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EDITOR'S PREFACE

Practitioners of technology transfer will attest to the multi-faceted nature of their profession, which combines aspects of business, science, and law. Previous volumes of this Journal have featured articles covering varied topics, including: specific legal issues, such as the art of patenting and licensing biotechnology, animals, and plants; business issues, such as product liability, licensee bankruptcy, withholding tax and unrelated business income tax; university administrative issues, such as conflict of interest and agreements governing ownership of university inventions; and analysis of the famous Bayh-Dole Act of 1980, on which the profession is based.

In Volume VI the emphasis is on intellectual property law. Three of the four articles focus on patent law, providing an "alert" to technology managers to watch for pitfalls in university practices that might cause problems later on in the patenting process. The fourth article concerns the North American Free Trade Agreement (NAFTA) and its effect on intellectual property law and rights at universities.

In his article entitled "The Prior Art Effect of Material Transfer Agreements," J. Steven Whitaker analyzes the use of MTAs and calls our attention to the potential loss of patentability when transfer agreements are utilized under certain conditions.

Ellen Winner examines the art and strategy of filing patent applications involving DNA segments. Her study, "Sequence Necessary for DNA Patent Claims," reviews the evolving state of the law in this area and calls for an appeal to the Federal Circuit.

In "What Counts: A Publication Guide for the Inventor Seeking a Patent," Patricia Hider compares various types of public disclosures, assesses their impact on the patent application process, and provides guidance derived from relevant case law.

On the second anniversary of the signing of the North American Free Trade Agreement, Sheldon Burshtein provides an extensive analysis of the NAFTA, with specific attention to its significance for intellectual property rights at universities in Canada, Mexico, and the United States. Mr. Burshtein's article is especially timely as the General Agreement on Tariffs and Trade (GATT) makes another appearance on the world scene.

The Editorial Board of the AUTM Journal welcomes letters and comments from its readers concerning issues raised in published articles or on other matters of interest to our colleagues. Letters may be considered for the "Letters to the Editor" section or forwarded to the individual author for reply, at the discretion of the Editor.

We thank the authors of this Volume, and encourage our readers to submit original papers on topics of interest to professional technology managers. Those contemplating writing an article or a letter to the Editor are asked to contact the Managing Editor for content and review procedures.

Jean A. Mahoney, Editor
December 1994

The Prior Art Effect of Material Transfer Agreements

J. Steven Whitaker, M.D., J.D.

ABSTRACT

Material transfer agreements (MTAs) are used to memorialize terms for transfer of research materials between investigators. Generally, these agreements and their associated material exchanges have no impact on the patentability of the transferred materials. When the transfer occurs before filing a patent application related to the transferred materials, however, (in some instances) the transfer may be deemed prior art to the claims and bar patentability of the transferred materials. While most currently used academic MTAs are adequate for post-filing transfers, confidentiality provisions may be required to avoid the prior art effect of some pre- filing transfers.

INTRODUCTION

Material transfer agreements are widely used by academia and industry to define the proprietary positions of the provider and recipient to the transferred materials, and to the improvements or derivatives thereof. To focus on advancement, instead of reproduction of the art, use of MTAs is particularly prevalent in biological sciences where materials such as cell lines or vectors may not be easily reproducible. Unfortunately, in certain limited circumstances, many currently used academic MTAs and the transfers memorialized therein, may prejudice patent rights to the transferred materials. It must be emphasized, however, that most material transfers and associated MTAs do not impact the patentability of transferred materials, and thus do not require revision of current university MTA practice.

These agreements serve other functions as well. For example, MTAs are used to limit the provider's potential liability for acts of the recipient by restricting the use of the transferred materials in human subjects and disclaiming warranties that might serve as a basis for product liability claims. They also often require acknowledgement of the source of the materials in publications or presentations to help further accepted academic disclosure standards.

Many scientific publications require that published material be generally available to third parties wishing to repeat or confirm published experiments, and as a result some institutions have incorporated additional provisions into MTAs that insure reasonable general availability of the transferred materials to third parties. Typically, these provisions obligate the provider to furnish samples of the transferred materials to third parties, as supplies allow. While furthering the academic goals of disclosure and publication, in a limited number of special circumstances these provisions may run afoul of patent laws and risk losing patent protection of the transferred materials; specifically, MTA- governed transfers that occur prior to the filing of patent applications (hereinafter "pre- filing material transfers") claiming the transferred materials may operate as prior art against the claimed invention.

LEGAL STANDARDS FOR THE PRIOR ART EFFECT OF MTAs

United States and non- U.S. patent laws require that claimed subject matter be "novel" to be patentable. In the United States, novelty is defined by statute. In relevant part, if the claimed subject matter was known or used by others in the United States before the patent applicant's "invention" thereof, the claimed subject matter is not patentable in the United States (35 U.S.C.

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[[section]] 102(a)). Although it seems self- evident that a patent applicant could not transfer her "invention" prior to making that "invention," present legal doctrines may allow for this apparent contradiction.

For instance, an invention may be deemed legally incomplete at the time of the transfer if the inventor had not yet discovered its full utility as claimed in a patent application. To illustrate, suppose a monoclonal antibody that is known to react with a lung adenocarcinoma cell line is transferred. Subsequent to the transfer, it is discovered (and claimed in a patent application) that the antibody reacts with, and kills, all types of adenocarcinoma cells. The United States Patent and Trademark Office (PTO) may then assert that the "invention" was not complete until it was known that the antibody could kill all types of adenocarcinoma cells. By this interpretation, the transfer would have occurred before the "invention" of the antibody was completed. In some instances, it may be possible to establish a date of invention prior to the transfer by use of declarations and tangible evidence if the transfer occurred less than one year prior to the filing date of the patent application in question, although this increases patenting costs and is not universally successful.

Whether pre- filing knowledge or use by others of an invention whose full utility is not known bars patentability awaits future clarification by the courts. Strong arguments can be made on both sides of the issue. Recent actions of the United States Patent and Trademark Office, however, suggest that the PTO interprets the law to mean that transfer of material prior to awareness of the material's utility as claimed in a patent application can constitute use by others prior to "invention."

Further, if the claimed subject matter was publicly used or sold more than one year before the filing date of the patent application, the "invention" is not patentable (35 U.S.C. [[section]] 102(b)). While the law is not completely settled, the provider's knowledge of the utility of the claimed invention is probably irrelevant in this instance. Disclosures of potentially patentable inventions more than one year prior to filing a patent application may bar obtaining patent protection of the invention in the United States. If the inventor makes a transfer that is legally deemed to be a public use more than one year prior to the date of patent filing, the transferred material would not be patentable. Non- U.S. laws are even less tolerant and bar patent protection for inventions disclosed prior to the filing date. Declarations are not effective to overcome these rejections.

The present controlling U.S. legal standard for both "knowledge or use by others" and "public use" is public accessibility. If a pre- filing material transfer is governed by an MTA providing public accessibility to the transferred materials, the transfer may bar patentability of those materials. Patent law doctrines of public knowledge and use should be considered when preparing MTAs for transferring inventions prior to filing patent applications. While technology managers might consider this inquiry merely an academic exercise, examiners in the PTO have seized upon such transfers as a basis for rejecting claims to transferred materials. To date, the PTO has not yielded, even in the face of evidence demonstrating that the transfers were confidential.

The term "known or used by others" (as recited in Section 102(a)) has been interpreted by U.S. courts to mean knowledge or use that is *accessible* to the public. It is unfortunate that the courts have not fully defined "accessible to the public" as it relates to use or knowledge. In the analogous context of publications, the courts apparently do not consider the relative accessibility of the reference to the public. For example, U.S. courts have ruled that a doctoral thesis shelved and indexed in a single German university library is accessible to the public, and thus is prior art. Therefore, a publication that is theoretically accessible, although inaccessible as a practical matter, is legally "accessible to the public." Secret uses protected from public access are deemed public uses if a publicly- available product results from the secret use. This is especially significant for

commercial purposes such as employing transferred materials for quality assurance programs. In all cases under Section 102(a), the use or knowledge must be by more than one person.

"Public use" under section 102(b) has been interpreted by appellate courts to include "any use" of the invention by a person other than the inventor who is under no restriction, limitation, or obligation of secrecy to the inventor. When an invention is transferred to a third party, the use is not considered public if the inventor retains control over the invention's use and distribution of information regarding the invention. The use of the invention in experiments to bring the invention to completion or perfection is not considered a public use under present law. Perfection of the invention must be the purpose of such experimental use, however, and not merely incidental to other purposes.

Recent cases suggest that MTA provisions preserving the inventor's control of the invention and information regarding the invention need not be written or even expressed in all instances. A court may infer control of the invention from the relationship between the parties and the surrounding circumstances. Reliance on oral or implied confidentiality agreements between the provider and the recipient is not without risk, however, and may necessitate costly appeals within the PTO or courts.

Most academic MTAs recite no express restrictions on publishing results of research with transferred materials. In fact, many contain provisions obligating the provider to make the materials generally available. These provisions seem to belie later arguments to the PTO of oral or implied confidentiality agreements. If the transferred materials are published by the recipient, such a disclosure may immediately bar patent protection for the provider in most countries (most notably Canada, Japan, and European countries). The publication may also be cited by the PTO as evidence that the prior material transfer was not confidential. As explained above, either the transfer or the publication may be deemed to be "knowledge or use by others" prior to the invention by the provider, or act as an absolute statutory bar to patentability in the United States if the transfer (or publication) occurred more than one year prior to filing the patent application.

THE IMPACT OF NON- CONFIDENTIAL MTAs ON UNIVERSITY TECHNOLOGY TRANSFER

In view of current patent law doctrines of confidentiality, pre- filing material transfers evidenced by MTAs lacking confidentiality provisions may adversely affect academic technology transfer in many ways. First, if an issued patent is ruled invalid on the basis of MTA- based transfers, the university may not be entitled to royalties from the claimed invention from the licensee. Second, even if a patent has not been challenged, pre- filing MTA- based transfers may be used by prospective licensees to discount the value of the patent. Industry has begun to investigate pre- filing material transfers by investigators more vigorously prior to licensing the materials or associated know- how. Identification of non- confidential material transfers occurring prior to the filing date of the patent application alerts companies of potential patentability risk to the transferred materials, which could cause a company to discount the value of the license. Even more significant, after discovering pre-filing material transfers, a company may abandon licensing negotiations and develop the technology without a license, knowing that if sued for patent infringement, a strong attack on the validity of the patent could be mounted. The existence of the transfers would provide the company with a good argument that the patent is invalid and therefore avoid increased liability for willful infringement.

Increased administrative burdens are another consequence for universities that use MTAs without confidentiality provisions. Potential licensees could legitimately require universities to produce additional information, such as declarations from providers as to the confidentiality of material

transfers, and documentation during negotiations. Any transfers not disclosed to potential licensees could constitute grounds for allegations of bad- faith bargaining and provide a basis for later avoidance of the licensing contract. Universities may also be requested to warrant the confidentiality of transfers during licensing. The due diligence requirements of securities laws could require significant investigation of university transfers during the financing (both public and private) of start- up companies intended to commercialize university- developed technology. Further, under current regulations of the PTO, university inventors and assignees may be required to disclose all MTAs evidencing transfers that occurred prior to the filing date of the patent application. Should any pertinent transfers not be disclosed to the PTO, patents issuing from the application could be held unenforceable as obtained through inequitable conduct or fraud on the Patent Office.

The requirements of present patent laws place academic institutions in a difficult position. Because a primary mission of academic institutions is the free and open dissemination of knowledge derived from research, many university officials consider placing restrictions on the academic recipients of material transfers contrary to the spirit of the academic mission, if not outright sacrilege. Universities are confronted with the choice of violating a basic academic tenet or potentially forfeiting valuable patent rights. This dilemma is becoming especially acute as university administrators and regents increasingly consider technology transfer offices to be important sources of university revenue.

To date, judicial decisions defining confidentiality of transfers have only addressed the extremes of confidentiality: either no restrictions on use by the recipient or complete control preserved with the provider. Although present law has not resolved cases falling between these extremes, a middle ground *might* exist that is consistent with the academic mission as well as protective of patent rights. A legally acceptable compromise may be a limit on the timing of disclosures by the recipient, rather than more limiting restrictions of confidentiality. For example, an agreement might forbid disclosure of the materials, whether by publication, presentation, or otherwise, absent notification of the provider coupled with a reasonable waiting period (30- 60 days) following notification to allow the provider time to prepare and file a patent application, if desired.

