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*The Journal of the National Council
of University Research Administrators*

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of University Research Administrators**

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EDITOR'S PREFACE

This issue of *Research Management Review* contains an eclectic mix of articles, thought-provoking in their own right, that make for an interesting read for research administrators. These articles reveal the depth of the research administration profession and how the field of research administration ties to and interacts with other professions and fields.

Attorney Todd E. Garabedian's article, "Recent Developments in Intellectual Property Law: Avoiding Traps in the Pursuit of University Research," begins this issue by discussing recent court cases, legislative actions, and patent office policy changes that impact the administration of intellectual property (IP). Of practical value to the research administrator and technology transfer professional are his suggestions for the administration of intellectual property.

Attorney Robert J. Kenney, Jr. discusses the Northwestern University settlement with the federal government in his article, "'Dual Compensation' and 'Separate Compensation' Arrangements in the Wake of the Northwestern University Settlement." This settlement, involving salary costs and effort reporting, has had an impact upon research administration that is still being felt.

A central issue in intellectual property is valuation of such assets. Professor Jeffrey H. Matsuura of the University of Dayton School of Law, in "An Overview of Intellectual Property and Intangible Asset Valuation Models," discusses different economic models for intellectual property and other forms of intangible assets. He points out that legal rights of ownership and control of intangible assets are critical components of the economic value of those assets and hence need to be incorporated into the most commonly used methods.

Lest you think that this issue is all about law and lawyers, the final article, Stephen Hansen's and Kim Moreland's "The Janus Face of Research Administration," should put your concerns to rest! This article is a thought-provoking read about the changing nature of research administration and how research administrators must adapt to and change in response to the environment. They conclude that only by being "Janus faced" can research administrators address the problems inherent in managing research and sponsored programs.

As these articles illustrate, the field of research administration is constantly changing. A prudent use of flexibility is the order of the day, understanding not only the past, but confidently meeting the challenges of the future.

JAMES J. CASEY, JR., J.D.
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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 owned 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 laws⁵; 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 (emphasis supplied).¹⁰

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. The views expressed in this article are solely those of the author, and nothing in this article constitutes legal advice.

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).

“Dual Compensation” and “Separate Compensation” Arrangements in the Wake of the Northwestern University Settlement

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ABSTRACT

This commentary makes the case for a re-examination of certain existing guidelines of the Department of Health and Human Services (DHHS) and the National Institutes of Health (NIH) regarding reimbursement of salary costs under NIH grants. The settlement earlier this year involving salary costs and effort reporting at Northwestern University has focused attention on arrangements under which grantee faculty and other personnel receive compensation from two or more legal entities (dual compensation), or from a legal entity other than the grantee (separate compensation). Existing NIH and DHHS guidelines define reimbursable salary narrowly, to include in general only compensation that is paid by the grantee itself. The commentary identifies certain problems that these guidelines cause for some grantees, researchers, and the Government itself, and argues for a more flexible approach that accommodates the many different compensation arrangements that exist today in the field of biomedical research. The commentary concludes that a dual or separate compensation arrangement should be permitted if it (a) results in salary levels that are reasonable and accurately allocated to grants by a workable effort reporting system, and (b) provides a reasonable assurance that the grantee’s performance and compliance obligations will be fully satisfied.

INTRODUCTION

It is becoming increasingly evident, especially in the aftermath of the settlement earlier this year involving compensation and effort reporting at Northwestern University, that some existing policies and practices on charging salaries and wages to grants of the National Institutes of Health (NIH) should be re-examined and adjusted. In particular, the Northwestern case has brought into focus a number of unanswered questions about arrangements under which grantee faculty and

other personnel receive compensation from two or more legal entities, or from a legal entity other than the grantee. There is a strong and growing sense in the research community that current government policies and practices do not always deal effectively with the wide variety of such arrangements that exist among NIH grantees. That problem is the subject of this commentary.

The basic difficulty arises from the fact that certain existing NIH and DHHS guidelines define Institutional Base Salary narrowly, for purposes of budgeting and charging NIH grants, to include only compensation that is paid by the grantee itself with a paycheck issued in its own name. For some institutions this narrow definition is entirely appropriate and workable. Many NIH grantees whose personnel receive compensation from two or more sources (e.g., university base salary and clinical practice plan salary) have built effective and fully compliant payroll allocation systems that are designed to account solely for the component of salary paid by the grantee itself. For some of these institutions it would be impractical if not impossible to include other sources of compensation in Institutional Base Salary. In other cases, however, the component of salary paid with a grantee paycheck does not always correspond to a clearly identifiable subset of the employee's effort, and even where it does, limiting Institutional Base Salary to the grantee salary component alone sometimes creates difficulties when personnel shift from one broad category of effort to another (e.g., from clinical to research).

The premise of this commentary is that either approach—including all components of salary in Institutional Base Salary or including only the grantee-paid portion—can in the right circumstances be the basis for a sound, compliant and effective payroll allocation system. Which approach is appropriate for a particular grantee will usually depend on circumstances that government policies and practices do not currently take into account. At present, these policies and practices more or less automatically disfavor the combined compensation approach, often to the detriment not only of grantees and researchers, but also of the Government itself.

Solving this problem will not require revolutionary thinking about payroll allocation, or a major overhaul of how NIH grants are charged for employee compensation. What is needed, rather, is for NIH and its grantees to take a fresh and pragmatic look at a few unresolved salary reimbursement questions and problems that have been lurking under the surface of NIH-sponsored research for some time. It seems clear that the key to any solution is an approach to compensation reimbursement that is flexible enough to accommodate the many different legitimate variations of compensation arrangements that exist today—and will certainly continue to exist in the future. The conclusion to this commentary attempts to sketch out in very broad terms what such an approach might look like.

THE NORTHWESTERN UNIVERSITY SETTLEMENT

In March 2000, an internal “whistleblower” filed a sealed complaint against Northwestern University under the *qui tam* provisions of the federal civil False Claims Act—*United States ex rel. Richard Schwiderski v. Northwestern University et al.* (C.A. No. 02 C 5287, N.D. Ill.). The gravamen of the complaint was that Northwestern had overstated the Institutional Base Salary charged to NIH and other Federal grants by including in the salary of its clinical faculty members not only the compensation paid by the university itself, but also the compensation paid by a separately incorporated clinical practice plan. On its face, the whistleblower's complaint appeared to be a direct challenge to dual compensation arrangements, although as we will see the government's view of the case appears to have been somewhat different. Northwestern ultimately

settled the matter with the government and the *qui tam* relator in January of this year, almost three years after the complaint was filed.

The Northwestern settlement has caused many grantees to take a second look at the panoply of different compensation arrangements under which grantee personnel receive compensation from more than one legal entity (referred to in this commentary as “dual compensation” arrangements), or from a legal entity other than the grantee itself (referred to here as “separate compensation” arrangements). Unfortunately, the resolution of the Northwestern case did not add much clarity to a subject greatly in need of it. It has been very difficult for universities to draw any clear guidance from the Northwestern settlement, and some lessons that are being drawn from it seem incorrect.

As in most such settlements, the parties to the Northwestern settlement expressly agreed to disagree as to what if any basis there might be for the allegations against the university, or what merit there might be to the university’s defenses. The government agencies principally involved in the matter—the Department of Justice, the DHHS Office of Inspector General, and NIH—have not yet issued any pronouncements on what principles they think were vindicated by the settlement, or what lessons they think the university community should draw from it. It is unlikely, in fact, that any such pronouncement will ever appear. Because of these circumstances, and because the detailed facts that gave rise to the allegations in the Northwestern case are not publicly known, great care must be taken in ascribing any particular meaning or precedential value to the case.

To my knowledge, the only public government reference to the Northwestern case (other than in the settlement agreement itself) is a summary that appeared in the DHHS Office of Inspector General’s semi-annual report for the period ending March 31, 2003. Although quite brief, the summary provides some insight into what the DHHS OIG feels is important about the case:

MISUSE OF PUBLIC HEALTH GRANT FUNDS

In Illinois, Northwestern University (Northwestern) agreed to pay the government \$5.5 million to resolve allegations raised in a False Claims Act *qui tam* complaint about the university’s effort reporting under NIH and other extra-mural research grants. The government alleged that in completing applications for the federal grants, Northwestern overstated the percentage of their researchers’ work effort devoted to the grant. Northwestern also allegedly knowingly failed to comply with federal requirements that a specified percentage of the researchers’ effort be devoted to the grant, and knowingly failed to ensure that total effort, broken down by activity, be reported on the university’s effort certification system. The settlement, which stemmed from an OIG audit and investigation, constituted one of the largest settlements with a university for allegations of civil fraud on NIH research grants (DHHS, OIG, Semianual Report, p. 36).

Interestingly, this summary makes no explicit reference to the “dual compensation” arrangement that was the centerpiece of the Northwestern whistleblower’s complaint. Instead, the summary focuses on three alleged effort-reporting problems—overstatement of actual effort devoted to grants, failure to comply with minimum effort requirements, and failure to account for “total effort” of researchers. There is, to be sure, a close link between what compensation should be included in Institutional Base Salary and what effort a grantee must account for. It is worth emphasizing, however, that the DHHS IG appears to have been concerned primarily if not exclusively with the effort reporting issues themselves. There is no suggestion in the DHHS IG’s

summary that dual compensation arrangements were considered inherently improper or even problematic.

In fact, the summary strongly implies just the opposite. The allegation in the summary that Northwestern “knowingly failed to ensure that total effort, broken down by activity, be reported on the university’s effort certification system” indicates that in the DHHS IG’s view university salary allocation systems should be based on total effort. Since salary allocation can be based on total effort only if total compensation is allocated, the implication of the summary is that it is better, in the DHHS IG’s view at least, to include all sources of compensation in Institutional Base Salary—not just the “university” component.

A careful comparison of the complaint and the settlement agreement in the Northwestern case indicates that the other government agencies involved in the case also did not consider dual compensation arrangements to be improper *per se*. As noted above, the central allegation of the whistleblower’s complaint was that salaries earned by clinical faculty members from an independent practice plan were improperly treated as part of the faculty members’ university salaries (*U.S. ex rel. Richard Schwiderski v. Northwestern University*, Complaint ¶¶ 14–21, 29). The settlement agreement, on the other hand, describes the university’s allegedly improper conduct as the inclusion of income from clinical activities compensated by a non-profit foundation “while excluding some or all such clinical activities in calculating the percentage of effort devoted to the grant” (Settlement Agreement II.C(a), emphasis added). The clear implication of the italicized language is that the inclusion of clinical practice income would not have been improper if the university had accounted for clinical activities in its effort reporting system.

