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Note

PUBLISH AND PERISH: PATENTABILITY ASPECTS OF PEER REVIEW MISCONDUCT

Edwin S. Flores Troy, Ph.D.[a]

Table of Contents

***48 I. Introduction**

The trust vested in the system of academic peer review is misplaced, and until inventors and patent prosecutors realize the potential danger to the patentability of the invention sought, submitting a manuscript or a grant proposal to a peer review panel may be a hazardous endeavor.

To determine whether an invention may be patentable, most patent prosecutors cope daily with the publication and public disclosure dates of inventors' confidential information. When dealing with inventors in the academic environment, it is alarmingly common for patent counsel to receive notice from the inventor that the data underlying the patent application being drafted is "*in press*" with a publication being mailed to subscribers within months, days or even hours.[1] Faced with a short time frame to prepare the application, the most immediate concern is over the quality of the patent application. In addition to concern over quality control, patent counsel is also concerned with the date that the publication is available to the public, the potential of interference in a highly competitive area, and perhaps, in the future, a first-to-file system.[2] Patent counsel, however, will also have to deal with the misplaced trust reposed by inventors in the peer review system.

The peer review system requires that scientists divulge confidential information to their peers in order to evaluate the merit of the research.[3] Peer review is used prior to publishing a scientist's findings, to further the scientist's research efforts and career, and to secure grant funds.[4] The peer review system's design, however, permits and perhaps even encourages an inventor's peers, especially in highly competitive fields, to use the information to their scientific and pecuniary advantage. One important way that the peer review system is flawed is through its reliance on the perfunctory confidentiality agreements that peer reviewers are asked to sign.[5] Even if scientists sign confidentiality agreements, a breach of such an agreement will not salvage an inventor's right to a patent.

What remedy does an inventor have against the alleged peer malfeasor other than charges of plagiarism[6] or fraud? What is the likelihood that a patent will issue ***49** to the true inventor, and who has the upper hand if a conflict arises? Under current patent doctrine, the invention date is the date of conception and reduction to practice given due diligence.[7] Without due diligence, the invention date is constructively the date that a complete application is filed with the Patent and Trademark Office once the application date is perfected.[8] What happens to the patentability of an invention when a direct competitor, a former student, or a peer in a position to use or pass on the valuable information acts contrary to the "gentleman's agreement" that permeates scientific peer review today? What happens to the patentability of an invention when a peer reviewer, upon being exposed to the information, directs one of his or her students to use the knowledge to advance his or her research and career?

A common form of patent disclosure that a patent counsel receives from an academic researcher is a manuscript that has been, or will be, submitted for publication. Other possible forms of patent disclosures include grant proposals and materials that are being readied for presentation to an academic council that determines tenure. This Note provides a description of the different forms of peer review, the rules that regulate the peer review system, the potential effect of a breach of confidentiality on the patentability of the client's invention, the incentives of the different parties, and the options available to patent prosecution counsel. This Note is written so that practitioners and their clients can be better informed of their options before and after materials are sent for peer review, and to facilitate the successful prosecution of patents. After reviewing the incentives and disincentives that face scientific peers, the Note explores solutions to the problem of peer review misconduct. This Note will not discuss research fraud and the fabrication of data as those topics have been extensively covered by others.[9]

The importance of peer review cannot be underestimated in either the scientific or legal arenas. In the judicial setting, peer review surrounds and permeates scientific discovery with a cloak of veracity and thoroughness that allows litigators to transfer scientific evidence from the laboratory into the courtroom.[10] In the patent arena, however, the level of scientific value and thoroughness necessary to meet the ***50** enablement and best mode requirements of 35 U.S.C. § 112, ¶ 1[11] does not approach the stringency of editorial peer review, discussed *infra* Part VIII.A.[12]

II. The Peer Review System

In the academic environment, peer review provides the primary means for scientists to control the publication of articles, to guide the direction and decide on the sufficiency of the research, to determine the allocation of limited financial resources, and perhaps most importantly to acknowledge the progress of a peer's career.[13] Peer review can be divided into three distinct categories: editorial peer review of a manuscript submitted for publication; intramural or career advancement peer review; and extramural peer review to determine which research deserves the award of a grant.

A. Editorial Peer Review

The editorial peer review of manuscripts containing an investigator's most recent discoveries is the most often performed type of peer review because it is common for sufficient data to be generated between grant proposals to support several manuscripts.[14] Editorial peer review is the process that is used to confirm the intellectual strength, relevance, and completeness of the research being presented by the author or authors for publication in a scientific journal.[15] Generally speaking, the peer review process is as follows.[16] First, an author drafts a manuscript that contains a short background section relating to the specific technology that is most closely related to his scientific contribution. Next, the author's manuscript contains the experimental methods and equipment used to obtain the data. After the experimental methods are disclosed, the data is presented and relevant observations in the art are noted. Finally, the manuscript includes a short conclusion discussing the significance of the investigator's observations. The manuscript's conclusion ***51** serves to place the author's contribution into the growing puzzle of scientific knowledge.

The written manuscript containing all of the author's data is then submitted to a scientific journal for editorial peer review. From the start, the editorial board of a journal may reject the manuscript for a number of reasons: it is perceived as incomplete; it is not in the proper journal format; the data disclosed is not considered timely or interesting; or simply because the editors do not think the readership of the journal would be interested. An editor of a journal has the option of rejecting the manuscript immediately, or sending the manuscript for peer review. Immediate rejection of a manuscript by the journal's editor is not as great a problem from a patentability perspective because the rejection is generally swift. It is also not as great a problem because his or her identity is known to the author, as the author generally sends the manuscript to a specific editorial board member.

Once the manuscript is sent to a journal, the first step in the peer review process is a determination by the editorial board of a journal whether or not they are interested in publishing the manuscript. The editorial board review of a manuscript may take as long as one or two months, depending of the board members' schedules and the number of manuscripts submitted. Often the members of the editorial board are volunteers, who have their own laboratories, research, and students to tend. In order to receive the best review possible, the journal is most likely to send the manuscript to those individuals most familiar with the field, i.e., the author's competitors, former students, and the like.

The potential for abuse of the peer review system begins when the manuscript is sent from the editorial board of the journal to the anonymous peer reviewers selected by the editorial board of the journal. Generally, a peer reviewer is asked to return the manuscript if he is not able to review the manuscript in a timely manner. If the reviewer accepts the manuscript, the editorial board is at the mercy of the peer reviewer to return a review of the manuscript. Experience shows that the time taken for a typical peer review can range from three to six months. Note that this three to six month time period may apply even if the manuscript is rejected by the peer reviewer, and may follow the month or two delay of the editorial board.

Once the rejected manuscript is returned to the original researcher, he or she still has to find another journal that may be interested in the work. To publish in the second journal of his or her choice, the researcher must reformat the manuscript for that particular publication. The researcher may also have to add experimental data to address the grounds that served to reject the manuscript previously. After all the changes, the researcher has to go through the entire process again, with the potential that the same malfeasing reviewer may be selected by the secondary journal to review the researcher's expanded findings. The entire process can be expected to last anywhere from six months to a year, with final publication occurring three to six months later. Alternatively, the researcher may attempt to address the grounds for ***52** the journal's rejection by performing additional experiments that address the reviewer's grounds for rejection. The author will then resubmit the paper to the original journal, which then sends the updated manuscript to the same reviewers! Therefore, the entire process, from submission to publication may take as long as eighteen months, giving a malfeasing peer reviewer plenty of time to trigger statutory bars, repeat and advance upon the work, and even file a patent application of his own, discussed *infra* Part III.B.

B. Extramural Peer Review

An extramural peer review is a very different type of peer review than the review of a manuscript. There are two main reasons why these types of peer review occur: 1) an extramural peer review is basically used to determine funding, and 2) grants are not normally part of scientific discourse. Extramural peer reviews are conducted by peer review panels or committees, generally referred to as "study sections,"[17] and are only used by government funding agencies to determine funding.[18] The specific methods used by four different federal granting agencies have been discussed by others;[19] however, for the purposes of this Note, a short review of the methods used by the National Institutes of Health (NIH) will be used as an example.[20] Like the peer review panels of the NIH, private organizations and companies use peer review panels to evaluate and determine the viability of an investigator's proposed research and work in progress. Peer review panels are used by both the public and private sectors to help decide whether they will continue to fund the investigator's research, or whether funding for the research will be terminated.

