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Recent Developments in Intellectual Property Law: Avoiding Traps in the Pursuit of University Research

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ABSTRACT

U.S. patent laws have undergone many changes in recent years, both through Congress and the courts. This article summarizes recent developments relating to judicial decisions, legislative initiatives, and patent office policy, and provides some practical advice relating to administration of intellectual property. As illustrated by the latest judicial decisions, the law makes no distinctions between academic research and research done for commercialization and profit. Therefore, those involved in research administration at not-for-profit organizations, colleges, or universities must not assume that they will be treated differently or that certain provisions of the patent laws do or do not apply to them. Such assumptions can have a severe impact on the ability to license the technologies developed at these institutions. Instead, those involved in research administration should adopt a "commercialization" mindset in order to successfully identify, protect, and capitalize on intellectual property generated at the institution.

INTRODUCTION

In 1980 Congress passed the Bayh-Dole Act,[1] which for the first time permitted universities and small businesses to own inventions made with federal funding and to become directly involved in the commercialization process of those inventions. The purpose of the new law was to have the public benefit from the fruits of federally funded research through the transfer of new technology from academia to the marketplace. After more than 20 years, it is readily apparent that university technology transfer has helped to create new businesses and industries, and open new markets.

Shortly after passage of Bayh-Dole, colleges and universities began to develop and strengthen their capabilities to effectively engage in the patenting and licensing of inventions. Although university technology transfer offices today perform a wide variety of highly specialized functions related to the patenting and licensing of inventions, most utilize outside patent counsel to develop and maintain patents that protect their intellectual property. Since enactment of Bayh-Dole, and with the assistance of outside patent counsel, technology transfer offices at most colleges and universities have become quite sophisticated in playing the "patent game."

Like everyone else, colleges and universities are subject to the U.S. patent laws, codified at 35 United States Code. The patent laws have undergone many changes and interpretations in recent years that add to the already complex tasks of the technology transfer office, its staff, and those involved in research administration. This article summarizes several of the more important judicial decisions and issues relating to intellectual property rights and what implications they have on university research policies and procedures. While in no way a comprehensive study, the following analysis can serve as a starting point for those involved in university research administration to enact or change conventional procedures in view of the changing law.

RECENT CASE LAW

New Railhead Mfg., LLC v. Vermeer Mfg. Co.:[2] Provisional Applications Must Meet Statutory Disclosure Requirements

On July 30, 2002 the Court of Appeals for the Federal Circuit, effectively the highest Federal Court to decide patent matters, held that New Railhead's patent was in public use more than a year before patent filing and therefore invalid. Although one issue in this case centers around "public use," this case is instructive for its discussion of the requirements of a provisional patent application.

Briefly, New Railhead owed United States Patent Nos. 5,899,283 ("the '283 patent") and 5,950,743 ("the '743 patent"), drawn to a drill bit for horizontal directional drilling of rock formations and a method for horizontal directional drilling, respectively. New Railhead sued Vermeer Manufacturing for infringement based upon its manufacture and distribution, respectively, of a competing drill bit. In the lower court, both patents-in-suit were invalidated based on sales made more than one year before the filing date of the patent application.

As a part of the Uruguay Round Agreements Act,[3] the patent laws were amended to allow applicants for United States patents to file provisional applications that could provide the priority date for a non-provisional utility application filed within one year of the provisional.[4] Such a provisional application need only include a specification conforming to the written description requirements of the patent laws[5]; no claims are required. However, the Court indicated that for the non-provisional utility application to be afforded the priority date of the provisional application, the two applications must share at least one common inventor and the written description of the provisional must adequately support the claims of the non-provisional application:

> An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application.[6]

According to the Court, the specification of the provisional must "contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms" to enable an ordinarily skilled artisan to practice the invention claimed in the non-provisional application.[7]

The Court indicated that because the parties did not dispute that the patented drill bit was the subject of a commercial offer for sale more than one year before the utility application was filed, the '283 patent was invalid if it was not afforded the priority date of the provisional application. After reviewing all the evidence, the Court concluded that the provisional application did not adequately support the invention claimed in the '283 patent. As a result, the '283 patent was not entitled to the filing date of the provisional application. Accordingly, because the utility application issued as the '283 patent was filed more than one year after the commercial offers for sale, the '283 patent was found to be invalid.