This is a critically important point in any attempt to draw “lessons learned” from the Northwestern case. As discussed in this commentary, certain current NIH and DHHS *policies and practices* discourage dual compensation arrangements, but there is nothing in the Northwestern case or any other source of legal authority that suggests that such arrangements are inherently improper. It would be a mistake, therefore, to read the Northwestern case as a legal precedent forbidding or discouraging dual compensation arrangements.

IDENTIFYING THE SOURCE OF THE PROBLEM

The problem addressed in this commentary does not arise because of any fundamental flaw in the cost accounting principles or legal rules that govern the charging of salary costs to federal research. The underlying system of effort reporting and payroll distribution for federal research, as set forth in OMB Circulars A-21 and A-122 and DHHS regulations, remains fundamentally sound and workable. It reflects many years of thinking and negotiation by and between the federal government and the United States research community, and represents in general a sensible balance among sometimes competing considerations. These considerations include, among others: (a) the need for a reasonably accurate allocation of compensation costs to federal research projects, and between organized research and other functions; (b) the practical difficulty of clearly distinguishing research from instruction and other activities in an academic setting; (c) the varying conceptions of full-time effort among, and even within, grantee institutions; and (d) the general reluctance to burden researchers with time-consuming and inflexible effort reporting procedures. Although no one I know is completely happy with the basic compensation reimbursement system created by the OMB Circulars, that situation may be more a mark of a

good compromise than of a broken system. On the whole, the system still works as it was intended to.

In the area of biomedical research, however, the OMB Circulars and other basic rules often provide only a starting point. The great variety and complexity of arrangements whereby medical faculty and other biomedical research personnel are paid make it difficult—if not impossible—to come up with simple rules on charging and documenting salaries that make sense in all cases. The principal complication in the biomedical research area, which the OMB circulars and other cost principles really don't address at all, is the large number of faculty members and other researchers whose salaries are paid or funded by two or more legal entities, or by an entity other than the named NIH grantee.

NIH and DHHS policies have attempted to address this complication, but unfortunately they have done so in a somewhat simplistic and inflexible way. NIH policies generally provide that a grantee may charge NIH grants only for salary costs that the grantee itself incurs—i.e., salary paid by a payroll check issued by the grantee. There are two principal exceptions to this general rule. The first, which appears in the NIH Grants Policy Statement under the heading “Services Provided by Affiliated Organizations,” is that in some circumstances legally separate but closely affiliated organizations (including but not apparently limited to research foundations) may charge for affiliates' costs as if they were their own costs (NIH Grants Policy Statement, p. 87). The second exception, which as far as I know does not appear in any formal written policy, is that grantees may include salary paid by a separate legal entity (such as a clinical practice plan) in Institutional Base Salary if: (a) the separate compensation is guaranteed by the university; (b) the effort related to the separate compensation (e.g., clinical practice effort) is included on the employee's appointment form, and the grantee is considered a “common paymaster” with the separate entity; and (c) the effort compensated by both salaries is included and accounted for in the grantee's effort reporting system. Such arrangements must be specifically approved by DHHS, and to my knowledge only a handful of arrangements have met the criteria and received approval.

As will be discussed, these current government policies and practices with respect to dual or separate compensation arrangements have consequences that are sometimes undesirable from the point of view of the government as well as of many grantees. To take just two important examples, current policies (a) discourage tracking of time and effort on a comprehensive basis by grantees who are otherwise able and willing to do so, and, (b) together with certain other NIH compensation policies, sometimes tend to work against university efforts to increase the participation of clinical faculty in biomedical research. The following sections summarize current government policies in this area, discuss the drawbacks of these policies in the context of certain typical scenarios, and suggest an alternative approach that would better serve the interests of all concerned.

SPECIFIC PROBLEMS THAT ARISE IN APPLYING NIH POLICIES IN DUAL OR SEPARATE COMPENSATION SITUATIONS

The terms “dual compensation” and “separate compensation” do not appear in any pertinent cost principles or policies; they are used in this commentary to identify and distinguish two types of arrangements with somewhat similar implications. A “dual compensation” arrangement is one in which an employee of a grantee receives salary from both the grantee and one or more other legal

entities. Typically the other legal entity has some kind of affiliation with the grantee, most often through common or overlapping management or a research affiliation arrangement. A “separate compensation” arrangement is one in which a grantee uses personnel (typically faculty members) on a grant who have appointments at the grantee institution, but whose entire salaries are paid by a separate legal entity (such as a local hospital or research institute). Again, the separate legal entity that pays the researcher’s salary usually has an affiliation of some kind with the grantee, although the nature of such affiliations varies widely.

The variations and permutations on these basic concepts of dual or separate compensation are practically endless. The following examples, though, illustrate the basic situations that appear to arise most frequently:

- **Example A:** A university has created an independently incorporated clinical practice plan, whose membership consists solely of clinical faculty of the university’s medical school. The total salaries of clinical faculty are established by the medical school department chairs on an integrated basis, taking into account the clinical, research, teaching, and administrative activities of each faculty member. However, the actual payment of each faculty member’s salary is made through two paychecks—one from the university and one from the practice plan.
- **Example B:** A university has an arrangement with two local research hospitals, under which researchers in each institution hold joint appointments in the other two. Each researcher is paid by the institution at which he or she spends most of his or her effort, but researchers often spend part of their time working on grants of the other institutions. The institutions compensate each other for this cross-entity effort through a transfer payment arrangement.
- **Example C:** A university has a longstanding relationship with a 501(c)(3) research institute formed and funded by a state government agency. Under this arrangement, the research institute has agreed to fund a portion of the salaries of university faculty members engaged in research. The total salaries of clinical faculty are established by the medical school department chairs on an integrated basis, taking into account the clinical, research, teaching, and administrative activities of each faculty member. Each faculty member receives two paychecks—one from the state research institute and one from the university.
- **Example D:** A university has a research affiliation with a local VA Medical Center, and many university clinical faculty hold part-time or full-time VA appointments and receive both VA and university salaries.
- **Example E:** A research hospital and a research institute, separate legal entities with common management, operate in effect as one entity for research purposes. Researchers are paid either by the hospital or the institute, but not both. Scientists employed and paid by the hospital often work on grants of the institute, and vice versa. Neither entity supports any of the salary of employees of the other entity, either by direct salary payment or by transfer payments to the other entity for time and effort expended on its grants by employees of the other entity.

In basic economic and research policy terms, none of these situations appears inherently problematic or in any way inconsistent with the interests of NIH or other federal sponsors. Depending on how the grantees in question charge for the costs of personnel working on NIH grants, however, existing NIH policies and guidelines may create problems both for the grantees and the government itself. These problems are of several kinds, as discussed below.

Compliant But Less Than Comprehensive Effort Reporting

The instructions to the standard PHS 398 grant application form make it clear that grantees may charge employee salary costs to NIH grants only on the basis of “Institutional Base Salary.” “Institutional Base Salary” is defined in the instructions as “The annual compensation *that the applicant organization pays for an employee’s appointment*, whether that individual’s time is spent on research, teaching, patient care, or other activities” (PHS 398 Instructions, p. 41, emphasis added). NIH has interpreted the phrase “that the applicant organization pays” to mean that a grantee may, in general, not include in Institutional Base Salary any salary paid to the individual by a separate legal entity, such as a clinical practice plan or an affiliated research institution.

In **Example A** above, therefore, the university would normally be able to include in Institutional Base Salary only the component of the individual’s salary that the individual receives in the form of his or her university paycheck. This is where problems begin.

In the example, the total salary received by each faculty member is established on an integrated basis, taking into account each faculty member’s clinical, research, teaching, and administrative contributions. It would be this integrated salary, and this salary alone, that would have any real meaning in an economic or market sense. By requiring grantees to include in Institutional Base Salary only the university base salary component that is paid with a university paycheck, NIH requires grantees to focus on a sub-component of salary that may or may not be economically meaningful.

In addition, focusing on a sub-component of compensation may prevent some grantees from tracking effort on a comprehensive basis. It is axiomatic that a grantee’s effort reporting system must track the total effort expended by each employee to earn the salary that is used as the basis for charging Federal grants (i.e., in PHS parlance, Institutional Base Salary). Accordingly, if an individual’s total compensation (clinical and university base salary) were used as the basis for charging federal grants, the grantee would be required to track the individual’s total effort on all activities—both clinical and non-clinical. On the other hand, where the Institutional Base Salary used to charge federal grants is restricted to the amount actually paid by a paycheck from the grantee, the grantee would be required to track only the effort expended by the individual to earn that sub-component of salary. In **Example A**, therefore, the effort that the university would be required to track for payroll distribution purposes would be the individual’s non-clinical effort.

An effort reporting system that tracks 100% of the effort expended by each employee to earn his or her Institutional Base Salary is a fully compliant effort reporting system. In fact, any effort reporting system that attempted to track effort that is compensated separately from Institutional Base Salary would be non-compliant for payroll distribution purposes. Other things being equal, however, an effort reporting system that tracks the entirety of an individual’s compensated professional effort, rather than just a sub-component of it, is more likely to be understandable to

the individual who fills out the effort report, and less likely to result in inconsistencies between or among different sub-components of reported effort.

For example, a university effort reporting system that tracks only non-clinical activity might record a level of sponsored research activity for a faculty member that is consistent with a full-time appointment, while failing to detect that the faculty member also has an exceptionally high level of clinical activity. Although in some cases faculty members may be able to sustain both a full-time non-clinical appointment and a high level of clinical activity, an integrated effort reporting system that tracks all effort is more likely to flag such situations and require confirmation that the high levels of reported clinical and non-clinical effort are not mutually inconsistent.

It should also be observed that a payroll distribution system that tracks effort at the total effort level, rather than at the sub-component level, is likely to be more understandable to the faculty members and other employees who have to fill out effort reports. The question “How do you divide your effort among all compensated professional activities” is simply less confusing than the question “How do you divide your effort among the activities for which you are compensated by the university sub-component of your salary?” (The latter question is particularly difficult to respond to where the university sub-component of salary is essentially just a funding component, and clearly represents less than full and fair compensation for any identifiable categories of activity.) Other things being equal, less confusion about what the effort reporting form is asking for should lead to better quality effort reporting.

Many NIH grantees whose researchers have two or more sources of compensation would, if they were allowed to include all sources of compensation in Institutional Base Salary, be fully prepared to track total effort on an integrated basis. Encouraging these grantees to move to a total compensation/total effort basis for charging salaries to NIH grants would enhance the comprehensiveness and quality of these grantees’ effort reporting systems, to the benefit of the grantees and the government alike. There does not appear to be any strong or even plausible reason for not allowing grantees to move in this direction if they are prepared to do so. Yet at this point, NIH policies definitely discourage many grantees from doing so.

