Research Management Review, Volume 14, Number 2
Spring 2005

MANAGING THE UNIVERSITY PATENT PORTFOLIO AND MAKING IT ATTRACTIVE TO LICENSEES: A COMMONSENSE APPROACH

Todd E. Garabedian and Elizabeth A. Galletta
Wiggin and Dana LLP

ABSTRACT

Building an attractive patent and technology portfolio for potential licensees requires involvement and diligence by the technology transfer office and the inventors. Steps outlined in this article, such as proper treatment of IP to assure rights are not lost, preventing premature disclosures, assuring proper ownership and inventorship of inventions, and filing priority patent applications that meet the proper legal requirements for disclosure, should be taken to assure a full complement of rights are available to any potential licensee. Proper IP handling and management by the university and inventors will bring maximum value of IP assets to both the university and the licensee.

INTRODUCTION

Prior to 1980, Congress was concerned that the products of federally funded research were not moving into the public domain to an extent sufficient to benefit the public. This problem stemmed, in large part, to the ownership aspects of research results. At that time, the law provided that the products of federally funded research were owned by the U.S. government. Unfortunately, the government is not efficient in taking these products into the marketplace. To remedy this situation, in 1980 Congress passed the Bayh-Dole Act[1] which permitted universities and small businesses to acquire ownership of the inventions and products made using federally provided funds. To move these inventions and products into the marketplace, technology transfer offices were established at many universities for the express purpose of licensing their technology to the public. The basic idea was to license to companies the university inventions and discoveries made with federal funds in exchange for a royalty, and those companies would use those inventions and discoveries in their product development. Under these arrangements, the university receives a predictable royalty income, and the company adds valuable technology to its products, which, in turn, benefits the public. After more than twenty

years, the large number of licensing arrangements and new companies originating from research universities is a testament to the effectiveness of the Bayh-Dole Act.

To initially secure the university's rights in the technology, the technology transfer office will typically file some type of patent application, and then make it known that this technology is available for licensing. However, despite filing for patent protection, many potential licensees may be reluctant to license the technology due to improper treatment of the intellectual property by the university. In many cases, the IP is tainted in some way that makes it less desirable or unattractive for licensing. The taint is typically caused by legal misunderstandings by the inventors, the university, or the technology transfer office itself, and renders the technology less valuable to the potential licensee. The technology may still be licensed under appropriate circumstances, but the royalty stream enjoyed by the university is less than it would otherwise be if the technology were not tainted. Fortunately, these "self inflicted wounds" can be largely avoided by a thorough understanding of the legal and procedural aspects of the patent procurement process. This article discusses steps that the university, as licensor, can take to secure broad IP rights in an invention and make the invention as attractive as possible to potential licensees so that maximum revenue can be derived from the licensing arrangement.

ATTRIBUTES OF A DESIRABLE PORTFOLIO

From the point of view of a potential licensee, a technology or patent portfolio is most desirable if it (1) addresses technology that relates to the licensee's business, (2) has worldwide rights available, and (3) is free from encumbrances or problems that could limit the scope of protection. Obviously, item (1) depends on an evaluation of the portfolio from a technological perspective, and whether it makes sense from a business standpoint to acquire some type of rights in the technology. These considerations are outside the scope of this article. However, items (2) and (3) can be seriously affected by how the intellectual property (IP) is treated by the inventors and/or the technology transfer office shortly after it has been identified and developed. Proper care and handling of the IP from the beginning is crucial to maximizing its attractiveness to potential licensees, and hence its ultimate value in the marketplace.

One desirable feature of a licensable portfolio is its patent protection (or the potential for patent protection) throughout the world. The availability of worldwide patent rights is particularly important in technologies such as electronics, software, and biotechnology, where the marketplace is worldwide. Having the option of protecting the invention anywhere in the world offers flexibility to a potential licensee to choose countries or regions that best meet his business needs and increases the value of the invention. However, due to the nature of the patent laws in different parts of the world, the inventors or the university may limit the places protection may be sought by actions taken before a patent application is ever filed.

