March 6, 2007

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 certain core values that can and should be maintained to the fullest extent possible in all technology transfer agreements.

In the summer of 2006, Stanford University's then Dean of Research Arthur Bienenstock convened a small meeting of research officers, licensing directors and a representative from the Association of American Medical Colleges to brainstorm about important societal, policy, legislative and other issues in university technology transfer. Representatives of the participating institutions, listed below, have tried to capture in this document certain shared perspectives that emerged from that meeting. Recognizing that each license is subject to unique influences that render 'cookie-cutter' solutions insufficient, it is our aim in releasing this paper to encourage our colleagues in the academic technology transfer profession to analyze each licensing opportunity individually in a manner that reflects the business needs and values of their institution, but at the same time, to the extent appropriate, also to bear in mind the concepts articulated herein when crafting agreements with industry. We recognize that many of these points are already being practiced. In the end, we hope to foster thoughtful approaches and encourage creative solutions to complex problems that may arise when universities license technologies in the public interest and for society's benefit.

California Institute of Technology
Cornell University
Harvard University
Massachusetts Institute of Technology
Stanford University
University of California
University of Illinois, Chicago
University of Illinois, Urbana-Champaign
University of Washington
Wisconsin Alumni Research Foundation
Yale University
and
Association of American Medical Colleges (AAMC)

March 6, 2007

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:

- to practice inventions and to use associated information and data for research and educational purposes, including research sponsored by commercial entities; and

- to transfer tangible research materials (e.g., biological materials and chemical compounds) and intangible materials (e.g., computer software, databases and know-how) to others in the non-profit and governmental sectors.

Clear articulation of the scope of reserved rights is critical. Recent examples of such "retained rights" clauses are included in the Appendix for reference.

Point 2
Exclusive licenses should be structured in a manner that encourages technology development and use

When significant investment of time and resources in a technology are needed in order to achieve its broad implementation, an exclusive license often is necessary and appropriate. However, it is important that technology transfer offices be aware of the potential impact that the exclusive license might have on further research, unanticipated uses, future commercialization efforts and markets. Universities need to be mindful of the impact of granting overly broad exclusive rights and should strive to grant just those rights necessary to encourage development of the technology.

Special consideration should be given to the impact of an exclusive license on uses of a technology that may not be appreciated at the time of initial licensing. A license grant that encompasses all fields of use for the life of the licensed patent(s) may have negative consequences if the subject technology is found to have unanticipated utility. This possibility is particularly troublesome if the licensee is not able or willing to develop the technology in fields outside of its core business. Universities are encouraged to use approaches that balance a licensee's legitimate commercial needs against the university's goal (based on its educational and charitable mission and the public interest) of ensuring broad practical application of the fruits of its research programs. There are many alternatives to strict exclusive licensing, several of which are described in the Appendix.

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 ability to receive corporate and other research funding and to engage in productive collaborations with scientists employed by companies other than the licensee – perhaps even to collaborate with other academic scientists. In particular, if such future rights reach to inventions made elsewhere in the university, researchers who did not benefit from the licensing of the original invention may have their opportunities restricted as well, and may be disadvantaged economically relative to the original inventors if the licensing office has pre-committed their inventions to a licensee.

For these reasons, exclusive licensees should not automatically receive rights to "improvement" or "follow-on" inventions. Instead, as a matter of course, licensed rights should be limited to existing patent applications and patents, and only to those claims in any continuing patent applications that are (i) fully supported by information in an identified, existing patent application or patent and (ii) entitled to the priority date of that application or patent.

In the rare case where a licensee is granted rights to improvement patents, it is critical to limit the scope of the grant so that it does not impact uninvolved researchers and does not extend indefinitely into the future. It is important to further restrict the grant of improvements to inventions that are owned and controlled by the licensor institution - i.e., (i) not made by the inventor at another institution, should they move on or (ii) co-owned with, or controlled by, another party. One refinement to this strategy would be to limit the license to inventions that are dominated by the original licensed patents, as these could not be meaningfully licensed to a third party, at least within the first licensee's exclusive field. As was discussed earlier, appropriate field restrictions enable the licensing not only of the background technology, but also of improvements, to third parties for use outside the initial licensee's core business. In all cases, a license to improvements should be subject to appropriate diligent development requirements.

