

Office of Internal Audit



Program Review

PATENT POLICIES AND ACTIVITIES

April 2000

SCOPE

The Office of Internal Audit reviewed the implementation of General Administrative Policy Paper (GAPP) 34, “Patent Policy”, and the level of patent activities at University of Wisconsin (UW) System institutions. Review procedures included:

- Visits to three UW System institutions that reported patent activities and to the UW-Extension;
- Surveys of UW System institutions not visited;
- Surveys of some researchers who submitted invention disclosures or were issued patents for their inventions; and
- Research and, in some instances, surveys of other major research universities’ policies and procedures associated with patents.

During our campus visits, we met with deans and/or associate deans for research. At UW-Madison, we also met with the director of University-Industry Relations (UIR), the managing director of the Wisconsin Crop Improvement Association (WCIA), and the managing director of the Wisconsin Alumni Research Foundation (WARF), a not-for-profit foundation which has been designated as UW-Madison’s patent management organization.

Our surveys of UW System institutions not visited involved telephone interviews with the administrators responsible for federal programs and/or university research.

Our review focused on:

- UW System institutions’ implementation of GAPP 34, specifically the existence of policies and procedures at UW System institutions associated with implementation and the extent to which these policies and procedures conform to GAPP 34;
- The level of patent activity occurring at the UW System institutions; and
- The extent to which GAPP 34 reflects patent practices at the institutions.

BACKGROUND

A patent is a property right protected by law.

Intellectual property can be protected in a number of ways, including copyright, trademark, patent, and plant variety protection. A patent is a property right that permits an inventor to “exclude others from making, using, or selling the invention”. In the United States, a patent is granted by the Patent and Trademark Office (PTO), U.S. Department of Commerce, and is protectable under the U.S. Constitution as codified under Title 35 of the United States Code.

There are three types of patents that can be issued: design, plant, and utility. A design patent protects the configuration or shape of an invention and is specifically created to protect ornamental features. A plant patent protects a new and distinct, asexually reproduced variety of plant. A utility patent -- the most commonly issued patent -- can be obtained on any “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”

Three requirements for patentability are utility, novelty, and non-obviousness.

Patent law specifies three requirements for patentability:

- Utility -- The invention (patentable discovery) must be useful; that is, the invention has a useful purpose and also performs its intended purpose.
- Novelty -- The invention must be new, or an original work.
- Non-obviousness -- The invention must not be obvious to someone of “ordinary skill in the art.”

The rights to a U.S. patent are granted for terms of 20 years (14 years for a design patent). After the patent term expires, the exclusive right to the invention is lost and the invention enters the public domain.

Patent application costs vary.

The cost for a patent application varies. The complete cost for a U.S. patent application may range anywhere from a few thousand dollars to about \$20,000, depending on the technology. The cost for a provisional patent application is significantly less than that of a full patent application. However, the provisional application must be converted into a full application within 12 months of the filing date. Otherwise, the provisional application will automatically be abandoned. For a foreign patent, the application may cost up to \$200,000.

Federal Patent Policies

New federal law allows universities to retain ownership of inventions and promotes universities' commercializing the inventions.

Following World War II, the desire to maintain technological superiority led to an increase in public support for research at academic institutions. However, harnessing inventions from this research remained a challenge. There was no uniform government-wide treatment of inventions. In addition, all university research supported by federal funds was legally the property of the federal government. As a result, few higher education institutions owned titles to patents and engaged in the commercialization of university inventions. In order to “bolster the economic impact of federal research and development investments”, the U.S. Congress enacted the Bayh-Dole Act (Public Law 96-517). This law was largely modeled on the Institutional Patent Agreement granted to UW-Madison by the U.S. Department of Health, Education and Welfare and the National Science Foundation in 1973. Key provisions of the regulations to implement Bayh-Dole (37 Code of Federal Regulations 401) include:

- allowing the university to retain ownership of any inventions created as a result of federal funding, unless the federal funding agency informs the university at the time funding is provided that the agency will retain title to inventions derived from the projects;
- requiring the university to disclose to the appropriate federal agency any invention created with the use of federal funds within two months of the date the inventor discloses the invention in writing to the university;
- requiring the university to attempt to develop the invention;
- requiring the university to provide the U.S. government a non-transferrable, irrevocable, paid-up, nonexclusive license to use the invention;
- allowing the U.S. government to take control (referred to as “march-in” rights) of the invention for health and safety reasons; and
- requiring the university to share a portion of the royalties with the inventor.