Disincentives to Increasing Research Effort by Clinical Faculty

Current NIH policies on charging salary costs sometimes can, and often do, have significant adverse effects on basic research objectives. A good example, which arises very frequently in actual practice, is the difficulty that dual compensation grantees often have in persuading clinical faculty to engage in more research. It seems illogical and arbitrary that whether clinical faculty members receive one or two paychecks should affect their willingness to do more biomedical research, but the reality is that it frequently does.

Referring again to **Example A**, assume a clinical faculty member receives \$90,000 in clinical salary and \$60,000 in university base salary. He currently works 30 hours a week on university duties (which satisfies his full-time university commitment), and 45 hours a week in clinical practice. He has an opportunity to pursue an NIH grant that would require about 15 hours a week of his time. In order to take advantage of this opportunity, he would have to reduce his clinical effort by 15 hours a week, which would reduce his clinical salary component by one-third, to \$60,000. However, since he is already a full-time faculty member, his additional 15 hours a week of research would in itself normally not, under current NIH policies, permit the university to

increase the university component of his salary. (The PHS 398 definition of Institutional Base Salary states that “Base salary may not be increased as a result of replacing institutional salary funds with grant funds” [PHS 398 Instructions, p. 41].) The result would be that by taking on the NIH grant he would suffer an overall reduction in his total salary, from \$150,000 to \$120,000.

If the same clinical faculty member received all of his compensation in a single paycheck from the university, on the other hand, he could readily shift effort from clinical practice to research without affecting his total salary at all. In that case, his Institutional Base Salary would be \$150,000 before and after the shift. He would show 20% effort (15 hours a week out of a total of 75) on his grant proposal, resulting in NIH salary funding of \$30,000, which would replace the economic value of the clinical activity he had given up in order to perform the research. That would be a sensible and positive result, which would be consistent with the objectives of the researcher, the university, and the government.

There is clearly no good reason for allowing technical compensation issues of this sort to create obstacles to greater participation in research by clinical faculty. However, as long as NIH’s current policies limit Institutional Base Salary to amounts paid with a grantee paycheck, such obstacles will remain.

Arbitrary Salary Amounts

Example A and **Example C** both involve situations in which the total compensation of employees working on NIH grants—although established on an integrated basis—is actually paid to the employees in two separate paychecks. In situations like these, as noted above, it is often only the total salary, and not its sub-components, that has any real meaning in an economic or market sense. The sub-components of the salary—clinical vs. university base in **Example A**, or university vs. state in **Example C**—may or may not have any economic or market significance in their own right, and often they don’t. In the clinical practice plan context, for example, it is not uncommon for the university base component to be set at a relatively low level, which does not in fact represent the “market value” of all of the non-clinical contributions that the faculty member makes. Where two different research institutions are supporting the salaries of researchers, as in **Example C**, the amount of each institution’s contribution to a particular salary may depend on availability of funding and other accidental factors, rather than on any conception of services rendered to the funding institution. In these circumstances, it seems arbitrary to require the grantee to include in Institutional Base Salary only the sub-component of a researcher’s salary for which it happens to issue a paycheck.

Inconsistencies in How Effort is Presented in Proposal Budgets

Assume that in **Example C** a particular researcher has total compensation of \$160,000, which he receives in two series of biweekly paychecks—one series in the annual amount of \$60,000 from the university and the other in the annual amount of \$100,000 from the state research institute. Assume also that the researcher is applying through the university for an NIH grant, on which he intends to spend 30% of his professional effort—or \$48,000 worth of effort (30% of \$160,000). How should he present this information in his proposal budget?

Under NIH’s interpretation of Institutional Base Salary, the researcher’s Institutional Base Salary would be limited to \$60,000—the amount paid with a university paycheck. Using that amount as

a base, the \$48,000 worth of effort that the researcher intends to devote to the NIH grant equates to 80% effort (\$48,000 divided by \$60,000). Although 80% effort is an accurate reflection of the percentage of university-compensated effort that will be devoted to the grant, it far exceeds the 30% that would be shown in the grant proposal if effort were to be expressed on a total, integrated basis. It seems obvious that the 30% figure is a more useful figure, because it allows NIH to (a) make a better judgment of how much effort will be expended in relation to total available effort; (b) consider the proposed level of effort in relation to other existing and pending research commitments of the researcher; and (c) compare the proposed level of effort more easily to levels of effort proposed by other researchers on a “total compensation/total effort” basis. For all of these purposes, the 80% effort percentage that the university would be required to show under current NIH policies would have much less informational value.

Institutions faced with this problem sometimes attempt to deal with it by presenting the proposed effort both ways. For instance, using the hypothetical described above, an institution might use the 30% effort figure in the proposal budget, but with a notation that if the effort were expressed in terms of the total effort compensated only by the university, the effort percentage would be 80%. This approach allows NIH to see the proposed effort both ways, but doing so invites potential confusion. In at least one instance where such an approach was taken, NIH informed the grantee that it would fund the researcher’s salary only on the basis of the university salary (\$60,000 in the example), *and* only on the basis of the effort percentage included in the proposal budget (30% in the example). In terms of the hypothetical, in effect, NIH took the position that it would fund only \$18,000 of the faculty member’s effort (30% of \$60,000)—even though \$48,000 worth of real, university-compensated effort was clearly being proposed and would indisputably be provided. This odd and unfair result could have been avoided if the grantee had simply been allowed to propose on the basis of total compensation.

Inconsistent Treatment of Grantees

Grantees that have dual compensation systems are treated differently from grantees that do not, and it is difficult to justify the differences in treatment. As discussed above, dual compensation grantees are not permitted to maintain fully integrated effort reporting systems, and their clinical faculty members have a built-in disincentive to engage in research. In addition, dual compensation grantees are restricted to Institutional Base Salary amounts that do not necessarily reflect the true economic value of the faculty member, and are often compelled to present their salary and effort percentages in proposal budgets in a way that can be confusing and misleading, to their detriment.

There appear to be no good reasons for imposing these kinds of disadvantages on dual compensation grantees. In economic and practical terms, there may be no real difference between a dual compensation grantee and one that has decided to combine all compensation in a single paycheck. Any differences that do exist and are of consequence to NIH and other federal sponsors should be dealt with in their own right, rather than by imposing broad restrictions on virtually all dual compensation arrangements.

A WORD ABOUT “SEPARATE COMPENSATION” ARRANGEMENTS

Most of the discussion in this commentary relates to dual compensation arrangements. The issues that arise in connection with “separate compensation” arrangements (in which a legal entity other than the grantee pays the entire salary of some or all grant personnel) are similar in origin, but different and generally less problematic in effect. **Example B** and **Example E** represent typical separate compensation arrangements. In both examples, all of the entities involved may have personnel working on their grants who hold appointments in the grantee institution, but whose salary is paid completely by a separate institution. In such cases, again, the NIH interpretation of “Institutional Base Salary” would normally preclude the grantee from budgeting and charging for the salaries of such employees, because the grantee does not pay their salaries. This creates difficulties of various kinds.

The issue here is not whether it is permissible for individuals who are not employed by the grantee to hold positions of responsibility with respect to grant performance. Generally speaking, grant personnel are employees of the grantee, but NIH recognizes that there may be circumstances in which even the Principal Investigator on an NIH grant may be employed by an institution other than the grantee (NIH Grants Policy Statement, p. 26). In such circumstances NIH requires “a formal written agreement with the PI that specifies the official relationship between the parties,” and NIH reserves the right to assess “whether the arrangement will result in the organization being able to fulfill its responsibilities under the grant” (Ibid.). There is, however, no *per se* prohibition of such arrangements.

The principal question is how such personnel should be presented in grant proposals, and how to charge NIH and other grants for their services. The “Personnel” sections of the PHS 398 budget forms state that they relate to personnel of the “Applicant organization only.” If these individuals cannot be listed in the “Personnel” section of the grant budget, however, there does not appear to be any alternative way of presenting them that fully and accurately reflects their true status. Such personnel rarely qualify as “subcontractors,” because they are not assigned a discrete sub-portion of the work and required to assume responsibility and risk in carrying it out, as a subcontractor would. Also, there are potentially undesirable F&A implications of treating such personnel as subcontractors, depending on the dollar amount of their services. It might be possible to treat the personnel as “consultants,” although their true role is normally to participate actively in the project team, not as an outside consultant. The “consultant” designation seems particularly ill-suited to arrangements in which the non-employee is the Principal Investigator on the grant.

Often it is suggested that the effort of such personnel should be shown as “purchased services.” The term “purchased services” is not a defined term under the OMB Circulars or NIH policies, but it appears to mean “employee-like services provided by non-employees.” This designation is at least accurate, but if it were used it would still require the grantee to show the personnel in question outside the personnel section of the proposal budgets. It is also unclear whether the grantee’s F&A rate would be applied to the full dollar amount of such services, as it would in the case of employee compensation.

The preferable approach, and the one that seems most consistent with the realities of how such employees of closely affiliated entities are used in research, is to allow them to be presented as “Personnel,” with a requirement that their employment by another entity be clearly noted in the

proposal. Inclusion of such an individual in the “Personnel” section should carry with it the obligation on the part of the grantee to ensure that the effort of the individual is tracked and documented in a compliant manner, either directly or by exchanging effort information with the individual’s employer. Assuming that this obligation is met, there does not appear to be any purpose served by requiring that such individuals be listed separately as subcontractors, consultants, or purchased services personnel.

What Purposes are Served by NIH’s Current Treatment of Dual and Separate Compensation?

There is nothing in NIH’s published policies that suggests a reason for restricting Institutional Base Salary to salary that is paid in the form of a grantee organization paycheck. As dialogue continues on this subject between NIH and the research community, possibly the reason or reasons for NIH’s policies will become more clear. In the meantime, however, we are left to speculate as to what the basis for the policies might be.

Ensuring that Grantees are Authorized to Charge for the Salary Costs Incurred by a Separate Legal Entity?

NIH obviously has a legitimate interest in ensuring that grantees do not claim reimbursement for salaries that they do not pay *and are not authorized to charge*. At a minimum, grantees claiming reimbursement for salaries paid by a separate legal entity must be prepared to demonstrate that they have been authorized by that separate entity to submit such claims.

NIH has dealt with this problem in the context of “affiliated organizations” by requiring the grantee to show either (a) that it has been charged for and is legally obligated to pay for the services in question, or (b) that it has been authorized in writing by the separate entity to claim and retain reimbursement for the salary costs incurred by the separate entity (NIH Grants Policy Statement, p. 87). It would appear that similar provisions would be both appropriate and sufficient in other dual and separate compensation arrangements.

Preventing “Excessive” Institutional Base Salary Amounts?

