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Ownership Rights of Patentable Inventions in Clinical Studies and a Review of MAGI's Clinical Trial Agreement Template

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When a commercially viable invention arises during the course of a clinical study, determining ownership and other patent-related matters is much easier with a clinical trial agreement (CTA) that clearly addresses such issues in advance.

A patent gives its owner the exclusive right to prevent others from making, using, selling, offering for sale or importing the goods or services that are covered by the patent's claims. Although patents are costly to obtain and maintain, they can be powerful instruments to support the commercial goals of the study sponsor. However, unless the parties' ownership rights are clearly deliniated, effective exploitation of the entire scope of the relevant patents may be hampered. To that end, a CTA that establishes a framework to identify patentable inventions arising during a study, sets forth the parties' responsibilities, allocates ownership rights and addresses the parties' freedom to operate in the space at issue can help avoid future problems for all parties involved.

Patents

Under U.S. patent law, the owner of a patent can prevent competitors from using what is claimed in the patent. The ownership of the patent, however, does not necessarily provide an affirmative right to exercise the scope of the granted patented claims. Having a clear title and the right to practice the patentable concept is an important goal to achieve for parties interested in commercializing their product under investigation.

Study sponsors want to maintain clear, marketable and protectable rights to patentable inventions covering the product under investigation. Academic sites, on the other hand, may want to protect their ability to disseminate and explore such knowledge not only for academic but also, possibly, for future commercial purposes.

In the multiplayer environment of a clinical study, establishing who conceived and contributed to an invention and who has the right to pursue the concept can get complicated. Patent conception is based on the complete performance of the mental part of the inventive act. It is the formation of a definite and permanent idea of the complete and operable invention. Under the U.S. patent regime, the persons who conceive the invention are the inventors and the first owners of the patent rights derived therefrom. In other words, a patent application and any resulting patent are first owned by the inventors of the claimed invention. The inventors can subsequently assign or tranfer their rights to their respective employers or third parties.

As the scope of a claimed invention may change during the patent procurement phase, the inventors' degree of contribution and, eventually, the ultimate list of inventors may also change. Maintaining an accurate list of inventors throughout the patent procurement process is a delicate and continuous task during the prosecution of the patent application. Moreover, access to the inventors may become an issue throughout the patent procurement

phase, as well as throughout the life of the patent. The CTA should specify responsibility for keeping track of events related to ownership.

The date of execution of the CTA vs. the date that a patentable invention was conceived are two other factors that can be crucial in establishing proper ownership rights in a patent conceived during a clinical study. This information helps in categorizing the patents that may be at issue.

Preexisting Patents

Negotiating the ownership of preexisting technology is relatively straightforward for the parties because the respective inventors and their assignees or employers have more likely identified, inventoried and processed their own patentable inventions before entering into the CTA. Such technology generally continues to be owned by the original inventors of that technology or their respective assignees. Access to such technology may be negotiated in the CTA by various legal mechanisms, such as a license, an option to license, an assignment, a covenant not to sue, or a non-compete clause.

CTAs use different nomenclature to define preexisting and background technologies and to allocate respective ownership rights. Commonly used terms include "institution inventions," "sponsor inventions," "background technology" and "background patent rights." MAGI's Clinical Trial Agreement Template[1] addresses the preexisting patent rights under the definitions of "Institution Inventions" and "Sponsor Inventions." For example, the MAGI Template (paragraph 9.2) provides that

> Institution shall own all right, title and interest in and to all Inventions (other than Study Inventions) that are made solely by Institution, Investigator or Study Personnel, and in each case together with all intellectual property rights relating thereto.

Similar language can be included to differentiate the sponsor's inventions. Doing so provides a reasonable certainty as to the ownership of any preexisting or background knowledge that is patented or undergoing patent prosecution.

Patentable Inventions During the Term of a CTA

Determining ownership rights in patentable inventions created during the term of the CTA is more complicated than for the preexisting and background technologies. Typically, two types of patentable inventions are at issue in such cases: (a) those that have a direct link to the study protocol or product, and (b) those that do not have a direct link but have been conceived through a joint collaboration between the research site and the sponsor.

The first category typically involve concepts that are protocol driven. For example, a research site might observe unique therapeutic benefit in a subpopulation among the study subjects who receive the study drug or device. In another example, a synergistic effect with another drug or device may be observed while the site's employees are following their respective subject--study participants. Regardless of whether this observation is a function of accidental deviation from the study protocol or not, the study sponsor will, naturally, want the option to own such inventions. Accordingly, patentable inventions that have a direct link to the study protocol or product and that may be expressed or naturally derived from the study protocol or the product are more likely to be assigned to the sponsor.

