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Joint Research Considerations As Biotech Responds To Virus

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The biotechnology industry's response to COVID-19 has been swift. Biopharmaceutical companies across the globe are entering into fast-forming collaborations to rapidly develop new vaccines, treatments and diagnostics to alleviate the impact of this pandemic. These joint efforts are forming between those in the private sector, governmental and nongovernmental entities, and academic institutions.

Well-crafted legal agreements can facilitate scientific collaboration by offering their participants assurances that the results of their joint efforts will be well-managed. Here we offer some key legal considerations for those engaging in joint research endeavors.

The Biotechnology Sector's Response to the Threat of COVID-19

COVID-19 has spurred a surge of collaboration within the biopharmaceutical industry. United against an urgent and pressing public health crisis, companies are investing significant resources to rapidly develop novel vaccines, testing platforms and treatments. GEN Magazine has identified more than 160 drug and vaccine pipeline candidates focused on COVID-19.[1] And as of April 21,the Lancet has reported that over 500 clinical trials have been registered at the various international and national clinical trial registry sites.[2]

Examples of private sector collaboration include:[3]

- AbbVie Inc.'s partnership with global authorities to investigate the efficacy of repurposed HIV medicines for application to COVID-19;
- Alnylam Pharmaceuticals Inc.'s expansion of its collaboration with Vir Biotechnology Inc. to advance RNAi therapy;
- BioNTech SE's collaboration with Pfizer Inc. to develop mRNA vaccine candidates;
- CSL Behring LLC's alliance to develop a plasma-derived therapy for treating COVID-19;

- Grifols SA's sharing of technology in convalescent plasma and work on diagnostic and screening tests;

- GlaxoSmithKline PLC's partnership with the University of Queensland and Clover Biopharmaceuticals and five other partners to support vaccine candidate research and development;

- Johnson & Johnson's use of Janssen Pharmaceuticals Inc.'s AdVac and PER.C6 technology to find a vaccine candidate;

- Eli Lilly and Co.'s and AbCellera's agreement to co-develop antibody products for treatment and prevention;

- Novartis AG's involvement in a range of collaborative research and development efforts;

- Seqirus' donation of its adjuvant technology, MF59, to a preclinical development program; and

- Southern Research Institute's co-development of the vaccine TNX-1800 in collaboration with Tonix Pharmaceuticals.

Legal Protections for Collaborative Research and Development

Joint research has the advantage of allowing partners to share resources and expertise, but it can present challenges when it comes to determining ownership and use of research assets and assigning financial responsibilities. While burdensome at times, having these legal protections in place before engaging in joint research will ultimately facilitate greater collaboration.

Collaborative research agreements come in many flavors, including sponsored research agreements, grants, licenses, material transfer agreements, equipment loan or lease agreements, visitor or visiting faculty agreements, public use of university facility or equipment agreements, and the like. They may also involve participants including nonprofits, academic institutions, commercial entities, governments or government agencies, foreign entities, and individuals.

Key Things to Consider When Forming Research Collaboration Agreements

There are a handful of legal considerations that frequently arise in the context of joint research. Thinking about these issues in advance and addressing them contractually can help avoid many of the risks and pitfalls that parties have faced in the past when they collaborate.

1. Set clear expectations regarding ownership, responsibilities and recourse.

Even with the best of intentions, parties to a collaboration should consider the division of research assets and responsibilities, financially and otherwise. This includes ownership of materials and data, how intellectual property will be assigned and managed, how the costs of labor and equipment will be allocated, and who will perform record keeping and periodic review.

Absent unique circumstances, a collaboration agreement should include strong nonagency language specifying, for example, that neither party has the authority to bind the other and that the joint research

agreement should not be construed as creating an employer/employee relationship, joint venture, partnership, or other such joint relationship between the parties.

