Perils of Public Disclosure and Peer Review: How to Protect the Fruits of Academic Research

Academic researchers and university professors work under the compounding pressures of publication productivity and openness. The number of publications in refereed journals is typically an important measure of merit, on which such weighty decisions as promotion, tenure and salary may depend. Academic institutions are also dedicated to wide and public dissemination of ideas. Students and research assistants have access to the latest advances and are trained with cutting-edge methodologies. Prestige and fame, as well as favorable recommendation letters and agency funding, may depend on exposure of one’s work at conferences, seminars and workshops. In some areas of research, competition to be the first to develop, and disclose success, is fiercely intense as the reward may ultimately be a Nobel Prize.

At the same time, many academic institutions are actively seeking to exploit the fruits of their research through licensing, product development and other arrangements that depend on the integrity of patent rights. Revenue from such sources is used to bridge gaps in research funding, provide seed money for new research and, in general, further scholarly and educational goals.

While public disclosure and research exploitation are mutually reinforcing in the long run by providing the appropriate incentives and creating a fertile environment for the fermentation of ideas, an ill-timed public disclosure may deprive the inventors and their institutions from any tangible benefits by extinguishing their patent rights in many countries throughout the world.

Public disclosure may, in some instances, occur unsuspectingly by such routine practices as:

- preparing a microfiche of a doctoral thesis after successful defense;
- describing ongoing research on a student’s personal website;
- displaying a poster in a poster session of a conference;
- sending preview copies of a presentation or journal article to fellow researchers; or
- submitting a manuscript for peer review.

These and other potential public disclosure pitfalls are discussed below.

I. THE PUBLICATION BAR

“A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.” 1

This rather dry recitation of the “publication bar” and its effect on an inventor’s ability to obtain a patent can have far-reaching ramifications in the academic world. The “publish or perish” rule has been paraphrased as “publish and perish” 2 when the publication involves a potentially patentable invention.

Prior art has been defined as “knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in an art.” 3

A manuscript will be considered prior art if it is “sufficiently available to the public interested in the art,” 4 “more than one year prior to the [application] date.” 5 The test for determining whether a prior art reference was sufficiently available to the public interested in the art is whether “it has been disseminated or otherwise made available to the extent that persons interested and of ordinary skill in the subject matter or art…exercising reasonable diligence can locate it....” 6

Massachusetts Institute of Technology v. AB Fortia 6 Although the determination of “public accessibility” is to be made on a case-by-case basis, 7 certain guidelines have emerged.

As is common in academia, manuscripts are regularly presented at peer gatherings. This can be a dangerous practice as demonstrated in MIT. In MIT the inventor was denied a patent where he presented a paper to a conference attended by between 50 and 500 persons interested and skilled in the art, and then distributed
copies without restriction to at least six attendees. The Federal Circuit, the court of appeals for patent cases, held that this constituted a “printed publication” under 35 U.S.C. § 102.

Cataloging and shelving of a doctoral thesis in a university library that is readily accessible to those interested in the art also satisfies the public accessibility standard. However, limited distribution, even to those skilled in the art, does not amount to public accessibility. Thus, distribution of a master’s thesis to three members of a faculty committee responsible for assessing the student’s entitlement to a degree, accompanied by “depositing the thesis in the university library where it remained uncatalogued and unshelved as of the critical data,” did not satisfy the standard.

Similarly, titles of theses listed on cards filed alphabetically by author in a shoebox in the chemistry department were not cataloged or indexed in a sufficiently “meaningful way” to make them reasonably accessible to the public. In analyzing whether a particular paper or manuscript has been published, it is irrelevant to the public accessibility determination whether “members of the public actually received the information.”

In the absence of evidence establishing a specific date of cataloging and shelving, “competent evidence of general library practice may be relied upon to establish an approximate time when a thesis became accessible.” However, a single cataloged copy of a thesis in a foreign university library is sufficient under 35 U.S.C. § 102(b).

It appears from the foregoing that distribution of a manuscript and presentation of the same (e.g., MIT) to a collection of peers or, in patent law vernacular, those having ordinary skill in the art, with no requirement of confidentiality or limit on distribution may constitute publication. However, submission to a journal, public funding agency, or colleagues for peer review may not trigger the publication bar under § 102(b) so long as the manuscript is not sufficiently available to that section of the public skilled in the art. Widespread dissemination to an inventor’s colleagues or posting on a website should be avoided.

If such publication occurs more than one year prior to applying for a patent, the inventors will be denied patent protection on their inventions in the U.S., which is one of the few countries in the world that provide a one-year grace period after public disclosure. Patent protection in foreign countries may be lost or compromised as soon as public disclosure occurs, although there may be some limited exceptions depending on the foreign country.

Another interesting wrinkle is the question of what happens when an inventor confidentially submits a manuscript for peer review and a malfeasor in the peer review process exploits the subject matter of the manuscript for his or her own gain. One of the reviewers could potentially be a competitor working on the same invention that has not reached the same point in development as the inventor but uses the inventor’s research to obtain a patent. What happens if the reviewer simply seeks a patent on the subject matter of the manuscript or seeks a patent on an obvious modification of the invention underlying the manuscript?