This case illustrates clearly that a provisional application must fully disclose the invention claimed in any subsequent utility application in accordance with the written description requirement of the patent laws, including a full description of how to make and use the invention, and the best way to practice the invention (e.g., the "best mode"). To not do so can result in denial of any priority filing claim, or, as in this case, invalidity of an issued patent. This point is significant because at many universities, it is often a practice to file a provisional application so that an early filing date may be claimed. In my experience, to save costs, those provisional applications may be filed by the technology transfer office itself, usually using a copy of the inventor's latest grant proposal (often including financial or collaboration information), a draft manuscript, or an invention disclosure form that was provided to the technology transfer office by the inventor. However, in many cases, these documents do not adequately meet the disclosure requirements of the patent laws, and thus the provisional application may be worthless for establishing an early filing date. In addition, any potential licensee of the technology will likely review the filed provisional application, usually in consultation with their IP counsel, and may conclude that the university's provisional application is too risky to license due to an ambiguous or incomplete disclosure.

A better practice would be to have IP counsel prepare and file the provisional application. IP counsel is in the best position to review the disclosure materials and make sure that the disclosure meets the written description requirements of the patent laws. IP counsel can also redact financial and collaboration information that a potential licensee may not wish to disclose, or statements that can affect the patentability of the invention. The former consideration is often important because the provisional application will become a public document on issuance of any utility patent that claims priority to it.

University of West Virginia v. VanVoorhies:[8] Graduate Students and Other University Employees Must Assign Patent Rights to University

On January 30, 2002, the Court of Appeals for the Federal Circuit held that a former graduate student must assign his patent rights to the University. The Court determined that one patent application must be assigned because an agreement executed by the graduate student covering an earlier patent required him to assign subsequent patent applications. A second patent application must be assigned because the University's patent policy statement requires assignment of all inventions made by graduate students. This case is instructive for its discussion of the broad language used in the assignments and patent policy.

Briefly, VanVoorhies was a Senior Design Engineer for General Motors Corporation before he enrolled in graduate school at University of West Virginia (UWV) to pursue a Ph.D. in engineering. He went to UWV specifically to work with one particular professor, Dr. James E. Smith, after which Smith and VanVoorhies investigated antennae for wireless power transmission. In November 1991, VanVoorhies submitted an invention disclosure form to UWV describing that invention and listing Smith as a co-inventor. The UWV Patent Policy applies to "University personnel" who are defined as "all full-time and part-time members of the faculty and staff, and all other employees of the University including graduate and undergraduate students and fellows of the University." The Policy states:

> The University owns worldwide right, title and interest in any invention made at least in part by University personnel, or with substantial use of University resources, and unless otherwise agreed, this Policy applies to any invention conceived or first reduced to practice under terms of contracts, grants or other agreements . . . . [t]he inventor shall cooperate fully with the University in all respects; to the evaluation of an invention, the preparation of the filing and prosecution of an application and the transfer of rights in the same as well as the maintenance and protection of any resultant patents.[9]

In November 1992, VanVoorhies and Smith assigned all rights to that first invention to UWV. The written assignment extended to that first patent application, as well as to all continuation-in-part ("CIP") applications relating to the invention, as follows:

> [T]he undersigned does (do) hereby sell, assign, transfer and set over unto said assignee, its successors and assigns, the entire right, title and interest in and to said invention or inventions, as described in the aforesaid application, in any form or embodiment thereof, and in and to the aforesaid application; . . . also the entire right, title and interest in and to any and all patents or reissues or extensions thereof to be obtained in this or any foreign country upon said invention or inventions and any divisional, continuation, *continuation-in-part* or substitute applications which may be filed upon said invention or inventions in this or any foreign country; and the undersigned hereby authorize(s) and request(s) the issuing authority to issue any and all patents on said application or applications to said assignee or its successors and assigns.[10] (Emphasis supplied)