One possible NIH concern may be that allowing grantees to combine separate sources of compensation would result in excessively high amounts of Institutional Base Salary. If in fact this is one of the reasons for the restriction on dual compensation arrangements, there are three possible responses. First, whatever may have been the case when the restriction was first imposed, the statutory NIH cap on compensation now protects NIH from being charged at an “excessive” salary rate. Second, the fact is that in most if not all cases it is the *combined* salary, not any of its sub-components, that best reflects the economic “value” of the employee; in such cases the combined salary is not “excessive,” but demonstrably reasonable in market terms.

Third, the fact that the combined salary is greater in amount will be partially, if not totally, offset by the fact that the salary will be allocated over a broader range of activity through a payroll allocation system based on total effort. Consider again the hypothetical of a clinical faculty member who receives \$90,000 in clinical salary and \$60,000 in university base salary, and works 45 hours and 30 hours, respectively, in clinical and non-clinical activity. If only the university base salary is included in Institutional Base Salary and 50% of his non-clinical (university) effort

is devoted to an NIH grant, the grant will be charged \$30,000. If, on the other hand, the entire \$150,000 is treated as Institutional Base Salary, then only 20% (15 hours a week divided by 75 hours a week) of that amount will be charged to the NIH grant, also resulting in a grant charge of \$30,000. It is true that if the faculty member is being compensated for clinical activity at a higher rate relative to time spent, then combining the two salaries into one Institutional Base Salary will tend to increase the charges to the NIH grant. However, such a result represents nothing more than NIH's reimbursing of the grantee at a salary rate that reflects the faculty member's true compensation and economic value.

Moreover, where the combined salary exceeds the NIH cap, allowing dual compensation arrangements may actually result in a *lower* charge to NIH grants. For example, assume a faculty member with a university base salary of \$70,000 and a clinical salary of \$105,000, for 30 hours a week of university work and 45 hours a week of clinical work. If the faculty member works 15 hours a week on an NIH grant and Institutional Base Salary is restricted to the university base salary, the university will recover \$35,000 in reimbursement for his salary. However, if the two salaries are combined for an Institutional Base Salary of \$175,000, the university will be restricted to a recovery of 20% of the NIH cap rate of \$171,900, or only \$34,380.

Obviously, different hypothetical numbers will produce different results, but the following facts remain: (a) the NIH cap will protect NIH from being charged "excessive" salaries in dual compensation situations; (b) fully integrated effort reporting and payroll allocation will at least partially offset any higher salary charges to NIH; and (c) to the extent that a dual compensation arrangement actually causes NIH to provide greater reimbursement for a faculty member's salary, this will only occur because the dual compensation salary represents the faculty member's true economic value—which after all *should* be the basis for reimbursement.

Avoiding Double Reimbursement of the Same Salary?

Where the total compensation of a grantee employee is supported both by the grantee and a separate legal entity, and the separate entity is itself engaged in sponsored research, allowing both sources of salary to be included in Institutional Base Salary creates a risk that some part of the employee's salary will be reimbursed twice. For example, where 75% of an employee's effort relates to an NIH grant, in a dual compensation arrangement the grantee would charge NIH for 75% of the employee's salary, including 75% of the salary funded by the separate entity. If the separate entity were also to use the same employee on one of its NIH grants and charge the grant for 50% of the employee's salary, there would clearly be an overlap in reimbursement.

It should be noted that the risk of such overlap is by no means limited to dual compensation arrangements. Even where grantee employees receive only one paycheck, there is no inherent reason to assume that more than 100% of an employee's time and effort will not be charged out to sponsored agreements and other activities. What prevents this from happening in a single compensation arrangement is an adequate system of tracking effort and other support. Exactly the same is true of a dual compensation arrangement.

The key to avoiding such overlap and duplication in a dual compensation arrangement is to require that the effort reporting systems of the grantee and the other "paymaster" are sufficiently coordinated. In the case of VA affiliations, for example, NIH requires a certification "that there is no possibility of dual compensation for the same work." In order to provide such a certification, a grantee must be able to verify, through some sort of coordination of effort reporting, that NIH is

not being charged for effort (and the associated salary) that is being separately compensated by the VA. A similar requirement would be appropriate in other dual compensation arrangements.

Avoiding Diminished Grantee Control over Employees Paid by a Separate Entity?

It would certainly be reasonable to ask whether a grantee whose grant personnel are compensated in whole or in part by a separate legal entity is able to exercise the necessary control over such personnel for grant compliance purposes. To be sure, the power to set salary is an important source of control. There is no inherent reason to assume, however, that such leverage is not present in dual compensation arrangements. Even where employees receive salary from two or more sources, very often the overall amount of the salary is established on an integrated basis, taking into account the full range of the employee's activities. (See **Example A** and **Example C** above.) In such cases at least, the "dual" nature of the compensation arrangement in no way diminishes the ability of the grantee institution to control salary levels.

It should also be noted that control of salary levels is not the only tool, or even the most effective tool, that grantees have available to them to help ensure compliance with grant requirements. The power to disapprove grant proposals or to deny further participation in research, the power to impose discipline, and the power to grant or withhold discretionary funding—to name just a few examples—are all at least as potent weapons as the power to set salaries. On the more positive side, compliance training, adequacy of support staff, and implementation of effective compliance policies and procedures are all tools that are just as available to a grantee in a dual or separate compensation arrangement as they are to any other grantee.

As noted above, NIH itself expressly permits arrangements in which even the Principal Investigator on a grant is employed by an institution other than the grantee (NIH Grants Policy Statement, p. 26). Quite appropriately, NIH cautions that such arrangements may raise questions as the ability of the grantee organization to fulfill its grant obligations. Any grantee that proposes to use non-employee personnel in key grant positions must be prepared to satisfy NIH that the proposed arrangement will not compromise the grantee's performance and compliance ability. Where separate compensation arrangements arise in the context of close research affiliations, there should be a research affiliation agreement under which each party commits to uphold the performance and compliance obligations of the other when its employees are performing on the other party's grants. With appropriate safeguards and procedures of this sort, the use of non-employees, or the use of employees paid only in part by the grantee, does not appear to be inconsistent with NIH's compliance objectives. That being the case, there does not appear to be any compliance-related reason for prohibiting the inclusion of non-grantee compensation in Institutional Base Salary.

Keeping Apples and Oranges Apart?

Although most dual compensation arrangements seem completely consistent with NIH's interests, there may well be some situations in which the separate sources of personnel compensation should remain segregated. One possible example would be a VA affiliation arrangement (see **Example D**), in which faculty members receive full or part-time VA salaries in addition to their full-time (or in some cases, part-time) university salaries.

Even in the case of a VA affiliation, there could be some advantages to integrating the two sources of compensation and the corresponding effort. Most importantly, an integrated system of effort reporting, covering both university and VA effort, would help to reduce inconsistencies in reporting of effort and make overlaps between the two appointments less likely.

On the other hand, since the VA salary is paid by a federal agency, there is no circumstance in which it would be permissible to combine the two components of salary for purposes of charging NIH or other federal grants. Moreover, the VA's own compensation system requires a separate accounting for the time and effort expended by a VA employee in carrying out his or her VA duties. That being so, in the special case of a VA affiliation it would probably not be feasible to combine the VA and university salaries in a single Institutional Base Salary.

There may be other situations where, for similar or other specific reasons, it may be necessary or appropriate to maintain a clear dividing line between dual sources of compensation and their associated effort. However, there does not appear to be a justification for prohibiting all dual compensation arrangements simply because some of them might not be workable or acceptable.

The Current Exceptions are Too Narrow

As indicated above, there are currently two exceptions to NIH's general rule restricting Institutional Base Salary to amounts paid by the grantee itself. As these exceptions are currently interpreted and applied, however, it is not clear whether most dual or separate compensation arrangements that exist today would qualify under either exception.

There is a good argument that the "affiliated organization" exception (NIH Grants Policy Statement, p. 87) should apply to situations in which there is an actual research affiliation between the grantee and a separate legal entity. There is some concern, however, that NIH may read this exception narrowly, to apply only to arrangements involving research foundations acting as an intermediary for universities. Although I am aware of a number of situations in which NIH has, in the past, read this provision more broadly, there is no guarantee in today's uncertain climate that it will continue to do so.

The second exception—the so-called DHHS "common paymaster" exception—is one for which few dual compensation arrangements would be able to qualify. Although grantees would presumably accept the requirement of an integrated effort reporting system corresponding to total effort and allocating total compensation, few grantees are in a position to act as a common paymaster, much less to "guarantee" the non-university component of salary. It appears, therefore, that unless this exception is liberalized it will be of very limited value.

CONCLUSION AND ELEMENTS OF A PROPOSED SOLUTION

The basic premise of this commentary is that both the government and the research community would be well served by a more pragmatic and flexible approach to reimbursement of researcher compensation. The issue is not whether a payroll allocation approach based on total combined compensation is better or worse, or more or less compliant, than an approach based solely on the grantee-paid component of compensation. Either approach can succeed—and either can fail—depending on the circumstances of its use and how it is carried out. A university payroll allocation system based solely on university base salary, where there is a sufficiently clear

delineation between what activity the university pays for and what it doesn't, can have significant advantages in terms of compliance and efficiency. For some institutions, where there is a significant organizational distance between clinical activity and the non-clinical activity paid for by university base salary, no other approach is practicable or desirable, and no purpose would be served by requiring them to change their current approach. However, other institutions, where the entities providing dual or multiple sources of salary are more closely integrated, may be in a good position to allocate total salary on the basis of total professional effort, and may be prepared to build an integrated effort reporting system capable of supporting such an approach. Any solution to the problem addressed in this commentary must be able to identify the circumstances under which the latter approach is acceptable.

Although it is premature to propose such a solution in detail, its most basic elements should, in my view, include the following:

- Redefining “Institutional Base Salary” to provide that, in certain circumstances, it may include compensation paid by an organization other than “the applicant organization.” No grantee would be required to include such additional compensation in Institutional Base Salary, but those who satisfy certain criteria (see below) should be permitted to do so on request.
- Allowing dual compensation arrangements in the clinical practice plan setting where compensation is established on an integrated basis, taking into account all professional activities of the employee, and effort is tracked on an integrated basis by the grantee on the basis of reliable information obtained from the practice plan. In these arrangements, Institutional Base Salary would include both the clinical and non-clinical components of compensation (perhaps excluding bonus payments that are strictly related to clinical practice). Again, no grantee would be required to combine the two components of salary.
- Allowing dual or separate compensation arrangements between affiliated organizations, pursuant to the existing NIH Grants Policy Statement provision on “Services Provided by Affiliated Organizations.” Participants in such arrangements would be required to maintain coordinated effort reporting systems to prevent duplication of effort and reimbursement. If necessary, the requirements of this exception could be clarified and tightened to ensure that any NIH compliance control concerns are satisfied.
- Identifying special situations (such as VA affiliation arrangements) where dual compensation may not be included in Institutional Base Salary.