II. THE PEER REVIEW RISK

Peer review is an essential element in academic publishing. It forms a pillar of expert witness testimony and adds legitimacy to the work of scientists. Peer review can be divided into three categories: editorial peer review, external peer review and internal peer review.

Editorial Peer Review

Editorial peer review is the process utilized by most scientific journals to ensure accuracy and to confirm relevance and completeness of the research being submitted to the journal. The process typically begins with the submission by the author of a manuscript containing a background of the technological field of the invention and experimental methods and equipment used in the research.

Upon submission to the journal, the journal’s editorial board may make an initial determination on whether to pursue the manuscript. If they decide to pursue it, the manuscript may be sent to reviewers familiar with the research, which may turn out to be the author’s competitors. This review can take up to six months or more to complete depending upon the reviewer’s schedule and the editor’s diligence.

The review may or may not be conducted under a confidentiality agreement between the journal and the reviewer. In highly specialized technical fields, there may only be a handful of scientists competent to review the submitted manuscript. If they refuse to sign a confidentiality agreement, the journal is essentially at their mercy. Moreover, these reviewers are likely to be the author’s competitors and are likely pursuing similar research objectives. In sum, there is no guarantee of confidentiality when submitting a manuscript to a journal for publication.

External Peer Review

External peer review is conducted to determine eligibility for funding from a public agency. A panel or committee of the prospective grantee’s peers generally conducts this form of review. The individuals comprising the panel typically review the individual grant applications independently and then meet as a panel or committee to make funding determinations.

While peer review for a journal is often anonymous, in external peer review the identity of the applicant is regularly disclosed to the panel member. Additionally, external peer review has the greatest potential for abuse. Most grant applications provide a list of research goals and objectives and a detailed plan of how to achieve these objectives. In the hands of a well-funded competitor, this detailed plan may be all that is needed to perfect the invention and obtain a patent on the same. Even with a confidentiality agreement in place, the applicant whose idea is pirated and publicly disclosed may lose patent rights, although other recognized legal remedies may be available to the applicant. As a

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precautionary measure, applicants should submit proposals in confidence whenever possible.

Internal Peer Review

Internal peer review employs a panel similar to external peer review; however, the panel typically comprises scientists from the inventor’s own institution.20 The purpose of the panel is to evaluate the inventor’s “worth” to the institution and to determine various items such as tenure, funding for the inventor’s research, graduate assistants, post-doctoral assistants, etc.21

This internal peer review typically involves presentation of potentially patentable research to the aforementioned panel. When working for tenure, funding or the like within the confines of one’s own institution, this presentation likely encompasses new contributions to the particular inventor’s field in an effort to impress one’s peers.

III. CONFIDENTIALITY AND PEER REVIEW

Confidentiality in the peer review process may be a two-edged sword. On one hand, a reviewer may breach even a signed confidentiality agreement, but on the other hand, a confidentiality agreement protecting the reviewer’s identity may effectively deprive legal relief to an interested party.

Confidentiality Breach

Many scholarly journals do not require a signed confidentiality agreement as noted above. In fact, many journals enclose a form letter admonishing the prospective reviewer to keep in mind that the matter is confidential. This type of arrangement is ripe for abuse as noted in Cistron Biotechnology, Inc. v. Immunex Corp. Although the case settled prior to the commencement of trial and a search revealed no judicial treatment of idea theft in the peer review process, the outcome of Cistron is instructive.

In Cistron, the plaintiffs alleged that Immunex used confidential information obtained in the peer review process to perfect and patent the nucleic acid sequence for human interleukin-1 (IL-1). The journal, prior to enlisting scientists at Immunex in the peer review process, learned that scientists at Immunex were engaged in the same line of research forming the basis for the manuscript, but were 6-12 months behind. Unbelievably, the journal submitted the manuscript to these scientists for peer review in light of this glaring conflict of interest.

As noted above, the case settled prior to trial commencement with Immunex agreeing to pay Cistron twenty-one million dollars and further agreeing to assign certain patents to Cistron.

Undercover Breach

Most reviewers are anonymous to the inventor, making it almost impossible for the true inventor to prove theft of his or her idea. A seemingly innocuous case from the Federal Circuit may have lain to rest any hope of an inventor proving idea theft during confidential peer review.

In Solarex Corp. v. Arco Solar, Inc.,22 the Federal Circuit held that the defendant in patent infringement suit was not entitled to disclosure of the identity of an independent referee who reviewed a manuscript submitted to a scholarly journal for publication and recommended its rejection, notwithstanding the defendant’s contention that the referee’s identity and deposition were necessary to determine whether he disseminated the manuscript, which would support the defense of patent invalidity.