Following completion of his dissertation and award of his doctoral degree from UWV, VanVoorhies then invented a second invention during the short interval between receiving his Ph.D. and beginning his work as a Post-Graduate Research Assistant Professor at UWV. UWV prepared a continuation-in-part ("CIP") application directed to the second invention, and named VanVoorhies as the inventor. However, VanVoorhies refused to sign an assignment on this second invention. Separately, VanVoorhies filed his own patent application, also directed to the second invention, listing himself as the sole inventor. However, unlike the application filed by UWV, VanVoorhies' application was not designated as a CIP of the original application. He assigned all interest in that application to his own company, VorteKx, P.C.

The Court first determined that VanVoorhies was obligated to assign the second CIP patent application to UWV under the assignment for the first application. The Court indicated that the second application met the criteria for being a CIP application. Since the assignment VanVoorhies signed with respect to the first invention expressly required him to assign all CIPs of the original application to UWV, the Court concluded that VanVoorhies was required to assign the CIP application to UWV, and that he breached his duty by refusing to do so.

The Court then determined that VanVoorhies was obligated to assign to UWV the second invention he filed himself and that was not designated as a CIP because that application fell under the University patent policy. According to the Court, that policy broadly applied to all "University personnel," which includes "all full-time and part-time members of the faculty and staff, and all other employees of the University including graduate and undergraduate students and fellows of the University." Under the policy, UWV owns all inventions that are made by University personnel or made with substantial use of University resources. Thus, any inventions made by VanVoorhies pursuant to his graduate studies rightfully belonged to UWV.

This case illustrates clearly the importance of assignments and a comprehensive university patent policy. With respect to assignments, in most cases it is desirable that the assignment broadly include language

referring to all types of continuing applications (both foreign and domestic), such as divisional applications, continuation applications, renewal applications, reissue applications, and, as here, continuations-in-part. It should be noted that in the case of a division or continuation application (which necessarily includes the same subject matter as the corresponding original application), the U.S. Patent and Trademark Office takes the position that a prior assignment recorded against the original application is applied to the division or continuation application because the assignment recorded against the original application gives the assignee rights to the subject matter common to both applications. In the case of a CIP, however, a prior assignment of the original application is not applied to the CIP application because the assignment recorded against the original application gives the assignee rights only to the subject matter common to both applications, and not the new material in the CIP application. As a practical matter, CIP applications should have a new assignment executed and recorded. In any event, an assignment should be signed by all inventors and recorded as soon as practicable.

With regard to patent policies at colleges and universities, most of the patent policies I have reviewed are deficient in one or more areas. In some cases, a university may not have a patent policy at all, or it has been years since it was updated (if they can find a copy of it). Regarding content of the policy, all university patent policies should broadly indicate, among other things, 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 also be broadly defined 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 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, should a dispute arise.

Madey v. Duke University:[11] A Narrowing of the Experimental Use Exception to Patent Infringement

On October 3, 2002, the Court of Appeals for the Federal Circuit overturned a summary judgment that Duke University had an experimental use defense against claims by former professor Dr. John Madey that Duke infringed his patents on free electron laser devices. Duke used equipment incorporating the patented inventions for a research project in a physics laboratory, and claimed the uses were immune from infringement under the so-called "experimental use exception" to patent infringement. However, the Court determined that the defense does not immunize any conduct that is in keeping with the alleged infringer's legitimate business. The Court found that research projects further a research university's business objectives, and are thus not entitled to protection under the experimental use exception. This case is significant because universities can no longer infringe valid patents, claim the activities are protected under "experimental use," and suffer no consequences.

