How to Protect Intellectual Property and Still Publish

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What Is a Publication?

A significant difference between academic and corporate research environments is reflected in publication. While most company inventors must have all publications reviewed and approved prior to submission, this is usually not the case in the academic setting. Although there may be agreements with corporate sponsors that require some prepublication review, compliance is imperfect. Outside of contractual obligations for prepublication review, most universities do not consistently review publications and, therefore, must often react quickly or after the fact to a disclosure that impacts on patentability. Accepting that academic freedom and publication rights are of paramount concern to academic researchers and their institutions, an understanding of what types of disclosures are novelty-destroying under U.S. and international patent laws is necessary.

An invention is not patentable if it was patented or described in a printed publication. United States law provides that an application must be filed within one year of the publication; however, any publication is a bar to patenting in most other countries.

Most researchers and technology transfer professionals understand that a peer-reviewed scientific paper published in a journal or textbook is a publication. Online publications are becoming common and often occur months before a journal is mailed. Therefore, it is necessary to know the journal and its publication practices. Usually this information is provided in publication guidelines available to authors or can be confirmed with the journal prior to submission. Authors are also usually, but not always, given warning through a galley-approval process or online notification of a publication date.

Abstracts, posters, and presentations for professional meetings or seminars should be evaluated as publications. Before widespread dissemination of information over the Internet, some materials were considered to be transitory and, therefore, not a publication. However, most patent offices view these types of materials as publications because they are publicly available and accessible to those skilled in the art to which the invention relates. Obtaining clear dates for publications of materials related to meetings can be very difficult depending on the size of the meeting and whether or not the meeting organizers are familiar with intellectual property (IP) issues. Unfortunately, it is not uncommon for a meeting representative to indicate that the abstracts will be online one date, only to have them show up days or weeks earlier. To be safe, some offices use the acceptance date of the meeting material as their warning for a potential online publication.

Theses or dissertations become publications once catalogued and shelved/made available online. The oral defense may be considered a publication if copies are provided to the audience, which includes anyone from outside the university.

Federal grant applications and abstracts become publications upon funding. This is because the grant application becomes publicly available at this point and may be requested under the Freedom of Information Act (FOIA). Unless information within the grant application is identified as confidential because it is a trade secret or commercial or financial information, it will be provided. While faculty members are sometimes reluctant to do so, unless information is marked as confidential, it is considered publicly available and will be considered as prior art as of the funding date. Abstracts of grants also are published online in a federal database. The content of the abstract, as well as the existence of the grant, will become public information and may elicit a FOIA request for detailed information about the technology.

Food and Drug Administration (FDA) applications also become available to the public upon approval and are available for review for prior art disclosures and admissions. There is often a wealth of data included that can show when and how an invention was made and when disclosures may have been made. Therefore, if data are to be included in an FDA submission, they should be reviewed for patentability before it is submitted to the

FDA so that there is a clear understanding of what is being disclosed and that it is consistent with patent filings.

Faculty members also make presentations either at companies or to visitors at their labs. If a confidentiality agreement is not in place, these disclosures will be considered public. Thesis and dissertation defenses where outside members are present also constitute public disclosures. E-mails with colleagues can constitute a public disclosure. In fact, any discussion of the technology outside of the university can constitute a disclosure from a prior art perspective; therefore, it is important that faculty understand that the first discussion of the technology should be with the technology transfer office.

The most frequent misconception is that any publication will destroy patentability. However, the law bars patenting only when the actual invention is patented or published. Therefore, careful analysis of a publication is required to assess what is actually being disclosed and what impact the disclosure could have on patentability.

A disclosure will be a bar to obtaining patent protection if the disclosure would be adequate to permit one of skill in the art to make and use the invention. In the U.S., this is referred to as an enabling disclosure. Other countries construe disclosures at least this broadly, with many limiting the publication to what is explicitly taught therein. It is often helpful to assess the impact of a potential publication from a prior art perspective, i.e., if it is published, how could it be cited in an anticipation or obviousness/lack of inventive step rejection? Clearly, if the publication teaches the basic invention, it will impact on patentability.

The typical case is not so clear because many early disclosures are incomplete and/or suggestive. The impact of the disclosure will depend on the nature of the invention, the state of the art, and the level of ordinary skill in the art. United States and international law are now much more closely aligned with respect to what would be obvious to one of skill. However, many countries do not have the same requirements as the U.S. concerning written description and enablement. Therefore, the impact of the disclosure may vary by country.

A conservative approach is suggested. It is important to review the publication as an examiner, not as the inventor or institution advocate. Review the disclosure objectively from the perspective of someone familiar, but not expert, in the art. Treat suggestions as at least an invitation to try. If a case can be made for anticipation or obviousness from this perspective, then it would be preferable to try and prevent the publication from becoming prior art.

