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In the Public Interest:
Nine Points to Consider in Licensing University Technology

Licensing approaches, even for comparable technologies, can vary considerably from case to case and from institution to institution based on circumstances particular to each specific invention, business opportunity, licensee and university. In spite of this uniqueness, universities share ce

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Point 1
Universities should reserve the right to practice licensed inventions and to allow other non-profit and governmental organizations to do so

In the spirit of preserving the ability of all universities to perform research, ensuring that researchers are able to publish the results of their research in dissertations and peer-reviewed journals and that other scholars are able to verify published results without concern for patents, universities should consider reserving rights in all fields of use, even if the invention is licensed exclusively to a commercial entity, for themselves and other non-profit and governmental organizations:

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In situations where an exclusive license is warranted, it is important that licensees commit to diligently develop the technology to protect against a licensee that is unable or unwilling to move an innovation forward. In long-term exclusive licenses, diligent development should be well-defined and regularly monitored during the exclusive term of the agreement and should promote the development and broad dissemination of the licensed technology. Ideally, objective, time-limited performance milestones are set, with termination or non-exclusivity (subject to limited, but reasonable, cure provisions) as the penalty for breach of the diligence obligation. Examples of diligence requirements (also known as performance milestones) are described in the Appendix.

Another means of ensuring diligent development, often used in conjunction with milestones, is to require exclusive licensees to grant sublicenses to third parties to address unmet market or public health needs ("mandatory sublicensing") and/or to diligently commercialize new applications of the licensed rights. Such a requirement could also be implemented through a reserved right of the licensor to grant direct licenses within the scope of the exclusive grant to third parties based on unmet need. In such situations, it is important to ensure that the parties have a common understanding of what constitutes a new application or unmet need for the purpose of implementing such a provision. An example of mandatory sublicensing language is provided in the Appendix.

Absent the need for a significant investment - such as to optimize a technology for wide use - broad, non-exclusive licensing of tools such as genomic and proteomic inventions can help maximize the benefits derived from those technologies, in part by removing obstacles to further innovation. Unlike most research tools or manufacturing methods, diagnostic tests often must go through the regulatory approval process, and so may warrant exclusive licensing when the costs of test development, approval or diffusion require substantial investment of capital. Nevertheless, licensing of diagnostic tests based on broadly applicable genomics or proteomics methods should strive to preserve sufficient flexibility to permit testing for multiple indications (i.e., not an exclusive licensee's single disease of interest) perhaps through multiple field-restricted or non-exclusive licenses. Exclusive licensing of a single gene for a diagnostic may be counterproductive in a multi-gene pathology where only a panel of genes can yield an adequate diagnosis, unless the licensee has access to the other genes of the panel. Such licenses can also be limited in other ways. For example, a university might license a genomics method exclusively for a company to optimize and sell licensed products for diagnostic use. The drafting of the exclusive grant could make it clear that the license is exclusive for the sale, <u>but not use</u>, of such products; in doing so, the university ensures that it is free to license non-exclusively to others the right (or may simply not assert its rights) to use the patented technology, which they may do either using products purchased from the exclusive licensee or those that they make in-house for their own use.

In general, when no alternative testing strategy is available for a given indication, consideration should be given to means of ensuring reasonable access for patients and shielding individual healthcare providers from the risk of suit for patent infringement. As with any medical technology, licenses should not hinder clinical research, professional

education and training, use by public health authorities, independent validation of test results or quality verification and/or control.

Point 3
Strive to minimize the licensing of "future improvements"

Although licensees often seek guaranteed access to future improvements on licensed inventions, the obligation of such future inventions may effectively enslave a faculty member's research program to the company, thereby exerting a chilling effect on their

Point 4
Universities should anticipate and help to manage technology transfer related conflicts of interest

Technology transfer offices should be particularly conscious and sensitive about their roles in the identification, review and management of conflicts of interest, both at the investigator and institutional levels. Licensing to a start-up founded by faculty, student or other university inventors raises the potential for conflicts of interest; these conflicts should be properly reviewed and managed by academic and administrative officers and committees outside of the technology transfer office. A technology licensing professional ideally works in an open and collegial manner with those directly responsible for oversight of conflicts of interest so as to ensure that potential conflicts arising from licensing arrangements are reviewed and managed in a way that reflects well on their university and its community. Ideally, the university has an administrative channel and reporting point whereby potential conflicts can be non-punitively reported and discussed, and through which consistent decisions are made in a timely manner.

Point 5
Ensure broad access to research tools

Consistent with the NIH Guidelines on Research Tools, principles set forth by various charitable foundations that sponsor academic research programs and by the mission of the typical university to advance scientific research, universities are expected to make research tools as broadly available as possible. Such an approach is in keeping with the policies of numerous peer-reviewed scientific journals, on which the scientific enterprise depends as much as it does on the receipt of funding: in order to publish research results, scientists must agree to make unique resources (e.g., novel antibodies, cell lines, animal models, chemical compounds) available to others for verification of their published data and conclusions.

