A Proposal for New Principles and Agreement Terms for Management of Intellectual Property Arising from Research Institution Programs Supported by Disease Foundations

The interests of universities, research hospitals, and non-profit research institutes (hereafter referred to together as "Research Institutions") are completely aligned with those of the disease foundations, non-profit societies and associations ("Foundations") in their desire to develop intellectual property ("IP") from the supported research into therapies for patients.

As experienced technology licensing officers, we understand and agree with the Foundations' desire to exercise good stewardship of the IP arising from their funding. We disagree on some of the required licensing terms that may, in practice, actually discourage industry's investment in the development of the IP, thus essentially preventing the therapies from reaching the patient.

For example, many Foundations require a fixed ("non-negotiable" in the research agreement) commercialization timeframe that may not be appropriate for very early-stage technologies. Many Foundations have clauses in their research agreements allowing them to strictly control how and to whom the intellectual property is licensed. More contentiously, some Foundations have insisted on the right to unilaterally "march-in" on Research Institution licensees to modify, or even terminate, the license if the Foundation believes that the company is not diligently pursuing the commercial development of the technology.[1]

These terms, often included as non-negotiable considerations under many Foundation awards, may in some cases discourage or even prevent commercialization. Joint strategy discussions both before and during commercialization efforts, rather than fixed non-negotiable terms, would be a more productive approach to bringing the strengths of all parties to bear on moving inventions toward patient treatments.

Since much of the IP arising from Research Institutions is at a very early stage, attracting investment for development is often difficult. These inventions arise from good science, but their commercial feasibility is unproven. It will take many years and tens if not hundreds of millions of dollars invested in development to bring these inventions to

[1] The Bayh-Dole Act allows the Federal government to "march-in" if it believes that Federally supported IP is not being diligently developed by an exclusive licensee. However, in the 35 years since the implementation of the Bayh-Dole Act, these march-in rights have never been exercised despite occasional competitors of licensees requesting march-in. The Federal government recognizes that exercising such rights will have a chilling effect on licensing by Research Institutions and should be exercised only in extreme circumstances. Technology transfer offices are therefore able to assure potential licensees that if reasonable efforts are made toward development, march-in by the Federal government is extremely unlikely.

market - and many will fail despite dedicated intention, substantial investment and capable development expertise.

Because of the high cost of development of these early stage inventions with very long times to market and high risk of failure, established pharmaceutical companies are often reluctant to invest in them. The Research Institutions are therefore often dependent on startup companies and their venture investors to develop the inventions to a level of maturity that will allow the startups to partner with the pharmaceutical companies to bring the products to market (or, very rarely, to attract sufficient capital for the startup to commercialize the product on its own.)

We strongly believe that clauses in Foundation agreements that allow modification or even termination of licenses by the Foundations if a licensee is not meeting certain date-specific milestones ("march-in rights") will greatly hinder investment. The path to development is too uncertain for investors to risk millions of dollars in a startup whose license could be unilaterally terminated by a third party (e.g. a Foundation) if a performance date is not met due to circumstances beyond the company's control. Our experience teaches us that investors will not even begin due diligence to evaluate an opportunity if they see such terms in the original research agreement that led to the IP. Similarly, established pharmaceutical companies will neither take an early license to the IP nor invest later in a partnership with a startup company if third party decision makers can endanger their investments.

The following proposal strikes a compromise intended to assure diligence in the development of Foundation-supported IP while attracting investment in such development by venture investors and established pharmaceutical companies.

We propose the following concepts for consideration:

1. Keeping the Foundations Informed:

We propose that Research Institutions notify the Foundation of their intent to grant both non-exclusive and exclusive commercial licenses in relevant patentable inventions.

2. March-in Rights:

Foundations are under increasing pressure from donors to demonstrate progress in developing effective treatments for diseases. Foundations, therefore, are concerned that Research Institutions and their licensees are diligent in pursuing the commercialization of inventions that arise from their research support. Foundations have proposed that failure to meet deadlines in the Research Institution's or licensee's plans to commercialize inventions could result in license termination or transfer of rights in Foundation-supported inventions to the Foundation ("march-in"). These march-in rights introduce uncertainties that are very problematic to potential licensees, generally discouraging them from investing significant resources in the development of an invention.

We propose the following steps to address these Foundation concerns:

- For all relevant patentable inventions, the Research Institution and Foundation will meet and discuss in good faith the development of a mutually agreeable commercialization plan - either through further Research Institution research, through other Foundation-supported research, or through licensing.