The provider in such an agreement retains a degree of control over disclosures and is assured of the invention's confidential status, at least until the waiting period following notification has elapsed. Although a recipient could not disclose the materials precipitately, the recipient would retain the right to publish research results. It must be remembered, however, that because this strategy has not been legally tested, a court could later find that such a transfer was not legally confidential, and patent claims to the transferred materials could be ruled invalid if the transfer occurred before the patent application was filed. This type of ruling would not only invalidate patent claims to the transferred materials at issue, but could also retrospectively impact other pre- filing transfers that employed the same agreement format. If a university cannot accept more stringent confidentiality terms in pre- filing MTAs, this type of compromise agreement might be the best alternative to an agreement having no confidentiality terms.

University technology transfer officers may face similar dilemmas if their investigators are required to sign confidential MTAs as a condition for receiving materials. By signing a confidential MTA, an investigator may be obligated not to publish or otherwise disclose the transferred materials. This non- disclosure agreement could breach university disclosure and publication policies. On the other hand, if the investigator refuses to sign the confidential MTA, the investigator may be denied access to the materials and lose research opportunities. Because only public use and knowledge in the United States can constitute a bar to patentability, these terms are generally not needed in MTAs transferring materials to non- U.S. institutions (as long as a patent application is filed prior to publication of the materials by the recipient). This gives non- U.S. institutions a competitive

advantage over U.S. universities. If the provider insists on confidential provisions in the agreement, no compromise is readily apparent.

SUMMARY

MTAs are a valuable and common tool used by academic researchers. Present patent law (both in the United States and elsewhere) suggests that unrestricted transfers, as generally preferred by universities, may bar patentability of transferred materials if a patent application is not filed prior to the transfer. This aspect of MTAs places a significant administrative burden on university technology transfer offices, both in patent prosecution and licensing. As no compromise solution has yet been legally validated, it is important for university technology managers to be aware of the risks inherent in MTA practice and balance those risks against their university's mission. Because of the unsettled nature of the law and diversity of goals among different universities, a single solution for all universities is probably not possible. Technology managers should remain apprised of legal developments regarding confidentiality and disclosure in order to make informed decisions regarding MTAs. Even if the risks cannot be eliminated, knowledge of these risks provides more informed decision making and avoids unpleasant surprises by the PTO or potential licensees.

ACKNOWLEDGEMENTS

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Sequence Necessary for DNA Patent Claims

Ellen P. Winner, Esq.

ABSTRACT

Recent case law indicates it may be necessary to provide exact sequence in order to obtain patent claims covering DNA. These holdings significantly narrow the scope of patent protection available. The validity and applicability to specific naturally- occurring genes of issued patent claims covering DNA molecules broadly, such as claims to all synonymous DNA sequences encoding a given amino acid sequence as well as claims to a given DNA sequence and homologous sequences, may also be in question. Both the evolving state of the art and the evolving state of the law are expected to alleviate this situation. Appeal of a test case to the Federal Circuit is needed.

University patent administrators may be disturbed by recent trends toward narrowing the protection afforded DNA inventions. It has always been important to develop patent strategies early in gene cloning projects, preferably even before invention disclosures are received, so that worthwhile coverage could be developed. In view of recent case law, patent strategies should now be reviewed and possibly modified. DNA sequence should be provided as early as possible.

Several recent opinions issuing from the Court of Appeals for the Federal Circuit (which decides all appeals in patent cases) and from the Patent Office Board of Patent Appeals and Interferences indicate the necessity for providing an exact sequence in support of any claim to a DNA fragment or gene.

In a typical gene cloning research effort a protein is purified and at least partially sequenced, degenerate DNA probes are prepared and used to probe a cDNA or genomic library, and the corresponding naturally-occurring DNA is isolated. Alternatively, antibody to the protein may be prepared and used to screen for expression of the gene, followed by isolation of the gene from the expression vector thus identified.

Patent strategists aiming for the earliest possible filing date have recommended submitting patent applications claiming the gene as soon as the protein is isolated or, at the latest, as soon as the protein is sequenced, reasoning that finding the gene from that point on is obvious and a matter of routine skill in the art. A number of patents have issued on DNA covering all synonymous DNA sequences encoding a given amino acid sequence, or to DNA encoding a named protein, and homologous DNA. These patents provide a reasonable scope of protection. The claims appear to cover the naturally-occurring gene as well as other coding sequences. Infringers are not able to circumvent the patents simply by changing a few base pairs in the sequence.

This strategy alone no longer appears to be effective for obtaining such broad patent claims. The validity of issued claims having such breadth, in fact, is now in question. In *Fiddes v. Baird*, 30 U.S.P.Q.2d 1481 (Bd. Pat. App. & Int. 1993), the Board of Patent Appeals and Interferences held that party Fiddes' claims to a human gene for basic fibroblast growth factor were separately patentable over party Baird's issued and pending claims specifying a sequence encoding "mammalian" basic fibroblast growth factor.

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Party Baird's issued patent was based on an application filed at the time the protein had been sequenced, and it disclosed the amino acid sequence of the protein, which had been isolated from bovine pituitary and a theoretical DNA sequence encoding it. The pending claims were from a continuation-in-part application, presumably disclosing the naturally-occurring coding sequence for bovine fibroblast growth factor. Between the filing of the first application and the continuation-in-part application, DNA sequences anticipating claims to the naturally-occurring human fibroblast growth factor were published. Party Baird's position was that the published sequences could not be used as prior art because it was entitled to rely on the filing date of the first application.

The Board held that party Baird was not entitled to the filing date of the first application for its claims to the mammalian DNA sequence because it did not set out specific DNA sequences of naturally-occurring mammalian genes in the first application and therefore did not meet the "written description" requirement of the patent statute. The Board stated that even with respect to the bovine gene for which the amino acid sequence was known, party Baird was "not in possession of the naturally occurring gene" at the time of filing the first application. The Board specifically stated that as of the relevant date (1987), knowledge of the amino acid sequence of a protein would not establish possession of the gene encoding the protein.

In *Fiddes*, the Board held the term "mammalian" was overly broad because "[t]he patent teaches no amino acid or DNA sequences for any mammalian FGF other than bovine pituitary FGF." If it had stopped there, the decision would not have been so damaging to subsequent applicants seeking claims to synonymous DNA sequences encoding a given amino acid sequence. In adding that party Baird was not even in possession of the naturally-occurring bovine gene after it had elucidated the corresponding amino acid sequence, however, the Board cast doubt on the future patentability of synonymous coding sequence claims.

The *Fiddes* decision follows Federal Circuit decisions in *Amgen v. Chugai*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), which held (based on the state of the art in 1981) that inventive "conception" of a gene cannot occur until the sequence is known, and *Fiers v. Sugano*, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993), which held (based on the state of the art in 1981) that a gene could not be adequately described for patent purposes by reference to a potential method for isolating it; the DNA itself must be described. The complete amino acid sequence, however, was not known in the *Fiers* case.

It appears that special consideration is being given to single naturally-occurring gene sequences as though they were deserving of patentability over other synonymous DNA sequences even without a showing of special properties such as improved expression. The *Fiddes* decision is clearly a holding that naturally-occurring gene sequences will not be patented unless the sequence is spelled out in the patent application.

Arguments can be made that claims to all synonymous DNA sequences encoding a known amino acid sequence should be patentable since the genetic code is known. In view of the large number of possible sequences such claims would encompass, however, the Patent Office finds it impossible to search all the many variants using sequence databases and therefore resists these claims. The Patent Office does not take the position that these claims are not enabled but rather that they are not supported by an adequate "written description." Without an adequate "written description," the applicant is assumed not to be "in possession of" the invention. The unfortunate language of *Fiddes* to the effect that "knowledge of the amino acid sequence coupled with the established relationship in the genetic code between a nucleic acid and the protein it encodes would not establish possession of the gene encoding the protein" can be used as a basis for rejecting all DNA claims unless the DNA sequences are given.

Fiddes, used to deny the patentability of DNA claims to all synonymous DNA sequences encoding a given amino acid sequence, is a move toward increasing the narrowness of allowable claims. Prior to this decision, the Board in *Ex parte Maizel*, 27 U.S.P.Q.2d 1662 (Bd. Pat. App. E. Int. 1992), had held that a claim to all DNA sequences encoding a given amino acid sequence and biologically functional equivalents to the protein was not enabled by a disclosure of the naturally-occurring amino acid sequence and a general teaching in the patent application that the protein would have "conservative" amino acid substitutions where the substituted acids have similar hydrophobicity and charge characteristics. The Board pointed out that the claim was so broad as to cover any protein regardless of its structure, such as a truncated protein. In *Maizel*, however, the Board had left open the question of the patentability of synonymous coding sequences for a known amino acid sequence.

In light of *Fiddes*, not only must the precise amino acid sequence encoded by the claimed DNA now be spelled out as *Maizel* indicates, it appears the precise DNA sequences claimed must also be spelled out where one claims a gene or other natural sequence.

The state of the law thus provides significantly narrower patent protection than would be desirable for the first in the race to isolate a given protein or gene, especially for universities, which often lack the resources to isolate and test alternative sequences. In fact, the validity of broad claims that may already have issued is questionable in light of these decisions.

On the other hand, for late-comers desiring market entry, separate patent protection may be available for unique DNA sequences encoding known proteins. Owners of broad patents to DNA sequences would be potential licensees for such patents.

In evaluating the patentability of DNA sequences, it should be kept in mind that the reasoning of these recent decisions should favor attempts to patent naturally-occurring DNA sequences even after the amino acid sequence encoded by the DNA has been published. This is contrary to the position generally taken by patent examiners in the past. In general, examiners routinely issued obviousness rejections to DNA claims when the amino acid sequence was known, citing the known amino acid sequence in combination with literature describing known methods of gene cloning based on the amino acid sequence.

In *Fiddes*, however, the Board held Fiddes' human gene patentable over Baird's bovine gene, stating it was "highly speculative" for one of ordinary skill in the art to have a reasonable expectation of success in obtaining the native human gene by using the native bovine gene, and therefore the human gene was unobvious over the bovine gene. This also follows the Federal Circuit's 1993 holding in *In re Bell*, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993) (based on the state of the art in 1987) that a narrow claim to the single isolated sequence of a human gene was patentable over the known amino acid sequence it encodes. The decision appeared to hinge on the fact that it would not have been possible to predict which of the myriad synonymous coding sequences was the human coding sequence.

The take-home lesson from these cases appears to be that an adequate "written description" of the claimed DNA (preferably sequence but perhaps not necessarily so) is required for patentability. This does not mean, however, that filing should be delayed until the DNA has been sequenced. The decisions all refer to the state of the art at the time of the inventions, inviting the argument that today an amino acid sequence does enable at least the naturally-occurring gene encoding it.

The decisions seem to suggest that the court will view specific DNA sequences encoding amino acid sequence variations, as well as amino acid sequence variations themselves, as unobvious even if the

functional properties of the variant protein are unaffected. Such a position is perhaps reasonable for applications filed in the 1980s. Increasingly, however, advances in the ability to predict structure/function relationships through analysis of known functional motifs are expected to erode the court's rationale.

In light of these decisions, when the naturally-occurring DNA sequence and specific sequences for the synonymous DNA are not spelled out and only the amino acid sequence is given, we expect that the Patent Office will routinely issue rejections of claims to synonymous DNA sequences based on failure to meet the written description requirement of the statute. This is an extremely undesirable state of the law because generally a patent with narrower claims, which fails to cover obvious variations of a DNA sequence, will be virtually worthless. Where such rejections are received, it is recommended that arguments based on public policy be made. The issuance of DNA patents so narrow as to be useless manifestly subverts the purposes of the patent system to stimulate progress in this technology.

Where a licensee is available to bear the cost, appeal of such rejections to the Federal Circuit is recommended. Otherwise, keeping applications pending while the state of the law evolves may be the best strategy.

Impact of the North American Free Trade Agreement on Canadian Intellectual Property Rights Relating to University Technology Management

Sheldon Burshtein

1.0 INTRODUCTION

1.1 Background

Canada has seen a recent flurry of amendments and additions to its intellectual property laws. Most of these were dictated by bilateral international agreements or were required to enable Canada to join its major trading partners in adhering to international conventions. The North American Free Trade Agreement ("NAFTA") among Canada, the United States, and Mexico has required further changes to Canada's intellectual property laws. This paper attempts to provide an overview of such changes as they may relate to university technology management.

Canada and the United States entered into The Canada-United States Free Trade Agreement (the "FTA") in late 1987. The FTA, which became an operative international obligation of the two countries at the start of 1988, is a bilateral extension of the General Agreement on Tariffs and Trade (the "GATT"), which already governed the two countries' international trade relationships. Like the GATT, the FTA allowed Canada and the United States to continue to pursue their trade relations with other countries independently. Building on the GATT, the FTA freed trade between Canada and the United States from a variety of tariffs and other barriers, moving ever closer to free flow of goods, services, and people between the two countries.

