

Nontraditional publications and their effect on patentable inventions

Less traditional forms of printed publications can compromise your IP position.

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Assume for a moment that you are the vice president of a biotechnology company. You fully appreciate that the intellectual property developed by your company is a major asset to the company, and that it deserves the best protection possible. In order to prevent loss of rights, you have instituted several policies designed to protect the company's intellectual property, including a policy that scientific papers will be submitted for publication only after patent applications are filed.

But have you covered all the bases? What about the National Institutes of Health (NIH) and Small Business Innovation Research (SBIR) grant applications your company submitted to federal granting agencies? What about the poster presentation your scientists made last year at the Protein Society meeting? What about the graduate student who worked at your company last summer as an intern, and who is now writing her master's thesis?

Any of these situations may be a cause to worry. The novelty-destroying disclosure provisions of the US patent laws are quite broad, and are certainly not confined to technical articles published in research journals. Less traditional forms of "printed publications" can significantly affect your IP rights.

The US law

The US patent laws provide an opportunity for an inventor to patent his or her invention unless the invention is already disclosed or is obvious in view of what is known in the art. In particular, the US patent laws make reference to certain prior "printed publications" which may be cited by the US Patent and Trademark Office to establish that an invention claimed in a patent application is anticipated by the disclosure in that printed publication, or that the invention is no longer patentable because the inventive concept was published more than one year earlier.

Under 35 USC §102(a), a patent or printed publication of another individual or entity, originating anywhere in the world, that discloses the invention prior to the earliest filing

date of the application under consideration bars patenting of the invention¹. Under this section, publication of the invention (e.g., in a technical journal article authored by a competitor) constitutes anticipation no matter where it occurs, as long as it predates the earliest filing date. Under 35 USC §102(b), inventions that were already patented, or described in a printed publication anywhere in the world, or in public use or on sale in the US more than one year before the earliest filing date may not be patented². Under this section, an applicant's own earlier publications can constitute prior art against the applicant's patent application if the publication occurred more than one year before the filing date.

Because Sections 102(a) and (b) of the patent laws refer to "printed publications," it is important to understand what can be considered a printed publication. Although most people realize that "printed publications" include such things as US or foreign patents, technical journal articles, reference texts, and the like, the list of possible items does not end there. Recent judicial opinions have indicated that the state of technology in document duplication, data storage, and data retrieval systems no longer makes "printing" the only form of "publication." Today, the term "printed publication" is defined as a work that is "disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation"³. Therefore, the question of whether a document is a "printed publication" pivots on the dissemination or public availability of the document to at least those interested in the field, regardless of form (printed, magnetic, digital, etc.).

Given this broad definition, many nontraditional forms of "printed publication" are routinely overlooked by inventors. Advertising brochures, catalogs, magazine articles, conference papers, poster presentations, grant applications, theses and dissertations, online journals, and online advertisements all may be considered "printed publications" under certain circumstances. Moreover, while the US laws provide a one-year grace period for appli-

cants to file a patent application before being barred by their own printed publications, most foreign countries have no such grace period. Thus, a publication disclosing the invention prior to filing a patent application acts as a bar in those countries. As markets become more global, loss of foreign patent protection can have disastrous consequences. It is therefore crucial to be aware of what is being "published" by your company or laboratory in order to prevent premature disclosures. The following examples illustrate several common scenarios.

Scientific meeting presentations

Scientific meetings present several situations in which "publication" of inventions may occur. At a scientific meeting, a printed publication may take the form of abstracts of exhibits published prior to the meeting, a poster session, or an oral presentation.

Abstracts. Meeting attendees who plan to present either a poster exhibit or an oral presentation frequently submit an abstract of their presentation to the meeting organizers. The abstracts are compiled into a volume that is typically made available to all meeting attendees one or two months prior to the meeting, either in print or on a website. Because the abstracts are made available to the attendees (e.g., disseminated to persons interested or skilled in the subject matter), it is likely that the abstracts meet the definition of "printed publication." Therefore, safeguards should be implemented to prevent unwanted disclosures in these abstracts. Ideally, abstracts should be reviewed and edited by patent counsel prior to submission to meeting organizers to make sure that no valuable inventions are prematurely disclosed. In addition, it is often useful to know when the abstracts will become available to meeting attendees, so that patent counsel can prepare and file patent applications in advance of the publication date.

Posters. Poster presentations are also a troublesome area for disclosures. Although no case has explicitly stated whether or not posters displaying scientific data are printed publications within the meaning of the patent laws, it is easy to imagine that a court could determine that the poster is "printed" and that it is available to the public, albeit for a limited time. Of course, if copies of the material

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described on the poster are photographed or are made available to meeting attendees, those copies would most likely be considered printed publications. Thus, the same precautions and safeguards described for meeting abstracts apply equally to posters.

Oral presentations. Oral presentations themselves generally do not constitute "printed publications." Moreover, visual aids, such as overhead transparencies, slides, or computer-based projections that are displayed along with the presentation, have also been held not to constitute "printed publications" because the visual aids are transitory⁴. However, copies of the overhead transparencies or other printed documents made available to the attendees at the oral presentation would most likely qualify as printed publications⁵. Likewise, distributed copies of written transcripts from authorized or unauthorized audio tapes of an oral presentation could also be considered printed publications. Like abstracts and posters, materials intended to be distributed to attendees as part of an oral presentation should be reviewed by patent counsel prior to dissemination.