It should be recognized, however, that not all "improvements" have commercial potential (for example, they may not confer sufficient additional benefit over the existing technology to merit the expense of the development of new or modified products), in which case a licensee might not wish to develop them. In general, it may be best simply not to patent such improvements.

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.

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 resolution that benefits both sides and promotes the continuing expansion and adoption of new technologies. Litigation is seldom the preferred option for resolving disputes.

However, after serious consideration, if a university still decides to initiate an infringement lawsuit, it should be with a clear, mission-oriented rationale for doing so-one that can be clearly articulated both to its internal constituencies and to the public. Ideally, the university's decision to litigate is based on factors that closely track the reasons for which universities obtain and license patents in the first place, as set out elsewhere in this paper. Examples might include:

- Contractual or ethical obligation to protect the rights of existing licensees to enjoy the benefits conferred by their licenses; and

- Blatant disregard on the part of the infringer for the university's legitimate rights in availing itself of patent protection, as evidenced by refusal on the part of the infringer to negotiate with or otherwise entertain a reasonable offer of license terms.

Under all circumstances, it reflects poorly on universities to be involved in "nuisance suits." Exclusive licensees should be encouraged to approach patent enforcement in a manner that is consistent with the philosophy described in this Point 6.

Point 7
Be mindful of export regulations

University technology transfer offices should have a heightened sensitivity about export laws and regulations and how these bodies of law could affect university licensing practices. Licensing "proprietary information" or "confidential information" can affect the "fundamental research exclusion" (enunciated by the various export regulations) enjoyed by most university research, so the use of appropriate language is particularly important. Diligence in ensuring that technology license transactions comply with federal export control laws helps to safeguard the continued ability of technology transfer offices to serve the public interest.

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

technology.[1] Without delving more deeply into the very real issues of patent misuse and bad-faith dealing by such aggregators, suffice it to say that universities would better serve the public interest by ensuring appropriate use of their technology by requiring their licensees to operate under a business model that encourages commercialization and does not rely primarily on threats of infringement litigation to generate revenue.

Point 9

Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world

Universities have a social compact with society. As educational and research institutions, it is our responsibility to generate and transmit knowledge, both to our students and the wider society. We have a specific and central role in helping to advance knowledge in many fields and to manage the deployment of resulting innovations for the public benefit. In no field is the importance of doing so clearer than it is in medicine.

Around the world millions of people are suffering and dying from preventable or curable diseases. The failure to prevent or treat disease has many causes. We have a responsibility to try to alleviate it, including finding a way to share the fruits of what we learn globally, at sustainable and affordable prices, for the benefit of the world's poor. There is an increased awareness that responsible licensing includes consideration of the needs of people in developing countries and members of other underserved populations.

The details involved in any agreement provisions attempting to address this issue are complex and will require expert planning and careful negotiation. The application will vary in different contexts. The principle, however, is simple. Universities should strive to construct licensing arrangements in ways that ensure that these underprivileged populations have low- or no-cost access to adequate quantities of these medical innovations.

We recognize that licensing initiatives cannot solve the problem by themselves. Licensing techniques alone, without significant added funding, can, at most, enhance access to medicines for which there is demand in wealthier countries. Diseases that afflict only the global poor have long suffered from lack of investment in research and development: the prospects of profit do not exist to draw commercial development, and public funding for diseases suffered by those who live far away from nations that can afford it is difficult to obtain and sustain. Through thoughtful management and licensing of intellectual property, however, drugs, therapies, and agricultural technologies developed at universities can at least help to alleviate suffering from disease or hunger in historically marginalized population groups.

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[1] A somewhat related issue is that of technology 'flipping', wherein a non-aggregator licensee of a university patent engages in sublicensing without having first advanced the technology, thereby increasing product development costs, potentially jeopardizing eventual product release and availability. This problem can be addressed most effectively by building positive incentives into the license agreement for the licensee to advance the licensed technology itself – e.g., design instrumentation, perform hit-to-lead optimization, file an IND. Such an incentive might be to decrease the percentage of sublicense revenues due to the university as the licensee meets specific milestones.