Since passage of the Bayh-Dole Act, there has been a significant growth of patent activities and the commercialization of these patents and other inventions at universities. A 1997 General Accounting

Office study and annual surveys of universities by the Association of University Technology Managers (AUTM) found the following:

- Prior to 1980, fewer than 250 patents were issued to U.S. universities each year. Today, U.S. universities are issued an average of almost 1,500 patents per year.
- In 1972, there were 30 patent offices/programs in nonprofit institutions. In 1995, this number had grown to 275.
- The royalties generated from patents issued to U.S. universities participating in the FY 1998 AUTM Survey totaled \$576.8 million. The royalties in FY 1991 were \$122.9 million.

UW System Patent Policy

To foster and support development of inventions for public use at UW System institutions, UWSA issued GAPP 34 in 1985. GAPP 34 delineates procedures required for UW compliance with federal regulations and other contractual obligations. These procedures include:

UWSA policies established disclosure requirements and procedures for reporting disclosures and disposing of the inventions.

- 1) **Agreement to disclose inventions.** GAPP 34 requires UW System institutions to secure written agreements from all employees, other than clerical and non-technical employees, and to disclose promptly in writing all inventions generated during the course of their university duties.
- 2) **Procedures for disclosing inventions.** GAPP 34 requires UW System institutions to establish procedures to use in the event a federally supported invention or discovery is made. These procedures require (a) UW System institutions to designate an institutional unit or organization to “accept assignment of the invention and take responsibility for its development”, and (b) UW researchers to use a designated form for the reporting of the invention.
- 3) **Procedures for disposing of inventions.** GAPP 34 requires UW System institutions to review the disclosures for contractual obligations that may exist and assign ownership of the inventions based on these obligations. UW System’s longstanding position is not to claim proprietary rights in any invention generated by the faculty, staff, or students. In the absence of other contractual obligations, the inventor is free to dispose of the invention in any manner of his or her choosing.

No substantive change has been made to GAPP 34 since it was issued in 1985.

DISCUSSION AND RECOMMENDATIONS

Patents are derived almost exclusively from research and a significant portion of the research discoveries does not meet the criteria for patentability. When conducting this review, we recognized that research was not the primary mission of some UW System institutions and, therefore, did not expect to find many UW System institutions with their own policies and procedures for the implementation of GAPP 34 or with significant levels of patent activities.

As expected, we found few institutions have established policies and procedures for the implementation of GAPP 34. The policies and procedures that were established appear to conform to GAPP 34. We also found that with the exception of UW-Madison, few UW System institutions have a significant level of patent activity. We concluded that while GAPP 34 has provided adequate guidance to institutions on certain issues, developments and practices at the UW System institutions and at the national level have raised a need to reevaluate GAPP 34.

PATENT POLICY IMPLEMENTATION

We focused our review of GAPP 34 implementation on the existence of established policies and procedures and the extent to which these policies and procedures conform to GAPP 34.

Patent Policies

Most UW System institutions reported having no need for their own patent policies. These institutions relied exclusively on GAPP 34. The two UW System institutions that had established their own patent policies at the time of our visits and surveys were UW-Madison and UW-Stout.

Few UW System institutions have established their own patent policies.

UW-Madison's patent policy and GAPP 34 are similar in many respects. UW-Madison's first policy, "Patent Policies and Procedures" or the "Red Book", was issued in 1984. UW-Madison's Red Book was used as the foundation for the development of GAPP 34. The Red Book was revised and reissued in 1998. UW-Madison's

revised Red Book is a single policy document covering intellectual property, including patents, copyrightable materials, data banks, material transfer, and computer software. UWSA maintains separate policies for patents (GAPP 34), copyrightable materials (GAPP 27), and computer software (GAPP 10).