PREMATURE DISCLOSURES

Disclosures of the invention made prematurely and in the absence of any patent filings are generally the most common reason that patent rights in an invention cannot be pursued outside the United States. Under current U.S. Patent Laws, a patent may be applied for in the United States provided that no more than one year has passed since the invention was described in a printed publication anywhere in the world, or in public use or on sale in the United States.[2] This "grace period" gives the inventor one year from such disclosure to file a patent application in the United States. However, while the United States affords a one-year grace period, most other

countries in the world do not. Other countries have a so-called absolute novelty requirement where the invention must not have been disclosed at all, and any such disclosure acts as a complete bar to filing in those countries. Loss of patent rights outside the United States can drastically reduce the value of a portfolio, particularly in big markets such as Europe or Japan. Therefore, in order to secure worldwide rights in an invention, and thereby make it more desirable and valuable to potential licensees, it is crucial that the invention not be disclosed at all prior to the filing of a patent application.

Preventing premature or unintended disclosure of the invention requires a coordinated effort by the technology transfer office and the inventors to make sure the rights in the technology are secured *before* the invention is publicly disclosed. In a university context, loss of these rights most frequently occurs through disclosure of the invention in a publication or at a scientific meeting prior to having a patent application on file. The law considers a "publication" any information that is available to the public, and includes not only technical journal articles, but meeting abstracts, presentation handouts, and, most recently, poster presentations.[3] It is therefore essential that the inventors inform the technology transfer office before any of these types of disclosures are made so that a patent application can be filed to preserve worldwide rights. Similarly, the technology transfer office should implement a policy that faculty submit their manuscripts, posters, and abstracts to the technology transfer office for review prior to any type of public disclosure. Patent counsel should also be involved in reviewing these potential disclosures to advise the technology transfer office of the consequences of these publications, and procedures to avoid unintended loss in the rights to university technology. These steps can add considerable value to a patent portfolio by securing worldwide rights at a very early stage.

FULL UNIVERSITY OWNERSHIP OF THE TECHNOLOGY

Another problem that arises frequently is ownership of the technology or patent portfolio to be licensed. As a practical matter, a potential licensee of university technology will want assurances that the university has full ownership of the technology and full rights to license that technology to the potential licensee. If the ownership rights in the technology are in doubt, or if the university is not the exclusive owner of the technology, the potential licensee may press for contract terms that are less favorable to the university, or forgo the licensing opportunity entirely. Fortunately, the university can take steps to secure its full ownership in the technology.

First, the university should have in place a patent policy (or an employment agreement) that clearly indicates that the university owns worldwide rights to all inventions made at the university by all university personnel who are funded by the university, or who use university facilities or materials. University personnel should be broadly defined in the policy as including full- or part-time faculty, staff, students (both graduate and undergraduate), postdoctoral associates, non-academic employees, fellows, residents, outside consultants, appointees, or visitors. The university patent policy should also state that acceptance of the patent policy is a condition of employment or enrollment, and that all university personnel agree to assign their rights in any inventions to the university. All employees of the university should be provided with a copy of the policy. These steps should make it clear that the university is the owner of all inventions made by all personnel affiliated with the university. Recently, such policies were crucial to determining university ownership of important technology.[4]

Collaborations between inventors at different institutions often present ownership challenges. For example, investigators at one or more universities frequently form collaborations to work on a

specific project. While this type of interaction is beneficial and should be encouraged, ownership of the products of this research should be set out in an agreement between the universities prior to undertaking the project. For example, each of two collaborating universities could each own the technology jointly, and equally share any royalty that results from licensing the technology. Similarly, if the collaboration is between a university and a company, the technology could be jointly owned, and the university could grant an exclusive license to the company for use of its portion of the technology. Of course, other types of arrangements are possible; however, in all cases, the ownership aspects should be established at an early stage to avoid problems later.

The university should also make sure it is the assignee of the inventions described in any patent applications that are filed. In the United States, patents have the attributes of personal property, and are owned by the applicants, unless there is an assignment assigning those ownership rights to another entity.[5] Therefore, each patent application filed by the university should be covered by an assignment whereby all the inventors assign their rights in the invention to the university. Further, such assignments should be recorded at the U.S. Patent and Trademark Office (USPTO) so that the assignment is part of the public record, and the inventors listed on the assignment match those on the patent applications. These steps will provide assurance to a potential licensee that the university is the record owner and is the proper party to license the technology.

