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Top 10 Considerations When Drafting and Negotiating SRAs, with U.S. and EU Perspectives

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Sponsored Research Agreements (SRA) are used by companies to contract a research organization, such as a university, to conduct research and development activities in exchange for fees and the university's rights to use the results for general research purposes. Care should be taken to ensure intellectual property (IP) of the sponsoring company (Sponsor) is properly secured. In this latest edition of MoFo's LST + L Top 10, we provide a list and explanation of our top 10 issues to consider when drafting and negotiating SRAs with universities, and we cover some of the distinctions that arise under U.S., EU, and German law.

1. Consider a Limited License Grant to Sponsor's Background IP

A research partner may need access to the Sponsor's background IP to conduct the research and development activities that are the subject matter of the project to which the SRA relates. The Sponsor should consider limiting any license to Sponsor's background IP to include the IP necessary for the research partner to conduct the research and development pursuant to the SRA for the benefit of the Sponsor. Sponsors frequently limit any such license in both scope and duration, solely for the performance of the services to be provided by the research partner, consistent with the scope of the project, and pursuant to the terms of the SRA. Any license to Sponsor's background IP is commonly non-exclusive to avoid interference with the Sponsor's and its other licensees' use of the licensed IP.

Sponsors should also consider obtaining a present assignment of all improvements to its background IP that the research partner creates (either solely or in conjunction with the Sponsor) during the term of the SRA. Since a patent does not grant a patent holder any right to improvements,

without an assignment, care should be taken to ensure that the research partner is prevented from blocking the Sponsor from practicing an improvement to its invention. When drafting the applicable assignment, it is critical that the assignment clause includes language that will be enforced to ensure automatic assignment to the Sponsor of all future interests in the improvements at the time of its creation. The phrase “hereby assigns in advance” is commonly appropriate, depending on the applicable circumstances.

2. Allocating Project IP Can be Challenging

A Sponsor may request complete ownership of the new intellectual property developed during the research project (commonly referred to as foreground IP). Unless the SRA is a services agreement, research partners commonly push back and seek to assert ownership rights to foreground IP. This is particularly true if the research partner is a university because it may want the public to have access to the IP, if the research is partially funded by the government or if the foreground IP is developed based upon the research partner’s background IP.

As a consideration for the Sponsor’s ownership of foreground IP, the research partner may ask for a license to use foreground IP for its own research and non-commercial purposes. It’s also true that research licenses may be mandatory in sponsored research projects conducted in the EU due to antitrust laws. Attention should be paid to the language of such research license to ensure that it does not interfere with the Sponsor’s right to grant licenses in the future and, to the extent admissible, that it excludes any direct or indirect commercial use. When universities require ownership of foreground IP, Sponsors commonly seek an exclusive license to use and commercialize the foreground IP. If further concessions need to be made to the research partner, exclusivity can be limited to specific field of use. In any license scenario, Sponsors should pay close attention to diligence requirements associated with licenses from research partners. These provisions often provide a step down from exclusivity to non-exclusivity or, eventually, a termination of the license, if the Sponsor neglects to use the foreground IP or fails to meet certain milestones.

Sponsors and research partners may also consider joint ownership of foreground IP. Joint ownership provisions need to be carefully crafted to address

the type of IP involved and the abundantly different requirements for joint ownership in various jurisdictions. For example, whereas in the United States each patent co-owner can freely grant licenses to third parties without a duty to account, under German law, a license will generally require the consent of the co-owner and may involve sharing of proceeds. While often complex and heavily negotiated, joint ownership of foreground IP is an option for Sponsors and research partners.

Finally, Sponsors must also obtain adequate access to the research partner’s background IP, if contained in the research results or otherwise necessary to use research results or any of the foreground IP, in order to avoid being blocked from use and exploitation.

3. Beware of the Limitations on Federally Funded Research and State Aid Laws

In the United States—and even more so in the EU—research institutes, like universities, are often state owned or state funded. Public funding and additional restrictions and obligations in an SRA commonly go hand-in-hand.

In the United States, if the research is partly funded by the federal government, the Sponsor should be aware of the restrictions and the federal government’s rights to the resulting inventions and its university partner under the Bayh–Dole Act, which is the federal legislation that permits ownership of patents resulting from federally funded research to remain with inventors and their employers. One particular restriction to note, inventions resulting from the project will have to be manufactured substantially within the United States. Furthermore, the funding federal agency will have a nonexclusive license to the research inventions and the “march-in rights” to grant a third party an exclusive or non-exclusive license if the university does not take reasonable steps to use or commercialize the inventions or if the inventions will not be manufactured substantially in the United States.

If the research does not require government funding, the Sponsor should obtain a representation from the university that the university will not use any government funding for the research. If government funding is necessary, SRAs commonly include a mechanism to separate the government-funded research from the research funded entirely by the Sponsor.

In the EU, to the extent patentable inventions are concerned, there is a trend that publicly funded universities oppose an upfront buyout and assignment of foreground IP and instead merely offer an option to acquire rights in such inventions at fair market value. There are similar trends with respect to access to background IP. The reason for this is that these institutions are concerned that fully paid-up upfront assignments (or licenses to background IP) will be considered illicit state aid. Sponsors are well-advised to have a solid understanding of the anticipated value created by the research partner and fund their projects appropriately.

Moreover, if the SRA is part of a wider EU or German government grant, the grant conditions may add more limitations on the Sponsor's ability to dispose of the research results. Examples are mandatory use and exploitation requirements within the EU or Germany and approval requirements for exploitation of research results outside the EU.