If the parties intend for intellectual property arising from the joint research to be co-owned, the agreement should address ownership of inventions. Absent such an agreement, the default rules of inventorship and ownership under U.S. patent law will generally apply. One goal of a well-crafted collaboration agreement is to avoid inventorship disputes and disruptive tactical behavior. This can arise where agreements allocate ownership based on who is named as an inventor. To avoid this, it is advisable to contract for ownership independent of inventorship.

It is not uncommon for one party in the collaboration to take primary responsibility for drafting and prosecuting patent applications for inventions resulting from joint research. The agreement should specify this arrangement to ensure that prosecution activities are coordinated. Such a provision should also specify who will be responsible for paying maintenance fees. The agreement should also require assignment of rights by inventors to their respective companies.

As in other contexts, a collaboration agreement should include confidentiality provisions, including any limitations and permissions applicable to publication. Parties will want to account for differing attitudes toward publication and set expectations accordingly. One way to balance the interest in allowing scientists to keep the public informed while minimizing the creation of prior art is to specify a process for having counsel review material before it is released publicly (e.g., abstracts, presentations, press releases). Given the rapid progress being made with respect to COVID-19, such provisions should be given considerable thought.

The agreement should also specify procedures for termination and amendment and include standard conflict of laws, venue, severability, and no waiver provisions. If the agreement takes the form of a contract, the offeror should provide consideration and the agreement should explicitly state the consideration.

2. Include provisions for commercialization, licensing and enforcement.

A collaboration agreement should also include provisions addressing commercialization, licensing and enforcement of subject intellectual property. In most cases, the allocation of such rights depends fundamentally on the parties involved and what they regard as the objective of the research — whether that is performing clinical testing or conducting basic research.

In some cases commercial embodiments will be known prior to entering into the agreement, in many cases they will not. In either situation, parties should carefully consider which rights associated with subject intellectual property are to be exclusively controlled and which rights are to be shared. Parties are typically best-situated to reach an agreement on such terms before research is underway.

3. Consider employing a joint research agreement under the CREATE Act.

One form of collaborative research agreement is a joint research agreement as defined by the Cooperative Research and Technology Enhancement Act of 2004.[4] The CREATE Act amended the patent laws to provide applicants the ability to disqualify certain prior art arising out of collaborative research endeavors.

To obtain the benefits of the CREATE Act, a qualifying joint research agreement must be in place. The

agreement must be signed by the parties before a subject patent application is filed and any corresponding invention must be made as a result of activities undertaken within the scope of the agreement. The agreement may be amended to add new parties or alter the field of the activity, but any such amendment must be in place before a patent application within the amended scope of the joint research agreement is filed. Preferably the agreement should expressly identify itself as a "joint research agreement" for purposes of the CREATE Act.

The joint research agreement should be executed by all parties before any information is exchanged between collaborators and before work is started. If collaboration is already underway, the agreement should be executed as soon as possible to minimize the risk that prior art has been created. The agreement should also clearly identify the date of entry into the agreement and the parties to the joint research agreement.

To maximize entitlement to the benefits of the CREATE Act, the scope of a joint research agreement is usually defined broadly, but this needs to be balanced against any interests the parties may have in circumscribing the collaboration. The scope of the agreement should be amended if joint research activities change or evolve over time. The agreement should require that all patent applications arising from the joint research agreement include, or be amended to include, notice of the agreement and all parties to it.

There are potentially significant pitfalls associated with enforcing patents that relied on the CREATE Act to gain issuance and they should be discussed with counsel. It is also important to note that, unless the joint research agreement specifies otherwise, parties can unilaterally invoke the CREATE Act when independently seeking patents on inventions within the scope of the collaboration. As a practical matter, this means that any party to a joint research agreement could invoke the CREATE Act to overcome rejections and secure patents to incremental inventions that would otherwise be obvious based on the collaborative work.