Institution policies are consistent with GAPP 34.

UW-Stout's policy was issued in 1986. No change has been made to the policy since it was issued. The bulk of UW-Stout's policy addresses ownership. In addition to inventions created with federal funds, UW-Stout's intent is for the university to have rights to inventions with substantial university support and involvement and to inventions produced as part of an employee's assigned duties or work for hire, regardless of funding sources. Such claims are allowed under GAPP 34 provided a written agreement between the employee and the institution is executed. UW-Stout's policy requires such a written agreement prior to the initiation of the work.

Although UW-Milwaukee has not established a formal patent policy, UW-Milwaukee has had in place since 1991 an agreement between the university and its employees to direct employees to disclose inventions and assign their inventions to the university. In return, the university agrees to attempt to develop the inventions and share any revenues with the inventors. At the time of our visit, UW-Milwaukee was in the process of recruiting for a position with responsibilities to include formalizing the patent policy.

Agreement to Disclose Inventions

UW-Madison consistently requires researchers to sign an Invention and Patent Agreement.

GAPP 34 requires UW System institutions to secure an Invention and Patent Agreement from employees to disclose promptly all inventions generated as part of their university duties as a condition of participating in extramurally sponsored research. We found that while all institutions require researchers to sign a Conflict of Interest/Financial Disclosure form (federal funding agencies require institutions to have a conflict of interest/financial disclosure policy in place), only UW-Madison consistently required researchers to sign the invention and patent agreement.

At UW-Madison, the invention and patent agreement is an addendum to the Extramural Support Transmittal Form (T-Form). The T-Form is an internal routing form used to request approval of project proposals and agreements between the university and sponsoring entities. UW-Madison's Sponsored Research Programs (SRP) will give an approval when the T-Form contains all required signatures. To ensure university researchers understand the requirement and to

encourage disclosure, the university offered seminars; held talks with faculty, department chairs, and deans; and published newsletters. WARF staff also see it as their role to increase invention disclosures by providing on-going encouragement and support to researchers.

Other UW System institutions' reasons for not securing an agreement varied. Some institutions indicated that they have not secured such an agreement because the types of research conducted at their institutions have minimal potential for patentability. Since the UW Board of Regents has the legal responsibility for complying with federal regulations on the disclosure requirement, it is essential that university researchers understand the requirement for prompt disclosure and that they disclose their inventions as required.

We recommend that the Invention and Patent agreement be secured as a condition of participating in extramurally sponsored research and other university research, even if the research may not lead to a patent.

Patent Development

Few institutions established formal procedures for patent development.

While new federal regulations allow the university to retain ownership of inventions created with federal funding, the same regulations also require the university to attempt to develop the inventions. GAPP 34 requires each institution to establish procedures that it will use in the event a federally supported invention is made. The procedures must designate an institutional administrative office or designate an external organization to accept assignment of the invention and take responsibility for developing it.

UW-Madison's procedures involve SRP, UIR, and WARF.

Getting an invention patented and developing or commercializing the patents are quite complex. Federal laws require attorneys handling patent matters with the federal patent office to obtain a special patent license. Getting an invention patented is a time sensitive and costly process, thus requiring knowledge and experience to assure some success. Developing or commercializing the patents requires considerable expertise and knowledge of the patents and the industry for these patents. Each patent essentially requires a unique marketing program, which involves the licensing staff combing through industry directories to locate potential licensees. In some instances, the new technology may be disclosed for industry evaluation or for publishing prior to getting it patented. In these instances, it is critical that patent rights are preserved during the disclosure. At the time of our review, only UW-Madison, UW-Milwaukee, and UW-Stout had established formal procedures for patent development.