The facts were as follows. An opportunity arose for Dr. Madey to consider leaving Stanford University, where he was a tenured professor, and take a tenured position at Duke University. In 1989, Dr. Madey moved his free electron laser ("FEL") research lab from Stanford to Duke. The FEL lab contained substantial equipment, requiring Duke to build an addition to its physics building to house the lab. In addition, during his time at Stanford, Dr. Madey had obtained sole ownership of two patents practiced by some of the equipment in the FEL lab.

At Duke, Dr. Madey served for almost a decade as director of the FEL lab. However, in 1998, he resigned from Duke. Duke continued to operate some of the equipment in the lab. Dr. Madey then sued Duke for

patent infringement of his two patents. The University contended that such operation was protected under the "experimental use exception" to patent infringement.

A so-called "experimental use" exception to patent infringement has long been recognized under U. S. law. This exception provides that infringement does not occur if the otherwise infringing acts are for amusement, to satisfy idle curiosity or for philosophical inquiry. However, if the infringing acts are for commercial purposes, the exception does not apply and infringement can result. Many universities have interpreted the experimental use exception to patent infringement as providing immunization for research activities that are conducted at a university that would otherwise arguably infringe a valid U.S. patent. However, the Court strongly disagreed and held that universities that conduct and derive benefit from research are not exempt from charges of patent infringement. The Court stated:

> . . . [o]ur precedent clearly does not immunize use that is any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institutions' legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students, and faculty.[12]

The Court continued:

> In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.[13]

Previous case law had suggested the experimental use exception may exempt university researchers from patent infringement if the research had no commercial application.[14] However, the Court has now held that the real test is whether the research furthers legitimate business objectives of the alleged infringer. Since the research activities at a university are now considered a legitimate business interest, colleges and universities can be sued for patent infringement if they do not obtain licenses from the patent holders for the patented technology or instruments they use in their research. The *Madey* case has been appealed to the U.S. Supreme Court for clarification of the experimental use exception. The Supreme Court will hear the case in Fall 2003 and a decision is expected by 2004.

Recently, Congress has become involved in addressing the experimental use exception. Two bills were introduced that relate to the effects of gene patenting on biomedical research and patient care, and seek to exempt the use of patented genetic sequence information "for the purposes of research."[15] The legislation specifically excludes individuals or entities engaged in commercial activities. The purpose of the bills is to provide medical personnel and medical institutions with protection from patent infringement, analogous to exemptions granted to doctors utilizing patented medical or surgical procedures. One bill, The Genomic Research and Diagnostic Accessibility Act of 2002 (H.R. 3967), provides an exemption from patent infringement liability for the use of any patent or for any patented use of genetic sequence information for purposes of research. Under the draft legislation, the exemption would apply to all genetic sequences and would also add an infringement exemption for medical practitioners using diagnostic tests. The bill is currently pending in Congress.

As evidenced from the *Madey* case and recent legislation, the experimental use exception is coming under closer scrutiny, and the courts will undoubtedly have a hand in resolving the issues in the future. In the meantime, colleges, universities, and other not-for-profit research institutions must investigate whether technology they or their faculty intend to use is protected by U.S. patents and whether those patents are currently in force. If the technology is covered under an enforceable U.S. patent, the university must either take a license from the patent owner, design around the claimed subject matter, or not use the technology. In all these cases, however, patent counsel should be involved in the decision-making process to assure the desired result.

Integra Life Sciences v. Merck KgaA et al.:[16] Activities Not Related to Clinical Testing Do Not Fall into the Statutory Exception to Infringement

On June 6, 2003, the Court of Appeals for the Federal Circuit upheld a decision that Merck infringed Integra's patents relating to peptides that promote adhesion of cells. Merck had conducted pre-clinical research using the patented peptides as tools to identify new drugs. The issue before the Court was whether Merck's use of the patented peptides fell within the "safe-harbor" exemption from infringement recited in the patent laws at §271(e)(1). The Court decided Merck's activities did not fall within the exemption because the activities were not "reasonably related" to clinical testing to obtain FDA approval. This case is significant for any institution that utilizes so-called "research tools" that are the subject of a U.S. patent because, in an infringement proceeding, the defense that at some point in the future the data generated by use of the tools could be used in a submission to the FDA is now applicable only under narrow circumstances.