It is clear that the effort reporting mechanisms necessary to ensure adequate coordination between or among separate organizations would have to be developed with considerable care. Indeed, one of the conditions of permitting inclusion of dual compensation in a single Institutional Base Salary should be the existence of such an “inter-entity” effort system, perhaps meeting certain specified requirements. If such requirements can be met, however—and I believe that many grantees involved in dual or separate compensation arrangements will be fully capable of meeting them—then a grantee that seeks to include dual or separately paid compensation in Institutional Base Salary should be allowed to do so.

Flexibility must be the guiding principle in developing any new policy or guidelines in this area. Any new policy must recognize the wide variety of different compensation arrangements among NIH grantees. The handful of examples of compensation arrangements included in this commentary, while broadly representative of compensation arrangements that actually exist, do not even begin to reflect the very large number of such arrangements and the many differences among them. Virtually all of these arrangements have been established for important and valid economic, legal, organizational or cultural reasons, and cannot easily be changed without considerable damage or cost.

In the absence of a compelling Government reason for a blanket rule disfavoring dual or separate compensation arrangements, I submit that each such arrangement should be evaluated on its own terms. If the arrangement results in (a) an Institutional Base Salary that is reasonable in market terms, (b) a workable system for tracking personnel effort, and (c) a reasonable assurance that the grantee's performance and compliance obligations will be fully satisfied, then the arrangement should be permitted.

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An Overview of Intellectual Property and Intangible Asset Valuation Models

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ABSTRACT

This paper reviews the economic models most commonly applied to estimate the value of intellectual property and other forms of intangible assets. It highlights the key strengths and weaknesses of these models. One of the apparent weaknesses of the most commonly used valuation models is the failure to incorporate legal rights into their calculations. Creation, maintenance, and enforcement of legal rights of ownership and control for intangible assets form a critical component of the total economic value of those assets. The failure to account for the value of those rights undermines the accuracy and the utility of the overall asset valuation process. This paper advocates a concerted effort by professionals involved in intellectual property law and intangible asset development and management to integrate more effectively the legal aspects of intangible asset creation, protection, and transfer into asset valuation models. Absent such integration, all intangible asset valuation models will continue to be incomplete. For research administrators involved in contract negotiation, intellectual property, and technology transfer, an understanding of these models is useful for job performance and professional development.

COMMON VALUATION MODELS

For the purposes of this paper, intellectual property includes all material that can be protected and managed under traditional legal principles of patents, copyrights, and trademarks. Intangible assets are those intangible materials that have commercial value, but are not in a form eligible for traditional intellectual property law protection. For example, while computer programs and music recordings can be characterized as intellectual property, as they are protected under the traditional intellectual property law rights, databases and other factual compilations may be more appropriately characterized as intangible assets, as they are not widely protected by intellectual property law. Developers and users of intellectual property and other intangible assets commonly apply a range of different economic models to estimate the value of that property. The choice of

model for that valuation is largely driven by the goals and concerns of the party developing the valuation. The most common models are: cost-based, market-based, income-based, and options.

Cost-Based Models

A cost-based valuation model focuses on the costs incurred to develop the intellectual property and intangible assets. It provides an estimate for the value of the asset that is tied to the cost to create or acquire the asset (Pitkethly, 2002). The cost-based model does not generally address the potential future benefits that can be derived from the asset (e.g., licensing revenue). A cost-based model is generally backward looking and often includes some form of adjustment for depreciation of the asset over time. Different companies will likely choose to incorporate different costs into their model. For this reason, cost-based models commonly vary from industry to industry and from company to company.

Cost-based valuation models are generally not intended to provide a true estimate of the value of intangible assets. Instead, these models are often applied in response to specific regulatory requirements. For example, cost-based valuation is commonly applied when intangible asset valuation is needed for accounting purposes. This approach to valuation is also often used for tax purposes. Cost-based valuation models have the virtue of being simple and accepted by regulators for tax or audit purposes.

The utility of cost-based models is limited, however, as the models do not present a complete picture of the potential applications for the assets. Most significantly, because of their historical perspective, these models do not account for future benefits that can be derived from the intangible asset. For example, revenues derived from licensing and value created through direct use of the asset are not effectively captured or recognized in most cost-based valuation models.

Cost-based models do not capture the full impact of legal aspects of intangible asset management. Although cost-based models account for legal costs associated with obtaining and maintaining intellectual property rights (costs of patent protections and maintenance, for example), they do not reflect the impact of other legal activities on the value of the asset. For example, cost-based valuation models do not evaluate, in any way, the future enforceability of patent or other intellectual property rights.

Market-Based Models

Market-based valuation models estimate the value of intellectual property assets by looking to the marketplace (Pitkethly, 2002). Assets that are comparable to those in question are identified, and the licensing revenue actually derived from those comparable assets in the marketplace is used as an estimate of the value of the new assets. When comparable intangible assets can be readily identified, market-based valuation models are relatively easy to apply, and can yield accurate projections. Different companies choose different markets as the basis for the valuation; there is substantial variety from company to company even when they each apply a market-based valuation approach.

A significant problem associated with market-based valuation models is appropriate choice of comparable intangible assets. The accuracy of a market-based estimate is largely driven by selection of a model asset that provides an appropriate point of comparison. It is often difficult to

identify an appropriate, and truly comparable, asset. For this reason, market-based models work well when there is an established marketplace for the asset in question, and they are ineffective when there is no clearly defined marketplace relevant to the asset.

The market-based models fail to account for the full range of legal activities that affect intangible asset value. To the extent that the comparable assets that form the basis for the valuation model have legal characteristics comparable to those of the company applying the model, the legal attributes included in the model are more likely to be valid. For instance, if the asset in question is a patent for a pharmaceutical product, and if the product used as the market model was commercialized by a company with access to resources comparable with those of the company applying the model, then the model may be appropriate as to the impact of legal rights on the asset value. If, however, the model product was commercialized by a very large pharmaceutical company, but the new asset was developed by a small company with access to far more limited resources, then the model will be far less appropriate. Patent rights obtained by the large company are more likely to have greater value, as that company will have the resources to enforce those rights in the future, than will similar rights held by the smaller company which is less likely to be in a position to enforce the patent rights. A patent held by a company with resources adequate to enforce the patent in the future has greater economic value than that same patent held by a company lacking the resources to enforce it.

Income-Based Models

Income-based valuation models make use of forecast future revenues to develop a current estimate of asset value (Pitkethly, 2002). Under this valuation model, an intellectual asset's value is primarily established by the royalty revenue it can generate in a licensing structure. These models adopt a forward-looking perspective, estimating future earnings that can be derived from commercial use of intangible assets. Different companies apply different definitions and projections regarding revenue forecasting. As a consequence of this diversity, the income-based valuation model differs, in practice, from company to company.

Basic income-based models can be expanded into models that assess asset value based on estimates of cash flow. Cash flow calculations take the cash receipts of a company or a product (net profits plus amounts deducted for depreciation, amortization, and depletion) over a given period of time and subtract all cash payments over that same period of time. Cash flow figures provide a sense of the financial health of a business over a specific time period. Income-based models are commonly built on future cash flow estimates associated with a particular asset. These models project future earnings and expenditures attached to the asset. Those estimates are also discounted to account for the time value of money and the uncertainty as to the accuracy of the projected cash flow. The net present value of the future earnings is calculated so that the estimated potential value of the asset can be compared with similar estimates for other potential projects, and current resource allocation decisions can be made based on comparative future value of different projects.

As is the case with market-based models, income-based models function best when there is accurate information to support the future income and cash flow projections. Such information is more likely to be available when the asset in question is very similar to one already in the commercial marketplace or when the asset will reach a clearly defined and well-established

market. Income-based models are less effective when market information is sketchy or speculative.

An important challenge associated with use of income-based models that apply a discount rate for uncertainty is the selection of an appropriate discount rate. The discount rates should address both the time value of money and the risk that the estimated income flow will be inaccurate. Selection of an appropriate discount rate poses a major challenge, particularly with regard to the estimate of risk. The accuracy of the overall forecast hinges significantly on the accuracy of the selected discount rate.

Income-based models do not fully account for the impact of legal rights on intangible asset value. Those models can effectively capture the costs associated with obtaining and maintaining intellectual property rights. However, they do not assess the costs associated with enforcement of the legal rights that are tied to the asset. While these models may capture the costs of patent prosecution and maintenance, for example, they do not incorporate costs of future litigation to enforce the patent (including risks associated with enforceability of the patent) or to enforce licensing agreements built around the patent.

Option Models

Another approach to estimating intellectual property value makes use of the concept of options. An option is a choice that can be exercised at a specific time, but need not be exercised. Owners of intellectual property have a variety of choices about the development and commercial use of their property. Those options include: what form of intellectual property rights to invoke, whether to license the asset, how to price the asset, and when to apply legal means to enforce rights associated with an asset. Option models attempt to estimate economic values for each of those choices (Van den Berg, 2002). The estimated economic values of the different options can be combined and compared, thus providing an analytical framework for selecting a commercialization strategy. Companies commonly define and identify options differently; thus, the versions of the option model applied by any two different organizations may be quite varied in structure and result.

Option models are most effective when the various options can be readily identified and valued. The models are more effective when the values for the options are stable, and not subject to dramatic shifts in value. Option models also perform more effectively when the options have set terms and cannot be exercised before they mature. Unfortunately, in the realm of intangible assets, these factors are difficult to satisfy.

There are several important challenges to effective use of option models for intangible asset valuation. For example, the risks associated with the various options associated with commercialization of the asset change continuously over time. For maximum accuracy, the discount factor applied to the option pricing process should, accordingly, be adjusted as the risks shift. It is not feasible to adjust the discount factor continuously; thus, that factor will never be able to reflect precisely the true character of the risks associated with the options.

It is also difficult to structure an option valuation model so that it effectively accounts for the actual future cash flow associated with commercialization of the asset. Over time, exploitation of the asset will generate cash, yet it is very difficult to develop an effective estimate of those

earnings. In addition, those earnings will affect the value of the options associated with the asset, yet it is also extremely difficult to introduce the estimated earnings from the asset, over time, into the option valuation model. This inability to project the evolving future returns from the asset, and to integrate those evolving estimates into the option model, presents another major challenge to the option model.

Advanced forms of option models could capture many of the costs associated with legal rights affecting intangible assets. Integration of those legal activities into the already complex option models is, however, a difficult challenge. The option models already face the disadvantage of being the most complex of the valuation systems. Incorporation of the legal factors into the option model could overwhelm the model, undermining its effectiveness.