Extramural peer review panels are generally comprised of a group of well-established experts from a particular field that evaluate the grant separately, and then meet to determine the grant status of each individual grant in that particular funding area. The experts selected to the peer review panel serve four year terms, and are selected by a member of the NIH staff known as a scientific review administrator.[21] The actual selection of the panelists is based primarily on the administrator's knowledge "of the scientists who work in the field and contacts at scientific meetings, NIH staff recommendations, existing research grant applications and awards, research publications, and recommendations of existing panel members."[22] ***53** To prevent bias, only one member of each panel can be from any one research institution.[23]

Before the panel meets, each member is assigned a number of grants for his or her review.[24] During this portion of the extramural peer review process, the panelists impartially review the actual and future studies proposed by the researcher, including the specific techniques that the researcher will use to complete the work. Unlike the editorial peer review process, grant proposals under peer review generally contain only a small amount of preliminary research, if any. The preliminary evaluation by each panelist is expected to occur confidentially within the confines of the panelist's office. The entire peer review panel then meets and ranks all of the grant submissions. The peer review panel then provides its funding recommendations and ranking for all of the applications that have been "deemed worthy."[25] The initial review panel's recommendations are then submitted, in the form of a summary, to the NIH Advisory Council, who then determines which grants will be funded based on the particular level of funding and percentile cut-offs assigned for funding.[26] Finally, the grants that fall within the funding "percentile" are granted.[27] One commentator has described membership on the Advisory Council as a "political plum" that is a sinecure bestowed upon prominent supporters of the "political party in power."[28] The reason that the Advisory Council serves a perfunctory function in the review process is because the Council gives the greatest deference to the expert panels that the NIH administration has assembled, and rarely acts against the panel's recommendations.[29]

It is important for the present discussion to note that these evaluations are hardly anonymous. The names of the investigators and the institutions where they conduct their research is a major factor in determining funding.[30] In terms of peer review misconduct, extramural peer review may be the most dangerous for an inventor, because grants include the ideas and goals that the inventor/scientist seeks to pursue, and includes a detailed map of how to achieve those goals. Although some work may have taken place to lay the ground work for the grant proposal, it may not be enough work to support a patent application. These grant applications, however, often contain detailed road maps of the means of achieving the final result, ***54** which in the hands of well funded competitors who can quickly complete the work, or have already completed some of the steps in secret, can lead to a rapid progression from theory to practice. Finally, it must be emphasized that each investigator's academic pedigree and his or her "grantsmanship" abilities play a significant role in determining the allocation of limited resources, and consequently, the researcher's livelihood.[31]

The funding manual to the NIH indicates that review panel members are not to share information contained within the grants, and that the information is strictly confidential.[32] Enforcement of these regulations, however, is dubious as "the agency's guidelines and regulations do not specify particular sanctions for breaches of confidentiality."[33] Short of filing suit, the only sanction that may be applied to a researcher that presumably takes advantage of his or her position of trust is the stigma that accompanies removal from a peer review panel.[34]

The disincentives to taking advantage of information obtained during extramural peer review include loss of funding, loss of access to confidential information due to removal from peer review panels, generalized scorn from the scientific community, and perhaps loss of employment. However, the advantage of a lead time to market and its concomitant pecuniary gains may

outweigh the disincentives.

Congress has also taken steps toward controlling fraud and abuse of government funds in response to alleged creation of faked results, and it might be possible to expand the definition of fraud to include abuse during peer review.[35] Legal recourse against a malfeasor after he or she has made a public disclosure of the invention, however, will not remedy the prospective patentee's position if an absolute bar under the patent act is triggered. As discussed below, the solution for institutions, corporations, and joint ventures that are patent "savvy" is to require a patentability analysis before extramural grants and editorial peer review are sought by the inventor.[36]

***55 C. Intramural Peer Review**

The final type of peer review panels are intramural peer review panels. Intramural peer review panels are used to make decisions involving the livelihood and continued employment of an individual scientist or scientific group within an academic or corporate institution. Although less stringent than editorial and extramural peer review, intramural peer review serves to evaluate the importance of the investigator to the institution, gauge the progress of his or her career, and determine tenure. Intramural peer review committees evaluate research with a lower level of scrutiny than editorial or intramural peer review for several reasons.[37] First, the evaluation is conducted in an atmosphere that is congenial to the researcher, usually his host institution. Second, the researcher is able to influence potential panelists, most of whom are departmental chairpersons through lobbying efforts within the host institution. Finally, it is the local scientific community that is making an assessment of the scientific value of an individual or research group, and it is this same local scientific community that was part of the efforts to spearhead the recruitment of each of the institution's faculty and staff.

Increasing the level of stringency of intramural peer review plays a major role in the reputation of the institution. In fact, intramural peer review, faculty retention, the number of publications per year, and the number of times publications are cited by other researchers are the key factors in assessing the reputation of the institution in the entire scientific community.[38] The harder it is to reach or earn tenure at an institution, the more likely it is that the investigator's effort has been a significant contribution to the field. Yet it is a result of the pressure to publish and to be at the forefront of scientific exploration that often leads scientists to cross the gentlemen's agreement of peer review.[39] The ability to secure funding for his or her laboratory, to secure jobs for graduating students, to attract top-notch students and post-doctoral fellows, should, in theory, be a reflection of each investigator's grasp of, and experience with, the peer review system.

Competing in all three types of peer review generally requires an inventor to divulge confidential information to a panel of scientists directly involved in her specific field of study. Fellow scientists must review the work because they are in the best position to understand the putative contribution to the field of the study and the technology used to obtain the information. Given the increasing sophistication and level of preparation required to understand cutting-edge scientific information, it is almost always the case that direct competitors review the information.[40] It is also the case that interested competitors determine which peers will review a manuscript ***56** submitted for peer review, because these competitors will be on the editorial board, or be a member of the editorial pool, for the journal that the author thinks will be most interested in his or her contribution to the field of research.[41] During extramural peer review, it is common for the information to reach those most able to act upon the work disclosed because the prospective grantee will direct his or her grant proposal to the funding agency and peer review panel that is most likely to understand and fund the work, namely, those in the same field of research.[42]

Formal and informal evaluations of a peer's work will often include the presentation and evaluation of novel, confidential information, often the same information that the inventor will use to meet the statutory enablement requirements of a patent.[43] It is these disclosures that encompass the investigator's new contribution to the pool of scientific knowledge. The peer review process, however, is also an opportunity for a malfeasing scientists to review the work of a competitor in order to acquire information that can advance her own personal research or the research of those within her research group. As a consequence of their unscrupulous use of the data evaluated, malfeasors may use or may make public the information months before the same information is actually published. More importantly, the malfeasor may reach the patent office before the true inventor. The malfeasor's actions would cause, at a minimum, an interference; intermediately, a loss of patent rights to both parties; and at worst, a patent issuing to the malfeasor.

III. Case Law Applicable to Peer Review Misconduct

A. Introduction

There are no reported cases in which patents were challenged or held invalid due to the disclosure by somebody, other than the inventor, who did not independently develop the subject matter of the invention. A recent report in the journal *Science*, however, reports a case filed against investigators who allegedly took advantage of information they were exposed to during peer review by using it to further their research and seek patent rights.[44]

***57 B. *"Cistron Biotechnology, Inc. v. Immunex, Corp."*[45]**

The issue of misconduct during peer review might have been adjudicated in a case filed in December of 1993 and set for trial November 5th in Seattle. The complaint alleged that researchers at Immunex Corp. used confidential information obtained from a manuscript that they evaluated during the editorial peer review process. The Immunex scientists were asked by the editorial staff of the premier British scientific magazine *Nature* to review a manuscript presented by the plaintiffs disclosing the cloning of an Interleukin-1 (IL-1) molecule. The defendants rejected the manuscript for publication citing a lack of sufficient information to merit publication.[46]

Under a seal of confidentiality,[47] this unprecedented lawsuit was filed by Cistron Biotechnology, Inc. against one of the leading biotechnology companies in the field of immunology research, Immunex.[48] Citing federal anti-racketeering laws, Cistron plead that Immunex "knowingly and fraudulently convinced Cistron, Cistron's partners and funding sources, potential investors ... and the public that Immunex had ownership and inventorship rights in "IL-1Beta", thereby fraudulently bringing about increased investment in Immunex."[49] Cistron's suit named scientists Steven Gillis and Christopher Henney as being responsible for taking information from a confidential manuscript under review for *Nature*.[50] Cistron's manuscript disclosed the nucleic acid sequence for human Interleukin-1Beta.[51] Surprisingly, the editorial staff of *Nature* permitted the manuscript to be reviewed by Gillis even though, in a telephone conversation with the editor, Gillis stated that "we recently purified IL-1 to homogeneity," and indicated that they were attempting to sequence the protein, a prelude to cloning the same, or a closely related DNA sequence.[52] In essence, *Nature*'s editorial board knowingly allowed a direct competitor that was at ***58** least six to twelve months behind in research to review their competitor's work.[53] Ironically, Immunex was issued a patent in 1992 for Interleukin-1Beta.[54]

The consequences of this lawsuit were recently determined, when Immunex agreed to pay Cistron twenty one million dollars and agreed to assign "'certain IL-1 beta patents' to Cistron," four days before trial was to commence.[55] Fearing that the trial would "become a trial of the peer review system itself," the settlement leaves open the "question of whether the peer review process binds participants to confidentiality."[56] The settlement of the suit may have revolved around the apparent copying of errors in Cistron's Interleukin-1Beta sequence in Immunex's patent application. The evidence of copying was likely to have been a centerpiece of Cistron's case against Immunex.[57]

As reported in the journal *Science*, Immunex's case was to be built on two defenses, first it was to deny any misappropriation of information gathered during peer review stating that "it had made its discoveries independently and that the sequence errors had been copied into its patent through a clerical error."[58] Immunex the report finds "appeared to be developing a second line of defense: that the law does not prevent the use of information gleaned from reviewing unpublished works."[59] Apparently, Immunex lawyers had developed an impressive list of statements from prominent experts to build a case that "there are no hard and fast rules of confidentiality in peer review, and that reviewers have no legal obligation to keep data secret, since they do not sign a contract with journals to do so."[60]