Through a blend of field-exclusive and non-exclusive licenses, research tools may be licensed appropriately, depending on the resources needed to develop each particular invention, the licensee's needs and the public good. As suggested with respect to genomics and proteomics method patents in Point 2 above, a university might license a research reagent, kit or device exclusively to a company to optimize and sell licensed products and services for research, diagnostic or other end uses. The drafting of such an exclusive grant should make clear that the license is exclusive for the sale, <u>but not use</u>, of such products and services; in doing so, the university ensures that it is free to license non-exclusively to others the right to use the patented technology, which they may do either using products purchased from the exclusive licensee or those that they make in-house for their own use.

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Point 6
Enforcement action should be carefully considered

In considering enforcement of their intellectual property, it is important that universities be mindful of their primary mission to use patents to promote technology development for the benefit of society. All efforts should be made to reach a re

Point 8
Be mindful of the implications of working with patent aggregators

As is true of patents generally, the majority of university-owned patents are unlicensed. With increasing frequency, university technology transfer offices are approached by parties who wish to acquire rights in such 'overstock' in order to commercialize it through further licenses. These patent aggregators typically work under one of two models: the 'added value' model and the so-called 'patent troll' model.

Under the added value model, the primary licensee assembles a portfolio of patents related to a particular technology. In doing so, they are able to offer secondary licensees a complete package that affords them freedom to operate under patents perhaps obtained from multiple sources. As universities do not normally have the resources to identify and in-license relevant patents of importance, they cannot offer others all of the rights that may control practice (and, consequently, commercialization) of university inventions. By consolidating rights in patents that cover foundational technologies and later improvements, patent aggregators serve an important translational function in the successful development of new technologies and so exert a positive force toward commercialization. For example, aggregation of patents by venture capital groups regularly results in the establishment of corporate entities that focus on the development of new technologies, including those that arise from university research programs. To ensure that the potential benefits of patent aggregation actually are realized, however, license agreements, both primary and secondary, should contain terms (for example, time-limited diligence requirements) that are consistent with the university's overarching goal of delivering useful products to the public.

In contrast to patent aggregators who add value through technology-appropriate bundling of intellectual property rights, there are also aggregators (the 'patent trolls') who acquire rights that cut broadly across one or more technological fields with no real intention of commercializing the technologies. In the extreme case, this kind of aggregator approaches companies with a large bundle of patent rights with the expectation that they license the entire package on the theory that any company that operates in the relevant field(s) must be infringing at least one of the hundreds, or even thousands, of included patents. Daunted by the prospect of committing the human and financial resources needed to perform due diligence sufficient to establish their freedom to operate under each of the bundled patents, many companies in this situation will conclude that they must pay for a license that they may not need. Unlike the original patent owner, who has created the technology and so is reasonably entitled to some economic benefit in recognition for its innovative contribution, the commercial licensee who advances the technology prior to sublicensing, or the added value aggregator who helps overcome legal barriers to product development, the kind of aggregator described in this paragraph typically extracts payments in the absence of any enhancement to the licensed

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APPENDIX

1. Commentary and examples of reserved or retained rights clauses and annotations as discussed in Point 1

Example 1

"Institution retains the right, on behalf of itself and all other non-profit academic research institutions, to practice the Licensed Patent and use Technology for any non-profit purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution. Institution and any such other institution have the right to publish any information included in the Technology or a Licensed Patent."

Example 2

"Nothing in this Agreement will be deemed to limit the right of the Institution to publish any and all technical data resulting from any research performed by the Institution relating to the Invention and to make and use the Invention, Licensed Product, and Licensed Services and to practice the Licensed Method and associated technology and allow other educational and non-profit institutions to do so for educational and research purposes."

> *the production or manufacture of products for sale or the performance of services for a fee."*

Definitions of non-commercial uses should be considered in light of John M.J. Madey

In drafting reservation of rights clauses and associated definitions, it is always important to keep both the *Madey* and *Merck* decisions in mind.

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2. Commentary and examples of exclusive license terms that encourage technology development as discussed in Point 2

While reservations of rights, above, enable continued innovation in non-profit and governmental laboratories, the suggestions contained in this section are intended to ensure that licensed inventions achieve broad commercialization.

2.1 Restrictions on fields of use, territory and term

- "Field-restricted" licenses grant rights that cover only specific products that a licensee is able, and will undertake a firm commitment, to develop. This approach safeguards the licensee's investment in a technology, while still leaving it open for development by other parties who do not compete with them (i.e., those who do not operate in the field of the exclusive license grant).