Comparison of the Valuation Models

It is helpful to illustrate how application of the different valuation models to one asset can generate different value assessments. Assume, for example, that a pharmaceutical company invested \$200 million to develop and ready a new drug for the marketplace. In addition, assume that the company is confident that the new drug is comparable (as to market size, pricing, and production costs) to a drug previously developed and marketed by the company, and that the previous drug provided \$800 million in profits to the company, from \$1.2 billion in total revenues, when its earnings were adjusted for the time value of money. Let us say that the value of the company's stock rose by \$400 million when the news that the new product was ready for the marketplace was released to the public, and that a competitor has offered to purchase the patent for the drug for \$500 million, at this moment. If we apply the different basic valuation models to this simple hypothetical situation, we generate grossly over-simplified results.

However, the exercise serves to illustrate how the different models can produce dramatically different estimates of asset value. In this case, a cost-based valuation model would estimate the value of the asset at \$200 million. The income-based model would present a valuation of \$1.2 billion. A market-based model could yield an estimate of \$800 million (the value of anticipated future profits from the drug, based on the prior experience with a similar product), \$400 million (the value of the increase in the company's market capitalization after the investment community became aware of the availability of the new product) or \$500 million (the price that another drug company is willing to pay to purchase the asset). Finally, the asset value could be identified, using some version of an options valuation model, as a figure that reflects the economic value to the company of having the current option of choosing between marketing the drug on its own for an estimated return, over time, of \$800 million or selling the asset to the other company for an immediate return of \$500 million.

There is no definitive correct or incorrect answer in this comparative example, and the same is true when valuation models are selected in actual practice. Each of the different basic models can be justified under many different circumstances. Within each of the basic valuation models, there are different variations that can be applied (as we see in the example with regard to the market valuation model). The choice of model significantly influences the valuation estimate that is ultimately derived. At least in part, the choices we make when we select an asset valuation model reflect our goals and concerns regarding the development and use of the asset.

IMPACT OF LEGAL FACTORS ON VALUATION

The value of intellectual property is largely influenced by several different legal considerations. In many instances, the impact of these legal considerations on the valuation of intellectual property and intangible assets is not fully appreciated or considered. Some observers are now beginning to recognize that the legal aspects of intellectual property protection can have a significant impact on the actual value of the assets, and that the strength of the legal rights of ownership and control over those assets should be incorporated into the asset valuation models (Benintendi, 2003).

For example, some now suggest that different elements of patent rights should be evaluated as part of the valuation process. Among the patent elements identified as having the most direct potential influence on the value of the patented asset are: the scope of the patent's coverage, the relationship of the patented invention to the prior art (i.e., pre-existing technology), and the inventiveness of the device covered by the patent (Reitzig, 2002). This approach suggests that the broader the scope of coverage of a patent and the more the patented invention represents a significant advance beyond the prior art, the greater the economic value of the intellectual asset associated with the patent.

Another consideration when assessing the economic value of an intangible asset is the ability of the owner of the property to enforce its rights against other parties. Although a particular asset may qualify for some form of legal protection (e.g., patent, copyright, trademark), effective enforcement of the legal right is not always feasible. For example, a patent may be obtained by an organization that ultimately does not have the resources to maintain the patent or to litigate to enforce the patent. Under those circumstances, the economic value of the patent and the associated intangible assets is significantly less than the value of those same assets when controlled by an entity with the economic resources to maintain and enforce them. Scope of ownership rights has little value if the owner of the rights is unable or unwilling to monitor the rights and act to enforce them, as necessary.

It thus appears that there are at least two key components of effective valuation of legal rights of ownership for intangible assets. The first is the scope of the rights associated with those assets. Generally, it seems that the broader that scope, the more valuable the asset. The second key component is the enforceability of the ownership rights. On this issue, it appears that the more likely it is that the owner will have the resources and the will to maintain, monitor, and enforce (through litigation, if necessary) the ownership rights, the more valuable those ownership rights will be. Accordingly, a broad proprietary right held by a resource-rich owner seems to present a setting in which the potential value of the intangible asset is maximized.

Even when the owner of an intangible asset is able to assert clear legal rights over the asset, however, there is no guarantee that the legal rights will retain full value for the duration of their effective life. For example, in the United States patents can be obtained for computer programs. Although there is a set effective term for patents, advances in the computer software industry move at a far more rapid pace. The value of a patent in the software industry, particularly in the later years of the patent term, is thus not comparable with the value of a patent in an industry in which the market changes less quickly and there are greater barriers to entry for new products and technologies (e.g., the pharmaceutical industry). Thus, the value of even clearly enforceable legal

rights associated with intangible assets varies from market to market and from one time period to another. An effective intangible asset valuation model should reflect that diversity.

Additionally, some intangible assets with significant potential economic value are not readily protected by traditional intellectual property rights or other legal principles. For example, compilations of data in the United States receive minimal intellectual property law protection, and inconsistent protection under alternative legal theories, including property law, contract law, and competition law theories. However, in Europe developers of factual compilations have enforceable legal rights to control access to, and reuse of, their content under legislation that grants specific database ownership rights. Efforts to assess the economic value of this type of intangible asset should recognize that some level of enforceable right of ownership and control can be applied, but the extent and enforceability of that legal right is notably limited in the United States.

Another legal factor affecting intellectual asset valuation is the ability of the owner of the asset to establish enforceable commercial relationships to facilitate commercial use of the asset. Some valuation models for intangible assets assume that the commercial transactions necessary to move the assets into commercial applications can be readily developed and have minimal transaction costs. This assumption may not always be correct. Intangible asset valuation models should, accordingly, include assessments of the feasibility of establishing enforceable asset transfer and access mechanisms, as the value of the asset is significantly lower if those transactions cannot be effectively managed.

Example: The Music Industry. A current example of the potential economic impact on intangible assets when rights of ownership, control, and access for those assets become difficult to enforce is provided by the music industry's ongoing struggles with online distribution of its content. The rise of the MP3 format for digital recordings and the dramatic development of peer-to-peer file-sharing technologies have made widespread circumvention of the traditional music distribution infrastructure a common occurrence. Growth of these technologies has made it far easier for music consumers to obtain and share pirated copies of music recordings. In effect, the controls on access to content and the mechanisms for enforcement of legal rights associated with the content have significantly eroded. This condition has a direct impact on the economic value of music industry assets. If one attempts to estimate the future economic value of music, an intangible asset, that estimate, reflecting the current and anticipated online distribution capabilities, should be less than the valuation associated with the former distribution system in which the record companies had far more control over content distribution and a greater ability to enforce effectively their rights of ownership and control over the content.

In some ways the music industry's struggle to manage online distribution of its content provides a useful laboratory for intangible asset valuation principles. This industry faces a situation in which the costs associated with enforcing its proprietary rights have increased dramatically. In addition, the industry now confronts an environment in which a notable portion of its customers appears to question the ownership rights of the industry. This condition leads one to question whether it might be possible for the future value of an intangible asset to be significantly eroded even when the legal rights of ownership remain valid and the asset owners continue to act aggressively to enforce them, as seems to be the case in the music industry. If this is possible, it could mean that asset valuation models should account not only for the scope and likelihood of legal enforcement of intangible asset ownership rights, but also for the potential impact of technical and market forces on the actual enforceability of those rights. In a market where consumer conduct is chaotic,

legal rights of ownership may lose their value, even when their owners are willing and able to invest significant resources in enforcement.

Each of the most commonly used intangible asset valuation models captures some, but not all, of the legal factors that affect the value of intangible assets. It is possible to introduce at least a rough estimate of the value of those legal factors into each of the different models. Estimates of the costs of establishing, monitoring, and maintaining legal rights of ownership for the assets can be readily developed and introduced into each of the models. Estimating the value of the ownership rights is more challenging. Identifying the scope of the ownership rights and assessing the ability and willingness of the owner to police and enforce the rights will likely involve a more complex analytical process. Estimating the potential for a runaway market where the rights become essentially unenforceable may also be a complicated task. Yet, even if the projections of the impact of these legal factors on asset valuation are very rough, the process of evaluating that impact and the introduction of some estimate for their value will improve the accuracy of the overall valuation effort.

Example: Open Source Software. Another interesting context for intangible asset valuation is presented by the open source software community. Open source software distribution generally involves licensing of the software subject to terms that permit the licensee to access and modify the source code, in exchange for a commitment to preserve the open source nature of the original source code, and in many instances, to make the modified code available on an open source basis. With the dramatic commercial success of Linux and other open source software products, the open source approach has had a significant impact on the computer marketplace. Open distribution models for intangible assets, such as the open source approach, raise interesting questions regarding asset valuation. Traditional intangible asset valuation models are likely to place a very low value on assets that are commercialized through a liberal licensing framework, such as open source. The relatively low value would be established as most open source licenses assess no license fee. It is, however, possible that the models would undervalue assets distributed using open distribution models. The models may not, for instance, effectively account for non-monetary value derived from open source distribution. Such value could include more rapid market penetration and reduced costs of product refinement. As open source and other alternative distribution systems for intangible assets grow in popularity, valuation models should evolve to recognize different forms of value generated by those alternative systems.

The online music distribution and open source licensing experiences illustrate an important lesson for intangible asset managers. Rapid changes in technology and commercial markets have a significant impact on legal rights of ownership and control over intangible assets. To the extent that the asset valuation models are eventually modified to reflect more effectively the impact of legal ownership rights on the valuation estimates, those models must be continuously updated, as the value of those ownership rights will continue to shift as new technologies and new market dynamics alter the relationships between the developers of intangible assets and their customers.

CONCLUSION

A variety of different analytical models are presently applied to estimate the economic value of intellectual property and intangible assets. All models have important strengths and weaknesses. One weakness common to all models is the failure to account adequately for legal aspects of intangible asset development, protection, and transfer. To account for those legal aspects

effectively, the valuation models should include estimates of the costs associated with creation and enforcement of the legal rights. In addition, the models should estimate the value of the legal rights of ownership and control of the assets.

Current valuations models can be readily modified to include estimates of costs of creation and maintenance of legal rights associated with intangible assets. More diligent evaluation of costs of patent prosecution and maintenance should not be difficult, and can be incorporated into the basic valuation models. Costs of enforcement of rights appear to be more difficult to integrate into the models, and estimates of the value of the legal rights seem to be the most difficult aspect of this effort.

Observers who have suggested that the value of legal rights of ownership of intangible assets can be estimated, at least in part, through evaluation of the inventiveness of the asset and the scope of any associated intellectual property protection (Reitzig, 2002) raise an important point. An intangible asset that can be protected under traditional intellectual property law principles and that represents a significant inventive advance over prior art should generally be valued at a level higher than that of an asset that does not have those attributes. However, in addition to the legal strength of the asset itself, valuation should also account for the ability of the owner of the asset to enforce the rights it possesses.