Briefly, Integra owned five U.S. Patents relating to a short tri-peptide segment of fibronectin having a specific sequence, termed RGD. Merck & Co., in collaboration with The Scripps Research Institute, worked on a research project to identify potential drug candidates, and utilized peptides claimed in the five Integra patents as "research tools." Believing the research was a commercial project that infringed its RGD-related patents, Integra offered Merck licenses to the patents-in-suit. However, after lengthy negotiations, Merck declined. Integra then sued Merck and Scripps for patent infringement. Merck answered that its work with Scripps fell under the safe harbor exemption to patent infringement afforded by the patent laws, §271(e)(1), which states:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) *solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products* (emphasis supplied).[17]

In rejecting Merck's claim that these activities were protected under §271(e)(1), the Court concluded that §271(e)(1) was enacted to permit generic drug manufacturers to conduct testing in advance of a patent's expiration so as long as those activities were reasonably related to securing FDA approval. The Court noted that the intent of the statute is to facilitate the immediate entry of safe, effective generic drugs into the marketplace upon expiration of a pioneer drug patent, and activities that do not directly produce information for submission to the FDA do not qualify for exemption under the safe harbor provision. The Court stated that the "FDA has no interest in the hunt for drugs"[18] that may or may not later undergo

clinical testing for FDA approval. Thus, the Court concluded that Merck's work was not reasonably related to clinical testing to obtain FDA approval.

After earlier judicial decisions of lower courts that first permitted the importation of products derived from the off-shore use of patent research methods,[19] and then protected from infringement liability the use of patented intermediate compounds to discover other compounds,[20] the Court emphatically found that early stage discovery research activities were not "solely for uses reasonably related to the development and submission of information under a Federal law"[21] and thus not protected by the safe harbor afforded by §271(e)(1).

In its analysis, the Court considered the RGD peptides to be "research tools" that could be used to facilitate the identification of new therapeutic drugs. The *Integra* decision provides owners of research tool patents with some comfort that unless the research tool is used for clinical testing, infringement of the patents may result. From a practical standpoint, this decision provides some breadth to research tool patents and may cause potential users of the patented tool to steer clear of the patents, or take a license. In addition, holders of research tool patents may now assert their patents against potential infringers, even if the infringing use is related to drug development activities that may be used at some indeterminate time in the future for the development of data for regulatory approval.

For institutions conducting biomedical research, this decision is a double-edged sword. On the one hand, patents that can be considered "research tools" owned by the institution have been reinvigorated because the infringement exemption under §271(e)(1) has been clarified to encompass only uses directly related to generating data for FDA approvals. As noted above, this clarification explicitly excludes early stage research designed to merely *identify* potential drug candidates. Accordingly, patents covering specific research tools may be used to stop infringing use of that tool in research by a competing laboratory or institution. On the other hand, research institutions must be careful not to infringe research tool patents owned by another institution. Since the §271(e)(1) defense applies only to testing performed that directly generates data for FDA use, any other unauthorized use of the tools claimed in these patents likely results in infringement. Research institutions that use research tools should consult patent counsel to determine if they are free to use a specific research tool, or, if the tool is patented, whether and what type of an arrangement with the patent owner would be advisable.

ADDITIONAL (AND OFTEN CRUCIAL) POINTS TO REMEMBER

While the above court cases illustrate some of the recent judicial decisions relating to intellectual property rights, those managing research institutions or groups should also be aware of additional pitfalls that could severely impact intellectual property rights.