PRIOR ART REVIEW

Once the university becomes aware of technology that may be suitable for patenting, it is usually worthwhile to do a preliminary search of the patent and technical literature to determine what obstacles could impede procurement of a patent, and how those obstacles can be effectively addressed so that the technology has a reasonable chance of being licensed. If it turns out that the search reveals that the same technology was developed previously and cannot now be patented, the university can avoid the expense of securing IP rights in this technology and pursue something else. If, on the other hand, the technology appears novel, the university may wish to proceed with a patent application and offer it for licensing with some level of comfort that the technology is not expected to encounter too many problems during the patenting process.
The difficult task in these types of investigations is how much time, effort, and expense should be invested by the university in these types of investigations. The answer, of course, depends on the circumstances. For example, if the technology is very important to the university, more expense could be justified. We believe, however, at a minimum, a simple patent search to determine if a patent can even be filed is always worth the cost. If a potential licensee is identified and wishes to have a more comprehensive search undertaken, it can do so at its own expense.

INVENTORSHIP

Determining the proper inventors on a patent application is an important part of the patent procurement process. However, this determination is frequently not easy, particularly in an academic or collaboration context. Since the consequences of not properly identifying the inventors can result in a patent being found invalid or unenforceable, it is very important to rigorously determine exactly who the proper inventors are.

The most common belief among academics is that inventorship on a patent is analogous to authorship on a technical journal article. This belief is incorrect. Inventorship, unlike authorship, has specific legal criteria that must be met, and these criteria are best evaluated by patent counsel, and not the principal investigator of the research project. Under the patent laws, an inventor on a

provisional patent application is anyone who contributed to the *subject matter that is disclosed* in the provisional application.[6] In contrast, an inventor on a nonprovisional (e.g., a utility) application is anyone who contributed to the conception of the *claimed subject matter* in the application. Determining the proper inventors for a patent application is a highly fact-dependent inquiry and is further complicated by numerous judicial decisions that affect who can be an inventor. It is therefore advisable that IP counsel be engaged to properly determine the inventorship on patent assets that are to be licensed. This rigorous determination will increase the value of the portfolio to potential licensees because the risk of improper inventorship, and hence the chance of patent invalidity or unenforceability, is reduced.

SMALL AND LARGE ENTITIES

In 1982, Congress provided for a 50% discount on patent application and maintenance fees if the applicant was a so-called Small Entity. Small Entities were defined to include, among other things, non-profit organizations such as colleges and universities anywhere in the world, certain tax-exempt organizations, a nonprofit scientific or educational institution, or a nonprofit organization in another country, which, if it were located in the United States, would qualify as a nonprofit organization. However, in all these cases, to assert and maintain small entity status, the nonprofit organization must meet a further criterion that it

> ...[h]as not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license any rights in the invention to any person, concern, or organization that would not qualify as [a small entity].[7]

Thus, if a nonprofit organization, such as a university, licenses its patents to an entity that is not a Small Entity (for example, a large pharmaceutical manufacturer), prosecution and maintenance fees for that patent must be paid under the Large Entity fee schedule. Thus, it is important to determine if the licensee qualifies as a Small Entity or a Large Entity. Unfortunately, these determinations are not always easy. A U.S. court recently articulated the consequences of improperly claiming Small Entity status,[8] after a lower court found a particular licensed patent was unenforceable and expired due to improper claiming of Small Entity status and paying Small Entity maintenance fees. Claims of inequitable conduct before the USPTO were also alleged. It is therefore very important to investigate whether a potential licensee is a Large or Small Entity, and whether the Entity Status should be changed to reflect the licensing arrangement. As the above court decision makes clear, if Small Entity status is to be claimed, a thorough investigation into whether claiming such status is appropriate must be conducted. Failure to conduct such an investigation before making any claim for Small Entity status could form the basis of a lawsuit that could render the university's patent assets unenforceable.

Of particular concern is the situation where the university licenses its patents to a company. Companies provide particular challenges in determining Entity Status because for a company to qualify as a small entity, it must have 500 employees or fewer, including affiliates. The definitions of "employee" and "affiliate" are open to interpretation depending on the time of the year, the business cycle, and the other partnering arrangements the company may have. In general, any transactions involving licensing, conveyance, granting, or assignment of any patent assets owned by the university should be reported to a patent attorney so appropriate steps can be taken to review the transaction and determine if Small Entity status should be changed. Further, with respect to small business concerns, a thorough investigation of all affiliations and

relationships, including investor relationships and obligations, are required. Moreover, the issue of whether Small Entity status is proper must be continuously reviewed and any change in status promptly disclosed to the USPTO. It should be noted that if the applicant or patentee makes an improper attempt to claim small entity status with the intent to deceive, the USPTO will regard that attempt as fraud and expose the applicant or patentee to a variety of sanctions as well as placing the enforceability of the patent in jeopardy.