Still pending, however, is the determination of the real market value of IL-1?Beta derived products. Cistron, who had filed for Chapter 11 bankruptcy as recently as 1989, is ranked 98th in the biotechnology market, posting a $273,000 loss in 1995.[61] Immunex, an industry giant at number six, posted a $33 million loss in the same period.[62] A spokesman for Cistron indicated that IL-1Beta may be potentially used to ***59** treat cancer, certain types of wounds and as a vaccine adjuvant.[63] A spokesman for Immunex, however, stated that "IL-1 beta is not a commercially successful product."[64] The settlement gives Cistron a large infusion of cash, which may pull Cistron "out of a financial hole."[65]

The scientific consequences are also uncertain. An important personal issue that was a consequence of the alleged breach of the peer review process was a change in the nomenclature of the Interleukins.[66] From a scientist's perspective, the prestige associated with the naming of the gene cloned or the molecule created can not be underestimated. The molecule cloned by the Cistron scientists, and whose publication appeared after that of Gillis and Henning, was later renamed human

Interleukin-1Beta.[67] Gillis and Henning, on the other hand, named the molecule they cloned Interleukin-1Alpha, thereby relegating the status of the first Interleukin cloned to a secondary status.[68] Adding insult to injury, it is now clear the expression of Interleukin-1Beta is more widespread. Within the scientific community Gillis and Henning can claim first rights to the identification and nomenclature of Interleukin-1 molecules.

IV. Rules that Regulate the Peer Review System

It is not surprising that professions that are less formal than the legal profession[69] have just begun to develop express codes of ethics to regulate their actions.[70] In fact, the codification and enforcement of the Model Rules of Professional Conduct for lawyers are a rather recent development.[71] Historically, the need to regulate scientific misconduct was perhaps less necessary because science was more concerned with scientific knowledge than with prestige, money and tenure.[72] One commentator has noted that after World War II, most research was conducted by individuals who were solely responsible for their work and prestige, ***60** while today success is often measured by the number of junior scientists under their supervision.[73] The increase in pressure brought about by increasing costs (due primarily to increases in the cost of technology) and the concomitant increase in individuals seeking funding, have had the expected economic result that occurs when demand increases at a faster rate than supply--scarcity of resources.[74] Certainly, other factors that have always existed, such as public recognition, scientific recognition and the need to carve out a livelihood, have led to an increase in alleged scientific impropriety.[75] The response from the scientific community has included the development of an awareness among scientists of potential conflicts of interest and ethics violations.[76] The response to potential improprieties, however, has been primarily in the form of ad hoc review panels.[77] The ad hoc review panels that inquire into the potential improprieties, however, are composed of the same types of individuals that sit on intramural peer review panels, namely, the investigator's local peers.[78]

Recently, research misconduct of a kind very different from peer review misconduct, namely fraud and the fabrication of data, was brought into focus by cases against a number of scientists, including Nobel Prize winner David Baltimore[79] and the co-purifier of the HIV virus, Robert Gallo.[80] In the wake of these investigations[81] the Department of Health and Human Services issued a report regarding research integrity that defined different types of professional misconduct, such as fraud.[82] The report addressed misappropriation specifically:

Misappropriation:
An investigator or reviewer shall not intentionally or recklessly
a) plagiarize, which shall be understood to mean the presentation of the documented words or ideas of another as his or her own, without attribution appropriate for the medium of presentations, or

***61** b) make use of any information in breach of any duty of confidentiality *associated with the review of any manuscript or grant application*.[83]

Interestingly, an earlier version of the report did not contain the language italicized above, which was contained in the final version.[84] The earlier report also indicated that " t hese behaviors are a subset of the professional misconduct that is the responsibility of institutions where research is conducted."[85] Practically speaking, however, the institutions that have the most to lose from the discovery and reporting of research misconduct are the entities responsible for the enforcement of the rules.[86] Furthermore, it is these same institutions that write and interpret the procedural and enforcement rules that they themselves created to police their scientific colleagues.[87] It became clear, however, that the sanctions against institutions that were reprimanded by the Department of Health and Human Services (DHHS) were "non-existent or ineffective."[88]

Not surprisingly, the combined report of the National Academy of Sciences, the National Academy of Engineering and the Institute of Medicine notes that "misconduct in science is unlikely to remain internal to the scientific community,"[89] and warns of the "extreme" consequences because of the increased involvement of the public, Congress,[90] the media,[91] and the courts[92] in the affairs of science. It is scientists themselves, however, that oppose the establishment of a professional code of conduct. Arguing in a recent workshop of professional ethics hosted by the American Association for the Advancement of Science, one influential commentator noted that "the whole notion of an organized professional ethics is an absurdity," both intellectually and morally.[93]

***62** Nevertheless, the present peer review system places the primary burden for investigating "research misconduct"--a term

that encompasses a broad range of behavior including intentional misrepresentations, fraud, and plagiarism--on the "awardee institution."[94] The fact that funding is awarded to the institution and not to the investigator directly, is the reason for placing the burden to investigate on the awardee institution[95] Federal granting institutions, however, do retain the right to conduct their own investigations if they perceive that the awardee institution is unable to properly pursue an investigation.[96] How or why one of these investigations would ever be joined is not clear.

As a last instance, federal or state law enforcement may be called upon to pursue the investigation if serious criminal misconduct has occurred.[97] The types of crimes contemplated under federal law are those included in the False Claims Act discussed below. Under state law, actions for fraud may also be contemplated. The circumstances that would trigger such an investigation, however, are rather limited and would require: 1) evidence that administrators at the awardee institution are involved in or covering-up research misconduct; 2) evidence that the institution's reporting requirements appear deficient; 3) evidence that the information known to the granting institution contradicts the awardee's report; or 4) evidence that the awardee institution appears to be delaying the investigation unnecessarily.[98]

The reasons that support allowing awardee institutions to carry the responsibility for investigating misconduct are primarily practical: they are the closest to the evidence, they have a wider range of remedies and sanctions that may be imposed for the misconduct, and they have the most to lose in terms of pecuniary interests and reputation.[99] Another rationale for a local investigation is that it will reduce the cost of investigation and will limit the extent of damage to the reputation of the accused wrongdoer if the allegations are unfounded.[100]

While these reasons may be valid for most allegations of fraud or misconduct during research, they are not applicable to situations involving peer review misconduct during editorial review, career advancement, intramural peer review, or extramural peer review. In order to preserve anonymity and objectivity, it is standard practice to choose peer reviewers outside the author's own institution. ***63** Furthermore, the journal has no legal jurisdiction over the malfeasing peer reviewer, meaning that they have no way of imposing legally binding sanctions of any kind. Finally, as the peer reviewers may not even be in the country, the cost of investigating peer review misconduct, and the effect that such an intrusive undertaking entails, would be very great.

V. The Incompatibility of the Peer Review and Patent Systems

The discussion and implementation of rules of ethics in the scientific arena is largely an unwritten skill that is taught by investigators to their graduate students or post-doctoral fellows via word of mouth, as scientific socialization involves conversations "in laboratories, in hallways, and over the telephone."[101] Likewise, the etiquette of all forms of peer review is a skill that has been passed on from principal investigator to his or her students.[102] In theory, at least, peer review is supposed to occur within the confines of the reviewer's office, where the peer examines the results and writes a confidential review to the editorial board of the journal. Ideally, the identity of the reviewer is known only by the editor or panel administrator that selects the reviewers, and not to the person who submitted the manuscript.

For example, in the case of referees for *Nature* magazine, prospective reviewers receive a form letter indicating that "[c]olleagues may be consulted (and should be identified for us), but please bear in mind that this is a confidential matter."[103] *Nature*'s editors, however, do not require reviewers to "identify conflicts of interest" or even to sign confidentiality agreements, although it appears that changes to this policy are underway.[104] *Nature* is not alone in its concern over peer review misconduct. The premier scientific journal in the United States, *Science*, "explicitly forbids dissemination and exploitation of information contained in the paper" in the warning that it sends potential reviewers.[105] The *New England Journal of Medicine* clearly states in its warning that "the manuscript should be considered a privileged communication. You should not show it to another person without calling us, and you should not photocopy it."[106] It has been this author's experience with at least one of these journals, however, that such warnings are not heeded or even acknowledged by peer reviewers. It appears that a major motivation for being asked to peer review manuscripts for a journal is to have access to such confidential ***64** information before it is published, often 3-12 months in advance. The line between reviewing manuscripts and research grants as part of a desire for knowledge, and the use of that acquired knowledge to advance a reviewer's career may be impossible to draw, let alone litigate.