- "Co-exclusive" licenses may be granted to a small, limited number of licensees. Such a licensing structure has the advantage of permitting competitive optimization of a product by spanning

- "Term-limited" licenses, wherein the period of exclusivity is limited to the time necessary to afford the licensee the competitive advantage conferred by early market penetration and to permit them to make a reasonable profit on their investment in research and development, after which the grant converts to that of a nonexclusive license and the market opens up to other companies. Times may vary from a few years for a technology that requires little optimization to much longer times for products requiring many years of development and/or testing to obtain regulatory approval.

- Territorial limitations, where patent rights exist in multiple jurisdictions (e.g., the U.S. or North America; Europe; Asia; major-market countries; or developing countries)

Hybrid license grants that combine features of those described above (e.g., a non-exclusive license with a standstill for a given area of art, for a given period of time) expand the range of creative possibilities for delineating an exclusive licensee's rights.

2.2 Mandatory sublicensing

The concept is that when the University grants a broad exclusive license then we must have a mechanism to ensure that the market demand is met. As future, perhaps unanticipated, new uses arise we have an obligation to fill new market niches for the public good. This is especially important when our inventions are developed using federal funds. If we become aware of a new use that our licensee is not addressing, or if a third party approaches us for the (licensed) rights in order to develop a new use or other unmet need then we ask our licensee to tell us within 90 days if it will: (a) develop the new application on its own, or (b) grant a sublicense to the third party. If the licensee chooses to develop the new application then it must diligently undertake the new development (and report such progress to us).

Suggested language:

> *"If Institution or if a third party discovers and notifies the Institution that the INVENTION is useful for an application covered by the LICENSED FIELD OF USE but for which LICENSED PRODUCTS have not been developed or are not currently under development by LICENSEE, then the Institution shall give written notice to the LICENSEE, except for: 1) information that is subject to restrictions of confidentiality with third parties, and 2) information which originates with Institution personnel who do not assent to its disclosure to LICENSEE.*
>
> *Within ninety (90) days following LICENSEE's receipt of Institution's notification LICENSEE shall give Institution written*

notice stating whether LICENSEE elects to develop LICENSED PRODUCTS for the application.

If LICENSEE elects to develop and commercialize the proposed LICENSED PRODUCTS for the new application, LICENSEE shall submit a progress report describing LICENSEE's commercialization efforts in developing the new application every six months to Institution pursuant to Article xx herein."

2.3 Examples of diligence requirements/milestone clauses

Example 1

"Milestones. Because the invention is not yet commercially viable as of the Effective Date, Licensee will diligently develop, manufacture, and sell Licensed Product and will diligently develop markets for Licensed Product. In addition, Licensee will meet the milestones shown in Appendix X, and notify Institution in writing as each milestone is met."

Example 2

A second approach, drawn from a distribution license covering a nucleic acid sequencing reagent, reads:

X.1 Appendix A sets forth the development and commercialization plan under which LICENSEE intends to develop and sell LICENSED PRODUCTs (the "PLAN"). LICENSEE shall be entitled, from time to time, to make such adjustments to the then-applicable PLAN as LICENSEE believes, in its good faith judgment, are needed in order to improve LICENSEE's ability to meet the PERFORMANCE MILESTONES, as defined below.

X.2 LICENSEE shall use reasonable efforts (including, without limitation, commitment of funding and personnel consistent therewith) and/or shall cause its AFFILIATEs and/or SUBLICENSEEs to use reasonable efforts (including, without limitation, commitment of funding and personnel consistent therewith): (i) to develop LICENSED PRODUCTs in accordance with the PLAN during the periods and within the timetable specified therein, (ii) to introduce LICENSED PRODUCTs into the commercial market and (iii) to market LICENSED PRODUCTs, and to keep each LICENSED PRODUCT reasonably available to the public, following introduction thereof into the market.

In addition, LICENSEE shall achieve the following within the designated time periods:

(a) On or before January 1, 2009, offer for sale a first LICENSED PRODUCT or SERVICE for nucleic acid sequencing.

(b) On or before January 1, 2009, initiate pre-clinical tests of a LICENSED PRODUCT that is a diagnostic kit for the detection of disease in humans.

(c) On or before January 1, 2012, offer for sale a first clinical diagnostic LICENSED PRODUCT or SERVICE for the detection of disease in humans.

Each of the activities recited in this Paragraph X.2 shall be referred to herein as a "PERFORMANCE MILESTONE".

INSTITUTION shall have the right to terminate this Agreement forthwith.

A version of Paragraph X.2 drawn from a clinical diagnostics license sets forth the following Performance Milestones:

> *"New Developments" means inventions, or claims to inventions, which constitute advancements, developments, or improvements, whether or not patentable and whether or not the subject of any patent application, but if patentable, are not sufficiently supported by the specification of a previously-filed patent or patent application within the Patent Rights to be entitled to the priority date of the previously-filed patent or patent application.*

Example 2

"Continuations-in-Part" means all continuation-in-part patent applications that are filed