The primary impact of the FTA was in the area of tariff elimination. The FTA provided for the bilateral elimination of tariffs, at different rates depending on the goods involved, over ten years. The FTA established the first virtually comprehensive international arrangement for trade in services between nations. Both countries were to provide for the right of establishment of service industries, particularly those providing financial services. The countries also agreed to provide national treatment to investors from both countries in relation to the establishment, acquisition, conduct, and sale of businesses. The FTA exempted certain sensitive areas from its ambit. For example, Canadian "cultural industries," as defined in the FTA, are exempt from the FTA.

Serious intellectual property issues were on the table in the FTA negotiations. A number of the changes requested by each side had already been made or were in the course of being made. It is not known for sure, but the negotiating process likely had a significant impact on Canadian legislative developments. However, despite the encouraging steps foreshadowed by the changes made during and subsequent to the negotiations, the impact of the FTA itself on intellectual property law in Canada was minimal in the final result. The Canadian government's explanatory notes reveal that, as suspected, during the course of the negotiations, the two governments worked

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on a chapter that would have provided an overall framework for the protection of intellectual property rights in both countries. However, in the end the chapter was abandoned.

Notwithstanding the FTA, Canada and the United States continued to maintain their own intellectual property laws and structures, respectively, so that protection of an invention, a trademark, an original work, a design, or a mask work in one country will usually not protect it in the other. The rules for obtaining protection continue to differ from one country to the other. It must not be assumed that the national rules of one country, with which one may be familiar, apply in the other country.

1.2 The North American Free Trade Agreement

Following the suspension of the GATT negotiations on December 20, 1991, with the publication of the so- called Dunkel Text, Canada, the United States, and Mexico embarked upon negotiations towards tripartite free trade. On December 17, 1992, Canada, Mexico, and the United States signed NAFTA. NAFTA seeks to create an expanded market for the goods and services produced in the three member countries to reduce trade distortions, eliminate barriers to trade and promote fair competition in their territories, and establish clear and mutually advantageous rules governing trade. While NAFTA does not generally change United States or Mexican access to the Canadian market, as many Mexican products already enter Canada with low tariffs or tariff- free, it does change Canadian and United States access to the Mexican market.

NAFTA incorporates much of the FTA, but expands on the FTA both geographically and in terms of the issues covered. Canada and the United States agreed that NAFTA takes priority over the FTA. The FTA provisions that Canada and the United States decided not to bring fully into NAFTA will remain operational between those two countries. NAFTA, like the FTA, attempts to level the playing field in both the goods and services sectors, using the principle of "national treatment."

Under NAFTA, all goods originating in Canada, the United States, and Mexico will be traded freely within the three countries once tariffs are phased out. For goods originating and traded between Canada and the United States, all tariffs will be eliminated by 1998, according to existing FTA reduction schedules. For goods originating in Canada and the U.S. and traded with Mexico, all tariffs will be eliminated in equal annual stages over 5, 10, or 15 years, depending on the type of goods.

Under NAFTA, as in the FTA, national treatment extends to service providers of the member countries. This means that the countries will treat service providers of other NAFTA countries no less favorably than they treat their own service providers. Service providers also cannot be required to establish an office or take up residence as a condition of providing the service.

National treatment is not an obligation to harmonize the treatment of service industries, however. As in the FTA, member countries are free to decide how they will regulate a particular service industry, as long as they do not discriminate between Canadian, American, and Mexican providers.

NAFTA includes an "accession" clause permitting other countries to join provided they meet all necessary requirements and submit to NAFTA disciplines. This provides a mechanism for other Latin American countries to join the group. News items suggest that several countries, including Chile, Venezuela, and Brazil, are considering this already. Each original NAFTA member will have the right to approve the admission of any other country.

On June 23, 1993, the Canadian government assented to the North American Free Trade Agreement Implementation Act ("Bill C- 115"), to implement the legislative changes necessitated by NAFTA. Bill C- 115 took effect on January 1, 1994.

2.0 NAFTA AND INTELLECTUAL PROPERTY

2.1 Nature of Obligations

Unlike the FTA, NAFTA has expressly adopted as one of its six stated objectives to provide adequate and effective protection and enforcement of intellectual property rights in each of the three jurisdictions. Intellectual property rights are defined as "copyright and related rights, trademark rights, patent rights, rights in layout designs of semiconductor integrated circuits, trade secret rights, plant breeders' rights, rights in geographical indications, and industrial design rights."

NAFTA expands on the FTA by including a chapter on intellectual property. Chapter 17 of NAFTA establishes detailed obligations on the parties in the area of intellectual property protection. Many of the provisions are similar to the provisions of GATT concerning trade related aspects of intellectual property rights ("TRIPS"). Chapter 17 adopts many of the protections, provisions, and principles which have been incorporated in the intellectual property laws of the parties, as well as other modern national intellectual property laws and international treaties. In many cases, NAFTA sets certain minimum standards of protection already provided by the countries' current legislation.

The intellectual property chapter follows the general approach taken in international intellectual property treaties: namely, that each country must provide to the nationals of another country effective protection of intellectual property. For this purpose, each country must accede to specified texts of international conventions. NAFTA has required amendments to the intellectual property laws of all member countries, although more significant changes will be required for Mexico.

Each country must provide in its territory to the "nationals of another country" adequate and effective protection and enforcement of intellectual property rights while ensuring that measures to enforce intellectual property rights do not themselves become barriers to legitimate trade. A country may implement in its domestic law more extensive protection of intellectual property rights than is required under NAFTA, provided that such protection is not inconsistent with NAFTA.

To provide adequate and effective protection and enforcement of intellectual property rights, at a minimum each country must give effect to the intellectual property chapter and to the substantive provisions of a number of international intellectual property conventions. These include:

(a) the Geneva Convention;

(b) the Berne Convention, although NAFTA confers no rights and imposes no obligations on the United States with respect to Article 6 of the Berne Convention or the rights derived from the Article;

(c) the Paris Convention; and

(d) the 1978 or 1991 UPOV Convention.

If a country has not acceded to the specified text of any such conventions on or before the date of entry into force of NAFTA, it must make every effort to accede. For Canada, this will mean joining

the Geneva Convention (1971 text) and upgrading its adherence to more recent versions of other conventions like the 1971 text of the Berne Convention (current accession is to the 1928 text) and the 1967 text of the Paris Convention (current accession text for some aspects is the 1934 text).

2.2 National Treatment

Each country must accord to nationals of another country treatment no less favorable than that it accords to its own nationals with regard to the protection and enforcement of all intellectual property rights. No country may, as a condition of according national treatment, require right-holders to comply with any formalities or conditions in order to acquire rights in respect of copyright and related rights. A country may derogate from the obligations of national treatment in relation to its judicial and administrative procedures for the protection or enforcement of intellectual property rights. No country shall have any obligation of national treatment with respect to procedures provided in multilateral agreements concluded under the auspices of the World Intellectual Property Organization ("WIPO") relating to the acquisition or maintenance of intellectual property rights.

Nothing in the intellectual property chapter prevents a country from specifying (in its domestic law governing licensing) those practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse affect on competition in the relevant market.

2.3 Protection of Existing Subject Matter

NAFTA does not give rise to obligations in respect of acts that occurred before the date of application of the relevant provisions of NAFTA for the country in question. However, except as otherwise provided for in NAFTA, each country must apply NAFTA to all subject matter existing on the date of application of the relevant provisions of NAFTA for the country in question, and for what is protected in a country on such date, or which meets or subsequently meets the criteria for protection under the terms of Chapter 17.

In the case of intellectual property rights for which protection is conditional upon registration, applications for protection that are pending on the date of application of the relevant provisions of NAFTA for the country in question must be permitted to be amended to claim any enhanced protection provided under the provisions of NAFTA, although such amendments may not include new matter.

A country is not required to restore protection to subject matter that, on the date of application of the relevant provisions of NAFTA for the country in question, has fallen into the public domain in its territory.

Any country may provide for a limitation of the remedies available to the right-holder as to the continued performance of any acts in respect of specific objects embodying protected subject matter that become infringing under the terms of legislation in conformity with NAFTA, and that were commenced or in respect of which a significant investment was made, before the date of ratification of NAFTA by that country, after the date of application of NAFTA to that country. In such cases, the country shall, however, at least provide for payment of equitable remuneration.

NAFTA preserves certain exemptions contained in FTA. These include guarantees of Canada's right to implement special measures for cultural industries in areas like publishing, film and video, music and sound recording, and broadcasting and cable industries. Also preserved is the right to

maintain existing cultural support measures and the right to introduce new ones. The provision is borrowed from the FTA, which specifically exempts "cultural industries" from its application.

The following is a summary of those key provisions that may impact university technology management.

3.0 PATENTS

3.1 Subject Matter

Subject to certain exclusions mentioned, each country must make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step, and are capable of industrial application. Patent protection must be the same in all industrial sectors.

A country may exclude inventions from patentability if prevention in its territory of the commercial exploitation of the inventions is necessary to protect public order or morality, including human, animal, or plant life or health, or to avoid serious prejudice to nature or the environment, provided that the exclusion is not based solely on the ground that the country prohibits commercial exploitation in its territory of the subject matter of the patent. A country may also exclude from patentability:

(a) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals;

(b) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production;

(c) plants and animals other than microorganisms, although each country must provide for the protection of plant varieties through patents, an effective scheme of *sui generis* protection, or both.

Subject to the exceptions mentioned above, patents must be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the country where the invention was made, and whether products are imported or locally produced. Patents are to be available without discrimination as to the signatory country where the invention was made.

The amendments made to the Canadian Patent Act in 1992 bring the protection for pharmaceuticals in line with that for other technologies. Canadian discrimination against pharmaceutical products not invented and developed in Canada was eliminated by the 1993 amendments to the Patent Act. NAFTA likely served as an impetus to enact this legislation. For the establishment of an invention date for United States patents, research done in Canada and Mexico is now on an equal footing with research done in the United States.

3.2 Term

Each country must provide a term of protection for patents of at least 20 years from the date of filing or 17 years from the date of grant. This provision accommodates the first- to- invent system of the United States. A country may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes. Owners of patented medicines and chemicals often do not reap the full benefits of the term of the patents in Canada. As Canada is a "first- to- file" country, inventors are anxious to file patent applications for new medicines as soon

as possible. Although the term of the patent is 20 years from the filing date of the patent application in Canada, the Health Protection Branch may not issue a notice of compliance to market and sell the medicine for many years after the Canadian Patent Office grants a patent on the medicine. The result is that the patent owner may have an abridged term of exclusivity. NAFTA provides the opportunity for Canada to adopt patent term restoration, following the paths of the United States, Japan, and European Community member states. Patent term restoration would enable a patentee to obtain an extension of the term of the patent to compensate for delays in selling the medicines caused by regulatory authorities.

3.3 Rights

Each country must provide that, where the subject matter of a patent is a product, the patent must confer on the patent owner the right to prevent other persons from making, using, or selling the subject matter of the patent without the patent owner's consent. Each country must also provide that, where the subject matter of a patent is a process, the patent must confer on the patent owner the right to prevent other persons from using that process and from using, selling, or importing at least the product obtained directly by that process, without the patent owner's consent.

Where the subject matter of a patent is a process for obtaining a product, each country must, in any infringement proceeding, place on the defendant the burden of establishing that the allegedly infringing product was made by a process other than the patented process where: (i) the product obtained by the patented process is new; or (ii) a substantial likelihood exists that the allegedly infringing product was made by the process and the patent owner has been unable through reasonable efforts to determine the process actually used. In the gathering and evaluation of evidence, the legitimate interests of the defendant in protecting its trade secrets must be taken into account.

Bill C- 115 has codified this by amending the Patent Act to provide that, in an action for infringement of a patent granted for a process for obtaining a new product, any product that is the same as the new product shall be considered (in the absence of proof to the contrary) to have been produced by the patented process.

3.4 Compulsory Licensing

A country may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patentee, taking into account the legitimate interests of other persons. Where the law of a country allows for use of the subject matter of a patent without the authorization of the right-holder, including use by the government or other persons authorized by the government, such use shall be considered on its individual merits.

Bill C- 115 revised the law relating to compulsory licenses in favor of Canadian governments to use a patented invention. The Patent Act has been amended specifically to cover provincial governments as well as the federal government. This will be particularly important for inventions relating to healthcare.

Bill C-115 also provided that such a license may only be granted on an application. Under prior law, the government could use the invention, subject to an application by the patentee for compensation. The Patent Act now provides that the use of the patented invention may be authorized for such purpose, for such period and on such other terms as the Commissioner of Patents considers expedient. The scope and duration of the use shall be limited to the purpose for

which the use is authorized, the authorized use shall be non-exclusive, and any use shall be authorized predominantly to supply the domestic market.