UW-Madison was a pioneer among higher education institutions in patent development. The procedures at UW-Madison are quite intricate and involve three entities: the Office of Sponsored Research Programs (SRP), University-Industry Relations (UIR), and the Wisconsin Alumni Research Foundation (WARF). (See Appendix 1.)

In 1983, UW-Milwaukee's efforts to develop university inventions led to the creation of the Office of Industrial Research and Technology Transfer (OIRTT). OIRTT was closed in 1997 due to a staff retirement. UW-Milwaukee has just recently entered into an agreement with Research Corporation Technologies (RCT), an independent technology management organization, to attempt to commercialize inventions developed at the university.

Informal procedures at other institutions involve a variety of entities.

UW-Stout instituted its procedures in contracts with research sponsors. Under the terms and conditions of these contracts, the sponsors are free to patent any inventions generated by university employees and students in the performance of the research projects, at the sponsors' own expense. The sponsors must, however, assign title to any patents to the university. As consideration for the sponsors' support, UW-Stout agrees to grant a royalty-bearing exclusive license to the sponsors for the life of each patent.

The remaining UW System institutions use informal procedures. These institutions also reported having received few, if any, invention disclosures. These procedures involve a combination of the chancellor's office, the provost's office, the business office, federal grants administrator, dean/associate dean/director for research, and/or UW System legal counsel.

The major challenges UW System institutions, including UW-Milwaukee and UW-Stout, faced when attempting to develop their procedures were finding an entity that could be designated to accept and develop their inventions and securing resources to pay for these services. University documents and officials we interviewed indicated that UW-Milwaukee's OIRTT services, prior to the office's closing, could be available to other UW comprehensive institutions. Even though GAPP 34 indicates that certain services in patent evaluation and patent filing services are available to other UW System institutions, WARF's mission is to serve UW-Madison.

Without procedures, some UW System institutions may not have been able to maximize the economic potential of their university inventions. Some may even be at risk of noncompliance with federal regulations, especially when these institutions require the inventor to

Some UW System institutions have not been able to maximize the potential of university inventions.

assign the invention to the universities. To ensure compliance with federal regulations and to enable institutions to maximize the potential of university inventions, it is critical to have the appropriate procedures established. Examples of where patent development procedures are available to all institutions within a system or to a group of state institutions include Indiana University, University of Massachusetts System, State University of New York System, University of California System, and Texas A&M University System.

Establishing centralized procedures for UW System institutions that currently do not have patent procedures may offer some benefits.

Possible alternatives for UW System institutions which have not developed or could not afford to develop their own procedures for patent development are (1) to have each institution develop its own procedures, or (2) to establish some centralized procedures that could serve these institutions. Even though some institutions, such as the University of California System and the State University of New York System, have recently shifted away from centralized to decentralized procedures, having centralized procedures for UW System institutions that have not developed or could not afford to develop their own procedures still offers UW System some benefits. Until other UW System institutions are able to take advantage of the commercial benefits of their university research on their own, centralized procedures would enable the UW System to offer a single point of assistance for these institutions in (1) obtaining funding to support the types of research that are likely to produce technology with commercial value, (2) stimulating faculty to engage in such research, (3) assisting researchers with obtaining protection for their inventions, and (4) working with researchers and other appropriate organizations to license their technology.

A proposal that has received serious consideration by UWSA and a number of UW System institutions is WARF's establishment of another patent management organization to serve the other UW System institutions. Details of this proposal have yet to be developed. Nonetheless, the proposal appears to offer a possible solution to potential patent activities in the UW System institutions. This proposed arrangement is consistent with the intent of GAPP 34. Under this proposal, other UW System institutions would benefit from WARF's considerable expertise and excellent track record associated with patents. At the same time, WARF would still be able to maintain its mission to serve UW-Madison.

PATENT ACTIVITIES

We collected information on the level of patent activities at the UW System institutions and from AUTM. Quantitative data we used to gauge the level of activities include the number of disclosures and patent applications filed, the extent of use of provisional patent applications, the number of patents issued, and the number of active licenses and amount of royalties.