Publication of Technical Research in the Absence of a Filed Patent Application

Publication of technical research without having first filed a patent application can have a tremendous negative impact on intellectual property rights. Under the U.S. patent laws, a one-year grace period is permitted between the publication date of a publication that discloses an invention and the filing of a patent application. However, many foreign countries have an "absolute novelty" criterion, which requires that the invention not be disclosed at all prior to filing a patent application. For example, in Europe or Japan, a patent application must be filed prior to any public disclosure of the subject invention. In other words, any disclosure of the invention can result in a complete bar to obtaining any patents on the invention outside the U.S.. The following point cannot be overemphasized: *In order to preserve both foreign and domestic intellectual property rights, patent applications must be filed prior to any*

publication of the invention. This point is important because in most cases, potential licensees of university research will take a license only if they can possess worldwide rights to the technology. Premature disclosures, however, can easily destroy some or all of the foreign rights, making the technology much less valuable for licensing. From a commercialization perspective, it is therefore very important that no disclosures of the invention be made prior to filing an application.

Unfortunately, there has been much confusion regarding what exactly is "a publication" as applied to intellectual property rights. While a comprehensive discussion of what qualifies as a publication is beyond the scope of this article, an abbreviated list of "publication" materials includes technical journal articles, books, conference papers, poster presentations, distributed abstracts, or any other materials that are publicly available and discloses the invention.[22] Since researchers are constantly working to publish their findings, it is of crucial importance that a research administrator be aware of the works being published by the various researchers at their research institution. To achieve this goal, a program should be established whereby investigators notify the technology transfer office or research administrator when a research manuscript is submitted to a journal for peer review. This notification will provide the technology transfer office with sufficient time to review the manuscript and file patent applications prior to publication. With regard to meeting presentations (posters, abstracts, seminars, etc.), researchers should be required to notify the technology transfer office of the scope and content of these disclosures so appropriate steps can be taken to preserve all intellectual property rights prior to the meeting. The technology transfer office or research administrator should also work closely with IP counsel to evaluate materials that will be disclosed, and determine what effect these disclosures will have on the IP position.

Authorship is Not the Same as Inventorship

In most research labs, authorship on a research paper is usually determined by who contributed to the effort. Generally, authors will include graduate students, post-docs, technicians, the principal investigator, and any other person who generated data, performed experiments, or provided advice that was relevant to the research project. The same amorphous standard is not applied regarding patents. Under U.S. law, inventorship is determined by the conception of a claimed invention. Unless an individual has made a contribution to the conception of the subject matter of a least one of the claims in a patent application, that individual fails to meet the legal test of inventorship under U.S. law.[23] In addition, U.S. patent law provides that patents must be applied for in the names of the actual inventors. Intentional failure to correctly identify all of the true inventors on a patent application may serve as a basis for invalidating a patent. The fact that an individual may be considered an author on a scientific paper does not automatically mean that that same individual will be considered an inventor on a patent.

Determination of inventorship is a factual analysis that is best undertaken by patent counsel during preparation of the patent application. Pride and politics should play no role in an inventorship analysis, and research administrators should resist including individuals as inventors on these bases. In one case, a research administrator asked me to include the chairman of the department on an application I was preparing because the chairman felt that he created the atmosphere and environment so that researchers could do their work. After some investigation, I determined that the chairman made absolutely no conceptual contributions to the claimed subject matter. After explaining to the research administrator that the chairman was not an inventor, and that including him could jeopardize the validity of the patent, his name was removed from the inventorship list. The chairman was not happy to say the least, but the patent asset that was to be owned by the university would not be found invalid by including this particular individual who was clearly not an inventor. Until the academic community becomes aware that traditional "authorship" does not always rise to the level of inventorship, rigorous investigation into inventorship will continue to be an important task of research administrators and IP counsel.

Proper Laboratory Recordkeeping is Essential

The U.S. patent system maintains a "first to invent" priority system in which the patent office awards a patent to the first person who conceived the invention, and successfully reduced it to practice. If a dispute on inventorship arises, U.S. courts often look to laboratory notebooks to determine who actually invented the invention first. However, most researchers in academia generally keep laboratory records with an eye toward peer review and publication of the findings, and not patenting the potential commercial products of the research. This can cause serious problems if the notebooks are not kept in a form acceptable for resolving an inventorship dispute.