The Commissioner must notify the patentee of any use of the patented invention that is authorized. Where such use is authorized, the user must pay to the patentee such amount as the Commissioner considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization. The Commissioner, on application by the patentee and after giving all concerned parties an opportunity to be heard, may terminate the authorization if the Commissioner is satisfied that the circumstances that led to the granting of the authorization have ceased to exist and are unlikely to recur, subject to such conditions as the Commissioner deems appropriate to protect the legitimate interests of the authorized user. An authorization granted under this provision is not transferable.

The Commissioner may not authorize the use of a patented invention by a government unless the applicant establishes that it has made efforts to obtain from the patentee on reasonable commercial terms and conditions the authority to use the patented invention, and its efforts have not been successful within a reasonable period. This provision does not apply in cases of national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.

The Patent Act formerly made it an abuse of patent rights that may result in compulsory licensing if the patented invention is not worked in Canada. Bill C- 115 has changed this because NAFTA provides that patent rights are to be enjoyable without discrimination as to whether products are imported or locally produced.

4.0 COPYRIGHT AND RELATED RIGHTS

Most of the amendments to the Copyright Act made by Bill C- 115 are for conformity to the Berne Convention. Most of the amendments to Canada's copyright law will impact non- technological industries, such as entertainment and publishing. However, a few changes may impact on the management of technology relating to computer software.

4.1 Works

Each country must protect the works covered by Article 2 of the Berne Convention, including any other works that embody original expression within the meaning of that Convention. In particular, all types of computer programs are literary works within the meaning of the Berne Convention and each country must protect them as such. Compilations of data or other material (in machine readable or other form) whether by reason of the selection or arrangement of their contents, shall be protected as such. The protection a country provides for a compilation must not extend to the data or material itself or prejudice any copyright subsisting in that data or material.

Bill C- 115 made a number of amendments to definitions in the Copyright Act. Among the new definitions are those for "compilations" and "translations." A "compilation" is "a work resulting from the selection or arrangement of literary, dramatic, musical or artistic works, or a work resulting from the selection or arrangement of data." A compilation containing two or more of the categories of literary, dramatic, musical, or artistic works would be deemed to be a compilation of the category making up the most substantial part of the compilation. The mere fact that a work is included in a compilation does not increase, decrease, or otherwise affect the copyright in the work or the moral rights in respect of the work. The definition of "literary work" was amended to clarify that it includes compilations of literary works.

4.2 Publication

The former definition of "publication" in the Copyright Act did not require, at least expressly, that sufficient copies be available to satisfy the reasonable requirements of the public, as required in the Berne Convention. The Copyright Act formerly provided a 14- day period for "simultaneous" publication while the Berne Convention calls for a 30-day period. To remedy these inconsistencies, a number of amendments were made. Bill C- 115 substantially revised the definition of "publication" to mean, among other things, in relation to any work, making copies of the work available to the public in such a quantity as to satisfy the reasonable demands of the public, having regard to the nature of the work. However, publication does not include, among other things, the communication of a work to the public by telecommunication.

A work is deemed to be first published within Canada and the other countries in the British Commonwealth or within a foreign country to which the Copyright Act extends recognition, notwithstanding that it has been published simultaneously in some other place. A work is deemed to be published simultaneously in two places if the time between the publication in one place and the other place does not exceed 30 days or such longer period as may for the time being be fixed by order in council.

4.3 Conditions for Obtaining Copyright

The Copyright Act arguably formerly required that to qualify for copyright protection in Canada a person must arrange for first publication in a country to which the Copyright Act extends, subject to the "simultaneous" publication provision. The Berne Convention stipulates that a national of a member country must have copyright irrespective of where first publication occurs. The Copyright Act was amended by Bill C- 115 to provide that copyright subsists in Canada in every original work if any one of the following conditions is met:

(a) in the case of any work, whether published or unpublished, the author was, at the date of the making of the work, a British subject; a citizen or subject of, or a person ordinarily resident in, a Berne Convention country; or a resident within Canada or the British Commonwealth; or

(b) in the case of a published work, including a cinematograph, the work was first published within Canada or the British Commonwealth or in a Berne Convention country.

Copyright does not subsist in Canada otherwise than as provided above, except in so far as the protection conferred by the Copyright Act is extended by Ministerial Certificate to foreign countries that the Copyright Act does not recognize.

4.4 Term

Each country must provide that, where the term of protection of a work, other than a photographic work or a work of applied art, is to be calculated on a basis other than the life of a natural person, the term must be not less than 50 years from the end of the calendar year of the first authorized publication of the work, or, failing such authorized publication within 50 years from the making of the work, 50 years from the end of the calendar year of making. To comply with NAFTA, Bill C-115 effected a number of amendments to the term of copyright.

1. All terms were extended to the end of the calendar year in which they would otherwise terminate.

2. A new provision was inserted for anonymous and pseudonymous works. Except in the case of a work of joint authorship, where the identity of the author of a work is unknown, copyright in the work subsists for the shorter of (i) a term of 50 years following the end of the calendar year of the first publication of the work; and (ii) a term of 75 years following the end of the calendar year of the making of the work. Where, during that term, the author's identity becomes commonly known, the ordinary term applies.

Where the identity of all the authors of a work of joint authorship is unknown, copyright in the work subsists for the shorter of (i) a term of 50 years following the end of the calendar year of the first publication of the work; and (ii) a term of 75 years following the end of the calendar year of the making of the work. Where, during that term, the identity of one or more of the authors becomes commonly known, copyright subsists for the life of whichever of those authors dies last.

3. Authors who are nationals of any country, other than a country that is a party to NAFTA, that grants a shorter term of protection are not entitled to claim a longer term of protection in Canada.

4.5 Rights

Each country must provide to authors and their successors in interest those rights enumerated in the Berne Convention in respect of protected works, including the right to authorize or prohibit:

(a) the importation into the country's territory of copies of the work made without the right-holder's authorization;

(b) the first public distribution of the original and each copy of the work by sale, rental, or otherwise;

(c) the commercial rental of the original or a copy of a computer program, except where the copy of the computer program is not itself an essential object of the rental. Each country must provide that putting the original or a copy of a computer program on the market with the right-holder's consent shall not exhaust the rental right. This commercial rental right for the original or a copy of a computer program is not exhausted where the copyright owner puts a program on the market. This right need not apply in any country to originals or copies purchased prior to the date of application of NAFTA in that country; and

(d) the communication of a work to the "public."

The Copyright Act was amended to include the right to rent a computer program that can be reproduced in the ordinary course of its use. An arrangement, whatever its form, constitutes a rental if, and only if: (i) it is in substance a rental, having regard to all the circumstances; (ii) it is entered into with motive of gain beyond the recovery of the costs, including overhead, associated with the rental operation; and (iii) the computer program constitutes an essential object of the rental. Some have suggested that this right is unnecessarily restricted to the storage format or technology used by the program.

4.6 Transfers

Each country must provide that any person acquiring or holding copyright and related rights may freely and separately transfer those rights by contract for purposes of their exploitation and enjoyment by the transferee. Each country must also provide that any person acquiring or holding

such economic rights by virtue of a contract, including contracts of employment underlying the creation of works and sound recordings, shall be able to exercise those rights in its own name and enjoy fully the benefits derived from those rights. If this language suggests that moral rights in works may be transferred, it may be inconsistent with the provisions of the Copyright Act and require clarification or amendment.

Each country must confine limitations or exceptions to these rights to certain special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right-holder. Bill C- 115 repealed the provision of the Copyright Act which, in certain circumstances, conferred a right to reproduce a published work 25 years after the death of the author. The current section of the Copyright Act that provides for a reversion to the author's estate 25 years after death was not addressed.

4.7 Topography Rights

Each country must protect layout designs (topographies) of integrated circuits ("layout designs") in accordance with the Integrated Circuit Treaty. Mexico is given a grace period with respect to topography rights. However, it must make every effort to implement these requirements as soon as possible and must do so no later than four years after the date of entry into force of NAFTA. No change was required to the Canadian Integrated Circuit Topography Act as a result of NAFTA. Bill C- 115 did not include any amendments to the Integrated Circuit Topography Act.

5.0 INDUSTRIAL DESIGNS

6.0 TRADE SECRETS AND REGULATORY DISCLOSURES

6.1 Trade Secrets

"Confidential information" is defined in NAFTA to include trade secrets, privileged information, and other materials exempted from disclosure under a country's domestic laws. Each country must provide the legal means for any person to prevent trade secrets from being disclosed to, acquired by, or used by others without the consent of the person lawfully in control of the information in a manner contrary to honest commercial practices, so far as:

(a) the information is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons that normally deal with the kind of information in question;

(b) the information has actual or potential commercial value because it is secret; and

(c) the person lawfully in control of the information has taken reasonable steps under the circumstances to keep it secret.

Each country must provide that for data that are submitted to the country after the date of entry into force of NAFTA, no person other than the person that submitted the data may, without the latter's permission, rely on the data in support of an application for product approval during a reasonable period of time after their submission. A reasonable period will normally not be less than five years from the date on which the country granted approval to the person who produced the

data for approval to market his product, taking into account the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there must not be any limitation on any country to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

Where a country relies upon a marketing approval granted by another country, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied upon shall commence with the date of the first marketing approval relied upon.

Bill C- 115 amended the Canadian Food and Drugs Act to enable the government to make regulations respecting the extent to which (if any) a person may rely on test or other data submitted by others in seeking to establish the safety or effectiveness of a new drug. If regulations relating to this paragraph are implemented, it may among other things affect the way in which the Health Protection Branch treats information provided to it in support of an investigational new drug application or new drug submission. Bill C- 115 also provides for amendments to the Canadian Pest Control Products Act to enable the making of regulations to implement these provisions.

7.0 ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

7.1 General Provisions

Enforcement procedures must be available under the domestic law of each country to permit effective action against any act of infringement of intellectual property rights, including expeditious remedies to prevent infringement and remedies to deter further infringement. Such enforcement procedures must be applied to avoid the creation of barriers to legitimate trade and to provide for safeguards against abuse of the procedures. Procedures for the enforcement of intellectual property rights must be fair and equitable, must not be unnecessarily complicated or costly, and must not entail unreasonable time limits or unwarranted delays. Among the provisions of NAFTA are articles relating to general provisions, civil administrative procedures (including evidence and remedies), provisional measures, and criminal sanctions and penalties.

7.2 Enforcement of Intellectual Property Rights at the Border

Each country must adopt procedures to enable a right-holder, who has valid grounds for suspecting that the importation of counterfeit trademark goods or pirated copyright goods may take place, to lodge an application in writing with its competent administrative or judicial authorities for the suspension by the customs administration of the release of such goods into free circulation. No country is obligated to apply the procedures to goods in transit. A country may permit an application to be made in respect of goods that involve other infringements of intellectual property rights. A country may also provide for corresponding procedures concerning the suspension by the customs administration of the release of infringing goods destined for exportation from its territory.

The state of the law in Canada regarding the seizure of counterfeit and pirated goods by Canada Customs has long been a source of frustration for owners of intellectual property rights. Despite the ever- increasing number of these goods being imported into Canada, the measures taken to halt the imports have not improved. Canada Customs' powers to seize counterfeit and pirated goods were limited to the provisions of the Copyright Act and the Trade- Marks Act. The narrow judicial interpretations given to provisions of these acts compounded the problem.

For works that are the subject of copyright, such as computer programs, the Customs Tariff provides that reprints of Canadian copyrighted works are prohibited goods. However, in order to

compel Canada Customs to seize those goods, a copyright owner had first to obtain an order under the Copyright Act. Section 44 of the Copyright Act provides that copies made outside Canada of any work in which copyright subsists, that if made in Canada would infringe copyright, and in respect of which that the owner of the copyright gives notice in writing to the Department of National Revenue that it desires that the copies not be imported into Canada, shall not be imported and are deemed to be included in Schedule IV to the Customs Tariff.

Section 44 must also be read with Subsection 37(1) of the Customs Tariff. Item 99202- 1 of Schedule IV references reprints of Canadian copyrighted works. Section 44 requires the Canadian owner to give notice to the Department of National Revenue. Upon the receipt of such notice, it appears that the Minister has no obligation to act. Consequently, the courts refused to issue a *mandamus* to force the Minister to apply this provision of the Customs Tariff. In addition to giving notice to the Minister, therefore, it is still essential for the Minister himself to make the decision to act so that Schedule IV can be amended to impose an obligation on the Canadian customs authorities to curtail imports.

The reluctance on the part of Canada Customs to seize material, combined with the narrow interpretation given to the existing legislation by the courts, has created a situation where counterfeit and pirated goods are allowed to enter into Canadian channels of trade with little difficulty.

7.2.1 Legislative Changes

Statutory amendments resulting from NAFTA have provided much needed relief for the owners of intellectual property rights in Canada. In addition to providing specific protection against the importation of copyrighted computer programs, NAFTA requires that each country adopt procedures to enable a right-holder who has valid grounds to suspect that counterfeit or pirated goods are going to be imported to make an application in writing to the authorities requiring Customs to detain the goods.