In many cases, the investigations described above could be costly and not provide a definitive solution with respect to small entity status. In addition, given the potentially severe consequences of improperly claiming small entity status in terms of claims of inequitable conduct and potential patent unenforceability, applicants or patentees should consider carefully whether to claim small entity status even though they may be entitled to do so. In certain situations, the university may wish to change the entity status to large entity and pay large entity fees. As the USPTO has noted:

> It should be appreciated that the costs incurred in appropriately conducting the initial and subsequent investigations may outweigh the benefit of claiming small entity status. For some applicants it may be desirable to file as a large entity ... rather than undertaking the appropriate investigations which may be both difficult and time consuming.[9]

In difficult circumstances, or where the determination of whether a licensee is a large or small entity in doubt, it is generally best to change the status designation to Large Entity to avoid potential problems.

THE U.S. PROVISIONAL PATENT APPLICATION

As mentioned above, to secure its rights in an invention, a university will generally file a provisional patent application in the United States to establish an early filing date and disclosure. The provisional application may be prepared and filed by outside patent counsel, or, in some cases (typically for cost reasons), the technology transfer office itself will prepare and file the provisional application. However, regardless of who prepares and files it, the provisional application must meet specific legal requirements set out in the patent laws with respect to the scope and content of the disclosure. In particular, the application must

> ...contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[10]

Unfortunately, many provisional applications are filed hastily (often to avoid a public disclosure as discussed above), and the "application" consists of a draft manuscript, an abstract, poster slides, or, in some cases, a grant application, which frequently do not comply with these requirements, and/or disclose information that the university does not wish to disclose (e.g., financial information or collaborators). These types of hasty filings can have a serious impact on the IP rights of the technology. The legal effect of not properly disclosing the invention was recently brought to light in a case before the Court of Appeals for the Federal Circuit (CAFC),[11]

where a provisional patent application did not adequately support the invention as claimed in the nonprovisional application. Since the patented product was the subject of a commercial offer for sale more than 1 year before the nonprovisional patent application was filed, the issued patent was found invalid.

To make a patent portfolio as attractive as possible to potential licensees, it is important to have filed provisional applications that describe the invention adequately and meet the requirements of the patent laws. Preferably, this application will have been prepared by patent counsel in conjunction with meetings with the inventors so that the application fully complies with the legal requirements for disclosure, and can be relied on as a priority filing for subsequent applications that follow. As a general rule, all relevant data should be included in the provisional patent application. The provisional application is not required to have claims, but including at least one broad claim is generally desirable. The provisional application should also not include any information the university wishes to remain confidential, such as budgetary or financial information, or names of collaborators or partners.

THE U.S. UTILITY AND INTERNATIONAL PATENT APPLICATIONS

Within one year of filing the U.S. provisional application, the applicants have an opportunity to file a nonprovisional U.S. utility patent application and/or one or more foreign national or international patent applications.[12] While the provisional application acted largely as a "placeholder" and established a priority date, the nonprovisional utility and foreign/international applications are the applications that will in fact be examined by patent examining authorities.

Like the provisional application, the nonprovisional U.S. utility application must meet the disclosure requirements outlined above, as well as have claims directed to the various embodiments of the invention. If the provisional application was prepared with the above considerations in mind, it is generally not a difficult task to prepare or revise it as a nonprovisional utility application.

Prior to filing any nonprovisional utility application, the technology transfer office should check with the inventors to determine if any new data has been developed. Typically, the research process continues after the provisional application has been filed, and any new data generated since the filing of the provisional application should be included in the nonprovisional utility application. This updating process serves three important functions. First, adding new data to a provisional application secures IP rights to the data since it has not yet formed part of a patent application. Second, the new data can provide additional support for broad claims, which is always desirable from the point of view of a licensee. This point is especially important in fields such as biotechnology where the USPTO takes the position that this art is "unpredictable," and therefore many examples and large amounts of data are usually required to obtain claims having any useful breadth. Finally, the new data provides an opportunity to refine and clarify the invention described in the claims of the application, which will generally make the examination process proceed more smoothly. As mentioned above with respect to premature disclosures, the technology transfer office should communicate with the inventors so that new data can be gathered and included in the nonprovisional utility patent applications in advance of the one-year filing deadline.

