements for federally funded inventions. The Act provides the federal government with certain "march-in" rights that require the patent holder to grant certain licenses to designated third parties if the government determines that: (1) such a compulsory license is necessary because the patent holder has not taken effective steps to achieve practical application of the subject invention, i.e., the patent holder has not taken reasonable measures to commercialize the invention; (2) such action is necessary to alleviate health or safety needs that are not reasonably satisfied by the patent holder; or (3) such action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by the patent holder.<sup>23</sup> Depending on the invention and the surrounding circumstances, it might not be in the university patent holder's best interests to license the invention in question. A savvy research administrator needs to be wary of the government's "march-in rights" for university inventions funded by federal monies and take appropriate measures to avoid undesirable licensing scenarios that could stem from the federal government exerting its "march-in" rights.

In addition, when licensing inventions funded by federal funds, a researcher administrator needs to be aware that another important requirement of the Act mandates that the university receiving title to the invention cannot grant to any person the exclusive right to use or sell the invention in the United States *unless* the licensee "agrees that any products embodying the invention or produced through the use of the subject invention will be *manufactured substantially in the United States.*"<sup>24</sup> Therefore, before a research administrator finalizes any exclusive license agreement involving federally sponsored technology, s/he should determine whether any planned manufacture by the licensee incorporating the licensed technology will be "substantially in the United States." A failure to meet this requirement can trigger the government's march-in rights under the Act.

From the foregoing discussion, it is clear that research administrators must ensure that researchers and university officials alike are aware of what the Bayh-Dole Act requires. A failure to follow its protocols could result in a loss of title in an invention, mandatory uses of the invention not fully desired by the researcher or university, and a loss in revenue and a failure to fully recoup investment dollars.



## THE IMPORTANCE OF LABORATORY NOTEBOOKS IN ESTABLISHING DATE OF INVENTION

Often, competing research teams at different university labs will independently examine the same issue or try to solve the same problem. Among these various research teams, there is a feverish and intense competition to be the first to discern the answer for any given issue. In addition to the accolades and the additional funding that usually go to the first team to discover a breakthrough, being deemed the "first" entity to render a discovery is of vital importance for purposes of obtaining proper patent protection.

In the United States, the person who first reduces an invention to practice is by default deemed the first and true inventor of a given invention.<sup>25</sup> This default position can be refuted, however, if another entity can show it was actually the first to "conceive" the invention and that it exercised reasonable diligence in later reducing that invention to practice, even though it may have reduced the invention to practice after another entity. *Id.* The purpose of requiring "reasonable diligence" to reduce the invention to practice" is to assure the invention was not abandoned or unreasonably delayed.<sup>26</sup> Therefore, if an entity can prove "conception" of an invention at a date earlier than another entity claiming title to the same invention, the entity with the earliest "conception" date will be deemed the true inventor so long as that entity can illustrate it exercised reasonable diligence towards reducing the invention to practice.<sup>27</sup> In other words, establishing the earliest possible conception date coupled with a reasonable diligence towards reducing the invention to practice will go a long way towards an inventor being granted title to an invention.<sup>28</sup>

Understanding what exactly encompasses "conception" and what constitutes "reasonable diligence towards reduction to practice" under U.S. patent law is vital for protecting the interests of both the university and its researchers. The university undoubtedly expects that any worthwhile discovery will ultimately receive patent protection, while the researcher wants to receive full credit for being the first to discover any given innovation. A research administrator who properly understands the importance of "conception" and "reasonable diligence towards reducing the invention to practice" in establishing patent rights and who from the first day of research implements procedures that capture evidence of "conception" and "reasonable diligence towards reducing the invention to practice" can act as an integral component in helping both the university and the researcher reach their stated goals.

In general, to prove "conception," an inventor must have formed in his or her own mind a "definite and permanent idea of the complete and operative invention, as it would be applied in practice."<sup>29</sup> The idea must be so "clearly defined" in the inventor's mind that "only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Id.* In addition, the inventor also needs to prove that after initial invention "conception," the inventor exercised "reasonable diligence towards reducing the invention to practice." When determining an invention "conception" date and "reasonable diligence towards practice," a court will take into account any and all relevant documentation and testimony. A court will consider the oral testimony of the inventors regarding "conception," and "reasonable diligence towards reduction to practice" but under such circumstances will also require corroboration from another source before vesting full credence in the inventor's testimony. *Id.* When relying on purely physical evidence to establish a "conception date" and "reasonable diligence towards reduction to practice," however, corroboration from another source is not required and the physical evidence will be judged on its own merits. *Id.*

With these legal principles in mind, a savvy university research administrator or other technology transfer professional should immediately recognize that the best methodology for proving an invention “conception date” and “reasonable diligence towards reduction to practice” is a total reliance on physical evidence. Unlike inventor testimony, physical evidence does not require corroboration and can stand on its own merits. The content and nature of physical evidence can be controlled from the initial stages of research and supplemented as needed. Conversely, inventor testimony in a court of law may not be controllable or there may not be sufficient additional evidence to corroborate the inventor’s testimony. Therefore, it is vital that universities concerned with establishing the earliest possible invention “conception date” and “reasonable diligence towards reduction to practice” take the proper measures from the very beginning of a researcher’s project to preserve all pertinent physical evidence pertaining to the expected invention.