There are two prerequisites for having goods seized. There must be a *prima facie* case of infringement of an intellectual property right, and the applicant must supply a sufficiently detailed description of the goods to make them readily recognizable by Customs. If these prerequisites are met and any required security has been furnished, Customs will be compelled to detain the goods for at least 10 working days. While not explicitly stated, Article 1718 contemplates that these applications be made without notice to the importer. It remains to be seen if the "competent authority" will remain the judiciary or whether authority will be transferred to an administrative body such as Customs itself.

Bill C-115 made significant changes to the Copyright Act, Trade- Marks Act, and Customs Act. More important than the legislative changes are the extensive changes that are taking place in the daily operations of Canada Customs. Formally, there was no system in place to monitor the flow of potentially infringing, counterfeit, or pirated goods. Customs is implementing procedures and acquiring the necessary equipment to enable them to examine goods at the border and to verify that their importation does not infringe any trade- mark, copyright, or other intellectual property right in Canada.

Bill C- 115 proposes significant amendments to the enforcement provisions of the Copyright Act. Where a court is satisfied, on application by a person who owns the copyright in Canada in a work, that

(a) the work is about to be imported into Canada, or has been imported into Canada but has not yet been released by Canada Customs;

(b) in the jurisdiction where the work was made, it was made without the consent of the person who then owned the copyright in that jurisdiction; and

(c) the work, to the knowledge of the importer, would have infringed copyright if it had been made in Canada by the importer;

the court may make an order

(a) directing the Minister (i) to take reasonable measures, on the basis of information reasonably required by the Minister and provided by the applicant, to detain the work; and (ii) to notify the applicant and the importer, forthwith after detaining the work, of the detention and the reasons therefor; and

(b) providing for other matters the court considers appropriate.

An application may be made in an action or otherwise, either on notice or *ex parte*, except that it must always be made on notice to the Minister. Before making such an order, the court may require the applicant to furnish security in an amount fixed by the court (i) to cover duties, storage and handling charges and any other amount that may become chargeable against the work; and (ii) to answer any damages that may by reason of the order be incurred by the owner, importer, or consignee of the work.

The Minister may apply to the court for directions in implementing such an order. The Minister may give the applicant or the importer an opportunity to inspect the detained work for the purpose of substantiating or refuting the applicant's claim.

Unless such an order provides otherwise, the Minister, subject to the Customs Act and to any other federal legislation that prohibits, controls, or regulates the importation or exportation of goods, must release the work without further notice to the applicant if, two weeks after the applicant has been notified, the applicant has not notified the Minister that the applicant has commenced an action for a final determination of the issues by the court. Where the court finds that the circumstances referred to existed, the court may make any order that it considers appropriate in the circumstances, including an order that the work be destroyed, or that it be delivered up to the plaintiff as the plaintiff's property absolutely.

8.0 CONCLUSION

The amendments effected to Canada's intellectual property laws by NAFTA are random, at least at first glance. What they do is make intellectual property protection in Canada similar to that in the United States and Mexico. With appropriate changes to United States and Mexican law, the intellectual property laws of all three members of NAFTA will be more consistent. However, it is essential to appreciate that, while the intellectual property laws of each country will meet the minimum standards imposed by NAFTA, there are still significant variations from country to country.

What Counts: A Publication Guide for the Inventor Seeking a Patent

Patricia A. Hider

INTRODUCTION

THE PATENT ACT - THE SOURCE OF THE RULES

In the United States the source of the rules governing the process of obtaining a patent is the Patent Act.[1] The original Patent Act was drafted in 1790 and the current version was codified by Congress in 1952.[2] The Patent Act is part of a set of statutes referred to as the United States Code. Today, an inventor can obtain a patent for any new and useful process, machine, manufactured article, or composition of matter.[3] Congress promulgated the Patent Act under authority derived directly from the Constitution, which states "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . . ."[4] The original version of the Patent Act in 1790 did not mention printed publications and provided no means for them to affect the patent process. It wasn't until 1836, when Congress passed a revised version of the Patent Act, that the words "printed publication" appeared in the statute.[5] Once it became part of the Patent Act, a printed publication could serve as both a bar to receiving a patent and a defense in a patent infringement suit.[6]

Today in the United States patent system, printed publications can count against or serve to deprive an inventor of the privilege of being granted a patent for his or her invention in two ways. First, certain acts of others (as opposed to actions taken by the inventor himself or herself) can prevent an inventor from obtaining a patent. A printed publication, authored by another person and existing anywhere in the world before the inventor conceived of his or her invention, can negate novelty, which is one of the mandatory prerequisites of every patentable invention.[7] Second, acts performed by an inventor more than one year before filing for the patent with the U.S. Patent and Trademark Office can prevent patentability of the inventor's own discovery. An inventor may be denied a patent if, more than twelve months before filing the patent application, the inventor disclosed the invention in a printed publication in the United States or a foreign country, put the invention on sale, or made the invention available for public use.[8]

In the United States a patent will be granted only if an invention is new; this essential requirement is referred to as 'novelty' in the patent law lexicon. The focus in a novelty inquiry is on events that occurred before the inventor even conceived of the idea for his or her invention. A printed publication that discloses enough of the substance of an invention to allow a practitioner, skilled in the technology, to duplicate the invention is described as "anticipating" the invention and negating novelty. An invention cannot be presumed to be new if another earlier practitioner in the field already described the invention before the later inventor made his or her discovery. Lack of novelty is a legitimate basis on which an inventor can be denied a patent, and the U.S. Patent and Trademark Office relies on the statutory law set forth in the Patent Act when it uses novelty as a basis for rejecting a patent application.[9] Section 102 of the Patent Act provides that "A person shall be entitled to a patent unless- (a) the invention was . . . described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent . . . ."[10]

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An inventor cannot receive a patent for any knowledge that the inventor has already dedicated to the public. Certain acts performed by the inventor are called "statutory bars" because under the patent statute, unless an inventor files for a patent within twelve months of disclosing the invention by means of a printed publication or by putting the invention on sale or in public use, the inventor is barred from receiving a patent for the invention. Dedication of an invention to the public is the basis for the publication bar of the Patent Act and has been described in the following way: "[I]f an inventor discloses his invention to another in any manner, without securing a promise of confidentiality, communication of the knowledge of the invention to the public results because the knowledge thereof is no longer controlled by the inventor, and thus is considered an irrevocable dedication to the public."[11]

The grant of a patent has been looked upon as a bilateral contract between the inventor and the public. A bilateral contract is formed when two parties exchange promises. Promises alone, however, are not enough to form a contract. The element of consideration (i.e., something of value) must be bargained for and exchanged by each party to the contract to make mutually exchanged promises binding and the resultant contract enforceable. It is consideration that distinguishes a contract from a mere gift.[12] In a contract between an inventor and the public, the consideration provided by the inventor is knowledge and that provided by the public is the patent itself granted to the inventor by the United States government. In the words of one court, "[I]n consideration for the patent grant, something must be given to the public which it did not have before . . . . If the public is already possessed of that 'something,' or if it is accessible to the public, there is a failure of consideration and no patent may be granted."[13]

If the inventor applies for a patent in spite of having previously disclosed the invention to the public, the application will either be denied by the U.S. Patent and Trademark Office or if a patent is granted, the activities of the inventor, if discovered, may later be used against the inventor in an effort to invalidate the patent in an infringement suit. Statutory authority for the printed publication statutory bar comes from the Patent Act, which states "A person shall be entitled to a patent unless... (b) the invention was . . . described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States . . ."[14] For the patentability bar to attach, the publishing must occur more than one year before the date of application for the patent.

Specific words, as they are used in statutes, garner their meaning either from the intent of the legislative body that wrote the law or from the interpretation given the words by courts when they attempt to apply the statute to facts in the disputes before them. This guide examines the meaning given "printed" and "publication" by the courts and attempts to identify the specific acts of the inventor or acts of other persons that might prevent an inventor from attaining a patent for an invention.

PHYSICAL FORMAT OF THE AUTHOR'S WORK AND THE MEANING OF "PRINTED"

Interpreting the meaning of the word "printed" has challenged more than one court. In 1937, the Patent Office Board of Appeals dealt with the issue in regard to a typewritten thesis placed in the library at the Massachusetts Institute of Technology (M.I.T.).[15] Harold Edgerton, the patent applicant, was barred from receiving a patent on a synchronous motor because the subject matter of his invention had been fully disclosed in the thesis of M.I.T. student, F. J. Zak. Zak completed his thesis more than two years before Edgerton filed his patent application. The inventor Edgerton argued, in defense of his application, that even though Zak had already described his invention, formal printing meeting traditional typesetting requirements was required before a document

should be considered "printed" under the statute. As Zak's thesis was produced on a typewriter and not a printing press, it was not a printed publication and could not bar Edgerton's patent. The Patent Office Board of Appeals decided that the thesis was indeed "printed" and denied Edgerton a patent.[16]

In support of its position, the Board of Appeals stated, " . . . . the statute does not leave the door open to anyone claiming to be a prior inventor to secure a patent on an invention of which there has been for two years a description in a public library, or the like, solely because the description there is typewritten and not printed on a printing press."[17] Subsequent courts have applied similar reasoning and kept pace with technology by declaring microfilm,[18] slides and drawings,[19] and photographs[20] as printed material under the statute.

Microfilm

In 1958, the Court of Customs and Patent Appeals held in the *Tenney* case that a microfilm of an unpublished German patent application placed in the Library of Congress and improperly indexed was not a printed publication.[21] After World War II, the German government patent office in Berlin was abandoned and permanently closed. United States government personnel obtained access to a collection of unpublished patent applications on file in the German office and recorded them on microfilm. The microfilm eventually found its way to the Library of Congress, and the microfilm of the unpublished patent application germane to the *Tenney* case was in a canister mistakenly labeled "German patent applications on aircraft," even though the patent apparatus related to a pulse jet engine used to produce dispersions of liquids in air or fog. The patent examiner, whose decision was later supported by the Patent Office Board of Appeals, rejected Mr. William L. Tenney's machine for making fog as unpatentable because a description of his machine was contained in the unpublished German patent on microfilm filed in a mislabeled canister in the Library of Congress.

The court hearing Mr. Tenney's case reversed the Patent Office Board of Appeals and held that the German patent had no legal effect, stating "While microfilming furnishes a means of multiplying copies, there is no probability, ... that the disclosure has achieved wide circulation and that, ... the public has knowledge of it."[22] Because the microfilm was incapable of being widely disseminated, it was not a printed publication within the meaning of the patent law. The probability of the microfilm's becoming public knowledge (not whether or not it actually became public knowledge) was the basis for the court's decision.

Recently, a microfilm copy of an Australian patent application preserved on a reel and a diazo photograph produced from a second microfilm copy was held to be "printed" within the meaning of the patent statute.[23] Mr. Joseph Wyer applied for a patent for a cable junction box, but his application was rejected by the examiner on the grounds that the same invention was described in a printed publication in Australia more than one year before filing of the application in the United States. The printed publication specifically referred to in the *Wyer* case was an Australian patent application preserved on 16 mm film. It was the custom of the Australian patent office to maintain two film copies. One of the microfilm copies was preserved in the Australian patent office as a security reel and the other was cut into strips, placed in a transparent jacket and used to produce a photograph of up to 36 microfilm frames (referred to as a diazo copy). Six diazo copies were made; one was retained at the Australian Patent Office and the other five were distributed to the Australian patent system sub-offices. The court noted that equipment was available to the public in the Australian Patent Office and in the sub-offices for producing enlarged paper copies or enlarged reproductions of the diazo copies.[24]

The court distinguished this microfilm from the German microfilmed patent in the *Tenney* case: "Since the patent office was ready to supply, on order, blown-up prints made from the diazo copies, the probability of public knowledge of appellant's application exceeds that for the German application in Tenney."[25] Thus, a microfilm of a foreign patent application maintained in a foreign patent office, accessible to the public and available for duplication, is a printed publication as of its date of accessibility.[26]

It is likely that any modern court would consider microfilm a "printed publication" under the current patent law. The focus of the inquiry regarding microfilm centers on whether or not the microfilm can be located by those skilled in the art and whether the essence of the claimed invention is disclosed on the microfilm. If the microfilm is easily accessible to practitioners in the field and clearly describes the invention, it may be considered a printed publication with the potential of barring patentability of an invention.

Slides and Drawings

Film and projection slides are considered printed publications under the patent law. Whether these forms of printed publications serve to bar patentability depends on the amount of information conveyed on slides used during a presentation and on the identity of the audience. The following two cases are illustrative.