There are a number of different tactics that can be employed to delay publication until a patent application can be filed: publication can be delayed; the publication can be revised, e.g., suggestions could be omitted and the publication focused on actual data only; or the audience could be limited to the university community (for a thesis or dissertation defense, for example). Explaining to inventors that their own suggestive or disparaging statements can later be their own worst prior art can often engender inventor cooperation. It is one thing to be scooped by a competitor, but quite another to destroy one's own opportunity for patenting. It can be disheartening when the worst prior art is the inventors' own publication. While there may be initial resistance to conferring with the technology transfer office about the timing and/or scope of disclosures, when options and consequences are explained and discussed, cooperation often follows.

When writing a grant application, faculty members review and follow the rules and requirements for the grant submission or they understand they may not receive funding. Manuscripts are written in accordance with the requirements of the journal. Faculty members understand that top peer-reviewed journals have specific requirements that they must follow if they hope to published in the journal. If they wish to present at a meeting, they follow the procedures to submit a proposal or abstract. When the rules and requirements of patenting are explained in a similar manner, faculty understand what is required to successfully maneuver through the patenting process. An inventor's guide, invention disclosure meetings, or a review of a patentability analysis with the inventor are helpful tools.

Is There Anything Ready for Patenting?

There are two elements for invention: conception and reduction to practice. Conception is complete when the inventor has a definite and permanent idea reflecting a specific approach to the problem at hand. It must also be sufficiently definite that one of skill could practice the invention without undue experimentation. Reduction to practice can be achieved when the invention is shown to be suitable for its intended purpose by either actually making the invention or by filing a patent application, which would enable one of skill to make and use the invention.

A publication should be reviewed to identify possible inventions. This requires an assessment of the subject matter. Under U.S. law, patentable inventions include processes, machines, manufactures, and compositions of matter. The focus is on the essential characteristics of the subject matter and its practical utility and includes anything touched by the hand of man. Other countries define patentable subject matter eligibility, such as the European Patent Convention. Under the EPC, positive and negative definitions of patentable subject matter are explicitly provided.

For example, diagnostic methods and software are specifically not eligible for patentability. Oftentimes scientific publications disclose very early research results or confirmatory data. In these cases, there may be nothing ready or appropriate for patenting. For example, if a composition and a use are known (such as treating cancer), the mechanism of action would not be patentable. Alternatively, discovery of a new pathway or mechanism of action may be patentable as a method for screening for drugs.

In addition to identifying patentable subject matter by statutory class, an assessment must also be made concerning the adequacy of the disclosure to support a claim to that subject matter. The disclosure must enable one of skill to make and use the invention. If the publication concerns identification of a novel pathway, it would not necessarily support claims for treating disease or therapeutic agents. Also, publication of a composition and its use for one indication does not necessarily preclude patenting other uses.
The challenge is often in determining how enabling or suggestive a disclosure could be. Again, the perspective of a conservative patent examiner is very useful. For patentability

purposes, the person of ordinary skill is often quite perceptive when determining obviousness but requires significantly more disclosure to make and use the invention from a written description standpoint. Although one of ordinary skill should be one in the same for both analyses, often they are not treated as such and even the slightest disclosure can render an invention obvious. This is especially true outside the U.S., where much less is required in terms of written description and one of ordinary skill is usually accomplished.

The amount of disclosure required depends on the type of invention. For a mechanical invention, a drawing can be adequate. For a biotechnology invention, much more is required. The challenge is to identify the point at which enough has been disclosed that the next disclosure would be damaging. Close coordination and good communication between the inventor and the technology transfer office are crucial so that patenting opportunities are not misjudged or missed.

Universities have different procedures for dealing with the inventor-patent attorney relationship. In some cases, direct access and communication are permitted. In other cases, communication is through the technology transfer office. Both can work well so long as someone is communicating effectively with the inventors. E-mail can be helpful. Inventor comments can be provided very effectively via e-mail. Conference calls can also be helpful. The most important factor is having a patent attorney/agent who understands the technology and the art or who is able to quickly learn what he or she needs to know from the inventor and/or technology transfer professional. It is also helpful if the patent attorney/agent is aware of the university's procedures, policies, and budget for patenting.

An effective strategy is to review all publications coming from an inventor or research group prior to submission as early as possible so that the relevance of the publication to the desired subject matter for patenting can be assessed. The point is to evaluate the disclosure in light of patentable subject matter, rather than filing something and then trying to figure out what could be patentable subject matter. Determining readiness to patent depends on defining what the claimed invention would be.