An intangible asset that carries strong legal rights of ownership is more valuable when controlled by an owner that has access to resources sufficient to support monitoring of the rights and litigation to enforce the rights. Broad intellectual property law rights for a highly inventive asset may not carry significant value if the owner of those rights does not have the resources to maintain or enforce them. Intangible asset valuation models should, accordingly, integrate assessments of the costs of development and maintenance of legal rights of ownership and control into their calculations. Those models should also include assessments of the value of the legal rights of ownership and control, and that assessment should evaluate both the scope of the legal rights and the likelihood that they will be effectively enforced. Legal rights of ownership and control form a critical component of the value of intangible assets. The costs of developing and maintaining those rights should, accordingly, be included in estimates of the value of the assets. The value of the legal rights themselves should also be reflected in asset valuation estimates. That value is directly tied to the scope of the rights and the likelihood that they will be effectively enforced. Intangible asset valuation models should, as a result, attempt to assess the scope of ownership rights and the extent to which their owner possesses the resources and the will to enforce them.

Finally, the valuation models should also assess the extent to which technical and market forces could overwhelm legal rights of ownership, even when the owners of those rights have both the resources and the will to use legal means to enforce them. The current experience of the music industry suggests that even financially strong and legally aggressive owners of intangible assets can see the value of their assets eroded by runaway customers. Intangible asset valuation models should be structured to recognize when that type of threat to asset value is present.

For research administrators involved in contract negotiation, intellectual property, and technology transfer, an understanding of asset valuation models is essential for at least two reasons: 1) research administrators would have a greater understanding of the true value of intellectual assets created on their campuses; and 2) research administrators can educate the faculty on what the true

economic value of their research is. As a result, research administrators can work with faculty more effectively while simultaneously advancing institutional interests.

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The Janus Face of Research Administration

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ABSTRACT

The principles of research administration emerged during the 1960s and 1970s, a time when research in institutions of higher education generally was unencumbered by external factors. Over the past three decades, however, regulatory, economic, and political forces have altered dramatically the boundaries of sponsored research, calling into question the viability of research administration's founding principles. Now, research administration faces a difficult dilemma. It cannot confront the future by ignoring the past, jettisoning the founding principles as irrelevant in today's more complex environment. Nor can it resolutely cling to those guiding principles and disregard the new, demanding context in which research is conducted. Only by being Janus faced will research administrators be able to address the problems inherent in managing research and sponsored programs in today's environment.

INTRODUCTION

Recently, Derek Bok, president emeritus of Harvard, darkly warned that American colleges and universities were in danger of losing their core values. One might discount Bok's warning as a lone jeremiad if it were not for the fact that other observers of higher education have also commented on the difficulties and challenges facing colleges and universities in the new millennium. The concern most frequently expressed by these commentators is that immense social, political, and economic pressures are threatening the mission and values of higher education.¹

Nowhere in the university are these pressures felt as keenly as they are in research administration. The management of externally sponsored projects makes research administration a kind of

barometer for the university, measuring the degree of social, political, and economic pressure. The mission and values of research administration, consequently, have themselves become particularly vulnerable to these same powerful forces.

By examining the impact of certain social, political, and economic changes over the past three decades, it is possible to see the effect those changes have had upon the guiding principles of research administration. The challenge for research administration is how to preserve its fundamental principles while responding to the pressures of continual social, economic, and political change. Research administration cannot afford to focus stubbornly on its past principles and back into the future, ignoring the social, economic, and political changes, nor can it blindly march into the future in response to these pressures and disregard its original principles. Only by being Janus faced can research administration respond to the external changes in the social, economic, and political environment and still preserve its own values and purposes.

The Roman god Janus is a useful metaphor for research administration. Janus is the god of entrances and exits, and his image was often found on gates and doorways. While research administration is the university's gateway for grants and contracts, it is a second, deeper, meaning that makes Janus a powerful symbol for research administration. Janus marks beginnings and endings. He sits at the moment in time between the past and the future. He is typically depicted, consequently, as having two faces, one looking forward and another backward. It is this image that metaphorically best describes how research administration can preserve its core values while responding to the pressures of change.²

PRINCIPLES AND VALUES OF RESEARCH ADMINISTRATION

No single publication defines either the core values or the guiding principles of research administration. Instead, the principles and values evolved as the profession grew in the first decades after World War II. In those early years, four basic principles emerged in the literature, which have been repeated since in publications in one variation or another.

The first of these principles was expressed by Alvin Eurich, who wrote that research administrators must serve as a kind of oil in the grants process, reducing the inevitable friction that occurs when the interests of the faculty, the university, and the sponsor collide. Writing in 1969, Eurich maintained that the interests of the faculty, the sponsor, and university often conflicted.³ Even when those interests did not conflict, they "rubbed" into each other with sufficient force and frequency to cause friction. The job of the research administrator was to reduce the friction and keep the process moving.

A second principle was articulated by Kenneth L. Beasley, who argued that research administrators should serve as "mediators-expeditors" of the grants process.⁴ Beasley maintained that the grants process was both delicate and complex, and required an individual to balance the entire gamut of tasks from identifying funding agencies to submitting financial reports. A research administrator needed to mediate between the interests of the researcher and the demands of an outside agency. In doing so, the administrator would expedite the grant process.

Raymond Woodrow best expressed a third principle, stating that the purpose of research administration was "management *for* research, not *of* research...."⁵ Woodrow meant that research

administrators were to make it possible for faculty to do research by managing the grants process for investigators, including all regulatory and fiscal matters. For Woodrow, it was clear that the research administrator was not to be involved in determining the direction or the shape of the research. Rather, the research administrator was to make it possible for researchers to do their work unencumbered by administrative burdens.

John Rodman and Michael Dingerson suggested a fourth principle. Effective research administration, they argued, depended upon positive collaborative relationships with the faculty.⁶ Rodman and Dingerson maintained that research administrators needed to have the trust of the faculty and that they should represent the faculty voice when mediating between the interests of the sponsor and the university.

These four principles were echoed in the literature in some fashion or another through the 1980s.⁷ Something began to change in the 1990s, however. Fewer articles discussed effective relationships with and services to the faculty, and more articles appeared exploring new issues, particularly the various aspects of management.⁸ The change in the literature reflected, in part, research administrators' concern with how to manage the growing complexity of the regulatory environment, the changing economic forces, and the narrowing of the political agenda affecting research. Equally important, the attention to these new issues reflected the beginning of an erosion of research administration's guiding principles.

CHANGES IN THE REGULATORY ENVIRONMENT

One of the most significant factors that began to wear on the principles of research administration was the change in the regulatory environment for federal grants and contracts.⁹ In the years immediately following World War II, federal grants were generally unencumbered by regulation. Proposal formats were flexible, deadlines were fluid, and terms and conditions were negotiable. In the 1970s and 1980s, however, federal management and oversight of grants changed.

One of the regulatory changes that profoundly affected federal grants to colleges and universities was Washington's growing number of rules concerning the management of research funds. The Office of Management and Budget, for example, issued Circular A-110 in 1976, revising it later in 1993. OMB also re-issued Circular A-21 in 1979, and modified it three more times between 1979 and 1987. These Circulars defined more precisely the administrative requirements for grant agreements. They codified and specified uniform requirements and provided a framework for the management of grants, forcing universities to create new systems for control.

A second regulatory change was a new emphasis upon auditing. The passage of the Single Audit Act in 1984 and the adoption in 1985 of OMB Circular A-128, Audits of State and Local Governments, ushered in a new era of fiscal accountability and control. Not only did these regulations address financial requirements, but they also gave auditors the authority to review "other control systems," which came to mean a wide variety of activities, ranging from subrecipient monitoring to compliance with the Civil Rights Act.

The third area of change was the explosion in the last two decades of regulations governing fraud and waste, protecting the environment, humans, and animals, and addressing individual rights. For example, regulations addressed employment of the handicapped, sex discrimination, age discrimination, clean air and water, hazardous materials, human subjects and animals in research,

biosafety, recombinant DNA, debarment and suspension, misconduct in science, procurement integrity, conflict of interest, and drug-free workplace.

Regardless of the reasons or the need for the regulations, these changes acted as an abrasive force, grinding and wearing away the original principles of research administration. Emphasis began to shift from services that helped faculty identify funding opportunities and facilitate the submission of proposals to control functions responsible for assuring compliance with a vast array of federal requirements. It became extremely difficult, if not contradictory, for offices of research administration to mediate, expedite, facilitate, and represent the faculty when federal requirements demanded that universities provide more regulation and control.

CHANGES IN THE ECONOMIC ENVIRONMENT

In addition to regulatory changes, a second significant factor affecting research administration was a change in the economics of higher education. Derek Bok wrote that universities controlled the three most important aspects of America's post-industrial economy—expert knowledge, research, and educated people.¹⁰ Government as well as industry wanted, needed, and demanded access to these assets, and they began to exert pressure on universities to produce even greater amounts of these resources. With demand so high, there was little social and political patience for the amount of time it took to develop knowledge, conduct research, and educate people.

Research had helped win World War II, cure polio, and put a man on the moon. The lessons were clear. Research could solve any number of problems, ranging from national defense to public health. Federal support for research, consequently, grew 46-fold after 1951, increasing from \$1.85 billion to \$84.9 billion. In the 1990s alone, federal support for research increased from \$65.8 to \$84 billion.¹¹ The tremendous increase in federal support for research reflected the faith society had in the ability of universities to solve problems.

The impact of society's confidence in university research to solve problems, and its impatience for progress, changed the concept of funding for research. Instead of viewing support for research as a long-term investment in the future, society came to view research as a commodity to buy, use, trade, and consume. This gradual, yet profound shift transformed research into an enterprise, sometimes independent of the academic mission of the institution. Because it was viewed as an enterprise, curiosity based research was overwhelmed by research driven by agendas external to the investigator and to the academy. State agencies in particular were active in attempting to "buy" research to solve a variety of economic and social issues. State agencies, for example, directed public universities to address local issues, such as teacher shortages and the quality of education from pre-school through high school.¹²

The use of research to solve economic problems, however, best typifies the trend of treating research as a commodity. Both federal and state agencies trumpeted the miracle of R&D as an engine of economic development. Articles proclaimed the virtues of technology transfer, advised industry on new strategies to attract and retain R&D talent, and extolled the benefits of public-private partnerships.¹³ The SRA and NCURA journals bristled with advice on industry and university collaboration, and a 1986 book advised that universities needed to undergo a cultural change in order to collaborate successfully with business and industry.¹⁴ R&D was seen as the key to economic success, and research was asked to power an era of unparalleled economic

growth. These economic factors pressured universities to direct research, making it difficult for research administrators to maintain the principle of managing for research.