Four orthopedic surgeons associated with the University of California at Irvine developed an artificial knee prosthesis.[27] Wright Manufacturing Company, a Tennessee corporation, assisted in the development of the final product and financially supported the prosecution of the patent application. After the patent was granted, Wright ultimately became the exclusive licensee of the patented artificial knee. After identifying what was thought to be infringement of the patent, University of California (owner of the patent) and Wright Manufacturing Company (licensee) joined together to bring suit against Howmedica, Inc., another manufacturer of an artificial knee prosthesis. As a defense against the infringement, Howmedica claimed that the University of California patent was invalid because the device had been described in a printed publication more than one year before the University's application, in violation of [[section]] 102 of the Patent Act. Howmedica pointed to two specific events to support its claim: 1) the success of the use of the artificial knee on a human patient was reported by the Associated Press in articles in various newspapers; and 2) two of the inventors described the invention using slides and drawings at a medical meeting.[28]

Dr. Smith, one of the inventors of the device, delivered a presentation at the California Medical Association meeting in which he discussed the development of the knee to approximately thirty persons. The slides and drawings used by Dr. Smith during the lecture showed the knee prosthesis, but Dr. Smith did not make any prints of the slides available, and no one at the meeting had access to the slides or was able to see them other than during the presentation. The court found that because the projection of the slides at the meeting was limited in duration, they could not disclose the invention to the extent necessary to enable a person of ordinary skill in the art to make or use the artificial knee.[29] Similarly, the court held that the newspaper articles did not bring the invention into the public domain because they did not sufficiently describe the invention.[30] Because the publications (newspaper articles and slides) were not disseminated such that persons interested in the artificial knee could comprehend and put to use the essentials of the invention, the publications were not a statutory bar under [[section]] 102 of the Patent Act.

In another case involving a drill string motion compensator used in offshore drilling, in its own defense an alleged infringer used printed publications produced by the patent holder to argue that

the patent was invalid. Vetco Offshore Industries, Inc., disclosed its motion compensator invention to producers and contractors in drawings, blueprints, and written descriptions of the invention. These materials were either delivered or displayed to sixteen companies and thirty individuals involved in offshore drilling.[31] In finding that Vetco violated [[section]] 102(b) of the Patent Act, the court noted that the drawings and blueprints were disseminated without Vetco's placing any restrictions on the use of the information by the recipients. Although the number of parties to whom Vetco provided the information was small in absolute numbers, the recipients represented the persons most concerned with offshore drilling and likely to be interested in the information.

maximum loaded weight, body capacity, maximum travel speed, and overall body width, length, and height. On the back page of the pamphlet were two drawings of the rollers, showing side and top views.

The court found that the inventive concept of the machine, which was the basis for the claims made in the patent, was fully disclosed in the pamphlet. Furthermore, the pamphlet enabled one knowledgeable about road-building equipment to build and produce the roller compactor described in the patent from the information in the pamphlet alone.[36] The court invalidated every claim of the Brothers Incorporated patent on the compactor because it was described in a printed publication more than one year before the filing of the application for a patent.

Courts no longer seem to search for a major distinction between "printed" and "publication." Each case is decided on the basis of its own facts and the burden is on the patent challenger to prove that the information is "printed, handwritten, or on microfilm or a magnetic disk or tape."[37] The major focus of a printed publication inquiry is generally not on the format of the document but on whether the work was accessible or was disseminated.

THE MEANING OF "PUBLICATION":

ACCESSIBILITY AND DISSEMINATION OF THE WORK

Today, whether or not a document has been printed in the traditional sense has little or no bearing on the probability of its dissemination. Determining whether or not a work is a publication centers on measuring the accessibility of the work for some types of documents, and on judging the degree of dissemination for other materials. Those documents that are determined to be either accessible or disseminated are likely to be called publications, and may bar patentability. Courts have used two main lines of reasoning in deciding whether a document is a publication: sufficient indexing or cataloguing in a library setting, so that the document is accessible; and actual dissemination, for other types of documents.

If a work has been placed in a library anywhere in the world with a proper reference, it has consistently been held to be published.[38] A single copy of a document properly indexed and catalogued is generally considered disseminated because it is accessible to someone searching for it. By the same reasoning, an improperly indexed document is not widely accessible and therefore not published.

The other method used for determining whether or not a document has been published is actual dissemination. Cases relating to works other than those placed in libraries focus not on the availability of one copy, but on the extent of dissemination and the number of copies circulated. Because a patent grant is a contract between the inventor and the public, it follows that the primary inquiry in determining whether a printed document constitutes a publication under the statute is public accessibility. The two determinations are separate and distinct, for if a document has been

sufficiently disseminated, it makes no difference whether or not it is indexed or catalogued in a library. Therefore, the threshold question is always whether the work has been disseminated. Courts have failed to develop clear tests for identifying sufficient dissemination, but there are some guidelines that can be drawn from the case law. The number of copies of a work produced and the identity of the readers to whom those copies were distributed are two important elements used in determining whether there has been sufficient actual dissemination.

Actual Dissemination: Importance of the Number of Copies and the Identity of Readers

Most conclusions of dissemination involve cases where more than one copy of the work was produced. One method that has been used to evaluate whether the number of copies produced is sufficient to constitute dissemination is to look at the method of reproduction used to produce the work. If the mode of reproduction used by a particular publisher would ordinarily be used to make a large number of copies for general distribution, then the work is likely to be considered a printed publication.

Some courts have found that accessibility to any segment of the public is all that is necessary for a work to fulfill the requirements of a printed publication.[39] Other courts have established that publication means accessibility to those skilled in the art and whether "persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and comprehend the essentials of the claimed invention without further research or experimentation."[40]

Speeches and Handouts Can Be Dissemination of an Invention

Delivery of a speech and accompanying paper at an academic conference may constitute a printed publication under the patent law.[41] Massachusetts Institute of Technology (M.I.T.), recipient of a National Science Foundation grant, initiated research in 1974 on microcarrier culture systems suitable for the *in vitro* cultivation of mammalian cells. Having achieved some success by September of 1975, Dr. David Levine of M.I.T. delivered an oral presentation at the First International Cell Culture Congress in Birmingham, Alabama. Approximately 50 to 500 scientists with expertise in cell culture techniques attended the conference. An important part of Dr. Levine's talk centered on the M.I.T. discovery that optimal cell adhesion and growth could be obtained by reducing the total charge capacity of the microcarriers to which the mammalian cells attach. This discovery was the essence of M.I.T.'s patent.[42]

Approximately fourteen months after Dr. Levine's presentation, M.I.T. filed a patent application covering the development of limited-charge cell culture microcarriers. After receiving a patent, M.I.T. licensed the microcarrier technology to a manufacturer of cell culturing products, Flow General, Inc., and its subsidiary Flow Laboratories, located in McLean, Virginia. Approximately six years later, M.I.T. and Flow jointly filed suit against another manufacturer of cell culture supplies, Pharmacia, Inc., (a Swedish company, formerly known as AB Fortia, with offices in New Jersey), claiming infringement of its microcarrier patent. Because the case involved importation of products from Sweden, and therefore potentially involved a violation of the Tariff Act by Pharmacia, Inc., it was decided by the United States International Trade Commission.[43] The Commission considered the presentation given by Dr. Levine in Birmingham as sufficient to invalidate the M.I.T. patent, and the United States Court of Appeals for the Federal Circuit agreed.

Dr. Levine had provided the head of the conference with a copy of his paper and distributed additional copies without restrictions to approximately six persons who requested them. M.I.T. argued unsuccessfully that Dr. Levine's presentation was not a "printed publication" within the

meaning of [[section]] 102(b) of the Patent Act. The court, however, held that a sufficient number of persons (between 50 and 500) skilled in the art were told of the existence of Dr. Levine's paper and copies of the paper itself were actually disseminated. The combination of Dr. Levine's oral presentation and the distribution of a transcript of his talk provided those skilled in the technological area with enough information to reproduce his work if they chose.[44]

After finding a printed publication, the court must establish that the publication is "enabling" or capable of teaching those skilled in the art the essence of the invention. A mere finding of a printed publication alone will not suffice to invalidate a patent. In another infringement suit involving a patented apparatus and process for underground drilling, the United States Court of Appeals of the Federal Circuit considered a one-page promotional brochure describing the results of a drilling process to be non-enabling.[45] "The mere fact that the Smith brochure, a one-page promotional brochure, boasts the ability and results of the process of the '903 patent' is insufficient, as a matter of law, to constitute an enabling disclosure of the process of the '903 patent.'"[46]

Intra-Company Distribution is Not Dissemination of a Work

Generally, documents circulated within one company or organization are not sufficiently disseminated to constitute publication and do not bar patentability. Similarly, internal corporate documents are not printed publications.[47] After certain claims in their patent application were rejected by the patent examiner, two inventors, Kratz and Strasburger, appealed to the United States Court of Customs and Patent Appeals. The inventors had discovered that the addition of small amounts of pure 2-methyl-2-pentenoic acid (2M2PA) to foods imparted a fresh fruit or strawberry flavor to those foods. Prior to applying for a patent, Kratz authored a memorandum concerning the objectives of the flavor research that was used internally at International Flavor and Fragrances, Inc., where Kratz worked. The memo was never distributed outside the company.

The dispute in the Kratz case centered on whether 2M2PA, a naturally-occurring constituent of strawberries, could be new or novel and therefore patentable. The court declined to use the internal memorandum, where Kratz had stated that 2M2PA is not new, as a printed publication because the memorandum was not a public document.[48]

Library Cataloguing: One Copy of a Thesis Constitutes Dissemination

The issue of whether a thesis is a printed publication has been considered on many occasions over the past fifteen years. Courts hearing these cases have provided significant guidance to inventors regarding when the inventor's own thesis may stand as a bar to a subsequent patent application. A document improperly indexed or catalogued is not widely accessible, as it may remain hidden from a person searching for it. A properly catalogued or indexed work, on the other hand, can easily be found by anyone searching for it. A properly indexed document within a library anywhere in the world is a printed publication within the meaning of the Patent Act, even where there has been no dissemination of the material, because it is accessible. Thus, accessibility is behind the indexing rationale, and cases relating to manuscripts and academic articles in libraries rely upon the indexing system under which the publication is filed to provide accessibility to persons ordinarily skilled in the art.

In 1978, the United States Court of Customs and Patent Appeals found an uncatalogued and unshelved master's thesis placed in the school library not to be a publication.[49] John Bayer, a graduate student in chemistry at the University of Toledo, wrote a thesis entitled "Coordination Complexes of 2-methyl-5-hydroxy-1,8-naphthyridine," which was submitted to a graduate committee in partial fulfillment of the degree requirements for a Masters of Science in chemistry. Mr.

Bayer applied for a patent on his discovery, but the majority of the claims were rejected by the patent examiner. The thesis was considered a printed publication that was received by the library more than one year before Bayer applied for a patent.

Mr. Bayer appealed the rejection of his patent application and was able to provide evidence to the court showing that after the library at the University of Toledo received his thesis it was withheld from public access for approximately ten months. It was the practice of the library to accumulate masters' theses in an office to which only library employees had access, until there was a sufficient number to send to a book bindery. Staff of the library collated the theses, assigned call numbers, and prepared temporary slips for the shelf list catalogue and temporary author slips for the public card catalogue, before the documents were sent out for binding. Once bound, theses were further processed before being transferred to the Circulation Department, where the temporary author slips were filed in the public card catalogue and the theses were shelved in the library.

The court reversed the rejection of Mr. Bayer's patent claims and held that the uncatalogued, unshelved thesis was not a printed publication under the Patent Act.[50] The court went on to note that " . . . under 35 U.S.C. [[section]] 102(b), delays within a university library or within any other organization responsible for the publication of printed documents, are of utmost significance because public access to the document is thereby deferred, thus postponing the commencement of the one year time bar."[51]

In 1989, the United States Court of Appeals for the Federal Circuit likewise found three undergraduate theses were not printed publications. Unlike the *Bayer* case, however, the theses in the *Cronyn* case had been shelved, but nevertheless were found by the court not accessible to the public because they had not been catalogued or indexed in a meaningful way. Marshall W. Cronyn, a professor of chemistry at Reed College in Portland, Oregon, applied for a patent on a chemical compound that was anticipated as being useful in cancer treatment. The patent examiner rejected the patent as anticipated by three undergraduate theses contained in the library of Reed College. The Board of Patent Appeals and Interferences agreed with the patent examiner, but the United States Court of Appeals did not and reversed the rejection of the Cronyn patent application.[52]

Reed College, a solely undergraduate institution, required each student pursuing a Bachelor of Arts degree to prepare a senior thesis based on laboratory or scholarly research. A copy of each thesis was filed in the main college library and in the library of the particular department in which the student's work was done. In both libraries, the theses were listed on individual cards and filed alphabetically by the author's name. In the main library, there were approximately 6,000 theses listed on cards, and in the chemistry department library there were approximately 450 cards in a shoe box. None of the theses in either library was indexed or catalogued.

