

## Publication Clauses and Other Problems Lurking in Sponsored Research Agreements

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Industry-sponsored research and clinical trials are the primary means for investigating the efficacy and safety of medical devices and pharmaceuticals. Enormous financial stakes are often involved in the outcome of these studies. A successful study can lead to substantial funding commitments for startups and other private companies, and a boost in the stock price of public companies. A study showing lack of efficacy or safety can often result in the opposite. Publishing the results in peer-reviewed journals provides a scientific basis for treatment and insurance reimbursement policies, and can help recruit new talent to an organization and help the career of the author(s).

Sponsored Research Agreements and Clinical Trial Agreements (collectively, Research Agreements) often involve hidden problems for a company's intellectual property in the form of unacceptable publication clauses. This article considers some key issues that should be considered in negotiating and drafting publication clauses in such Research Agreements to help ensure that a company is not losing substantial value through poorly worded agreements.

### Prepublication Review

The basic issue is the need to balance timely disclosure of sufficient study results with the temporary secrecy needed to first make patent filings, and to consider trade secret and patient confidentiality issues. Authors tend to have different interests to protect than do the companies sponsoring the research or clinical trial. By ensuring their Research Agreements provide for adequate procedures for prepublication review of proposed publications, companies can better stay in control of this balancing. Failure to take control permits decisions to be made by one or more authors, who often move toward publishing without careful regard to securing patent rights. Prepublication review by a sponsoring company typically involves having authors submit the publication for internal review for a sufficient amount of time before publication. The sponsoring company can then review the proposed publication and will have an opportunity to redact any confidential information or patentable subject matter. With a sufficient review time, the sponsoring company can even have a patent application prepared and filed by competent patent counsel without a need to disrupt the publication schedule.

The sponsor's period of review is typically limited by the Research Agreement language to thirty days, but can typically range from

ten to sixty days. Well drafted Research Agreements will contain a publication clause that is at the longer end of that range, or that provides for an additional short delay of up to sixty days for the sponsoring company to make any needed patent filings before public disclosure of the invention(s). In general, careful consideration should be given to evaluating publication clauses to ensure that no other traps for the unwary lurk in the wording.

### Protecting Patentable Subject Matter

Patent rights may be inadvertently lost when an invention is published or otherwise disclosed to the public prior to the filing of a patent application. In particular, most of the major foreign countries follow a concept of "absolute novelty." In general, publication or public disclosure in the U.S. or elsewhere may result in the loss of patent rights in foreign countries when following the absolute novelty standard, and even in the U.S. if enough time passes between the publication act and the patent filing.

Under U.S. patent laws, publication or public disclosure starts the clock running on a one-year grace period. A patent application must be filed in the U.S. within one year from the date of publication or public disclosure. Some examples of public disclosure include speeches, indexed postings on the web, and records available under the Freedom of Information Act. Another example is merely disclosing a proposed paper to a group of fellow panelists in the absence of a confidentiality agreement. In a recent court case, a publication was disclosed only to a conference chair and posted to an unindexed website. Based on the specific facts, the publication was found not to be an early public disclosure and, after much litigation, the patent survived attack.<sup>1</sup> The best practice, of course, is to have a patent application on file before disclosing anything about a publication outside of the sponsoring company.

Additionally, it is advisable to have a written confidentiality agreement in place before disclosure of the invention to a third party. A written confidentiality agreement is evidence that the inventor(s) (and the sponsoring company) have controlled knowledge of the invention. This helps show the inventor(s) and sponsor have deliberately attempted to keep the invention secret, for example, until any needed patent filings are made. A written confidentiality agreement is not required, however, as long as the inventor can suitably prove that the disclosure to the third party was confidential, such as disclosure to sponsor's intellectual property counsel.

Ensuring sufficient prepublication review rights provides the sponsor with an opportunity to preserve patent rights by filing a patent application before public disclosure of the inventive subject matter. Prepublication review should extend beyond publications (i.e., peer-reviewed articles) to include any type of public disclosures. Some examples of other public disclosures that can destroy patentability and possibly violate other laws include verbal presentations, written abstracts, poster sessions, teaching handouts, grant proposals, indexed postings on the web, and any other public dissemination of information related to the research. Careful drafting of the publication clause can help ensure that there is a legal basis for the sponsor to conduct this review.

Disclosure of patentable inventions to a third party without a confidentiality agreement may and often does constitute a public disclosure. Therefore, it is recommended that the sponsor request a copy of the confidentiality policies of the research institution and consider whether additional written confidentiality agreements may be necessary. For example, some public universities are required by law to disclose everything their faculty puts in writing—including email correspondence—to a sponsor disclosing information about research or trials.

### Protecting Confidential Information

It is rare that innovation is protected solely by patents. Thus, when a sponsor licenses the use or research of an innovation, the sponsor often must provide confidential information and other trade secrets to the investigator. The sponsor should take appropriate measures to prevent the public disclosure of confidential information including trade secrets. The Research Agreement(s) can also be reviewed for suitable confidentiality provisions, which contain various nuances that can greatly weaken or strengthen the hand of the sponsor who is disclosing its confidential information.

For starters, the term “confidential information” should be carefully defined in the Research Agreement. Confidential information can be defined as categories of information (e.g., business processes, drawings); as material that is not publicly available; and, even better, includes some of the specific types of secret information that will be provided to the investigator. The Research Agreement can be drafted to require that all information given from one party to another party is confidential unless otherwise designated, or that any material boldly marked as “CONFIDENTIAL” is confidential information. The definition of confidential information must comply with applicable state laws and not be far reaching. Overly broad confidential information provisions can be stricken in litigation in certain states as being contrary to public policy by limiting competition.