- The Research Institution will provide periodic reports that will include feedback from companies.

- If the Foundation has concerns with the Research Institution's activities in pursuit of the commercialization of patentable inventions, the Foundation will notify the Research Institution and request a meeting to discuss the progress against the mutually agreed upon commercialization plan.

3. Definition of "Foundation Inventions"

When is an "invention" made?

From a patenting and licensing perspective, a complete invention is formed when it has been conceived and reduced to practice. The dilemma for most Research Institutions is that many inventions are conceived but not reduced to practice sufficiently for a patent application to be filed. Often, an invention has been conceived under previous funding and the Foundation may help fund the reduction to practice, or vice versa. Other times, a Foundation may fund both the conception and reduction to practice of an invention.

Given the trade-offs, we propose that the Research Institution report to the Foundation any invention disclosure that lists the Foundation as a research sponsor. However, if it is determined that the reported data is insufficient to support a patent application, the Research Institution will notify the Foundation of its decision not to file. If, by the time Foundation funding is complete, the invention has not been reduced to practice, the Research Institution must be free of any further obligations to the Foundation in order to attract future sponsors. On the other hand, where conception of the invention may have preceded the Foundation's funding, but data sufficient to support a patent application is first is obtained under Foundation funding, the Foundation will be notified. Any reporting or financial obligations will adhere to the patent even though the initial conception was made before Foundation funding.

4. Principles and Guidelines for Granting Exclusive Licenses:

If the Research Institution has developed and published principles or guidelines for granting exclusive licenses, it will provide a copy to the Foundation. To the extent that these do not directly conflict with Foundation policies, the Foundation will defer to the Research Institution's principles and guidelines.

It is recognized and accepted that such guidelines are recommendations and not intended to be contractually binding. As such, they are intended to set licensing priorities consistent with institutional missions and to provide flexibility to accommodate case-specific circumstances. Licensing decisions should be based on the best commercialization path for the specific invention.

The Research Institution will provide the Foundation with a draft license agreement, including the commercial due diligence plan to be undertaken by the licensee, at least 30 days prior to granting an exclusive commercial license. If the Foundation provides comments within 30 days, the Research Institution will respond to these comments and work in good faith with the Foundation and potential licensee to accommodate these requests.

The Research Institution will not need to notify and consult with the Foundation for an exclusive commercial license solely in another therapeutic field outside the Foundation's area of interest.

5. Streamlining Award Terms Negotiation

We ask the Foundations to remain open to discussing award terms that present problems to the Research Institutions. A policy of not negotiating award terms hampers much-needed communication and delays the resolution of significant issues. Research Institutions who readily accept problematic terms may face compliance and commercialization issues during and after the grant period.

Research Institutions should consider developing standard procedures for reviewing and approving Foundation awards. Standard procedures could include having a single point of contact within the Research Institution who can facilitate internal coordination and avoid creating multiple uncoordinated conversations between the Foundation and the researchers, tech transfer office, research administration, department, and Foundation relations group. A standard system of notifications and approval processes would streamline messaging, expedite award term review, and reduce internal confusion.

Research Institutions should discuss potentially problematic award language with the researchers at the time of award to ensure that the researchers understand the unusual obligations that may be imposed by the award and agree to help the Research Institution fulfill its contractual obligations.

6. Confidentiality and publication rights

Research Institutions ask that Foundations update their proposal submission and award terms to treat proposals, reports, and data as proprietary confidential information of the Research Institution to be used solely for the evaluation of the proposal or grant performance. To treat them as non-confidential jeopardizes meaningful patent protection. Researchers should not fear that their creative research proposals, whether funded or not, might make their way into the hands of a third party without their knowledge or permission. The researcher's ability to publish and the Research Institution's ability to

patent inventions should likewise not be jeopardized by a "leak" of results through informal non-confidential disclosure channels.

7. Request process for IP ownership transfer

Research Institutions ask that Foundations agree to discuss the various possibilities for the disposition of IP that the Research Institution chooses not to commercialize.

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We hope that Foundations will consider these proposals as we work to develop more effective ways to commercialize Foundation-funded IP. We did not address financial issues such as royalty sharing or indirect costs. We welcome a dialogue with Foundations about this proposal and you can send comments to Lita Nelsen (lita@mit.edu), Jon Soderstrom (jon.soderstrom@yale.edu) or Katharine Ku (kku@stanford.edu).