Solarex has far-reaching implications in academic circles. If a reviewer steals an inventor’s idea and obtains a patent on the same, the inventor cannot now easily prove this, as an inventor may not be able to compel a scholarly journal to divulge the identity of its peer reviewers. A typical scenario could unfold as follows. The inventor submits a manuscript for review. The journal assigns the manuscript to a reviewer where the reviewer is a person skilled in the art and could potentially be a competitor. Upon receiving the manuscript, the competitor uses what is disclosed in the manuscript to perfect his own system or merely makes obvious changes to the invention and then seeks a patent. This may well be a breach of the confidentiality agreement executed with the journal, but how would the inventor prove it? Under the holding in Solarex, the inventor probably cannot compel the journal to provide the names of the persons to whom the journal provided copies for review. How would the inventor then go about proving that a well-respected peer and competitor in his chosen field “stole” his idea? The inventor is essentially out of luck.

Another form of malfeasance equally as deleterious to the inventor would be a reviewer who disseminates the manuscript in the pertinent field, again in violation of the confidentiality agreement. Although there are no reported cases, if this dissemination is widespread and occurs more than one year prior to the inventor’s patent application, the inventor could be denied patent protection under the 35 U.S.C. § 102(b) publication bar. Here the reviewer does not steal the inventor’s idea, he merely “submarines” the inventor’s ability to obtain patent protection allowing anyone to make, use and sell the inventor’s idea. This allows the malfeasing peer to take advantage of the time and resources of the inventor free from licensing constraints under a patent.

IV. RECOMMENDATIONS AND CONCLUSION

As we have seen, the pitfalls of public disclosure come in many forms. Academic institutions that have a stake in patent rights of their employees need to educate all the participants of a research enterprise of the potential of unintentional public disclosures.

It is also important for those involved in the peer review process, whether they be academic institutions submitting manuscripts for review or reviewers reviewing the submitted transcript, to understand their rights and liabilities. “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.\textsuperscript{23}

The peer review system is here to stay, and there are ways for the patent system and peer review system to peacefully coexist. Prior to submission of a paper or application for a research grant, it is incumbent upon all prospective patentees to fully investigate the journal or agency’s confidentiality and conflict of interest policies. In an ideal world, the prospective patentee would file a utility patent application\textsuperscript{24} prior to submission for publication or grant application. If this is not possible, then a provisional patent application may well protect the invention at a minimal cost.

A provisional patent application\textsuperscript{25} may be filed with only a specification, necessary drawings, a coversheet and the requisite fee, although the inclusion of at least one broad claim is advisable. The provisional application must be converted to a utility application within one year of filing the provisional application. This provides the inventors a one-year window to perfect the inventions as well as the opportunity to publish or solicit grants without fear of someone commandeering their ideas. Additionally, the provisional patent application may protect the inventor’s rights abroad.\textsuperscript{26} If, at the end of the one-year period, the invention is not commercially viable or is not worthy of publication, the inventor can abandon his provisional application and walk away paying only a relatively nominal fee. If, however, the invention is met with enthusiasm in commercial and/or academic circles, the inventor and his patent attorney can convert the provisional application into a utility application and perfect his rights under the patent system without fear of theft by someone involved in the peer review or grant application process.

ENDNOTES

4 In re Cronyn, 890 F.2d 1158, 1160 (Fed. Cir. 1989) (quoting Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1568 (Fed. Cir. 1988)).
5 35 U.S.C. 102(b).
6 774 F.2d 1104, 1109 (Fed. Cir. 1985) (quoting In re Wyer, 655 F.2d 221, 226 (C.C.P.A. 1981)) (hereinafter referred to as “MIT”).
7 See In re Hall, 781 F.2d 897, 899 (Fed. Cir. 1986).
8 MIT at 109.
9 See Id.
10 See In re Hall, 781 F.2d at 899 (finding a doctoral thesis catalogued in a university library, easily accessible to the interested public, a “printed publication”).
12 Id. (citing In re Bayer, 568 F.2d 1357, 1362 (C.C.P.A. 1978)) (the critical date is one year prior to the date of the patent application).
13 In re Cronyn, 890 F.2d at 1161.
14 Constant, 848 F.2d at 1569.
15 In re Hall, 781 F.2d at 899 (relying on the affidavit of the director and manager of the Loan Department of the Library of Freiburg University with respect to general library procedures in estimating the time it would have taken to make the dissertation available to the interested public).
16 See Id. at 900.
17 In addition to the U.S., Mexico and Thailand, for example, provide a one-year grace period for certain disclosures.
18 See Daubert v. Merrell Dow Pharm., 509 U.S. 579 (1993) (one factor considered in determining the admissibility of scientific expert testimony is whether the expert’s theories have been subjected to review by the expert’s peers); Kumho Tire v. Carmichael, 119 S. Ct. 1167 (1999) (peer review is an important factor in determining the admissibility of non-scientific expert testimony).
19 Troy at 50.
20 Id. at 55.
21 Id.
22 870 F.2d 642 (Fed. Cir. 1989).
23 Id. at 74.
24 A utility application is “full” patent application having a specification, drawings and claims.
25 Provisional patent application requirements are set forth in 35 U.S.C. § 111(b).