How to Assess the Impact of a Disclosure

There are two aspects to evaluating publication impact on patentability. In the first case, the determination focuses on what rights would be lost if an application is not filed prior to publication. In the second case, the evaluation focuses on what could be patented in light of a prior art disclosure. In both cases, an assessment of the prior art, what is disclosed in the publication, and differences between the prior art and publication must be made. When patentability is being evaluated, the adequacy of the disclosure to support a desired claim is required, i.e., is there sufficient information or data to enable one of skill to make and use the invention.

In the second case, the evaluation focuses on whether what is being disclosed is sufficiently different from the prior art to be patentable. It is helpful to actually draft a claim set at this point that reflects what is actually disclosed in the context of the prior art and decide whether the scope of the possible claims is worth patenting. Often it will not be because the information available when realistically assessed may not support the type of claim that may be of commercial interest. The U.S. written description requirements in particular will limit the types of claims that can be obtained based upon basic research results.

A patent attorney can generally come up with a way to claim subject matter, however, the technology transfer professional must decide if the patent protection would be of any value. Managing expectations at the outset can be challenging, but sometimes deciding not to file anything is the best choice. In cases such as this, however, it is a good strategy to maintain a relationship with the inventor and continue to follow his or her work and publications. It is also helpful to discuss with the inventor what results would be helpful for filing an application directed to desirable claims.

It is important to understand that there must be an adequate written description to enable one of skill in the art to make and use the invention as of the filing date. A section-112, first-paragraph problem cannot be solved later. If data are not available, there must be at least an adequate prophetic disclosure or the priority date may be meaningless. Filing a quick provisional is often not the best solution because the priority

date is only as good as the disclosure, and a provisional is subject to the identical 112 standards as a nonprovisional application.

Filing an application to prevent a publication from becoming prior art is justified when the disclosure would preclude or limit the patentability of an invention one wishes to claim. However, one must still have a clear idea of what the claimed invention will be and understand what disclosure will be required to support the claim. Filing a series of provisional applications to track ongoing, competitive research may be justifiable so long as it is understood what needs to be in the application that will be ultimately prosecuted. This may be a good strategy if there are going to be publications that are not quite ready for patenting but which could be used to make a strong case of obviousness. Ultimately, the value of a priority date and the applicability of prior art depend upon the quality of the disclosure. When patenting, it is wisest to file when adequate disclosure has been developed. Filing too early can preclude patentability because the claim cannot be adequately supported. The same publication can then become a fatal prior art reference because enough is disclosed to make a case for anticipation or obviousness, but not enough to support a claim to the invention.

Deciding What and When to Publish

Deciding what and when to file will depend on resources. In a case of limited resources, determinations will have to made about the types of inventions and applications that should be filed. Most universities are not in a position to pursue international filings without a licensee. Deferring prosecution costs by filing a provisional application has limited utility. The one-year period for filing a nonprovisional U.S. application and foreign applications passes quickly, and a priority date is only valid if the disclosure provided is adequate to support the claimed invention.

It is challenging to review a publication and evaluate with certainty whether patent protection is feasible. Identifying areas of licensing interest and filing applications that meet basic patenting requirements can help manage expectations and conserve resources. Setting thresholds for patent applications in terms of adequacy of disclosure and advances in the art is important. If inventors understand what can and cannot be

achieved based on the publication being evaluated, they are less likely to be disappointed and more likely to work with the technology transfer office to create additional data or information toward what would be needed to obtain a desired patent claim.

There is a delicate balance between academic freedom and the value of the intellectual property. It is not feasible, or necessary, to protect every publication. Most publications can go forward without filing patent protection to cover the scope of the publication. This sometimes requires a provisional filing with a few general claims that can be followed up by a more complete disclosure. This prevents the publication from becoming troublesome prior art and also permits securing a valid priority date for the desired claim.

It is reasonable for the technology transfer office to be as demanding as a reviewer for a peer-reviewed publication. If a publication does not meet the basic requirements for patentability in terms of written description, enablement, and as an advance in the art, it is not ready for patenting just as it would not be ready for publication in a journal if reviewers raised issues about the research results, completeness of the manuscript, or significance of the results to the field. Papers are often turned down for publication for these reasons. Filing a patent application when the basic requirements for patentability are not met should be equally acceptable.

It important that the technology transfer office explains the patenting process to its faculty, researchers, and students. Patenting has very different requirements from grant or manuscript drafting. The patent prosecution process is not the same as grant or publication review. The standards for patentability are quite different than funding or journal guidelines. If a researcher understands what is needed, he or she can more realistically assess his or her ability to provide the needed information and cooperation. There are specific requirements for filing and prosecuting a patent, just as there are for writing and obtaining grant funding or publication in a top peer-reviewed journal. As it takes years of experience, and often several failed attempts to meet grant and publication goals, patenting should be understood to require much the same experience level. Educating the researcher about the process can go a long way in managing expectations.