The attitude of a former editor-in-chief for *Nature*, John Maddox, is particularly troubling. In an interview with *Science* concerning his deposition in the *Cistron* case, he stated that in 15 years at the helm of *Nature*, he had observed just a few cases of "hanky panky" regarding the misuse of papers.[107] In his deposition, Mr. Maddox discussed one instance of peer

review misconduct where "an author discovered, when he went to visit a friend's lab in New York, that not merely did the friend have a copy of his paper, but so did the postdocs in the lab as well, and he was offended."[108] Mr. Maddox went on to state that he perceived peer review misconduct as an iceberg, but that "the iceberg must be very small," and that peers can be relied upon to "sniff out" alleged wrongdoing.[109] In this author's experience, Mr. Maddox is absolutely wrong on both accounts. What Mr. Maddox's friend observed is, in fact, the *modus operandi* of many investigators. It is well known that colleagues openly discuss the information, and do not turn their peers in for admonishment by their host institutions, the journal, or the scientific community. In fact, a recent cross-disciplinary survey indicates that "significant numbers of scientists have encountered misconduct and a variety of dubious research practices."[110]

As apparent from the tenor of the confidentiality form and letters that peer reviewers are asked to sign, it should be clear that during the peer evaluation process it is expected that the confidential information being reviewed should neither leave the reviewer's office, nor enter or leave the reviewer's laboratory. Upon reading the information, however, it is unlikely that the reviewer will sit idly and wait for the publication of the manuscript before mentally digesting and applying the information. To forget the information or to wait for the publication to reach the shelves of the library before using the information, runs contrary to the pursuit of science and to human nature. It is also impossible to regulate the use of the information pending publication since the information has been evaluated and entered the pool of knowledge retained by a highly motivated and inquisitive researcher. Clearly, if the information is known, useful, and even remotely related to the reviewer's work, it will easily enter the stream of knowledge.

*65 VI. Effect of a Breach of Confidentiality on Patentability

A. Statutory Aspects

There are several ways that the malfeasance of a peer can result in loss of patentability. One effect of a breach of confidentiality is the creation of a potential bar under 35 U.S.C. § 102(a).[111] The Section 102(a) bar would be a knowledge, use or publication bar, which would theoretically be found during a prior art search for the determination of patentability.[112] Generally, Section 102(a) bars can be overcome if the inventor is able to swear that she conceived and reduced to practice her invention in the United States prior to the public knowledge, use, or publication of the malfeasor.[113]

Perhaps, the most pernicious bar in a breach of confidentiality scenario is the "on-sale" bar under Section 102(b),[114] because most patentability searches do not include proposed sales of technology or information. If acquired during peer review, information and the products derived from the information could be placed on the market in advance of product completion, thereby initiating the one year time period under Section 102(b).[115] The danger of an on-sale bar, loss of foreign rights by a prior publication or public disclosure by a competitor is very real in areas where the time from invention to market is short, such as for electrical and mechanical inventions because the products reach the market without having to overcome regulatory hurdles.[116]

The potential for danger of a statutory bar resulting from extramural peer review and editorial peer review is different, due to the nature of the information that is disclosed in a grant (extramural peer review) versus a manuscript (editorial peer review). Extramural peer review causes greater difficulties in terms of competitors taking advantage of information under peer review because of the highly confidential and somewhat speculative nature of the proposed research. Since the ***66** investigators most likely to review grants are senior and mid-level faculty, the danger of revealing proposed research to a direct competitor is less likely. In my experience, it is not uncommon, however, for the members of extramural peer review panels to return to their host institutions and discuss proposed techniques and preliminary results. Since the research proposed in grants is generally directed at projects with a one to five year timeline,[117] the danger of an on-sale or a publication bar being caused by a malfeasing peer reviewer is directly proportional to the level of competitiveness in the field and the amount of resources each party is willing to expend toward completing the research.

For example, suppose a researcher in a small mid-western medical school submits a grant for review. The researcher's grant proposes to use a graduate student and perhaps a research technician for the proposed work. Under these conditions it is likely to take the entire time period proposed in the grant to complete the work (generally 1-5 years). The malfeasor, on the other hand, may have at his or her disposal an entire research group, institute, or company. The malfeasor can dedicate an entire team to rapidly complete the work. By dividing the different aspects of the work among highly skilled or specifically dedicated divisions, the work can be completed in a fraction of the time it would take a graduate student and a technician.

Adding to the problem is the likelihood that the malfeasor may be aware of, interested in, and have the resources to seek patent protection (as is the case in *Cistron v. Immunex* discussed above). This example is not extreme in today's research climate, but rather, may become a common occurrence from the perspective of academic researchers.

The danger caused by editorial peer review is just as real, but the original researcher has the advantage that some work has been completed. This advantage, however, may be vitiated by the simple reason that a direct competitor is very likely to be reviewing the completed work, meaning that the competitor may already have completed similar or complementary work. Alternatively, the editorial peer reviewer has the advantage of being able to reject the manuscript. Rejecting the manuscript would not be a problem if the review and rejection process were rapid.[118] The malfeasor during editorial peer review has the advantage of being able to hold on to the manuscript for as long as possible before finally rejecting the manuscript. As discussed before, this delay time can range from three to six months. For the malfeasors that are willing to submit patent applications based on their own work or a combination of their work and the insight of others, as is alleged in the *Cistron* case, the peer review system is ripe for abuse.

***67 B. Section 102(b) Prior Art of the Inventor**

Under the language of 35 U.S.C. § 102(b) and relevant case law,[119] it is clear that anyone, not necessarily the inventor, will trigger a statutory bar by placing the invention "on-sale".[120] Also troublesome is the fact that inventions made in foreign countries receive a "constructive" invention date in the United States as of their filing date with the Patent and Trademark Office.[121] Although changes in the patent laws following enactment of the North American Free Trade Agreement (NAFTA) and the General Agreement on Tariffs and Trade (GATT) have moved the United States into greater harmony with the patent laws of other countries, invention in the United States has retained special protections.[122] The protection granted to inventors in the United States under 35 U.S.C. § 102 accentuates the peer review misconduct problem because the patent statutes favor those who make or use the patented invention in the United States.[123] Inventors in the United States are favored because the United States follows a first-to-invent system, rather that a first-to-file system. The Patent Act has been amended to provide that inventions made in NAFTA and WTO member nations are treated as if invented in the United States.[124] The real effect of these changes to the Patent Act remain to be seen, as foreign inventors would have to comply with United States legal discovery requirements because they would be filing suit in the United States. Lacking compliance or knowledge of United States discovery rules creates a *de facto* first-to-file system in the United States for true inventors overseas. Although life may not always be fair to foreign inventors in any country, creating a race to the United States patent office circumvents the legislative intent behind the latest version of the patent laws. It also places the burden on inventors outside the United States to prove, at a level or standard satisfactory under United States evidentiary requirements, that the overseas inventor was the first to invent. Lacking such proof, the constructive invention date of the foreign invention is the inventor's filing date in the United States, thereby judging the foreign inventor a different standard.

If the malfeasor attempted to file a patent application for the invention, the easiest response by the true inventor would be to show that the malfeasor did not ***68** invent the matter for which a patent is sought.[125] Preventing patentability by a competitor based on an allegation of peer review misconduct is not only likely to be difficult, it would hardly be an adequate remedy for the loss of patentability by the true inventor. Furthermore, because the malfeasor may have already used the information to expand upon and create derivatives of the work taken during peer review, patentability may have been lost completely for future studies. In fact, the malfeasor might simply be seeking to prevent any patent from being issued. Why would a malfeasor want to prevent a patent from being issued? By preventing the true inventor from obtaining a patent, the malfeasor can take advantage of his or her capital and financial resources, marketing capabilities, and lead-time to market for sales of any product based on the work. In conclusion, the true inventor who thought that he or she was submitting a manuscript for confidential review, may have lost the most valuable right: the right to exclude others from making, using, selling or importing his or her invention.[126]

The problem of a malfeasing peer placing the true inventor's product "on sale" or submitting a competing or blocking patent at about the same time as the true inventor is particularly acute for inventors at universities and small research companies or centers. The problem is further accentuated in the case of inventors who are not patent savvy, because they generally lack the resources to compete with large corporations or focused venture capital enterprises. In fact, it is large corporations and focused venture capital enterprises that have the most to gain from the public nature of the information. They gain the advantage of obtaining the technology free of encumbrances, such as licensing fees, and can take advantage of their business know-how, marketing expertise, distribution systems, and established client bases to take advantage of technology that the companies have succeeded in placing in the public domain.[127] These organizations can then expand on the original work by

taking it to the next level of technological development, and then seek a patent for the improvement.

Furthermore, the above discussion assumes that it is easy to show that the malfeasor did not invent the matter sought to be patented or that the true inventor conceived and reduced to practice the invention before the malfeasor began using the information. Proving that a competitor did not arrive at a similar conclusion or make a similar discovery contemporaneously is not only difficult, but may be impossible. The impossibility is created because an investigator that reviewed ten or twenty grant applications and a few papers during one week several years past, can easily believe that the idea was his or her own. Furthermore, they may truly believe that they developed a more complete idea based on a combination of information and ***69** their own research. Lacking hard evidence from lab notebooks or experimental notations, it would be difficult to demonstrate that malfeasance occurred during peer review. In fact, if a malfeasor has demonstrated his or her willingness to break the rules of peer review, what is to prevent him or her from back-dating notebooks and the like?