The court concluded that the three theses were not accessible to the public because they were not indexed in a meaningful way.[53] The three theses were listed on cards among 450 others and because they were listed only by the student's name, a researcher in the field would not have been able to find the theses by subject. The nature of the indexing system seems to have played a significant role in determining patentability, although the case was decided by a three-judge panel, with one judge dissenting.

A single catalogued thesis in one university library has been found to be sufficient to constitute accessibility.[54] In *Hall*, a dissertation was found accessible because it was indexed, catalogued, and shelved. A patent examiner rejected the patent of Leo M. Hall, citing a dissertation entitled "1,4-alpha-Glucanglukohydrolase ein amylotylishches Enzym . . ." by Peter Foldi. The Foldi

dissertation was contained in the library of Freiburg University in what was then the Federal Republic of Germany. A director of the library was able to testify by affidavit that copies of the Foldi dissertation were made available to the public approximately one month after they were received by the library. Mr. Hall was denied a patent because the Foldi dissertation was considered prior art that anticipated his invention.

It is interesting to note that the United States Court of Appeals for the Federal Circuit in the *Hall* case relied on the routine of the library in Germany in much the same way that the United States Court of Customs and Patent Appeals did in the *Bayer* case. In the *Bayer* case, evidence was presented that the University of Toledo routinely took months to properly index and catalogue a thesis after receiving it, thereby delaying its access to the public. The *Bayer* court relied on this information in reaching its decision that the thesis was not a printed publication. Similarly, in the *Hall* case, evidence was available showing that the University of Freiburg library made theses available to the public one month after their receipt by the library. The *Hall* court stated that "competent evidence of the general library practice may be relied upon to establish an approximate time when a thesis became accessible."[55] The *Hall* court found that the thesis at issue was a printed publication.

Additionally, in the *Gulliksen* case discussed above under "Physical Format of the Author's Work and the Meaning of "Printed,"" the Patent Office Board of Appeals concluded that a master's thesis that was properly indexed and catalogued would be considered published.[56] By placing his work in the library, the author dedicated it to the public. This position has been criticized under the reasoning that without dissemination, knowledge is not available to the general public. Nevertheless, interpretation of the meaning of printed publication still focuses on the indexing system under which the publication is catalogued if it is part of a public library.

A FEDERAL RESEARCH GRANT

IS A "PRINTED PUBLICATION"

A district court in California recently decided that a research grant proposal, which resulted in the award of a federal grant for its submitter, was a printed publication under [[section]] 102(b) of the Patent Act.[57] Using reasoning similar to that used by courts in determining whether a thesis is a printed publication, and citing the *Hall* case where a thesis that was indexed, catalogued, and shelved in a university library was held to be a printed publication, the California court decided that a grant proposal was a printed publication because it was accessible. The court based its determination of accessibility on the fact that the grant proposal was: 1) indexed by title, author, institution, and grant number; 2) made available to the public at large through the Freedom of Information Act; and 3) had been cited by its grant number in a scientific publication written by the author of the grant proposal.[58]

In 1972, Dr. H. Gobind Khorana submitted a grant proposal entitled "Chemical and Biological Studies of Nucleic Acids" to the National Science Foundation. As a result of the proposal, Dr. Khorana received a research grant and subsequently directed the work that was performed in his laboratory under the grant. Two years later, Dr. Khorana co-authored a scientific publication, "Studies on Polynucleotides: the Linkage of Deoxyribopolynucleotide Templates to Cellulose and Its Use in Their Replication," which was published in the *Journal of Biological Chemistry*. On the first page of the scientific publication, Dr. Khorana and his co-author, Dr. Panet, cited the National Science Foundation grant number, under which the research for the publication was conducted. In 1989, the work of Dr. Khorana became the subject of a dispute between E. I. Du Pont De Nemours & Co. (Du Pont) and Cetus Corporation (Cetus) when Du Pont claimed that two patents covering

polymerase chain reaction (PCR) technology, issued by the U.S. Patent and Trademark Office in 1987 and held by Cetus, were invalid. Among other things, Du Pont alleged that the Cetus inventions lacked novelty under 35 U.S.C. [[section]] 102(b) because they were described in a printed publication by Dr. Khorana in his grant proposal in 1972, more than one year before the Cetus patent applications were filed on March 28, 1985 by Dr. Kary B. Mullis.

Du Pont, in moving for summary judgment, attempted to show that the existence of Dr. Khorana's scientific publication and grant proposal were sufficient evidence on which the district court could find the Cetus patents invalid without proceeding to a trial. The United States District Court for the Northern District of California did not agree, and in denying Du Pont's motion for summary judgment, implied that the issue of whether the Cetus patents were invalid due to the content of the publications of Dr. Khorana remained for a jury to determine. Although the court did not reach the question of the validity of the Cetus patents, the court did conclude that a grant proposal that is indexed, available to the public under the Freedom of Information Act, and cited in a scientific publication is a printed publication under the Patent Act.

Accessibility of a Grant Proposal Does Not Depend on Indexing Alone

In the *Du Pont* case, Cetus argued that the grant proposal was not a printed publication under the Patent Act because an investigator interested in PCR technology could not have discovered the work easily. Cetus relied on reasoning similar to that used in the *Cronyn* case, where an indexing system consisting of 450 cards in a shoe box resulted in the inaccessibility of a thesis, and argued that the grant proposal was not indexed in a meaningful way because the National Science Foundation did not file the grants by subject matter. To bolster their argument, Cetus also claimed that the title, "Chemical and Biological Studies of Nucleic Acids," was vague.

The California court did not just evaluate the accessibility of the single grant proposal the way other courts have evaluated the accessibility of a single thesis, but expanded its reasoning beyond the indexing system alone and based its judgment of accessibility, in part, on the professional reputation of the author of the grant proposal. The California district court reasoned that any investigator in the field of nucleic acid synthesis is likely to have seen the publication of Drs. Khorana and Panet because of their stature as pioneers in the field. The combination of the title of the grant proposal and the authors' reputations made the grant proposal accessible once its number was reproduced in Khorana and Panet's article in the *Journal of Biological Chemistry*.

It is impossible to predict what effect the *Du Pont* case will have on future determinations of whether grant proposals are printed publications under the Patent Act, and one can only speculate as to the decision the court might have reached had the number of the grant not appeared in Drs. Khorana and Panet's scientific paper. If future courts are persuaded by the reasoning of the United States District Court for the Northern District of California, however, they are free to consider the reputation of a grant proposal's author in reaching their decisions. In the case of a thesis, indexing, cataloguing, and shelving in a library are sufficient to make the thesis accessible.[59] In the case of a research grant proposal, indexing must be combined with the power of the Freedom of Information Act to make the grant proposal accessible.

The Freedom of Information Act (FOIA) and Accessibility of Grant Proposals

The FOIA legislation was passed by Congress to alter an attitude of secrecy that had developed in the government in the years before its enactment in 1967. The fundamental purpose of the FOIA is to allow the public access to government records. The FOIA requires all federal agencies to make their records available to any person requesting them, unless the records contain information

included in one of nine exemptions specified by Congress.[60] The United States Supreme Court held in 1982 that nearly everyone is free to request government records, under the FOIA, regardless of his or her motive.[61]

A party who submits information to a federal agency and wishes to prevent its disclosure to a third party FOIA requester must attempt to establish that the information submitted is included in one of the nine exemptions. Otherwise, the federal agency is required by law to disclose the information to the public under the FOIA. It is only when information can be classified into one of the nine exemptions that a federal agency has the authority to use its discretion and choose to either withhold the information or release it to the public.

In developing the FOIA legislation, Congress did not specify the impact it intended FOIA to have on scientific grant administration.[62] Information disclosed by a researcher in a grant proposal submitted to a federal agency becomes an "agency record" and subject to disclosure to the public under the Freedom of Information Act even if the agency does not award the grant.[63] Two of the FOIA exemptions sections 552(b)(3) and (4), however, are arguably applicable to the type of information contained in grant proposals. If information in a grant proposal is exempt from being disclosed to the public under the FOIA, a federal agency is not required by law to supply the contents of the proposal to any person who requests it, and the agency can exercise its discretion and choose to withhold the information. If a grant proposal is not accessible, it should not be considered a printed publication under the Patent Act.

The first exemption that applies to grant proposals is exemption 3, which states that records exempted from disclosure by "other statutes" do not have to be released to the public under the FOIA.[64] The Patent Act requires that the U.S. Patent and Trademark Office keep patent applications confidential until the patent is granted.[65] If the information contained in a grant proposal is the subject of a patent application pending before the U.S. Patent and Trademark Office, then the grant proposal qualifies under the Freedom of Information Act as an agency record that is exempted from disclosure by another statute (in this case, the Patent Act). The Patent Act and its requirement that patent applications be kept confidential overrides the compulsory disclosure of information mandated by Congress in the FOIA. It may be possible, therefore, to keep a grant proposal from being disclosed to the public under the Freedom of Information Act if the subject matter of the grant proposal is part of a patent application simultaneously submitted to the U.S. Patent and Trademark Office.

Not every statute that requires confidentiality on the part of the government, like the Patent Act, automatically overrides the requirement of mandatory disclosure under FOIA. Statutes only qualify under exemption 3 of the FOIA if they clearly specify nondisclosure and refer to particular types of information to be withheld or establish particular criteria for withholding information.[66] Congress must have explicitly expressed its desire to prohibit the federal agency subject to the statute from disclosing certain information to the public. If Congress delegates to the federal agency the authority to exercise its discretion regarding disclosure, the statute does not fall under FOIA exemption 3 because it is not sufficiently specific. An example of a statute of this type is the Trade Secrets Act, which prohibits federal employees from disclosing trade secrets acquired during the course of their employment.[67] The Trade Secrets Act is not a statute that falls under FOIA exemption 3 and even though it requires that certain information be kept confidential by the government, it does not by itself override the mandatory disclosure requirement of the FOIA.[68] If information falls within another exemption such as FOIA exemption 4, then the Trade Secrets Act may prohibit a governmental agency from disclosing the material.[69] The second exemption that applies to a grant proposal is FOIA exemption 4, which excludes from mandatory disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential."[70] The

exemptions under the FOIA are interpreted narrowly, and one court has held that a noncommercial scientist's research designs are not trade secrets because a scientist is not engaged in trade or commerce.[71] A federal agency, however, may still be able to use its discretion and deny a request under FOIA exemption 4 for information contained in a grant proposal if the commercial value of the research described in the proposal can be demonstrated.[72] Research with commercial value is exempt from disclosure under FOIA exemption 4 as "commercial information" as long as it is also considered confidential by its submitter. Commercial or financial matter is "confidential" for purposes of the exemption if disclosure of the information is likely to "impair the Government's ability to obtain information in the future or to cause substantial harm to the competitive position of the person from whom the information was obtained."[73]

The competitive position of a researcher employed in a nonprofit setting may be harmed by the release of confidential information contained in a grant proposal in at least two ways: first, business organizations may try to exploit the discoveries of nonprofit research organizations revealed through the Freedom of Information Act in an attempt to save on research and development costs; second, other scientists may attempt to find promising avenues of research by following grant proposals.[74] The substantial harm caused to a researcher by the release of confidential information contained in a grant proposal can also be measured by any loss of professional or peer recognition and the concomitant benefits that accompany such recognition due the researcher and author of the grant proposal.[75]

A grant proposal is a printed publication within the meaning of the Patent Act and can prevent an inventor from being granted a patent in two ways. First, if the grant proposal was available for dissemination under the Freedom of Information Act by a federal agency more than one year before the date on which the inventor filed for a patent, the grant proposal will bar patentability. Second, if the grant proposal was authored by someone other than the inventor and filed with a federal agency before the inventor conceived of his or her discovery, the inventor will be denied a patent because the invention is not new. A disclosure of an invention in a publication of any type, however, only has the potential of denying an inventor a patent if the disclosure is enabling or clearly describes the invention so that a practitioner skilled in the technological field could make or use the invention.

There are steps under the inventor's control that can be taken to prevent a grant proposal from being interpreted as a printed publication. The inventor can draft the grant proposal so that it is not enabling. As was the case with slides, drawings, speeches, and handouts, a grant proposal must enable a practitioner skilled in the technological art to reproduce the invention to be considered a printed publication under the Patent Act. If the grant proposal does not teach another researcher in the field how to conduct the research or make or use the invention, it cannot be considered a printed publication. An inventor can file a patent application within one year of submitting the grant proposal to a federal agency. Filing of the patent application within one year assures that the inventor's own grant proposal will not bar patentability under the Patent Act. The inventor's patent, however, may still be barred by a grant proposal submitted by another researcher, as then the invention would not be considered new.