UW-Madison, UW-Milwaukee, and UW-Stout have patent activities.

We found that three UW System institutions -- Madison, Milwaukee, and Stout -- have received disclosures of inventions, have applied for and obtained patents for some of these inventions, or have received royalties from the patents issued.

Number of Disclosures and U.S. Patent Applications Filed

GAPP 34 requires members of the staff or students on appointment to disclose all inventions made in the course of their university duties, or on university premises, or with university supplies or equipment. Submitting a disclosure is typically the first step in the patent process. Following the disclosure, a determination is made as to the invention's patentability and commercial value. Based on this determination, a patent application is then filed.

Method of counting disclosures varies.

We reviewed data on the number of disclosures and patent applications filed between FY 1993 and FY 1998. There appears to be some variation in methods for counting the number of disclosures. UW-Stout's practice had been to count only disclosures that resulted in patents. Between FY 1993 and FY 1998, UW-Stout reported only one filed patent application and one patent having been granted. Between FY 1993 and FY 1998, UW-Madison reported having received a total of 1,070 disclosures. During the same period, 614 patent applications were filed. (See Appendix 2.) The number of disclosures from UW-Milwaukee was not available due to the office closing. Since 1983 when OIRTT was established, UW-Milwaukee reported having filed 14 patent applications.

UW System's number of disclosures and proportion of disclosures accepted for patent filing compares favorably with other institutions.

The UW System's number of disclosures compares favorably to other universities and university systems. For instance, the 132 U.S. universities participating in the 1998 AUTM survey averaged about one invention per every \$2.2 million of research expenditures. Based on this average, UW System institutions spent about \$442.9 million on research in FY 1998 and should expect to receive about 198 disclosures. UW-Madison alone, which accounted for 93.7 percent of

the total research expenditures in the UW System, received 204 disclosures in FY 1998.

At UW-Madison, a team of staff from WARF evaluates all invention disclosures for their patentability and commercial potential. The team decides which disclosures to accept for patent filing. WARF has also developed procedures for inventors whose disclosures were rejected to discuss and to appeal the decision. According to AUTM, the four-year average proportion of disclosures accepted for a U.S. patent filing at UW-Madison between FY 1995 and FY 1998 was 62.4 percent. UW-Madison's four-year average compares favorably with the Big Ten institutions and is close to the average for the institutions with the highest sponsored research expenditures. (See Appendix 3.)

Extent of Use of Provisional Patent Applications

UW-Madison has filed some provisional patent applications.

Provisional patent applications are specific to U.S. patent law. The provisional application provisions went into effect June 8, 1995. UW-Madison appears to be the only UW System institution filing provisional patent applications. UW-Madison typically files a provisional patent application when there is a time constraint, such as the inventor having to present or publish the discovery, and when the invention is determined to have some commercial value but additional information is desired before a patent application is filed. Between FY 1996 and FY 1998, UW-Madison received 606 disclosures and filed 288 patent applications. Seventy, or 24 percent, of the applications filed were provisional applications. (See Appendix 2.)

Number of Patents Issued

UW System institutions and their patent management organizations were granted 737 patents.

A patent is issued if and when all requirements for patents are met. Our search of the U.S. patent database showed a total of 737 patents were issued to UW System institutions or their designated patent management organizations between 1976 and March 16, 1999: UW-Madison (722 patents), UW-Milwaukee (9 patents), and UW-Stout (6 patents).

Number of Licenses and Amount of Royalties

A license agreement grants a licensee the right to use the invention being licensed in exchange for the licensee's commitment to provide the resources required to further develop and commercialize the invention and to pay fair consideration on that right. Inventions could be licensed without having them patented, though the patent would

have provided more protection. Even though not all license agreements generate revenues, the amount of revenues generated by some licenses can be very substantial.

UW-Madison, UW-Stout, and UW-River Falls received some revenues from their inventions.