C. Remedies Beyond the Patent Laws

The problem of discovering a breach of confidentiality clearly favors the malfeasor. Discovering the breach is particularly difficult in the case of editorial peer review because of the very limited number of people who know the identity of the reviewer of the manuscript. The problem is highlighted by a recent decision holding that the identity of a referee for a scholarly journal is confidential information and is not discoverable for allegations of inequitable conduct.[128] In response to a suit for patent infringement the defendant attempted to prove invalidity of the patent and inequitable conduct by the inventor.[129] To prove the inequitable conduct of the inventor, the defendant sought the identity of a referee from the journal *Physical Review Letters*, which was not a party to the suit. The journal refused to turn over the information, citing a need to "maintain confidentiality in order to receive candid, meaningful critiques by referees."[130] The reason that the defendant's counsel sought the identity of the reviewer was because the reviewer had indicated, in an anonymous review obtained by the defense counsel, that he or she was rejecting the manuscript because "the subject matter of the manuscript was already reported in extant literature."[131] The defendant wanted to depose the reviewer regarding dissemination of confidential information to the inventor, in order to prove access and inequitable conduct.[132] The Court of Appeals, however, upheld the Magistrate's decision to maintain the confidentiality of the reviewer, finding that based on the competing interests of the parties and the "speculative" nature of the defendant's claims "APS's need for confidentiality was persuasively established."[133] This decision shows that a third party scholarly journal does not have to reveal the identity of the referees that reviewed the true inventor's publication.

Although the particulars of the case are not directly on point, it serves to point out two propositions that relate to peer review misconduct. First, courts seem to ***70** give great deference to a journal's need to maintain confidentiality. Second, it is unlikely that the journal or the malfeasors will willingly reveal that they were a referee or that the information was not their idea.

If an irregularity during editorial peer review is discovered by peers and the journal is confronted, or if the journal discovers the impropriety, it has limited recourses against the malfeasor. If the journal publishes a retraction or chastises the malfeasor publicly, it exposes itself to charges of libel and slander.[134] From an economic point of view the analysis is as follows. The malfeasor is willing to expend large amounts to protect his or her reputation (or that of their company or host institution), regardless of the merits of the case. More importantly, the malfeasor can easily place a heavy financial burden on the journal to defend itself against the charges, especially since a scholarly journal is rarely a for-profit organization. Furthermore, if the malfeasor has made an economic gain from the use of the information that far outweighs the scientific scorn or the embarrassment of the withdrawal, the public reprimand may cause the malfeasor to either leave the field or to never seek to publish in that particular journal again. Alternatively, the malfeasor may choose to send his or her contribution to other journals, assuming his malfeasance is not generally known. Therefore, the malfeasor has the economic as well as the legal upper-hand when it comes to taking advantage of valuable confidential information. The malfeasor can take advantage of the improperly obtained information because he or she knows that it is not in the economic best interest of a journal to expose the malfeasance. The journal also knows that it not in its best interest to bring legal action for the breach of a confidentiality agreement because the journal was not directly affected, and the legal costs of defending against a suit for libel or slander are far greater than any damage caused to the journal by the breach.

To address the concerns of journals when they publish a withdrawal, retraction, or reprimand, it has been proposed that federal law be changed to protect journal publication, or else "scientific journals will shoulder an unjustifiable risk in some states when they publish retractions and explanations regarding questionable scientific papers."[135] A major shift in the law of

libel and slander, however, would require action at both the federal and the state levels, since these types of actions are generally within the jurisdiction of the states.[136] Furthermore, journals are not likely to expose themselves to the possibility of a suit, given the lower standard of proving damages for individuals who are not public figures.[137]

***71** In addition to the financial risks scientific journals encounter when they publish a reprimand against an alleged peer review malfeasor, they also take on risks within the scientific community. For example, it is likely that the journal will face the potential of losing present and future peer reviewers (who volunteer their time to review manuscripts), and a decrease in the number of submitted manuscripts. Furthermore, it is inevitable that the journal will be the subject of scorn from the scientific community because it not only allowed the breach to occur, but because it also reported the identity of the miscreant. Therefore, it is unlikely that a journal's editorial board would seek to expose the malfeasance of a peer they trusted with the confidential information of others. Even if a journal did expose the malcreant, this would not save the patentability of an invention or prevent economic exploitation by others.

Intramural and extramural peer review suffers from additional problems due to the effects of conflicting duties and incentives placed on the awardee institution receiving public or private funds.[138] Besides the disincentives to exposing an editorial peer review malfeasor described above, there are additional internal conflicts that exist in institutions. For example, as the awardee entity for federal funding, the institution must gather a panel of the malfeasor's peers to investigate the wrongdoing.[139] Unless the institution is large or compartmentalized, it would be difficult to imagine a scenario where an impartial panel could be joined.[140] Colleagues will either seek to protect a valued peer or carry out a long standing vendetta.

The internal institutional pressures are irreconcilable and without remedy. On the one hand, it is in the best interest of the institution to eliminate individuals that are not following the proverbial "gentlemen's agreement" of science. It is also in the host institution's best interest to remove that individual from the faculty as a breach of the "gentlemen's agreement" reflects poorly on the institution, which the scientific community would identify as a faculty that harbors alleged malcreants. Furthermore, the institution should discipline the individual, to show that breaches of confidentiality will not be tolerated. Unfortunately, the institution also wants to attract and retain highly motivated and successful researchers, some of whom may be willing to walk in the gray area of propriety. Because of the nature of the scientific inquiry, the concept of the confidentiality of information is less developed among scientists than among lawyers and bureaucrats. Some scientists even view maintaining information confidential as inconsequential in comparison to the pursuit of scientific information. Hence, scientists are less attuned to the potential legal repercussions of breaching confidentiality, civil and criminal.

***72** What will an awardee institution do if one of the researchers under investigation attracts a lion's share of federal funding and the best and brightest students and post-doctoral fellows? Under these circumstances, it is easy to see how the imposition of even minor sanctions may be almost impossible. It is also in the best interest of the institution to keep the investigation as quiet as possible to avoid the media circus that follows both the allegation and the discovery of wrongdoing.[141] Other strong disincentives for initiating a very public disciplinary action against a malfeasor from the perspective of the awardee institution may be the potential loss of outside private funding from corporations, charitable organizations, and the very important alumni contributions.

Institutional peer review must also confront the problem of the whistleblower.[142] As can be expected, the whistleblower, whether extra or intramural, will be placed under considerable pressure by fellow employees, graduate students, administrators, supervisors, department heads, and the like, to drop the charge.[143] The pressure can only be increased by the malfeasor's reputation and popularity among his or her immediate colleagues. From the perspective of a whistleblowing student, such an allegation can easily become scientific suicide. Although much legislative progress has been made toward protecting whistleblowers,[144] the personal toll caused by conflicts between highly trained professionals who will continue to work in the same field are never extinguished by a legal action or a final judicial determination.

VII. Options Available to Patent Counsel

The remedies available to a scientist using the peer review system can basically be divided into four categories: (1) none; (2) sanctions internal to the institution, corporation or journal[145]; (3) civil remedies[146]; and (4) federal criminal indictments.[147] Tort remedies of breach of confidentiality and anti-trust violations may be invoked. As discussed above, the barriers to bringing and maintaining these suits are many. Legal remedies are greatly complicated by the need to obtain evidence of the malfeasance, evidence that is likely to involve complicated issues of scientific fact and law.

***73** As mentioned earlier, sanctions internal to the institution are available for peer review misconduct, and can range from admonition to termination. If the researcher has received grants from federal funding institutions, the miscreant can be sanctioned with disbarment, meaning that the individual "is excluded from financial and nonfinancial assistance under federal programs, including research grants."[148] The effect of disbarment of funding from one federal agency is extended to all federal granting agencies.[149] The entire process, however, is designed to protect the alleged miscreant from false accusations and the effect that a breach of confidentiality would have on the alleged miscreant's reputation.[150] Thus, the legal system places high barriers to investigating alleged malfeasance by scientists. Given the potential prejudice such an investigation would cause, and the adverse effect on the reputation of the alleged miscreant that may result, it does not seem unreasonable to have a high barrier initially for bringing allegations against an investigator.

A. Civil Remedies

Civil remedies may be brought, for example, through an action under the Federal False Claims Act (FCA), which allows a private plaintiff to bring a *qui tam* action to recover for making a false claim to the United States government.[151] However, even if all the elements of a FCA are satisfied,[152] and damages are recovered, they are limited to a penalty of "not less than $5,000 and not more than $10,000, plus three times the amount of damages which the government sustains because of the act of the person."[153] For a *qui tam* plaintiff, who has lost his or her patentability rights, this level of damages is hardly an adequate remedy.

B. Federal Criminal Remedies

Also inadequate as a remedy for loss of patentability are federal criminal claims. Although it appears that the suit filed in Seattle against Immunex[154] is based on a cause of action for conspiracy under the Racketeer Influenced and Corrupt ***74** Organizations (R.I.C.O.),[155] these provisions don't save the patentability of an invention. Furthermore, it will be difficult to apply the provisions of R.I.C.O. to an area that is highly technical and where the stream of information can be very amorphous. Other federal charges that may be brought are, for example, those pleaded by Cistron against Immunex for wire and mail fraud,[156] permitting Cistron to recover damages of over $100 million if treble damages are awarded.[157] Even if successfully litigated or settled, the patentability of the true inventor's discoveries will still be lost, and the information now in the public domain can become prior art against the true inventor's future discoveries. In the case of Immunex, which has invested large amounts of money in the development and testing of Interleukin-1Alpha,[158] its right to exclude others will be completely lost.