How to Deal with Unexpected Publications

The first step in evaluating the impact of an unexpected publication is to understand what has actually been disclosed and its contribution to the prior art. Oftentimes there is minimal or no impact from journal articles. This is because most peer-reviewed scientific publications are focused on research results that do not translate easily into invention. Presentations, posters, abstracts, and other public disclosures may be more problematic. While the results could be incorporated into a patent application, it would be necessary for the patent attorney to craft a patent disclosure that explains and develops the result into a patentable invention. For example, discovering a mechanism of action may or may not be an invention. If it could be developed into a drug-screening assay, perhaps a method patent would be feasible. However, figuring out how a known agent works will not likely be patentable.

On its own, the publication may become a reference that could raise an obviousness issue or preclude patentability on some aspect of a future invention; however, in the area of academic research, the full range of an invention is often not disclosed in a single publication. Since publication is of paramount importance to academic researchers and their institutions, the patenting process should work within the publication process and not impede it. There will almost always be a way to work around an unexpected publication. Given that filing too early is just as dangerous as filing too late, all that often changes is the timing for an application. Too little disclosure is just as deadly as an unexpected publication in many cases.

Damage control and mitigation can be helpful if there are research sponsors involved. If the prepublication provisions have been violated, they are likely to be upset. However, understanding the impact of the publication and explaining it to the sponsor will be very helpful in managing the situation. There is usually a way to work around the publication, whether it is just pursuing U.S. rights by taking advantage of the one-year grace period or filing international applications that work around the actual disclosure.

It is key to focus on the invention, and not the publication. The information in the publication may be helpful in providing the disclosure necessary to support a claim but rarely

will the publication on its own be adequate to meet the requirements of patentability. By focusing on the claimed invention, and not the publication, it will be easier to find a solution that will be workable for the sponsor and the institution.

Sometimes, there is a preexisting patent portfolio that can be relied upon, either for arguing that the invention was disclosed therein and, therefore, the publication was not novelty-destroying and/or as the basis for a U.S. continuation-in-part application to cover the disclosure. If a researcher has changed institutions, it is wise to understand the intellectual property that was created at the prior institution and to create an interinstitutional agreement to cover follow-on work at the new institution. This can help smooth the transition of the research and help prevent publications from falling through the cracks since publications are often written some time after the work is completed. If the researcher is aware of what is claimed in the patent portfolio, he or she can be helpful in identifying new subject matter and placing it in the context of prior work. This can help avoid the situation of creating his or her own worst prior art.

The philosophy of doing the best that can be done under the circumstances comes in handy when dealing with unexpected publication. Only after coming to an understanding of the circumstances, e.g., what was published and when, assessing the publication in the context of the prior art and an existing patent portfolio, and assessing the impact on patentability, can the damage be assessed and dealt with. Assuming damage and launching immediately into damage-control mode usually is not helpful. Realistically calculating the loss and then determining what could be done and at what cost is a much better approach. Filing a provisional application based on undefined fear is usually the worst option. It is better to only file when there is an invention at stake. Creating a quick review process to assess the nature and scope of the invention should always be the first step. Only if and when an invention is identified and quickly assessed as an asset to the university patent portfolio should the patenting process be started. Having a patent attorney or agent involved in the preliminary assessment can save time and money and posture the case for quick filing, if necessary.

However, it is crucial that the attorney or agent not be asked if a patent application could be filed because the answer will almost always be yes. That is what patent attorneys and agents are trained to do, i.e., figure out how to package information as an invention. Rather, they should be asked to do a quick patentability assessment, which should include drafting a few broad claims that are supported by the publication and outside of the prior art based on a quick patentability search.

Once this information is on the table, it can be assessed from a legal and business perspective and a rational filing decision made. Just because a patent application could be filed does not mean it should be. The claims could have no commercial value because of subject matter or scope; there could be significant written description, enablement, or prior art issues identified that impact on the likelihood of patenting success; the researcher may not be cooperative; or there may be third-party rights involved. Multiple factors need to considered and weighed and, more often than not, in the final analysis, the publication will not be fatal.

Keeping a realistic perspective on the impact of a single publication can only improve the decision-making process for patenting. And it should be a decision-making process, not a reactionary process. In reality, there are many more bad filing decisions than truly damaging publications. Keeping this in mind will reduce anxiety about unexpected publications and result in better patenting decisions.