Ancillary to such circumstances are those inventions that are derived from confidential information shared by the sponsor relating to the study protocol or the product. These types of inventions, when identified, should also be assigned to the sponsor. One argument in favor of such position is that the sponsor is funding the research and the site would not

have been able to conceive the invention in the absence of the study or the sponsor's confidential information. As the sponsor's competitive advantage relies on protecting its product from competitors, sponsors are more likely vested in prosecuting patent applications and are in the best position to exploit the invention for the benefit of the public.

The MAGI Template (paragraph 9.1) grants ownership of such patentable inventions to the sponsor. It first defines "Study Inventions" to include all inventions (inclusive of all patentable inventions) that are conceived by investigator or study personnel

> (i) that incorporate or use Sponsor's Confidential Information, or (ii) that are directly related to the Study Drug and/or Study Device and all such rights relating thereto to the Sponsor.

It then assigns the right to the sponsor by declaring that Study Inventions "will be the sole and exclusive property of Sponsor."

Tracking ownership rights of an invention may be more complicated in the absence of a direct link to the study protocol or product and where the conception is realized through joint efforts of the parties. These scenarios may occur when the research site's personnel propose or identify an issue that could lead to an amendment to the protocol or when the site employee or investigator conceives a new way to administer the study drug or implant a medical device. The research site will, naturally, want the option to own such invention as the new observation relates only indirectly to the study protocol.

In these circumstances, all collaborators can assume inventorship rights. In the absence of a negotiated framework, the ownership rights of the resulting patent can get complicated, and more likely will be jointly owned by all declared joint inventors. Such scenarios may have different consequences in different jurisdictions. They can lead to ownership disputes, particularly if each inventor exploits the patent or grants licenses to the patent without permission of or to the detriment of the other joint owners.

Including a joint ownership provision in a CTA can remedy potential complications. In addition to defining a "joint invention," the parties can also agree to include a mechanism for how to proceed when faced with a joint inventorship situation. The roadmap provided in the MAGI Template (paragraph 9.2) defines the scope of a joint invention:

> Sponsor and Institution shall jointly own all Inventions other than Sponsor Inventions and Institution Inventions that are jointly made by Institution, Investigator or Study Personnel and one or more employees, agents, independent contractors or related personnel of Sponsor and, in each case, together with all intellectual property rights relating thereto ("Joint Inventions").

The MAGI Template (paragraph 9.2) then allocates related obligations to the parties.

Chain of Title and the Parties' Responsibilities

Perfecting the chain of title and the parties' responsibilities should be addressed during the CTA negotiation. Regardless of the instrument — an employment, a consulting or an assignment agreement — the parties should strive to facilitate and articulate an appropriate mechanism for transferring the chain of title. (A "chain of title" is the historical sequence of transfers of title to the patentable invention that affords the patent owner proper standing to enforce its rights available under the patent.

The MAGI Template (paragraph 9.3) establishes a timeline to initiate the negotiation process of transferring invention rights from the site to the sponsor:

> Institution hereby grants to Sponsor the first option to negotiate for an exclusive (or, at Sponsor's election, non-exclusive), worldwide, royalty-bearing license, with the

> right to sublicense, under Institution's interest in any and all Institution Inventions and Joint Inventions for all purposes on reasonable and customary terms and conditions (the "Option"). Sponsor shall advise Institution in writing within ninety (90) days after Institution's disclosure to Sponsor of a particular Institution Invention or Joint Invention (such 90-day period, the "Option Period") whether it wishes to exercise its Option with respect to such Invention. If Sponsor exercises its Option with respect to a particular Institution Invention or Joint Invention, the Parties shall in good faith negotiate the terms of a license agreement, for a period of up to six (6) months from the date on which the Option is exercised, or …

Most such clauses attempt to create a framework whereby the parties can reach a degree of confidence regarding future ownership rights in a patentable invention. The parties may negotiate option language that includes different periods or other means in order to fairly benefit both parties.

Conclusion

Patentable inventions during clinical studies are relatively unlikely, especially in late-stage studies. However, they do occur and can be very valuable. Study sponsors and sites should therefore negotiate relevant CTA terms consistent with an invention's likelihood and likely value to each party. These terms should include a framework for indentifying the inventors and establishing a proper transfer of ownership that creates a reasonable degree of confidence as to the chain of title for any patentable invention arising during the course of the study.

Reference

1. Several versions of MAGI's Clinical Trial Agreement Template can be found at www.magiworld.org/Standards. This article refers to the industry-sponsored-study version of the Template, titled "MAGI's Clinical Trial Agreement Template."

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