VIII. Suggestions to the Technology Transfer Specialist and the Patent Prosecutor

Since it is unlikely that the damage to an inventor's position can be remedied, the solution to the problem of peer review misconduct from a patentability viewpoint is education and prevention. In this regard, the best defense is a good offense. Instead of passively trusting the peer review system to right itself, institutions must actively engage technology transfer specialists and patent prosecution counsel to educate their potential inventors in the pitfalls caused by the nature of the peer review system. The peer review system will never go away, nor will it change very much from its present state because it remains the only efficient means of ensuring, as much as possible, the quality and veracity of human knowledge.[159] Given the increasingly technical nature of confidential information, manuscripts and grants will always have to be reviewed and evaluated by competing peers that can determine the scientific strength of the data.

To resolve the problems confronting faculty members ranging from non-tenure track investigators to department heads, institutions must implement procedures and policies that help them evaluate the potential patentability of a discovery or line of work before the manuscript or grant is sent. These procedures and policies, however, must be drawn with the greatest convenience to the scientist in mind. For example, an institution can create a review board that meets as often as is necessary, depending on the specific size and needs of the institution, to review manuscripts for ***75** patentability. A patentability review board will allow institutions to improve their patent portfolios and to meet their statutory oversight duties for receiving federal grants.

Another solution to this problem may have been addressed inadvertently by Congress in recent changes to the Patent Act.[160] Provisional patent applications can now be filed under 35 U.S.C. § 111(b), which permit the applicant to obtain a constructive filing date at a greatly reduced fee.[161] Also, provisional patent applications are simple, requiring only a cover

sheet and a specification.[162] In addition to the advantages of lower cost and greater simplicity, the filing of provisional patents is encouraged by an "extension" of the statutory patent term by one year. In practice, the patent term is "extended" because the filing of a provisional patent application does not start the 20 year patent term, but does give the applicant a constructive filing date for inventions that are sufficiently enabled.[163] Within a year, the applicant must decide whether to mature the provisional patent application into a regular patent application at full cost, and must also comply with all the formalities of patent applications, including claims and the names of all the inventors.[164] Importantly, the filing of a provisional application does start the clock running for foreign filing.[165]

The greatest advantage of provisional applications, from the viewpoint of the technology transfer specialist, is the ability to approach potential licensees with the filing date and constructive reduction to practice that attaches to provisional patent applications. From the point of view of the prospective licensee, the provisional application secures a filing date, provides documentation of the level of development of the invention, and affords a prospective insight into the potential patent rights that might arise out of the technology he is looking to license. In the case of inventors at institutions of higher learning and small companies that are developing patent portfolios, provisional applications provide a means of pre-empting potential peer review misconduct. A provisional application can be filed on the disclosed technology prior to or during peer review, securing a filing date for prospective patent rights.

Most importantly, these rapid review procedures and policies should only serve to review technology for patentability and not to evaluate the merits of the research. The sole purpose of the technology review committees should be to review ***76** technology. In fact, it would not only be impossible, but unnecessary, for any institution to maintain a standing committee to concomitantly review both patentability and scientific merit.

Also, the procedure should only delay submitting a manuscript by a few days at most. The fear of being "scooped" in highly competitive areas is very real, and investigators should be given incentives to patent, not disincentives. The more standardized and streamlined the procedure, the easier these procedures can be implemented. The implementation of the procedures will be possible since researchers will not perceive the technology review as burdensome or mettlesome. If all fellow peers must submit grants and manuscripts for patentability, and that is the policy of the institution upon arrival (for young or transferring faculty), friction will be minimized and efficiency maximized.

A more expedited procedure may be necessary for some cases; however, it is rare for manuscripts to be investigated or written overnight. Again, a well developed and presented policy will prevent most review emergencies. Institutions can also reduce their legal fees as fewer expedited applications will be filed, and patent counsel will have the ability to do what they do best, write and prosecute quality patent applications. Finally, the potential inventor should be allowed to reap some of the benefit of licensing the technology via institutional incentives such as money, laboratory space, staff and the like.

A. The Patentability-Publishability Dichotomy

An abridged review is possible, as a result of the difference between the statutory requirements of enablement and the level of stringency associated with scientific peer review of grants and manuscripts. The level of scientific completeness necessary to meet the "best mode" requirement of the first paragraph of 35 U.S.C. § 112 pales in comparison to the level of scientific thoroughness necessary to convince peers that a real contribution is being made toward the advancement of scientific knowledge; a mathematical formula may well be publishable provided it is new knowledge, but it is not patentable subject matter.[166] The difference in the level of knowledge and understanding necessary to satisfy the requirements of patentability and the standard applied to a manuscript for publication in a peer-reviewed journal can be referred to as the patentability publishability dichotomy. For example, the "best mode" requirement does not call for data and experiments within the four corners of the document to make a significant contribution to scientific knowledge, only that they meet the requirements ***77** of patentability under the Patent Act. The utility of an invention under the Patent Act is not the same type of usefulness required to satisfy the scientific stringency of an extramural or intramural peer review panel. From a scientist's perspective, useful is defined as making a significant contribution toward advancing the scientific understanding of the natural world.[167] In other words, a manuscript is publishable if it helps to answer interesting scientific questions and creates new questions. For example, one may obtain a patent for the identification and partial purification of a novel human growth factor, given a sufficiently enabling disclosure. From a scientific perspective, however, these early steps toward purifying a novel growth factor are most likely to be found premature when it comes to publication in a scientific journal because the factor may not be cloned or sufficiently pure to satisfy a peer reviewer, as is often the case when a competitor is scrutinizing a manuscript.

But the patentability-publishability dichotomy may also cause the inverse problem. A recent example was the isolation of a large number of novel DNA sequences from the brain. While Dr. Craig Ventner's peers found his techniques and discoveries of great interest, the fact that he lacked some use for the DNA sequences beyond mere research interest made the newly discovered sequences unpatentable.[168] However, the same gene sequences may be patentable if a use is found, such as use as a diagnostic test for a particular disease. In the above described scenario, the publishability-patentability dichotomy led to the publication of sequences that are forever in the public domain.

Therefore, while a patent application must simply teach those of skill in the art how to make and use an invention and disclose the best mode of the invention, scientific publications require that a manuscript make a contribution to scientific knowledge, not just the public.[169] In other words, the scientific "best mode" threshold for patentability from a scientists perspective is lower than the burden of scientific value needed to succeed in peer review. Furthermore, if a patent examiner rejects an application for lacking one or two interesting controls,[170] confirmation can be presented in the form of a declaration,[171] thereby saving the original application date.

***78 IX. Conclusion**

Imagine a hypothetical situation: a scientific colleague enters your office with the copy of a manuscript that she has received for review from a research group in Canada (or anywhere outside the United States, except military installations).[172] Since you are an active member of that specific field of study, she has sought your advice on the review of the manuscript. It turns out the manuscript reveals that a heretofore unknown competitor has cloned the same molecule you recently cloned and has gone on to show that it is responsible for a severe genetic defect in a mouse model system. You rush over to the student in your laboratory that cloned the molecule, show him the manuscript, discuss it, find a superficial reason to reject the publication of the paper, and urge the colleague that brought the paper to recommend rejection. Based on the information obtained, you direct your student to contact a scientist that studies that particular mouse model system, propose a collaboration, quickly replicate the results, and rush a paper to publication or present the work at a symposium in a related field. The publication of the manuscript or the abstract book from the meeting appears before that of the competitor, and the competitor's patent application claiming the new gene is rejected based on 35 U.S.C. § 102(a). While the publication of the paper or abstract might not precede the true inventor's invention date in the United States, given due diligence, what the true inventor has brought upon him or herself for trusting the peer review system is, at least, a potential interference. But given the publication timeline described above, which in many cases can easily exceed one year from submission to publication, an absolute statutory bar under 35 U.S.C. § 102(b) may be triggered.

What are the remedies available to the group in Canada from within the scientific community? From the legal system? From a patentability perspective? As discussed in this Note the answer for each question is that the inventor has few to none. Patentability will be lost, and any action against the malfeasor will be purely administrative: from a slap on the hand to a loss of funding from government agencies. Those disincentives, however, are unlikely to deter a malfeasor that stands to gain greatly from the lead time to market or the public accessibility of the information. By preemptively analyzing the patentability of technology and initiating the patent process ahead of submittal to a journal peer review panel, the inventor and his or her assignee will maximize lead time and minimize accidental or willful disclosure of confidential information.

Even if criminal or civil sanctions are sought--as in the case of Cistron for violations of R.I.C.O.--in addition to mail and wire fraud, such a path should not be followed lightly. The true inventor must be prepared to engage in a very expensive and time consuming endeavor. Given the complexity of patent cases, the value of the loss of the patent and other damages must be significantly greater than the cost of ***79** litigation multiplied by the probability of winning to justify bringing suit. The cost of litigation also increases dramatically if the defendants have large financial resources, and are willing to engage in "scorched-earth" litigation. And even after all the fires are put out, and the claim is laid to rest, the inventor will still not be able to patent his or her invention.

As more scientists compete for slowly increasing funding, the cases of reported abuse are likely to increase. An honest discussion of the peer review system and the present rules that scientists follow will aid patent prosecution counsel and technology transfer specialists in discussing patentability issues with inventors. The discussion of these issues is particularly important to technology transfer specialists, because they are most often the primary access port for scientists to the legal system. This Note provides technology specialists and attorneys with a discussion of their client's position against a malfeasor and proposes solutions to the problem of peer review misconduct.