In such a situation, parties to the joint research agreement may have diverging interests that make this undesirable. For example, if there are no prior agreements in place as to incremental inventions, those incremental inventions could create freedom to operate issues down the road for one or more of the other parties to the joint research agreement. Parties to a joint research agreement can contract to neutralize this effect by, for example, including a requirement that any party invoking the CREATE Act must first notify all other parties. This can be accompanied by a veto right held by the other parties to the joint research agreement, allowing them to restrain CREATE Act invocation by the invoking party if necessary.

Finally, patents arising out of patent applications filed prior to entering into a joint research agreement cannot invoke the CREATE Act. As a result, careful coordination as to how different families of patent applications are prosecuted is necessary to avoid unintended and insurmountable rejections.

The Role of Intellectual Property in Meeting a Public Health Crisis

The response to COVID-19 will yield important innovations, the protection of which ensures that these significant research and development investments can make the financially intensive transition to becoming accessible commercial solutions. Intellectual property plays a crucial role in ensuring that those who have invested time and resources to combat the threat of COVID-19 can continue investing resources to address these challenges and whatever others the future may hold.

Indeed, many of the innovations resulting from these collaborations will have applications outside the COVID-19 context. Intellectual property for those innovations will be essential to supporting commercialization of those applications independent of the current crisis.

From mass producing penicillin during World War II to developing a vaccine against the Ebola virus, the biopharmaceutical industry has a long-standing history of working closely with governments to address public health crises by providing uninterrupted access to innovative lifesaving products. And there are a growing number of examples in the response to COVID-19.

For example, Johnson & Johnson announced that it is investing $1 billion in COVID-19 research and has committed to expanding its manufacturing capacity to help bring an affordable vaccine to the public on a not-for-profit basis for emergency use.[5] Gilead Sciences Inc. has also offered its 1.5 million dose supply of remdesivir at no cost to patients with the most severe symptoms.[6]

COVID-19 has created new and compelling reasons for rapid scientific collaboration. Well-crafted legal agreements facilitate scientific collaboration by offering their participants assurances that the results of their joint research will be managed properly and predictably.

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[1] Alex Phillippids, Vanquishing the Virus: 160+ COVID-19 Drug and Vaccine Candidates in Development, GEN (Apr. 13, 2020), available at https://www.genengnews.com/a-lists/vanquishing-the-virus-160-covid-19-drug-and-vaccine-candidates-in-development/.

[2] Kristian Thorlund et al., A real-time dashboard of clinical trials for COVID-19, The Lancet (Apr. 21, 2020), available at https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30086-8/fulltext#figures; see also Matt Apuzzo and David D. Kirkpatrick, Covid-19 Changed How the World Does Science, Together, The New York Times (Apr. 14, 2020) available at https://www.nytimes.com/2020/04/01/world/europe/coronavirus-science-research-cooperation.html; Joseph Walker, Peter Loftus, and Jared S. Hopkins, Scientists Rush to Find Coronavirus Cure—but It Still Isn't Fast Enough, The Wall Street Journal (Apr. 6, 2020), available at https://www.wsj.com/articles/inside-the-race-to-find-a-coronavirus-cure-11586189463.

[3] Biotechnology Innovation Organization, Coronavirus Resources, Biopharmaceutical Innovators Lead the Charge in Fight Against Coronavirus, available at https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus.

[4] 35 U.S.C. § 100 defines "joint research agreement" as "a written contract, grant, or cooperative agreement entered into by 2 or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention."

[5] Jonathan Shieber, Johnson & Johnson partners with BARDA to fund $1 billion in COVID-19 vaccine research, TechCrunch (Mar. 30, 2020), available at https://techcrunch.com/2020/03/30/johnson-johnson-partners-with-barda-to-fund-1-billion-in-covid-19-vaccine-research/.

[6] Linus Chua, Gilead to Donate Experimental Coronavirus Drug Remdesivir, Bloomberg News (Apr. 4, 2020) available at https://www.bloomberg.com/news/articles/2020-04-04/gilead-to-donate-experimental-coronavirus-drug-for-140-000-cases.