Submitted manuscripts and online publications

In general, manuscripts submitted to peer-reviewed journals are treated with confidentiality by the editors and reviewers of those journals. The journals often provide written guidelines stating that the submitted manuscripts will remain confidential and will not be released to the public prior to publication. Thus, submitted manuscripts are generally not viewed as being "publications" within the meaning of the patent laws.

It should be noted that the current view of "publication" includes articles available in electronic or digital form, as well as conventional print media. Many journals now offer online publication in advance of the actual printed publication, so it is important to determine in advance the exact dates of both online and printed availability in order to protect any IP prior to publication. The same precautions apply to preprints available through online preprint or e-print servers.

Grant applications

As a general rule, grant applications submitted to a federally funded granting agency are held in confidence by the agency and those individuals reviewing the grant until the grant is funded. However, with the exception of certain types of information that may be considered proprietary or private information that cannot be released, after the grant is funded most grant-related information submitted to federal granting agencies by the applicant is considered public information, and is subject to possible release to individuals or organiza-

tions outside the agency. For example, the NIH routinely makes information about awarded grants, including project title, name of the principal investigator, and amount of the award, available to the public through the NIH Computer Retrieval of Information on Scientific Projects (CRISP) system, available on the Internet. Additionally, the project description abstract is sent to the National Technical Information Service (NTIS) at the US Department of Commerce, and made available to the public. At least one court has held that a grant proposal was a "printed publication" because it was accessible by the public⁶. Therefore, it is important to consider the content of documents provided to federal granting agencies that could thereby become publicly accessible.

The Freedom of Information Act (FOIA)⁷ requires federal granting agencies such as NIH to release certain grant documents and records requested by members of the public, regardless of the intended use of the information. In response to a FOIA request, for example, NIH will generally release information relating to funded applications, pending and funded noncompeting continuations, grant progress reports, and final reports of any audit, survey, or evaluation of grantee performance. NIH will generally withhold information pursuant to a FOIA request relating to, among other things, trade secrets and commercial, financial, or otherwise intrinsically valuable information, information that could affect the competitive position of a person or organization, and patent or other commercial rights (so-called "exempt" information). If NIH has substantial reason to believe that information in its records could reasonably be considered exempt, before the information is released in response to a FOIA request, NIH will notify the grantee, and he or she will be given an opportunity to identify potentially patentable or commercially valuable information that should not be disclosed. After NIH consideration of the grantee's response, the grantee will be informed of the agency's decision regarding which documents will be disclosed. If a document contains both disclosable and nondisclosable information, the agency will delete the nondisclosable information and disclose the balance of the document.

Any organization that receives federal funds for research must keep careful track of the grant process and any FOIA requests so that premature publication of inventions is avoided. NIH actually discourages submission of information that could be considered proprietary unless it is essential for proper evaluation of the grant application. Patent counsel should be consulted regarding the content of the grant application and how best to protect potential inventions that could become public through the grant review process.

Theses and dissertations

Theses and dissertations typically qualify as printed publications under the patent laws. In many cases, abstracts of theses and dissertations are publicly available through various companies (such as ProQuest and UMI) that copyright these works (for example, I was able to find the online citation and abstract to my Ph.D. thesis from Dissertation Express in less than 5 minutes). Additionally, the researcher's university library will contain a catalogued and publicly available copy of the thesis. The Court of Appeals for the Federal Circuit has expressly stated that a thesis that is indexed and catalogued in a university library is regarded as publicly available, and therefore qualifies as a printed publication⁸. However, the same court also indicated that theses that were catalogued by author's name only on cards held in a shoebox are not "printed publications" because they were not reasonably accessible to the public⁹. Based on these holdings, accessibility is crucial, and it is worthwhile to determine not only the content of the thesis, but exactly how it will be catalogued.

Conclusions

Although each potential disclosure situation is different and requires its own analysis under the circumstances, all persons concerned with foreign and domestic intellectual property rights should be aware of all types of printed publications being generated by their organizations. Patent counsel should be engaged early on to make a formal review of all materials that could become public in order to determine whether it is appropriate to file patent applications prior to publication.

1. 35 USC §102(a) states that "[a] person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent...."
2. 35 USC §102(b) states that "[a] person shall be entitled to a patent unless (b) 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...."
3. *In re Wyer*, 210 USPQ 790 (CCPA 1981).
4. *Regents of the University of California v. Howmedica, Inc.*, 210 USPQ 727 (D. NJ 1981) Projection of slides at a lecture was limited in duration and could not disclose the invention to the extent necessary to enable a person of ordinary skill in the art to make or use the invention.
5. *Massachusetts Institute of Technology v. Fortia*, 227 USPQ 428 (Fed. Cir. 1985) Research paper teaching claimed cell culture technique which was presented orally to conference of 50-500 cell culturists and distributed without restrictions to a number of scientists is a printed publication.
6. *E.I. du Pont de Nemours & Co. v. Cetus Corp.*, 19 USPQ 2d 1174 (N.D. CA 1990).
7. 5 USC §552 and 45 CFR Part 5.
8. *In re Hall*, 228 USPQ 453 (Fed. Cir. 1986). See also *Baxter Diagnostics Inc. v. AVL Scientific Corp.*, 924 F.Supp. 994 (C.D. CA 1996).
9. *In re Cronyn*, 13 USPQ 2d 1070 (Fed. Cir. 1989).