Footnotes

[a] Ph.D., Molecular Immunology, Washington University in St. Louis (1993); J.D. candidate, The University of Texas School of Law, Dec. 1996. This Note is dedicated to the memory of my father, Victor Flores Maldonado, Ph.D., in honor of his commitment to science in México.

[1] Often the actual client is not the inventor himself or herself, but rather, in-house counsel for academic research institutions or research foundations. Throughout this Note, the term "inventor" will be used generically to refer to the client.

[2] Edward L. MacCordy, *The Threat of Proposed Patent Law Changes to the Research University*, 20 J.C. & U.L. 295, Winter 1994.

[3] COMMITTEE ON SCIENCE, ENGINEERING, AND PUBLIC POLICY, NATIONAL ACADEMY OF SCIENCES, ON BEING A SCIENTIST: RESPONSIBLE CONDUCT IN RESEARCH 10 (2nd ed. 1995) [hereinafter, ON BEING A SCIENTIST].

[4] *Id.*

[5] Eliot Marshall, *Suit Alleges Misuse of Peer Review*, 270 SCIENCE 1912 (Dec. 22, 1995).

[6] Although plagiarism may not be illegal per se, it can have severe repercussions in the scientific arena, such as loss of grant funding and scorn from peers.

[7] Fiers v. Sugano, 984 F.2d 1164, 25 U.S.P.Q.2d (BNA) 1601 (Fed. Cir. 1993); Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376, 231 U.S.P.Q. (BNA) 81, 86 (Fed. Cir. 1986) (stating that reduction to practice is a question of law).

[8] Rosen v. N.A.S.A., 152 U.S.P.Q. (BNA) 757, 760 (B.P.A.I. 1966).

[9] Dan L. Burk, *Research Misconduct: Deviance, Due Process, and the Disestablishment of Science*, 3 GEO. MASON INDEP. L. REV. 305 (1995).

[10] FED. R. EVID. 803(18); *see generally*, Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 27 U.S.P.Q.2d (BNA) 1200 (1993).

[11] 35 U.S.C. §§ 101-112 (1994). For a general review of patentability requirements see Bill Schuurman and D.C. Toedt, III, *Analyzing the New Dangers of Potential Patent Controversies: A General Guide*, 41 BUS. LAW. 727 (1986).

[12] The author's observations of the scientific requirements and contribution of inventors are based on several years of being a practicing patent agent.

[13] Beth Sise, *Scientific Misconduct in Academia: A Survey and Analysis of Applicable Law*, 28 SAN DIEGO L. REV. 401 (April/May 1991); Howard P. Tuckman and Jack Leahy, *What is an Article Worth?*, 83 J.L. & POL. 951, 953 (1995).

[14] For example, this author has published five peer reviewed publication's during one five year granting period.

[15] Sise, *supra* note 13, at 409.

[16] This description of the peer review system is based on the author's experience during his scientific career in the field of molecular immunology. The systems used in other areas of science may differ in insignificant details, which do not alter the thesis of this Note. A list of the author's peer reviewed scientific publications is available upon request.

[17] Thomas O. McGarity, *Peer Review in Awarding Federal Grants in the Arts and Sciences*, 9 HIGH TECH. L.J. 1, 5 (1994).

[18] *Id.* at 2.

[19] *Id.*, and citations therein.

[20] *Id.* at 7.

[21] *Id.* at 9.

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.* at 10.

[27] *Id.* at 11.

[28] *Id.* at 8.

[29] *Id.*

[30] *See id.* (discussing how investigators are assigned and how the political and academic clout associated with being a study section member influences decisions).

[31] Interview with Dr. Casey Weaver, Professor of Pathology, The University of Alabama at Birmingham, in Taladega, Alabama, May 1994.

[32] NATIONAL INSTITUTES OF HEALTH MANUAL 4510: REFERRAL AND INITIAL REVIEW OF NIH GRANT AND COOPERATIVE AGREEMENT APPLICATIONS (1982), cited in McGarity, *supra* note 18, at 11.

[33] McGarity, *supra* note 17, at 8.

[34] Sise, *supra* note 13, at 417 ("The stiffest sanction either the NIH/DHS or NSF may impose for scientific misconduct is

debarment.").

[35] *See* Sise, *supra* note 13, at 407 (reviewing ways in which fraud may occur in scientific study).

[36] *See* Daniel F. Perez, *Exploitation and Enforcement of Intellectual Property Rights*, 10 THE COMPUTER LAWYER 10 (1993).

[37] The following reasons are derived from the author's personal observations.

[38] Burk, *supra* note 11, at 310-11.

[39] Sise, *supra* note 13, at 407-08.

[40] McGarity, *supra* note 21, at 4-7.

[41] See Marshall, *supra* note 5, 1912-13 for a description of the different peers that reviewed the submitted manuscript.

[42] Weaver, *supra* note 31.

[43] 35 U.S.C. § 112 (1994).

[44] Marshall, *supra* note 5, at 1912.

[45] *Id.* It is not clear who the named parties are in this suit because the district court judge has placed the case under seal and the interested parties are not talking about any particulars. *Id.*

[46] *Id.*

[47] *Id.* at 1914.

[48] *Id.* at 1912.

[49] *Id.* at 1914.

[50] *Id.* at 1912.

[51] *Id.* at 1912-13. The Interleukins are proteins that serve as chemical messengers between cells. Interleukins were originally named because they were identified as being produced by immune cells, however, many other cells can produce certain Interleukins under normal circumstances or during periods of environmental stress.

[52] *Id.* at 1913.

[53] Although current cloning methods may allow a competitor to clone the same molecule in two weeks to a month, at the time this controversy arose in the mid-80's cloning took considerably longer.

[54] Pat. No. 5,122,459 issued June 12, 1992. Interestingly, neither Gillis nor Henney appear as inventors.

[55] Elisabeth Kirschner, *Biotech Firms Settle Suit Charging Data Theft by Peer Review*, 74 CHEM. & ENG'G NEWS 9 (1996).

[56] *Id.*

[57] *Suit Alleges Theft of Trade Secrets by Peer Reviewer*, West's Legal News 2360, Apr. 23, 1996, *available in* WESTLAW, 1996 WL 260050.

[58] Eliot Marshall, *Battle Ends in $21 Million Settlement*, 274 SCIENCE 911 (Nov. 8, 1996).

[59] *Id.*

[60] *Id.*

[61] Leading 100 Biotechnology Companies, MEDADNEWS, Fri. Dec. 1, 1995.

[62] *Id.*

[63] Kirschner, *supra* note 55, at 9.

[64] *Id.*

[65] *Id.*

[66] Marshall, *supra* note 5, at 1914.

[67] *Id.*

[68] *Id.*

[69] Burk, *supra* note 9, at 348.

[70] ON BEING A SCIENTIST, *supra* note 3.

[71] The ABA approved the contemporary Model Rules of Professional Conduct based on the Canons of Professional Ethics on August 2, 1983.

[72] ON BEING A SCIENTIST, *supra*, note 3 at 11. For example, geneticist Barbara McClintock stated, "I was just so interested in what I was doing I could hardly wait to get up in the morning and get at it. One of my friends, a geneticist, said I was a child, because only children can't wait to get up in the morning to get at what they want to do." *Id.*

[73] Sise, *supra* note 13, at 408.

[74] *Id.*

[75] *Id.*

[76] *See e.g.*, ON BEING A SCIENTIST, *supra* note 4.

[77] Sise, *supra* note 13, at 414-15.

[78] *Id.* at 415.

[79] D.P. Hamilton, *Baltimore Throws in the Towel*, 252 SCIENCE 768 (1991).

[80] B.J. Cullinton and E. Rubenstein, *Inside the Gallo Probe*, 248 SCIENCE 1494 (1990).

[81] P. Aldhous, *Trouble for Healy over Misconduct Office*, 252 SCIENCE 361 (1991).

[82] COMMISSION ON RESEARCH INTEGRITY, INTEGRITY AND MISCONDUCT IN RESEARCH: REPORT OF THE COMMISSION ON RESEARCH INTEGRITY, Nov. 3, 1995, as mandated by Pub. L. No. 103-43, § 126, presented to the Secretary of Health and Human Services, The House Committee on Commerce, and the Senate Committee on Labor and Human Resources [hereinafter INTEGRITY AND MISCONDUCT], *available at* < ftp://ftp.os.dhhs.gov/pub/ori/report.exe.>.

[83] *Id.* at 55 (emphasis added).

[84] The HHS Commission on Research Integrity, *Professional Misconduct Involving Research* at 1, *available at* <http://www.nih.gov.> (This report represented an early version of the full report presented at note 82.).

[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] INTEGRITY AND MISCONDUCT, *supra* note 82, at 2.

[89] ON BEING A SCIENTIST, *supra* note 3, at 16.

[90] W. Roush, *John Dingell: Dark Knight of Science*, TECH. REV. 58 (Jan. 1992).

[91] *After the Whistle Blows*, WASH. POST, Dec. 30, 1995, at A18.

[92] *Id.*

[93] Vincent N. Hamner, *Misconduct in Science: Do Scientists Need a Professional Code of Ethics?*, May 1992, (quoting John Ladd of the Department of Philosophy at Brown University) *available at* <http:// www.chem.vt.edu/ethics/ethics.html>. Mr. Hamner is quoting from a symposium hosted by R. Chalk, M.S. Frankel and S.B. Chafer, *AAAS Professional Ethics Project*, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, AAAS Publication 80-R-4, 1980.