Often, the best available tool for providing physical evidence of an invention is a researcher’s laboratory notebook. Numerous courts have placed great credence in evidence comprised of laboratory work performed by scientists and contemporaneously recorded in a lab notebook for establishing an invention “conception date” and “reasonable diligence towards reducing an invention to practice.”<sup>30</sup> It is important to encourage university researchers to maintain detailed laboratory notebooks. Not only is a meticulously kept laboratory notebook important for recording pertinent test results and guiding ongoing research protocols, but maintaining an accurate laboratory notebook can help a researcher and the funding university to secure patent rights to any patentable concept that may result during a given research phase.

Given the time constraints of impending deadlines and the demands of ever changing research direction, experience has shown that instead of maintaining detailed lab notebooks, some researchers may be tempted instead to keep a general notebook for “final” results and otherwise take notes and record observations in “working” notebooks, on loose-leaf sheets, or on anything within arm’s length that can be grabbed and written upon. Although recording results in such a haphazard matter may seem to be a necessary reality for many researchers, it presents a logistical nightmare for research administrators attempting to document a researcher’s use of resources, progress towards reaching research milestones, and efforts in establishing the earliest invention conception date and subsequent reasonable diligence towards reduction to practice. Armed with the knowledge of how important physical evidence is in establishing an invention “conception date” and “reasonable diligence towards reduction to practice,” university research administrators must educate the researcher that it really is in the best interest of the researcher, the university, and the project sponsors to keep a singular set of detailed notebooks for use in recording *all* aspects of the research, including everything from raw data and observational jots to more articulate observations and thought out plans on how the research will proceed. Compiling this information in one centralized location is vital not only because the notebook can be used as evidence to prove invention conception, but also in establishing the earliest possible invention conception date. With that documented evidence, the university can protect its interest in any possible issued patents.

To this end, administrators should implement a system that encourages the researcher to employ consistent practices in maintaining a detailed laboratory notebook for patent purposes and assure the researcher that the time spent in doing so will actually supplement the research and not serve as an impediment or undue burden on progress. What follows are a series of suggested, simple protocols that research administrators should consider when advising researchers and when examining the efficacy of existing university policy on laboratory notebooks: (1) Advise researchers to use bound notebooks with numbered pages and to make consecutive entries. This will ensure the proper chronology of the research and ensure no vital conception data are misplaced

or lost. (2) Recommend that the researcher not leave any spaces or blank pages between entries and draw a line through a blank page to indicate it was intentionally left blank. By implementing this simple requirement, the research administrator can eradicate the possibility the researcher might backdate entries or place results in an incorrect chronological order. (3) Advise that the researcher use pens with non-erasable ink and avoid using pencil or other erasable writing instruments. Implementing such a simple measure will ensure the data are not compromised or inadvertently rendered unreadable via the passage of time. In addition, the use of permanent recording instruments will dispel any concerns that results were doctored or manipulated to meet patent requirements. (4) If a researcher finds it necessary to delete incorrect entries, advise the researcher to strike out mistakes or entries intended to be removed and then date and sign or initial any changes or deletions. (5) Follow the advice of your first grade teacher and write legibly! The most meticulously kept laboratory notebook is absolutely useless if nobody (including the researcher) is able to decipher the entries after the fact. (6) Recommend that the researcher err on the side of providing more detail and clarity, with the goal that someone not familiar with the book or the person making the entries could read it and understand what was done and observed. (7) The notebook should not be limited to actual test results. Encourage researchers to include dated entries that outline when important ideas were conceived, including notes from brainstorming sessions, and when work on ideas began and was completed. Too often, many researchers believe this type of information to be immaterial and neglect to include it in their notebooks. But for the purpose of establishing an invention conception date, this data is invaluable to the university research administrator and should be captured as best as possible. (8) If a researcher finds it necessary to rely on materials external to the laboratory notebook, efforts should be made to include them in the notebook. For example, instead of placing printouts from instruments in a separate location or loosely placing the printouts in the notebook, the researcher should permanently fix such materials to the notebook with glue, tape, or staples, and date the entry and sign across the external page and the notebook page to evidence its original, unaltered placement in the notebook. This will ensure vital research data are not lost or misplaced and will maintain the integrity of the research timeline. (9) The research administrator should implement a regularly scheduled (i.e., weekly) meeting wherein a person uninvolved in the research reviews and signs laboratory notebook entries as a witness. This person should *not* be someone who might be considered an inventor or might otherwise be disqualified as not constituting a bona fide, disinterested witness should he or she ever be called to testify about the invention conception timeline.