4. Unfettered Publication Rights May Affect the Patentability of the Research Inventions and Loss of Trade Secrets

University partners commonly seek the right to publish or publicly present the results or study data from the research under an SRA to maximize public access to the data. Without a mechanism in place to control the scope and forum of such disclosure, a Sponsor may risk losing the confidentiality and trade secret status of its proprietary information. Furthermore, the publication may be deemed a prior art disclosure, which may severely affect the patentability of the research inventions.

A Sponsor often requests that a procedure be in place that requires the university to provide the Sponsor with the content of the publication well in advance, a right to review such content over a specified period of time, and the right to request, and often require, the removal of any of the Sponsor's confidential information or trade secrets contained within the proposed publication. Sponsors may also seek to impose an "embargo period," which is a specified period of time during which the university cannot publish the research results. The embargo period would be a sufficient period to allow the Sponsor to evaluate and file patent applications for the resulting inventions.

Sponsors commissioning research in the EU should also be aware that in certain EU countries (e.g., Germany), if not contracted away, university scientists may have statutory rights to either publish their research results or to elect not to disclose their research results at all.

5. Consider Limiting Sponsor's Indemnity Obligations

Overlooking indemnification provisions, often considered boilerplate, can be a serious mistake for a Sponsor. Failing to pay attention to an indemnity provision in terms of application and scope may result in Sponsor's indemnity obligations extending to indemnification of all costs and expenses incurred by the university resulting from third-party claims and direct claims. In that case, the Sponsor may have to cover attorney's fees and litigation expenses for its research partner in direct lawsuits between the research partner and the Sponsor. Additionally, Sponsors shouldn't overlook the scope of the indemnification (*i.e.*, from the Sponsor's use or sale of the embodiments of the project research only) and include carve-outs that exclude damages caused by the university's gross negligence, intentional misconduct, or the illegal actions of the university's principal investigator. It is also common to include the Sponsor's right to control the defense and settlement of the indemnified claims.

6. Consider Impact That a Change of Control Has on the SRA

Sponsors are often emerging growth companies, venture-backed companies, or companies who are otherwise anticipating some sort of exit in the future. These companies may likely go through different rounds of funding, asset sales, and public offerings during their life cycles. It is important that these significant events not be delayed, impacted, or conditioned by the requirement to obtain consent from a research partner pursuant to an SRA. Sponsors should be mindful to draft assignment clauses in order to permit the Sponsor to assign the SRA freely in important events such as an equity sale, asset sale, merger, or an assignment by operation of law.

7. Pay Attention to the Effects of Termination

While it is important to pay attention to the scenarios pursuant to which an SRA may be terminated, termination provisions also commonly address the consequences following the termination. Ideally, the SRA should require the automatic reversion of any background IP licenses granted to the research partners. If the research partner needs to use the Sponsor's background IP for wind-down activities following the termination, the parties should clarify the scope and limited term of the license for those activities. Additionally, consider what obligations will survive the termination of the SRA. For example, as a market standard, Sponsors and research partners often agree to a continued term, of a specified period of time, for the confidentiality obligations to the exchanged confidential information (other than trade secrets, the confidentiality of which commonly continues as long as the information remains a trade secret or as long as permissible under applicable law). Additionally, restrictions on publication of the study data often survive the termination of the SRA.

8. Consider Nondisclosure Agreements between the Research Partner and its Third-Party Advisors and Contractors

Research partners often require the ability to disclose the Sponsor's proprietary information to its third-party advisors or contractors, often in order for the research partner to support the project pursuant to the statement of work or other scope document that is part of the SRA. Sponsors should take care to expand the scope of information subject to the confidentiality obligations of the SRA to include all of the information disclosed by the Sponsor to the research partner, whether or not the information is marked "confidential," "proprietary," or with some other similar marking. Additionally, Sponsors can limit the disclosure by the research partner to any third party to a "need-to-know" basis and only in order for the research partner to fulfill its obligations and requirements pursuant to the SRA. Additionally, SRAs often include a requirement that there be a confidentiality agreement between the research partner and each recipient of the Sponsor's confidential information that is at least as protective of

the Sponsor's confidential information as the terms of the SRA. Note that absent such an agreement, a third-party consultant or advisor may freely disclose the Sponsor's confidential information, trade secrets, and patentable subject matters.

9. Right to Control Patent Prosecution and Enforcement

It is important to ensure that the SRA provides clarity with respect to whether the Sponsor or the research partner will control patent prosecution and enforcement actions and how the costs and awards resulting from enforcement actions will be allocated. When allocating the rights to control patent prosecution and enforcement, note that it is common that the owner of the applicable intellectual property have the first option to take control over the prosecution process and any associated enforcement. Furthermore, if the parties agree on joint ownership of foreground IP, consider including in the SRA obligations of both parties to cooperate and join in an infringement lawsuit.

10. Establish Proper IP Assignment Agreements between the Research Partner and the IP Contributors

A university often involves its faculty members, staff, or contractors in conducting the research under an SRA. If there are no IP assignment agreements between the university and the IP contributors, the contributors may claim rights or ownership interests in the Sponsor's intellectual property. Consequently, SRAs often contain representations from the research partner that it has properly entered into assignment agreements with individuals and entities involved in the research, which enable the transfer of rights or the license of IP from the research partner to the Sponsor. In some cases, the Sponsor may ask the university to provide forms for IP assignment agreements entered into between the university and its IP contributors as part of the diligence process.

In the EU, and particularly in Germany, it is also common practice for Sponsors to enter into an additional agreement with faculty members of the university research partner that are crucial for the research project. This is due to certain research privileges that prohibited the university to assign research scientists to a specific project and to seek waiver of the right to conceal research results (*see* section 4).

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