The nonprovisional utility patent application process also requires that the inventors, technology transfer office, and anyone else involved with the preparation and/or filing of the application

submit relevant prior art to the Patent Office.[13] This "duty of disclosure" is imputed not only to the inventors, but to other laboratory personnel, support staff, and even those in the technology transfer office, and the consequences of not divulging known prior art include possible patent invalidity, unenforceability, or fraud. It is therefore very important to file a complete Information Disclosure Statement (IDS) divulging all of the prior art that the inventors or other parties are aware of. Filing an IDS will assure potential licensees that the university and the inventors are meeting their obligation to cite relevant prior art to the USPTO. A comprehensive IDS should be filed either with or shortly after filing the nonprovisional application. Moreover, any new and relevant prior art that was not included in the original IDS should be cited to the USPTO in one or more supplementary IDS as soon as possible.

In addition to an IDS, a signed Oath and Declaration must be filed along with the nonprovisional application. This is an important document in the application process because formal examination of the application by the examiner cannot proceed without having a signed Oath and Declaration on file with the USPTO. The signed Oath and Declaration must meet several legal criteria, including (1) identifying each inventor, his home address and country of citizenship, (2) stating that the person(s) making the oath or declaration believes the named inventor(s) are the original and first inventor(s) of the subject matter that is claimed, (3) stating that the person(s) making the oath or declaration has reviewed and understands the contents of the application, including the claims, and (4) stating that the person making the oath or declaration acknowledges the duty to disclose to the USPTO all information known to the person(s) to be material to patentability.[14]

Like the IDS, a signed Oath and Declaration should be filed either with or shortly after filing the nonprovisional application. Additionally, since the Oath and Declaration must be signed by each of the inventors, the technology transfer office should keep track of the whereabouts of each inventor so that the proper information can be supplied to the USPTO. During the course of prosecution, inventors (particularly graduate and postdoctoral students) will move, change jobs, etc., and it is important that the technology transfer office be able to locate these people if additional signatures are required. Having the signed Oath and Declaration on file, as well as current addresses for each of the inventors, will assure a potential licensee that the application file is in good order and that examination of the application can proceed.

In addition to the nonprovisional U.S. utility application, one or more foreign or international patent applications may be filed within one year of the provisional application filing date. While many options are available to the technology transfer office with respect to foreign filings, the most common approach is to file an international application under the Patent Cooperation Treaty (PCT). This type of application is advantageous because it covers many countries with a single application, and is relatively inexpensive to file. Preparation of the PCT application is also fairly efficient since the same document that is used for the U.S. utility filing can be used for the PCT filing, hence saving separate preparation costs. From the point of view of a potential licensee, having U.S. utility and PCT applications complete and properly on file provides assurance that all filing deadlines have been met and that the patent applications have a proper priority filing date.

CONCLUSION

Building a patent and technology portfolio that is attractive to potential licensees takes involvement and diligence by the technology transfer office and the inventors. The most important factor that is within the control of the university and the inventors is treating the IP properly to assure rights are not lost. Preventing premature disclosures, assuring proper

ownership and inventorship of the inventions, and filing priority patent applications that meet the proper legal requirements for disclosure are effective and easy steps that any technology transfer office can take to assure a full complement of rights are available to any potential licensee. If the technology meets a licensee's needs, and the university has treated it properly, the licensee will be confident knowing their investment has a good chance of success. Proper IP practices by the university and the inventors will bring maximum value of the IP assets to both the university and the licensee.

ENDNOTES

1. P.L. 96-517 (December 12, 1980).

2. 35 U.S.C §102(b) states that "A person shall be entitled to a patent unless ... (b) the invention was patented or described in a printed publication in this or a foreign country, or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States...."

3. *In re Carol F. Klopfenstein and John L. Brent Jr.*, Slip Op. No. 03-1583 (Fed. Cir., August 18, 2004).

4. *University of West Virginia v. VanVoorhies*, No. 00-1440,-1478 (Fed. Cir., January 30, 2002).

5. 35 USC §261.

6. 37 CFR § 1.45(c).

7. 37 CFR §1.27(a)(3).

8. *Ulead Systems, Inc. v. Lex Computer Management Corp.*, 351 F.3d 1120 (Fed. Cir., December 9, 2003).

9. Definition of Small Entities and Establishing Status as a Small Entity to Permit Payment of Small Entity Fees, 54 Fed. Reg. 54, 604 (2000).

10. 35 USC §112, First Paragraph.

11. *New Railhead Mfg., LLC v. Vermeer Mfg. Co.*, No. 02-1028 (Fed. Cir., July 30, 2002).

12. 35 USC §119(e).

13. 37 CFR §§ 1.97 and 1.98.

14. 37 CFR §1.63.