Three UW System institutions reported having their inventions licensed and receiving some revenues from these licenses. These are UW-Madison, UW-River Falls, and UW-Stout. UW-Stout received about \$20,000 in gifts from the patents the university licensed to the sponsors of the research projects. UW-River Falls licensed a plant to the University of Maryland and received a small amount of royalties.

In FY 1998, UW-Madison reported having executed 74 licenses and options through WARF. At the end of FY 1998, UW-Madison had a total of 313 active licenses and options. One hundred sixty (160), or 51 percent, of these licenses and options were generating revenues. UW-Madison received \$16 million in FY 1998 from these licenses and options. (See Appendix 2.) According to AUTM, UW-Madison ranked second among the Big Ten institutions and eleventh among 132 U.S. institutions participating in the survey for royalties received in FY 1998. (See Appendix 4.)

UWSA PATENT POLICY

GAPP 34 may need to be reevaluated.

UW System institutions found GAPP 34 provides adequate guidance. However, changes at the national level and practices at some institutions raise the need to reevaluate the following areas in GAPP 34.

Federal Policy and Regulation Citations

GAPP 34 refers to Office of Management and Budget (OMB) Circular A-124. OMB Circular A-124 provides policies, procedures, and guidelines with respect to inventions made with federal funds by small business firms and nonprofit organizations. This particular circular was rescinded in 1987. Even though this citation has minimal bearing on the policy, GAPP 34 may need to be revised. It is important to keep a policy current.

Annual Report Requirements

GAPP 34 requires institutions to submit an annual report to UWSA. The report is to be submitted by December 1 of each year and to include the following information: a listing of patent applications by invention title, the inventor(s) name and title, identification of funding sources, and a brief description of the invention(s).

Annual reporting requirements need clarifying.

We found that UW System institutions have not submitted these reports and UWSA has not requested that institutions submit them. University officials we interviewed also indicated confusion as to who should receive the reports, as this was not specified in the policy. UW System Legal Counsel recommended, and we concur, that this section of the policy be revised. It was suggested that the reports to be submitted to UWSA, if they are continued, be similar to what the UW System institutions submit to the federal government.

Review of Disclosures Of Inventions Made Without External Funding Support and Inventions Made Independently of University Duties

GAPP 34 requires all inventions made with extramural support -- federal or non-federal -- be disclosed. GAPP 34 appears to be less clear to institutions regarding inventions made without any external funding support and inventions made independently of university responsibilities but during university employment.

At UW-Madison, the T-Form is only required when external funding is involved. Inventors required to sign a T-Form have to disclose their inventions. All invention disclosures go through an equity review to determine whether federal funds are involved. Inventions made without federal funds involvement are returned to the inventors to be disposed of by the inventors in a manner of their choosing. Two other UW System institutions were aware that certain faculty members at their institutions were issued patents for inventions made independently of their university assignment but during their university employment. These institutions indicated they had not reviewed these inventions for possible conflict of interest or relationship to the inventors' university duties.

Procedures to review disclosures to determine federal funding involvement and conflict of interest may be needed to protect UW System's interest.

To protect UW System's interest, UW System may want to consider requiring that UW System institutions establish procedures to review all inventions made at university facilities to determine whether federal funds are involved and to review all inventions made independently of university duties to ensure that no conflict of interest exists. Our review of 20 research institutions' policies showed that while these institutions generally do not claim rights to an invention made independently of university responsibilities, about half of the institutions require the inventor to disclose it.

CONCLUSION

Our review indicates that few UW System institutions have established policies and procedures for the implementation of GAPP 34. The few policies and procedures that have been established were consistent with GAPP 34. At this time, most UW System institutions have little or no patent activity. However, the level of activity at UW-Madison looks favorable in comparison to the Big Ten and other research institutions.

Areas in which we have made recommendations or which we have suggested for consideration include:

- requiring an Invention and Patent agreement from all employees participating in extramurally sponsored research and other university research, even if the research may not lead to a patent;
- establishing procedures for patent assignment and development; and
- revising GAPP 34 to ensure it reflects current practices and developments at the UW System institutions and at the national level.