By implementing these relatively simple procedures, the research administrator will be able to protect the university's investment and intellectual property return, while not saddling the researcher with processes that are detrimental to furthering research goals.

## CONCLUSION

For a research administrator and other technology transfer professionals, the challenge of meeting a plethora of different interests while still adhering to the intricacies of the law is certainly not an easy one. But with careful planning, constant communication, and the implementation of a detailed protocol that governs proper procedures from the very beginning stages of research to the very end of an issued patent's term, research administrators have the tools to assist the university in making inventions from research available under conditions that will promote their effective development and utilization in the public interest while still protecting the underlying intellectual property.

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## ENDNOTES

1. A version of this section appeared in *The Chronicle of Higher Education* (May 27, 2005).
2. See *In re Cronyn*, 890 F.2d 1158, 1159 (Fed. Cir., 1989).
3. See 35 U.S.C. §102(b) (Lexis, 2006).
4. See, e.g., *In re Cronyn*, 890 F.2d 1158 (Fed. Cir., 1989) (circumstances that constitute publication).
5. See, e.g., *In re Klopfenstein*, 380 F.3d 1345, 1349 (Fed. Cir., 2004).
6. 781 F.2d 897 (Fed. Cir., 1986).
7. See, *In re Hall*, 781 F.2d 897, 899 (Fed. Cir., 1986) (finding single copy of thesis available to the public as sufficient to trigger the printed publication bar).
8. See, e.g., *In re Klopfenstein*, 380 F.3d 1345, 1351 (Fed. Cir., 2004).
9. 35 U.S.C. 103(a) (Lexis, 2006).
10. 35 U.S.C. 103(c) (Lexis, 2006).
11. 122 F.3d 1396, 43 U.S.P.Q. 2d 1641 (Fed. Cir., 1997).
12. See *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 43 U.S.P.Q. 2d 1641 (Fed. Cir., 1997).
13. 35 U.S.C. 103(c)(2).
14. 37 CFR 1.321.
15. <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/createtext.html>
16. 35 U.S.C. §200, et. seq. (Lexis, 2006).
17. See 35 U.S.C. §200, et. seq. (Lexis, 2006) (establishing federal policy to use the patent system to “promote the utilization of inventions arising from federally supported research or development . . . [and] to promote collaboration between commercial concerns and nonprofit organizations, including universities”); 35 U.S.C. §202 (Lexis, 2006) (providing for disposition of rights to inventions made in the performance of work under a federal contract).
18. See 35 U.S.C. §201(g) (Lexis, 2006).
19. See 35 U.S.C. §201(a–c) (Lexis, 2006).

20. See 35 U.S.C. §201(c)(1) (Lexis, 2006).
21. See *Campbell Plastics Eng. 'g & Mfg. v. Brownlee*, 389 F.3d 1243 (Fed. Cir., 2004).
22. See, e.g., *TM Patents L.P. v. Int'l Bus. Machines Corp.*, 58 U.S.P.Q.2d 1171 (S.D.N.Y., 2000) (holding that because plaintiff failed to perfect title and government subsequently acquired rights to patent in issue, plaintiff lacked standing to bring an infringement action).
23. See 35 U.S.C. §203(a) (Lexis, 2006).
24. See 35 U.S.C. §204 (Lexis, 2006). Note: this requirement may be waived by the contracting federal agency "upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible." *Id.*
25. *Mahurkar v. C.R. Bard, Inc.*, 79 .3d 1572, 1577-79 (Fed. Cir., 1996).
26. *Brown v. Barbacid*, 436 .3d 1376, 1378 (Fed. Cir., 1996).
27. *Mahurkar v. C.R. Bard, Inc.*, 79 .3d 1572, 1577-79 (Fed. Cir., 1996).
28. Note: Proving the date of invention for chemical or biological compounds may require a slightly different analysis under U.S. Patent Law. Depending on the compound involved, proper conception may not truly be possible until a reduction to practice has occurred. See generally *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200 (Fed. Cir., 1991).
29. *Mahurkar v. C.R. Bard, Inc.*, 79 .3d 1572, 1577-79 (Fed. Cir., 1996).
30. *Brown v. Barbacid*, 436 .3d 1376, 1378 (Fed. Cir., 1996).

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