CHANGES IN THE POLITICAL ENVIRONMENT

Like the expansion of regulations and the change in the economics of higher education, the intrusion of politics into the research process affected the ability of research administration to maintain its guiding principles. Granting taxpayers' money gave policy makers the right to determine how that money would be spent, and since the public demanded solutions to any number of problems, why not direct research to address those problems? In 1992, the President's Council of Advisors on Science and Technology declared that the nation could no longer afford the "intellectual luxury" of funding all research and that government must focus the research mission.¹⁵ The Government-University-Industry Research Roundtable echoed the same desire to focus and control research. It called for policy-makers to "set overall national priorities." Without irony, the Roundtable declared that we must think of the future and develop a strategic plan to manage the "pace and nature of research."¹⁶

Federal agencies managed the pace and nature of research in a variety of ways. Agencies set priorities for funding in some areas, while prohibiting research in other areas. For example, research in breast cancer received significant attention for a period of time in the early 1990s and was even included in the Department of Defense budget. Conversely, investigators were restricted from certain stem cell research, while others were discouraged from following other lines of research. Recently, for example, researchers studying AIDS and other sexually transmitted diseases were warned to avoid certain politically controversial topics.¹⁷ The intrusion of politics into the research endeavor made it difficult for research administrators to mediate among the interests of the sponsor, the university, and the faculty when politics made the interests of the sponsor pre-eminent.

The way universities responded to the changes in the regulatory environment, the economic factors, and the political agenda for research also affected the principles of research administration. In 1987, Robert Rosenweig wrote that "compared to forty years ago, today's universities are larger, more complex, more competitive for money and people, have more capital needs, [and] are more dependent on government...."¹⁸ That dependency on government funding led another academic observer to wonder if universities did not look now to research as a business, and grants as a source of revenue, instead of as supplemental support for the core educational mission.¹⁹

CHANGES IN THE UNIVERSITY

Universities created increasing complex bureaucracies to manage the dramatic rise in R&D funding and the complicated legal and regulatory environment. In 1988, the American Association of Higher Education observed that the "relationships with government have been marked by increasing bureaucratization and control."²⁰ The change could be seen most clearly in biomedical research. A study by the Pew Higher Education Research Program, for example, stated that "each new federal program carries with it substantial monitoring requirements that often lead to the establishment of new internal bureaucracies....Health and safety regulations are a prime example. Most research universities have to increase their staff of health and safety inspectors fivefold or better."²¹ Paradoxically, the more money Washington granted to

universities for research, the more research cost and the more cumbersome it became to conduct that research. It became increasingly difficult for research administrators to facilitate the grants process as the institutional bureaucracy grew in magnitude.

Along with the growth in the size and complexity of the bureaucracy came what can be best described as a change in the institutional culture for research. One such change in the culture has been viewed as a decline of “social capital” within the university, i.e., the loss of mutual social obligation, loyalty, and dedication. The loss of social capital meant fewer shared values, more parochial interests, less communication, and more antagonisms. Relationships between faculty and the administration, for example, become adversarial instead of collaborative.²² A second cultural change has been the shift in faculty loyalty from the institution to the academic discipline and finally to the research funding agency, resulting overall in less collegiality within the academy.²³ The third change in the research culture has been the erosion of traditional academic values. The values and standards of excellence and of academic freedom, some have argued, have eroded to the point that universities needed external regulations to govern conflict of interest and misconduct in research.²⁴ These changes in the university increased pressure to the point that it became impossible for research administrators to act as a lubricant to reduce the friction between the faculty and the university.

STRUCTURAL RESPONSE TO THE CHANGING ENVIRONMENT

With the change in the regulatory environment, the increase in economic pressures, the impact of political agendas, and the universities’ response to those factors, it has become very difficult for research administration to manage for research, to facilitate the grants process, to collaborate with the faculty, and to mediate among the conflicting interests. One reaction has been for research administrators to change their organizational structures to accommodate the new rules and demands. At a recent national conference, three major research institutions unveiled new models for organizing research administration. Additionally, a study at SUNY Albany proposed a fourth approach to organizing sponsored programs.²⁵ Each organizational model reflected an attempt by research administration to accommodate the guiding principles to the changes in the environment.

One model for organizational change was initiated by Stanford University. The purpose for changing the structure was to make research administration more “responsive, timely, and accountable.” The mission of the research administration office, Stanford declared, was “to support outstanding sponsored research and education by providing service, expertise, innovative leadership, and by promoting a collaborative model of stewardship among all faculty and staff.” To achieve this mission, Stanford combined its pre- and post-award functions. It adopted a “portfolio” approach to the management of awards, i.e., research administrators in the central office followed a single grant through its entire “life cycle.” This approach focused the research administrator upon individual researchers with the goal of enhancing “customer service.”²⁶

The Dana-Farber Cancer Institute offered a second model. In response to the increasing grant volume that was crushing the old organizational structure, the Institute abolished its old divisions, de-centralized grants management, and re-defined administrative roles. Its goal was to create a “seamless” grants process for investigators by making the departmental research administrator the “facilitator” for the researcher and the central administrator the “mediator” among the various interests.²⁷

Washington University addressed the changed research environment in a third way. It recognized that its central research administration structure was fragmented and plagued by weak service, slow response, and little or no support for proposal development. Its response was to create a “one stop shop,” where faculty could have all of their grants needs taken care of by a single office. To support this concept, Washington University re-defined roles for the departmental research administrators and for the pre- and post-award offices.²⁸

A report from the Center for Technology in Government at SUNY Albany stands in dramatic contrast to the organizational responses of Stanford, Dana Farber, and Washington University. Offering an organizational model from a national rather than an institutional perspective, the SUNY report agreed that the mechanisms supporting research were collapsing in the current environment. Its solution to the problem, however, was to recommend a plan that would manage the direction of research rather than the processes for facilitating research.²⁹

The SUNY report argued that the ideal organization for research would invest only in *a priori* defined significant social and scientific research in contrast to supporting curiosity-driven research. The organization would foster collaboration to address these issues and direct resources only to qualified researchers for qualified projects. The ideal research organization would be able to identify emerging issues, develop human capital, and take investment risks. An organizational structure directed to these goals would result in lower overhead costs, create a standardized method of conducting business, enhance communication, and target resources better. By directing research, this kind of organization would eliminate inefficiency in the research enterprise.

TRENDS

These four examples show a number of trends. First, it is clear that the complex environment necessitated the creation of an equally complex system to manage it. All four cases recognized that the system for supporting sponsored research was crumbling under the strain of trying to manage grants in the current legal, regulatory, economic, social, and political environment. Stanford, Dana Farber, and Washington University responded by re-structuring their programs supporting sponsored programs in order to preserve the four founding principles of research administration. Although they re-structured differently, all three stated that their goal was to enhance the facilitation of the grants process for the faculty. In order to achieve that purpose, they had to create new organizational structures, and administrative roles. The SUNY report was similar in also proposing a structural response to the complex legal, regulatory, social, and political environment. Its response, however, differed from the other three in calling for sponsors and universities to adopt uniform methods and standards of accountability. This approach, the report argued, would better facilitate research than would university organizational re-structuring.

Second, these four examples show how the terms “facilitate” and “mediate” have come to have meanings different than when they were used by Woodrow, Beasley, Eurich, and Dingerson and Rodman. For example, Stanford’s collaborative model incorporated the sponsor as part of the partnership with the researchers. Facilitation, consequently, meant facilitation for the sponsor as well as the investigator. It was a subtle yet significant recognition of the active role the sponsor now played in the grants process. The Dana Farber model, in contrast, did not include the sponsor but split the roles of “facilitator” and “mediator.” The facilitator function was left to the departmental research administrator while the mediator role was given to the central research office. Washington University’s “One Stop Shop” maintained a traditional approach to

facilitation and mediation, while the SUNY report addressed facilitation in terms of setting research agendas as a means of gaining efficiency in grants management.

In terms of the meaning of facilitation, probably the greatest change illustrated by these four examples was the recognition that facilitation also now meant regulation. The legal and regulatory environment had grown so complex that universities had to create significant office structures to assure compliance. Facilitation had come to mean not just helping investigators comply with regulations, but also enforcing the regulations to protect the university.

Last, these four examples demonstrate the transformation of the principle of managing *for* research. Stanford, Dana Farber, and Washington University clearly were attempting to manage *for* research, but the new realities were forcing them to make concessions and adjustments. Traditional structures of research administration were designed to support research. These new organizational models, however, sought not just to manage *for* research in terms of support, mediation, and facilitation; they attempted to *protect* research from the intrusion of external regulations, economics, and politics so that it could be conducted in as unencumbered a manner as possible. The social and political agendas, regulations, priorities for funding, cost of research, and institutional liability all made the possibility of curiosity-driven research problematic. The university examples illustrate how those institutions tried to mitigate those factors.

The report from SUNY, however, took a radically different approach. Its response to the new environment was to abandon the principle of managing *for* research and propose the management *of* research, i.e., manage the direction and agenda of research. Only by setting research priorities, directing resources, and imposing a research agenda, the report argued, could research be conducted efficiently and effectively in the current environment.

CONCLUSION

Regulatory, economic, and political changes over the past three decades have been an abrasive force grinding hard against the guiding principles of research administration. It has indeed been difficult to manage *for* research, facilitate *for* research, mediate the research process, and be a voice for the faculty in the face of these changes.

In reality, regulation, economics, and politics have always formed the boundaries for research administration. Over the past thirty years, however, those boundaries shifted and narrowed radically, permanently altering the landscape for research and its administration. It is within these new boundaries that research administrators must seek to understand the relevance of their founding principles in a new millennium. The first principle of research facilitation remains a critical precept, but it must now encompass the management of pervasive regulation. The profession's second principle, to mediate among the needs of faculty, sponsor, and institution, now extends to an environment in which powerful political, economic, and legal forces frequently make the interests of the sponsor pre-eminent. The third principle of building collaborative relationships with faculty faces new challenges now that both the sponsor and the institution require research administration to regulate faculty. Last, the task of managing *for* research is more complex and difficult now that external factors engage in the management *of* research.

Research administrators need to address the challenges of the regulatory, economic, and political environment, and search for new ways to facilitate and mediate *for* research. In doing so, research

administrators can neither face the future by turning their backs on the past, jettisoning the guiding principles as irrelevant, nor steadfastly cling to the founding principles and back into the future, ignoring what lies in front. Only by being Janus-faced will research administrators be able to answer the question of how to support research. One face of research administration must always focus forward on the ever-changing environment, adaptive and dynamic, while the other face must never lose sight of the guiding principles of managing for research, facilitating research, mediating the process, and supporting the faculty. The task is to determine how best to provide those services in the shifting boundaries of a new environment.

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