Summary

As often is the case, guidance as to implementation of practices that will advance the mission of university technology transfer lags behind our collective awareness of both the needs that exist and our obligations to foster an environment in which they can effectively be met. While we may generally agree on the commonality of the above challenges, a multiplicity of approaches are possible to address the dual goals of nurturing future research and using the innovations of university research to provide the broadest possible benefit to the public. The participating universities put forth these considerations in an aspirational sense and we encourage all of our colleagues to stretch the boundaries of conventional technology transfer practice and share with the greater technology transfer community the insights that they gain in doing so.

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."

Example 3

"INSTITUTION reserves the rights, for itself and others, to

(i) make and use, solely for NON-COMMERCIAL RESEARCH PURPOSES, the subject matter described and claimed in PATENT RIGHTS and covered by PROPERTY RIGHTS; and

(ii) provide to others the BIOLOGICAL MATERIALS;

each solely for NON-COMMERCIAL RESEARCH PURPOSES.

As used herein, the term "NON-COMMERCIAL RESEARCH PURPOSES" means: Use of PATENT RIGHTS for academic research or other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not use PATENT RIGHTS in

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 v. Duke University. 307 F.3d 1351; 64 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2002), *cert. denied,* 123 S. Ct. 2639; 156 L. Ed. 2d 656; 71 U.S.L.W. 3799. In Madey, the Court of Appeals of the Federal Circuit narrowly interpreted the so-called "experimental use" exception to patent infringement, such that use of patented technologies in the course of "business" activities of universities and other not-for-profit organizations (which activities include education of students, making application for grant funding and patenting of inventions) falls outside its scope. The decision effectively limits permitted uses of unlicensed technology to aimless tinkering with patented technologies, and sets the stage for infringement suits against non-commercial researchers.

To address the Madey issue in recent agreements, we have attempted to make clear that we are reserving rights broader than those of a mere unlicensed party, and that activities held under Madey to be the "business" activities of universities are within the scope of our reserved rights. One current example reads:

"NON-COMMERCIAL RESEARCH PURPOSES" means: Use or practice of LICENSED PATENT RIGHTS for academic research and other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not involve the production or manufacture of products for sale or the performance of services for a fee. Without limiting the foregoing: (i) "academic research and other not-for-profit or scholarly purposes" includes, in non-limiting fashion, research that leads, or may lead, to patentable or unpatentable inventions that may be licensed or otherwise transferred, either directly or indirectly, to third parties; and (ii) neither (A) receipt of license revenues on account of such inventions or receipt of reimbursements for the costs of preparation and shipping of samples of materials provided to third parties as a professional courtesy, in response to post-publication requests or otherwise in accordance with academic custom nor (B) receipt of funding to cover the direct and/or indirect costs of research, shall constitute sale of products or performance of service for a fee.

Another case (*Merck KGaA v. Integra Lifesciences I, Ltd.*) clarifies the scope of a 1984 safe-harbor that exempts some patent users from suit for patent infringement. That case, as reviewed by the Supreme Court, protects infringing activities that are directed at the generation of data in support of FDA filings; however, it affords academic researchers and institutions far less cover than it does corporate infringers who actually are preparing FDA filings. Typically, academic research is too remote from the regulatory filing process to fall within the safe harbor, for which reason it remains crucial to reserve under license agreements all of the rights, for one's own institution and others, that will enable academic research to proceed unimpeded.

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 spurring each member of the limited pool of licensees to attempt to achieve product launch and market penetration first, or to develop a product that is simply better than that which is marketed by the other licensees. This strategy, in which multiple licensees carry out their research and development efforts in parallel, is particularly justified where there is a significant unmet need for a given product (e.g., a critically-needed diagnostic test or vaccine), as it minimizes the delay inherent in an exclusive license, where failure by the licensee to appropriately develop a product necessitates license termination, identification of a new licensee, negotiation of a new license and re-initiation of product development efforts, perhaps from scratch.

- "Convertible exclusive" licenses permit the licensor to render an exclusive license either co- or non-exclusive if a third party wishes to develop products not yet made available by the exclusive licensee, usually after the initial licensee has had a time-limited opportunity to bring to market the product in question.