While many of the criteria essential for keeping a proper notebook have been published elsewhere,[24] several important points bear repeating. First, the records should be maintained in a bound and numbered laboratory notebook, all entries should be in permanent ink, and changes or additions to the record should be initialed and dated. Second, the dates when an idea was formed and when work on the idea was begun and completed should be recorded. This information is important in establishing a clear date of conception and reduction to practice. Third, and possibly most importantly, every page of every experiment in an notebook should be signed and dated by the inventor, and at least one non-inventor witness should corroborate the record by reading, signing, and dating the record on every page. This last component has historically been the most troublesome for colleges and universities to implement. It has also historically been one of the first reasons that courts exclude notebooks as evidence of the date of invention. Research administrators should implement a policy whereby research notebooks must be signed and witnessed on a regular basis so that if an inventorship dispute arises, the university has the best evidence of the conception of the invention. As long as the U.S. patent system maintains a "first to invent" priority system, researchers and research administrators should understand that the most important function of laboratory records from an intellectual property perspective is to support the testimony of the inventor regarding dates of conception, reduction to practice, and diligence. Without properly maintained and corroborated laboratory records, priority to patent rights in an invention could be lost.

CONCLUSION

The U.S. patent laws have undergone many changes in recent years and are likely to go through more changes in the future. The most recent policies of the patent office, as well as the judicial decisions, are setting forth a single standard that is applicable to all inventors. Universities and other research organizations must not assume that the patent laws do not apply to them simply because they are academic institutions or not-for-profit entities. By gaining an understanding of the patent laws and adopting policies, procedures and mindsets that emphasize commercialization of the fruits of university research, research administrators will be in a better position to fully protect and exploit the intellectual property generated at their research institutions.

ENDNOTES

1. P.L. 96-517 (passed December 12, 1980). Amendments to the Bayh-Dole Act were included in P.L. 98-620, passed in 1984.

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

3. Public Law 103-465, enacted December 8, 1994.

4. 35 U.S.C. § 111(b).

5. 35 U.S.C. § 112 ¶1.

6. 35 U.S.C. § 119(e)(1).

7. 35 U.S.C. § 112 ¶1.

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

9. Ibid, p. 3.

10. Ibid, p. 4.

11. *Madey v. Duke University*, No. 01-1567 (Fed. Cir., October 3, 2002).

12. Ibid, p. 20.

13. Ibid, p. 20.

14. *Ruth v. Stearns-Roger Mfg. Co.*, 12 F. Supp. 697, 713 (D. Colo. 1935).

15. H.R. 3966 and H.R. 3967 (March 14, 2002) available at http://www.house.gov/science_democrats/member/lr031402.htm.

16. *Integra Life Sciences v. Merck KgaA et al.,* No. 02-1052, -1065 (Fed. Cir., June 6, 2003).

17. 35 U.S.C. § 271(e)(1).

18. *Integra v. Merck*, page 9.

19. *Bayer AG v. Housey Pharmaceuticals, Inc.,* 169 F. Supp. 2d 328, 61 U.S.P.Q. 2d 1051 (D. Del. 2001).

20. *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.,* 2001 WL 1512597 (S.D.N.Y. 2001).

21. 35 U.S.C. § 271(e)(1).

22. For a detailed discussion on various types of publications and their effects, see Garabedian, T. E., "Nontraditional Publications and their Effect on Patentable Inventions", *Nature Biotechnology* 20: 401–409 (2002).

23. Inventorship on a utility, design, or plant patent is determined by who made conceptual contributions to the *claimed* invention. However, inventorship on a provisional patent application is determined by who contributed to the *disclosure*. 37 C.F.R. § 1.45(c). Thus, like a technical research publication, a provisional patent application can name inventors who may not necessarily be inventors on a utility application.

24. Garabedian, T. E., "Laboratory Recordkeeping", *Nature Biotechnology* 15:799–800 (1997).

ABOUT THE AUTHOR

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