The sponsor should restrict the disclosure of confidential information to only those investigators that require the confidential information to perform their obligations under the Research Agreement. The sponsor should discuss confidentiality issues with each investigator and require that each investigator sign a nondisclosure agreement. Photocopying of material marked confidential should be prohibited unless the photocopying is necessary to conduct research under the agreement. The provisions should require all material marked as confidential to be locked in a safe or otherwise be protected with commercially reasonable measures that are no less than the protections the investigator uses for its own confidential information.

A so-called “sunset” clause can also be included in the Research Agreement. If the confidential information is made public through no fault of the investigators, or if a court or government agency demands disclosure of the information, the confidential information may be disclosed by the investigator, subject to certain recommended limits to help the sponsor intervene if needed.

Finally, the sponsor should review any proposed publications for the disclosure of confidential information and trade secrets and, if

found, require that the information be removed from the publication. Suitable language in the publication clause or confidentiality provisions of the Research Agreement can help ensure the sponsor has this ability.

### Multi-Site Research

If the research or clinical trials involve multiple sites, the right to independently publish may be waived by the individual sites. An individual site, however, may retain the right to publish after completion of the site’s research.

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## Publication Delays

Disputes over the interpretation of the results may delay publication, especially when the results are unfavorable to the sponsor. The Research Agreement should provide investigators with the right to independently analyze and publish the results whether they are positive, neutral, or negative. In fact, most research institutions reject provisions permitting the sponsor to entirely block publication or to decide which results should be selectively published.<sup>2</sup>

Sponsors should consider the legal ramifications of Research Agreement provisions that substantially delay publication of negative data and place severe restrictions on investigators seeking to present competing data. For example, Immune Response Corporation (IRC) delayed the publication of negative clinical trial results and withheld negative data from the researchers to lessen the chances of publication.<sup>3</sup> Even though IRC had knowledge of the negative results, IRC issued a press release that emphasized positive data from a smaller-scale trial. The negative results were eventually published, and a class action lawsuit followed alleging that IRC violated federal securities laws, including false misrepresentations.<sup>4</sup> IRC settled the class action lawsuit for approximately \$9.6 million.

## Export Control Laws—The Investigator's Side

Another often-overlooked issue in conducting research and clinical trials is U.S. export control laws, which govern the export of technology, software, and goods between U.S. and foreign individuals and entities. Before exportation, a government license may be required for restricted technologies, possibly including equipment and samples, and even for the research results alone. The consequences of violating export control laws can be quite severe, including loss of research contracts, fines, and even imprisonment.

Academic and research institutions can qualify for the fundamental research exclusion from the export control law requirements. The fundamental research exclusion is defined as basic and applied research in science and/or engineering at an accredited institution of higher learning in the U.S., where the results of such research has been, or is about to be published. Depending on the category, fundamental research is distinguished from research that is protected for proprietary or national security reasons.

Since the fundamental research exclusion depends on publication, restricting or substantially delaying publication of results can destroy the fundamental research exclusion in a given situation, which can result in fines and criminal liability. The research will not qualify under the fundamental research exclusion if there are: (1) *any restrictions on the publication* of information resulting from the research, other than limited prepublication reviews by research sponsors to prevent inadvertent divulging of proprietary information or to ensure that publication will not compromise patent rights; or (2) the research is federally funded, and specific access and dissemination controls regarding the resulting information have been accepted by the institution or investigator.

Troublesome clauses restrict publication and dissemination of information to foreign nationals on some research projects and

thus, the fundamental research exclusion can be lost because of the restrictions on publication. Some examples of federal government clauses that restrict publication and dissemination are listed below:

Clause	Title
DFAR 252.204-7000	Disclosure of Information
ARL 52.004-4400	Foreign Nationals Performing Under Contract
AFMC 5352.227-9000	Export Controlled Data Restrictions
FAR 52.227-17	Rights in Data, Special Works

In negotiating the language of a Research Agreement, investigators should object to and avoid any restriction on publication other than a prepublication delay allowed for the redaction of confidential information, or to secure appropriate intellectual property protection. If restrictions on publication are accepted, investigators may be required under export control laws to seek and be granted export control licenses before exporting technology in the form of physical products or information. Moreover, the investigator may be liable for violations of export control laws by the sponsor if the investigator knows, or has reason to know of such violations.

## Conclusion

A Research Agreement defines the bargain between the sponsor and investigator and, as such, it should anticipate the emergence of intellectual property and the need to comply with various other laws. Therefore, in drafting and negotiating the Research Agreement, and considering later compliance obligations under such an agreement, emphasis should be placed not only on the scope of performance, responsible parties, and payment provisions, but also on publication rights, recordkeeping, and intellectual property.

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1 *SRI Int'l Inc. v. Internet Security Systems Inc.*, 511 F3d 1186 (Fed. Cir. 2008); see also J. Wolfson and G. George, *Be Careful Where You Save That File*, IPLaw360 (July 24, 2008), available at [www.hayboo.com/be\\_careful\\_where\\_you\\_save\\_that\\_file/](http://www.hayboo.com/be_careful_where_you_save_that_file/).

2 Michelle M. Mello et al., *Academic Medical Centers' Standards for Clinical-Trial Agreements with Industry*, 352 *NEW ENG. J. MED.* 2202, 2204 (2005).

3 P.J. Hiltz, *Drug firm, scientists clash over HIV study*, *CHI. TRIB.*, at N4 (Nov. 1, 2000).

4 J.O. Kahn et al., *Evaluation of HIV-1 Immunogen, an Immunologic Modifier, Administered to Patients Infected with HIV Having 300 to 549 x 10<sup>6</sup>/L CD4 Cell Counts*, 284 *JAMA* 2193, 2193-2202 (2000).