- "Convertible nonexclusive" licenses where if additional expressions of interest are not received within a defined period of time, then a non-exclusive license converts to exclusivity, at least within a particular territory or field of use.

- "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".

X.3 LICENSEE shall inform INSTITUTION, on or before the deadline for meeting any PERFORMANCE MILESTONE, whether such PERFORMANCE MILESTONE has been met.

X.4 No later than sixty (60) days after December 31st of each calendar year, LICENSEE shall provide to INSTITUTION a written annual progress report describing progress by LICENSEE and any SUBLICENSEE(s) on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the most recent twelve (12) month period ending December 31st and plans for the forthcoming year. If multiple technologies are covered by the license granted hereunder, the progress report shall provide the information set forth above for each technology. LICENSEE also shall provide any additional data INSTITUTION reasonably requires to evaluate LICENSEE's performance and compliance with the terms of this Agreement.

X.5 If LICENSEE fails to meet any of its obligations pursuant to Paragraphs X.1 through X.4 of this Agreement, INSTITUTION may notify LICENSEE in writing of LICENSEE's failure and, in such event, shall allow LICENSEE ninety (90) days to cure. LICENSEE's failure to cure such breach within such ninety (90) days shall constitute a material breach of this Agreement and

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:

(a) within one (1) year after EFFECTIVE DATE, establish a Scientific Advisory Board that will oversee the development of LICENSED PRODUCTs;

(b) commence a human clinical trial of a first LICENSED PRODUCT as follows: (i) if the patient data collected in the RESEARCH can be used to support the filing of an investigational device exemption (IDE), within two (2) years of the EFFECTIVE DATE or, (ii) if the patient data collected in the RESEARCH cannot be used to support the filing of an investigational device exemption (IDE), then within three (3) years of the EFFECTIVE DATE; and

(c) within two years of commencement of the human clinical trial described in clause (b), conclude analysis of data from such clinical trial and submit to the FDA any and all documentation required for marketing approval of a first LICENSED PRODUCT.

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3. Commentary and examples of limitations on grants of rights in improvements as discussed in Point 3

Example 1

"Patent Rights" means the Valid Claims of, to the extent assigned to or otherwise obtained by the Institution, the United States patents and patent applications, corresponding foreign patents and patent applications (requested under Paragraph xx.x herein), and any reissues, extensions, substitutions, continuations, divisions, and continuation-in-part applications (only to the extent, however, that Valid Claims in the continuation-in-part applications are entirely supported in the specification and entitled to the priority date of the parent application) based on the following patents and patent applications: _____. This definition of Patent Rights excludes any rights in and to New Developments.

"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 within two years of the original application and only to the extent that they cover technology disclosed, claimed in and dominated by the original application. The continuations-in-part also do not include continuations-in-part that have different named inventors than the original application or that are burdened by, for example, sponsored research or any other collaboration between Institution and a third party.

Example 3

"IMPROVEMENT" means: Any invention the practice of which would infringe at least one claim within the PATENT RIGHTS, which invention is made by at least one or both of the INVENTORS and is owned and controlled by INSTITUTION.

In a license that contains a field-exclusive grant of rights under PATENT RIGHTS and IMPROVEMENTS, PATENT RIGHTS are defined, in relevant part, as including any claim of a continuation-in-part application that is (i) directed at subject matter described in at least one listed patent application or patent and (ii) is entitled to the priority date thereof. The effect is to grant rights in technology dominated by what exists at the time of license. Tracking of the promised improvements is facilitated by their limitation to the work product of a defined pool of inventors. The institution is further buffered against liability (i.e., for breach of contract on account of inadvertent grants to different parties of overlapping rights or failure to meet obligations as to licensee participation in patent prosecution) by restricting IMPROVEMENTS only to those which the institution owns and controls.

Example 4

"IMPROVEMENT" means: Any invention the practice of which would infringe at least one claim within the PATENT RIGHTS, which invention is made by at least one or both of the INVENTORS and is owned and controlled by INSTITUTION and is disclosed to the TLO within 3 years of the date of the license and subject to any rights of sponsors in the research leading to the invention.