[94] Robert M. Andersen, *The Federal Government's Role in Regulating Research Misconduct in Scientific and Technological Research*, 3 J.L. & TECH. 121, 132 (Winter 1988).

[95] *Id.*

[96] *Id.*

[97] *Id.* at 132; *see also* 45 C.F.R. § 689 (1996).

[98] *Id.* at 133.

[99] *Id.* at 134.

[100] *Id.* at 135.

[101] ON BEING A SCIENTIST, *supra* note 70, at 16.

[102] *Id.*

[103] Marshall, *supra* note 5, at 1913.

[104] *Id.*

[105] *Id.*

[106] *Id.*

[107] Marshall, *supra* note 5, at 1913.

[108] *Id.*

[109] *Id.*

[110] Pamela S. Zurer, *Survey Finds Researchers Often Encounter Scientific Misconduct*, 71 CHEM. & ENG'G NEWS 24 (1993).

[111] Section 102(a) basically states that a patent will not issue if the invention was known or used by others, or patented or published prior to the date of invention in the United States. *See generally* John E. Vick, *Publish and Perish: The Printed Publication as a Bar to Patentability*, 18 AIPLA Q.J. 235 (1990); 35 U.S.C. § 102(a) (1994).

[112] 35 U.S.C. § 102(a) (1994); *see e.g.*, Huszar v. Cincinnati Chemical Works, 172 F.2d 6, 80 U.S.P.Q. (BNA) 466 (6th Cir. 1949).

[113] 35 U.S.C. § 102(a) (1994); *see* 37 C.F.R. § 1.131 (1996), *and* Manual of Patent Examining Procedure (MPEP) § 715.07 (1994).

[114] Kraus v. Emhart Corp., 320 F. Supp. 60, 167 U.S.P.Q. (BNA) 385 (N.D. Cal. 1970).

[115] Spalding & Evenflo Companies, Inc. v. Acushenet Co., 718 F. Supp. 1023, 13 U.S.P.Q.2d (BNA) 1081 (D. Mass. 1989) (finding that the prior use statute is intended to force inventors, whether or not they are the first to invent, to proceed to file their patent after commercialization of public use of the invention).

[116] The converse is true for biotechnology products for human use that require compliance with extensive Food and Drug Administration regulations.

[117] Typical time periods for National Institute of Health Science Foundation grants.

[118] Authors whose manuscripts have been rejected receive the reviewer's comments.

[119] E.I. duPont de Nemours & Co. v. Union Carbide, 250 F. Supp. 816, 820, 148 U.S.P.Q. (BNA) 532, 534 (N.D. Ill. 1966) (stating that the one year bar is not discretionary but is an absolute rule established by the operation of law), *rev'd on other grounds*, 369 F.2d 242, 151 U.S.P.Q. (BNA) 558 (7th Cir. 1967).

[120] *Id.*

[121] Automatic Weighing Mach. Co. v. Pneumatic Scale Corp., 166 F. 288, 297 (C.C. Me. 1909) (interpreting the precursor to 35 U.S.C. § 102, 35 U.S.C. § 31).

[122] Patent Harmonization Act of 1992, H.R. 4978 and S.2605, 102d Cong., 2nd Sess., 138 CONG. REC. H2672, S.5219 (Daily ed. April 9, 1992).

[123] 35 U.S.C. § 102(b) (1994).

[124] 35 U.S.C. § 104 (1994).

[125] 35 U.S.C. § 102(f) (1994).

[126] 35 U.S.C. § 271 (1994).

[127] MacCordy, *supra* note 2, at 298 (summarizing the counter-arguments of opponents to the first-to-file system).

[128] Solarex Corp. v. Arco Solar, Inc., 870 F.2d 642, 10 U.S.P.Q.2d (BNA) 1247 (Fed. Cir. 1989).

[129] *Id.* at 644, 10 U.S.P.Q.2d at 1249 (attempting to show that the manuscript in question constitutes prior art invalidating the patent or that the dissemination the manuscript shows inequitable conduct).

[130] *Id.* at 643, 10 U.S.P.Q.2d at 1249.

[131] *Id.*

[132] *Id.* at 644, 10 U.S.P.Q.2d at 1249.

[133] *Id.*

[134] R. Hostetler, *Fear of Suit Blocks Retractions*, SCIENTIST, Oct. 19, 1987, at 1, col. 4; *see also*, Paul Friedman, *Correcting the Literature Following Fraudulent Publications*, 263 J.A.M.A. 1416 (1990).

[135] Andersen, *supra* note 94, at 136.

[136] *Id.* at 137.

[137] Hutchison v. Proxmire, 443 U.S. 111 (1979).

[138] Andersen, *supra* note 94, at 134.

[139] *Id.*

[140] *Id.*

[141] *See e.g., supra* notes 77-79.

[142] Ian Jackson, *The Lonely Road of the Whistleblower*, TODAY'S CHEMIST AT WORK, May 1993, at 18.

[143] Anderson, *supra* note 92, at 145 and notes therein.

[144] Justin Gillis, *Whistleblowing: What Price Among Scientists?*, WASH. POST, Dec. 28, 1995, at A21.

[145] *See e.g.*, Sise, *supra* note 13, at 417.

[146] *Id.* at 418.

[147] *Id.* at 418-19.

[148] *Id.* at 417.

[149] *Id.; see also*, 45 C.F.R. § 76.100(a) (1996).

[150] Sise, *supra* note 13, at 415; *see also*, 45 C.F.R. § 50.103(d)(3) (1996).

[151] Sise, *supra* note 13, at 423; *see also*, 31 U.S.C. § 3728 (1994). *Qui tam* is derived from the Latin phrase, "*qui tam pro domino rege quam pro seipso*," meaning "he who as much for the king as for himself," *see generally, The History and Development of Qui Tam*, 1972 WASH. U.L.Q. 81, 83 (1972).

[152] A False Claims Act claim requires: (1) that the defendant presented, or caused to be presented a claim for payment or made a statement to get a claim that was false against the United States; (2) that the claim was false; (3) that the defendant knew it was false or fraudulent; and (4) that the United States suffered damages as a result. *See* 31 U.S.C. § 3729(a) (1988); *see also*, United States *ex rel.* Stinson v. Provident Life, 721 F. Supp. 1247, 1258-59 (S.D. Fla. 1989).

[153] 31 U.S.C. § 3719(a) (1994).

[154] Marshall, *supra* note 5, at 1912.

[155] 18 U.S.C. § 1961 (1994).

[156] Marshall, *supra* note 5, at 1912; *see also*, 18 U.S.C. §§ 1341, 1343 (1995).

[157] *Id.*

[158] *Cytokines ... A Diagnostic Marketing Opportunity? Interleukins, the Chemical Messengers*, Genesis Rep. 1, 1992 WL 2780893, Wed. Jan 1, 1992 (indicating that the Immunex Interleukin-1Alpha was in phase II clinical trials as a bone marrow suppressant and as a cancer immunotherapeutic agent).

[159] *See generally* Burk, *supra* note 9, at 307.

[160] The Uruguay Round Agreements Act of 1994 (URAA), Pub. L. No. 103-465, codified in part at 35 U.S.C. § 111(b)(1994).

[161] Michael Gollin, *Provisional Patent Applications: File Early, File Often*, THE LAW WORKS, Aug. 1995, at 15.

[162] *Id.*

[163] *Id.*

164 *Id.*

165 *Id.* at 17.

166 Zumbro, Inc. v. Merck and Co., Inc., 819 F. Supp. 1387, 1400 (N.D. Ill. 1993) (finding that the purpose of the best mode requirement is to restrain inventors from holding back their best invention, thereby, not playing "fair and square" with the patent system). To satisfy disclosure of the best mode requires that the inventor disclose the "best mode" known at the time that the application is filed for making and using the invention. *Id.*

167 *See e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (1980).

168 *See generally* Paul B. Thompson, *Conceptions of Property and the Biotechnology Debate*, 45 BIOSCIENCE 275 (1995); Susan Watts, *The Genetic Goldrush*, INDEPENDENT, Apr. 27, 1994 at A1; Victoria Slind-Flor, *Patents Pending? Lawyers, Inventors Battle Over New Technologies*, 14 NAT'L L.J., June 8, 1992, at 1.

169 Glaxo, Inc. v. Novopharm Ltd., 830 F. Supp. 869 (E.D.N.C. 1993), *aff'd*, 52 F.3d 1043, 34 U.S.P.Q.2d (BNA) 1126 (Fed. Cir. 1995), *cert. denied*, 116 S. Ct. 516 (1995).

170 As used herein, the term "control" is used to describe an ancillary experiment that serves to complete the scientific picture necessary to satisfy a person highly skilled in the relevant field of study, most often a competitor.

171 37 C.F.R. § 132 (1996); *see also*, DAVID BAHLER AND THOMAS CRMSON, PREPARATION OF PATENT APPLICATIONS ON COMPUTER SOFTWARE. 7TH ANNUAL COMPUTER & INFORMATION TECHNOLOGY LAW INSTITUTE, Dallas, Texas Sept. 23-25, 1993, at 16.

172 34 U.S.C. § 104 (1994).