An inventor can also claim that the grant proposal is exempt from mandatory disclosure under FOIA exemptions 3 and 4. First, the inventor can inform the government agency to whom the research grant is submitted that the subject of the grant is also the subject of a United States patent application and is exempt from disclosure under 5 U. S. C. [[section]] 552(b)(3). The inventor can also claim that the grant proposal should not be disclosed to the public and is exempt from disclosure under 5 U.S.C. [[section]] 552(b)(4) because the grant proposal is commercial information due to its commercial value and confidential nature. To alert a federal agency to the

confidential nature of any information submitted with a grant proposal, the inventor should mark each document with a legend indicating that the information is considered confidential by the sender.[76]

SUMMARY

WHAT COUNTS AGAINST AN INVENTOR

A printed publication can prevent an inventor from receiving a patent for an invention if the printed publication was either produced by the inventor more than one year before the inventor submitted a patent application to the U.S. Patent and Trademark Office, or if the printed publication was authored by someone other than the inventor before the inventor conceived of the discovery. For a printed publication to invalidate a patent, two criteria are required: the publication must be printed; and it must be accessible to persons skilled in the technology. "Accessible" means indexed and catalogued, if the document is a thesis. For documents other than a thesis, "accessible" means that the work has been generally disseminated. Printed publications that count against an inventor and may prevent the inventor from receiving a patent include microfilm, slides, blueprints, drawings, and written descriptions of the invention. One court held that an oral presentation of an invention constituted a printed publication because the speaker also distributed a transcript of the talk without restriction to those who requested it. The courts have kept pace with evolving communication technology and interpret the meaning of "printed" broadly.

The accessible or disseminated printed publication is likely to be interpreted by a court as a bar to patentability if the document sufficiently describes a patented device so that one skilled in the technological area of the invention, or "art" as it is called in the patent law, can recognize and comprehend the essentials of the claimed invention without the need for further research or experimentation. Therefore, when evaluating the potential for patenting an invention, it is important to investigate the activities of the inventor to determine whether they may foreclose the grant of a patent. The activities that count against an inventor are those involving disclosure of the essence of the invention in printed documents (slides, drawings, photographs, or written descriptions) to those considered skilled in the technological area, without restriction, and more than one year before a patent application is filed with the U.S. Patent and Trademark Office.

One court recently held that a grant proposal is a printed publication within the meaning of the Patent Act. A grant proposal can bar its author, the inventor, from being granted a patent if the grant proposal was available for dissemination under the Freedom of Information Act by a federal agency more than one year before the date of filing for a patent. A grant proposal authored by someone other than the inventor and filed with a federal agency before the inventor conceived of an invention will deny an inventor a patent because the invention will be deemed to lack novelty. An inventor can guard against having a previously submitted research grant count against patentability later by not disclosing all of the details of the invention in the grant proposal, by appropriately marking the application confidential and requesting FOIA exemptions, and/or by filing a patent application within one year of the submission of the grant proposal to assure that the proposal will not bar patentability under the Patent Act.

NOTES

1. 35 U.S.C. [[section]][[section]] 1-376 (1988).

2. Richard W. Hoffman, Comment, *What Constitutes a Printed Publication under the Patent Act*, 1988, Det. C. L. Rev. 961 (Winter 1988).

3. 35 U.S.C. [[section]] 101.

4. U.S. Const. Art. I, [[section]] 8.

5. Richard W. Hoffman, Comment, *What Constitutes a Printed Publication under the Patent Act*, 1988, Det. C. L. Rev. 961.

6. *Id.*

7. 35 U.S.C. [[section]] 102(a). "The similarity in wording between subsections 102(a) and 102(b) is a constant source of confusion in patent law. Section 102(a) is a *novelty* provision - determining whether subject matter is new as of the inventor's invention date in view of prior art of others. Section 102(b) is a *loss of right* provision, which contemplates that the right to a patent on an invention that was patentable as of the date of invention is lost when the inventor delays too long in filing a patent application. Different policy considerations support the two subsections." *quoting* Donald S. Chisum & Michael A. Jacobs, Understanding Intellectual Property Law [[section]] 2C[5], 2- 84 n.305 (1992).

8. 35 U.S.C. [[section]] 102(b).

9. 35 U.S.C. [[section]] 101.

10. 35 U.S.C. [[section]] 102(a).

11. Richard W. Hoffman, Comment, *What Constitutes a Printed Publication under the Patent Act*, 1988, Det. C. L. Rev. 961.

12. Steven H. Gifis, Law Dictionary, 92 (3d ed. 1991).

13. *In re Tenney*, 254 F.2d 619, 624 (C.C.PA. 1958).

14. 35 U.S.C. [[section]] 102(b).

15. *Gulliksen v. Halberg*, 75 U.S.P.Q. (BNA) 252 (1937).

16. *Id.* at 254. The court stated, "It seems to us that an inventor should not be precluded from dedicating his invention to the public by using modern printing means now available, such as the typewriter, and that he should not be restricted to printing press printing to effect such dedication." The court could not have foreseen that their comment made in 1937 would apply to the computerized technologies that have become available for disseminating information almost sixty years later.

17. *Id.*

18. *In re Tenney*, 254 F.2d 619; *In re Weyer*, 655 F.2d 221 (C.C.P A. 1981).

19. *Regents of the Univ. of Cal. v. Howmedica, Inc.*, 530 F. Supp. 846 (D.N.J. 1981); *Vetco Offshore Indus. v. Rucker Co.*, 448 F. Supp. 1203 (N D. Cal. 1978).

20. *Torin Corp. v. Phillips Indus.*, 625 F. Supp. 1077 (S.D. Ohio 1985);*Bros. Inc. v. Browning Mfg. Co.*, 317 F.2d 413 (8th Cir. 1963).

21. *In re Tenney*, 254 F.2d 619, 627. The United States Court of Customs and Patent Appeals (C.C.P.A.) was abolished in 1982 when the United States Court of Appeals for the Federal Circuit (C.A.F.C.) was created. The C.A.F.C. has exclusive jurisdiction over all appeals from patent cases heard anywhere in the United States.

22. *Id.*

23. *In re Wyer*, 655 F.2d 221, 226.

24. *Id.*

25. *Id.* at 225.

26. *Id.* at 224.

27. *Regents of the Univ. of Cal. v. Howmedica, Inc.*, 530 F. Supp. 846, 849.

28. *Id.* at 859.

29. *Id.* at 860.

30. *Id.* at 859.

31. *Vetco Offshore Indus. v. Rucker Co.*, 448 F. Supp. 1203, 1208.

32. *Torin Corp. V. Phillips Indus.*, 625 F. Supp. 1077, 1090.

33. *Id.* at 1082.

34. *Id.* at 1083.

35. *Bros. Inc. v. Browning Mfg. Co.*, 317 F.2d 413, 414.

36. *Id.* at 416.

37. *In re Wyer*, 655 F.2d 221, 227.

38. Richard W. Hoffman, Comment, *What Constitutes a Printed Publication under the Patent Act*, 1988, Det. C. L. Rev. 961.

39. *Pickering v. Holman*, 459 F.2d 403, 407 (9th Cir. 1972) ("[T]he key factor is not access by a specific segment of the public, or number of persons, or even by any specific means, but simply distribution to any segment of the public.").

40. *I.C.E. Corporation et. al. v. Armo Steel Corp.* 250 F. Supp. 738, 743 (S.D. New York 1966).

41. *Massachusetts Institute of Technology v. AB Fortia*, 774 F.2d 1104 (Fed. Cir. 1985).

42. *Id.* at 1106.

43. 19 U.S.C. 1337 (1988).

44. *Massachusetts Institute of Technology v. AB Fortia*, 774 F.2d 1104, 1109.

45. *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 645 (Fed. Cir. 1984).

46. *Id.* at 651, 652.

47. *In re Kratz*, 592 F.2d 1169 (C.C.P.A. 1979).

48. *Id.* at 1174.

49. *In re Bayer*, 568 F.2d 1357 (C.C.P A. 1978).

50. *Id.* at 1362.

51. *Id.*

52. *In re Cronyn*, 890 F.2d 1158 (Fed. Cir. 1989)

53. *Id.* at 1160.

54. *In re Hall*, 781 F.2d 897 (Fed. Cir. 1986).

55. *Id.* at 899.

56. *Gulliksen v. Halberg*, 75 U.S.P.Q. (BNA) 252, 254.

57. *E.I. Du Pont de Nemours & Co. v. Cetus Corp.*, 1990 U.S. Dist. LEXIS 18414 (N.D. Calif. 1990).

58. *Id.* at *24.

59. *See supra* note 54 and accompanying text (single, catalogued thesis in the library of Freiburg University in Germany was accessible because it was indexed, catalogued, and shelved).

60. The Freedom of Information Act (FOIA) is codified at 5 U.S.C. [[section]] 552. The exemptions to the mandatory disclosure required under the FOIA, and listed in subsections (b)(1) to (9), are: 1) records related to national defense and foreign policy; 2) records related to internal personnel rules and practices; 3) records exempted by other statutes; 4) trade secrets and confidential commercial or financial information obtained from a person; 5) internal government communications and notes that fall within a generally recognized evidentiary privilege; 6) records that if disclosed would constitute a clearly unwarranted invasion of personal privacy; 7) government records compiled for law enforcement purposes; 8) records concerning regulation or

supervision of financial institutions; 9) geological and geophysical information and data, including maps, concerning wells. The United States Supreme Court has held that exemptions are discretionary and that a federal agency may choose to disclose information, even if the information falls within an exemption and the federal agency is not required to disclose it. *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979).

61. *Baldrige v. Shapiro*, 445 U.S. 385 (1982).

62. Judith Lowitz Adler, *The Impact of FOIA on Scientific Research Grantees*, 17 Colum. J. L. & Soc. Probs. 1, 2 (1981).

63. Jerome S. Gabig, Jr., *Federal Research Grants: Who Owns the Intellectual Property?*, 16 Pub. Cont. L. J. 187, 208 (1986).

64. 5 U.S.C. [[section]] 552(b)(3) (1988).

65. 35 U.S.C. [[section]] 122 (1988).

66. *See, e.g, Irons & Sears v. Dann*, 606 F.2d 1215 (1979).

67. 18 U.S.C. [[section]] 1905 (1988).

68. *See generally*, *Westchester General Hospital, Inc. v. Department of Health Education & Welfare*, 464 F. Supp. 236 (M.D. Fla. 1979); *Guerra v. Guajardo*, 466 F. Supp. 1046 (S.D. Texas 1978).

69. *Chrysler Corp. v. Brown*, 441 U.S. 281, 301 (1979) *quoting* the House Committee on Government Operations H. R. Rep. No. 94- 880, pt. 1, p. 23 (1976)

70. 5 U.S.C. [[section]]552(b)(4) (1988).

71. *Washington Research Project, Inc. v. Department of Health, Education & Welfare*, 504 F.2d 238 (D.C. Cir. 1974). *See also Public Citizen Health Research Group v. Food and Drug Administration*, 704 F.2d 1280 (D.C. Cir. 1983) (A trade secret, for the purpose of 5 U.S.C. [[section]] 552(b)(4), has been defined as a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort"). *See also* Jerome S. Gabig, Jr., *Federal Research Grants: Who Owns the Intellectual Property?*, 16 Pub. Cont. L. J. 187, 209 (1986) (Definition of trade secret was created in a case that involved a request by a consumer advocacy organization seeking information on the safety of intraocular lenses, and another court dealing with an issue other than health and safety may not choose to use the same definition.).

72. Judith Lowitz Adler, *The Impact of FOIA on Scientific Research Grantees*, 17 Colum. J. L. & Soc. Probs. 1, 13, 14 (1981); Jerome S. Gabig, Jr., *Federal Research Grants: Who Owns the Intellectual Property?*, 16 Pub. Cont. L. J. 187, 208 (1986).

73. *National Parks and Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974). See also Jerome S. Gabig, Jr., *Federal Research Grants: Who Owns the Intellectual Property?*, 16 Pub. Cont. L. J. 187, 210 (1986) ("An obvious example of impairing the

government's ability to obtain information in the future would be where the grantee is incited by the FOIA request to seek alternate sources of funding to avoid federal involvement in the research.").

74. Jerome S. Gabig, Jr., *Federal Research Grants: Who Owns the Intellectual Property?*, 16 Pub. Cont. L. J. 187, 210 (1986). *See also* Judith Lowitz Adler, *The Impact of FOIA on Scientific Research Grantees*, 17 Colum. J. L. & Soc. Probs. 1, 14 (1981) ("Commercial enterprise, with access to large numbers of research designs, could select ideas of potentially great commercial value and fund and develop them before their originators could do so.").

75. Jerome S. Gabig, Jr., *Federal Research Grants: Who Owns the Intellectual Property?*, 16 Pub. Cont. L. J. 187, 210 (1986).

76. *Id.* at 208.

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