Statement of

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Before the

House Committee on the Judiciary

Subcommittee on Courts, the Internet, and Intellectual Property

On

"Stifling or Stimulating - The Role of Gene Patents in Research and Genetic Testing"

October 30, 2007

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Mr. Chairman, thank you for the opportunity to testify before your Subcommittee on the topic of whether gene patents are helping or hurting research in the life sciences.

My name is Jon Soderstrom. I am the Managing Director of the Office of Cooperative Research (OCR) at Yale University. The Office of Cooperative Research is the intellectual property management and licensing organization for Yale University. I also serve as the President-Elect for the Association of University Technology Managers known as AUTM. AUTM is a nonprofit organization created to function as a professional and educational society for academic technology transfer professionals involved with the management of intellectual property. AUTM was founded in 1974 as the Society of University Patent Administrators. That group laid the foundation for the association that exists today with more than 3,000 members strong representing over 1,500 institutions and companies across the globe.

Sources of Concern

Scholars have recently argued that patents may impose significant costs upon noncommercial biomedical research. Heller and Eisenberg[1] suggest that the patenting of a broad range of the inputs that researchers need to do their work may give rise to an "anti-commons" or "patent thicket" that may make the acquisition of licenses and other rights too burdensome to permit the pursuit of what should otherwise be scientifically and socially worthwhile research. Merges and Nelson[2] and Scotchmer[3] highlight the related possibility that, in some fields of technology, the assertion of patents on only one or two key upstream, foundational discoveries may significantly restrict follow-on research. A further concern is that the prospect of realizing financial gain from upstream research may make researchers reluctant to share information or research materials with one another, thereby impeding the realization of research efficiencies and complementarities. Similarly, researchers may be trading away rights to conduct future research or to freely disseminate their discoveries in exchange for current access to research inputs or financial support.[4] Finally, prospective financial gains from the exploitation of intellectual property may induce researchers to choose research projects on the basis of commercial potential rather than scientific merit.

Another aspect of the debate about whether intellectual property fosters or hinders biomedical research relates to the 'research tools,' which are the ideas, data, materials or methods used to conduct research. Many such materials and methods are disclosed or claimed in DNA patents. Among DNA patents, there is particular concern about the subset of gene patents and their relevance to research tools because genes are not only inputs to developing genetic tests and therapeutic proteins, and thus directly relevant to medically important products and services, but also are crucially important tools for ongoing research. Concern over the impact of patenting and licensing on biomedical research has grown since the Court of Appeals for the Federal Circuit's 2002 *Madey*

[1] Heller, M.A. and Eisenberg, R. S. 1998. "Can Patents Deter Innovation? The Anti-Commons in Biomedical Research." *Science*, Vol. 280. No. 5364, pp. 698 – 701

[2] Merges, R. P. and R. R. Nelson. 1990. "On the Complex Economics of Patent Scope. "Columbia Law Review 90:839-916

[3] Scotchmer, S. 1991. "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law." *Journal of Economic Perspectives* 5:29-41.

[4] Cohen, W. M., R. Florida, and R. Goe. 1994. "University-Industry Research Centers in the United States."; Thursby, Jerry G. and Marie C. Thursby. 2003. "University Licensing and the Bayh-Dole Act." *Science* 301:1052.

v. Duke decision, which visibly affirmed the absence of any research exemption shielding universities from patent infringement liability. Patent claims based on DNA sequences can be infringed by research activities that entail making or using the claimed sequence, not just by selling products or services.

Without diminishing the importance of these potential concerns, it should be pointed out that the evidence offered to support these contentions is primarily anecdotal. Although these isolated instances have received significant attention, there is no evidence that widespread assertion of patent rights on genes has significantly hampered biomedical research. Contrary to these prevailing beliefs, findings from a recent survey of 414 biomedical researchers in universities, government, and nonprofit institutions offers little empirical basis for claims that restricted access to intellectual property is currently impeding academic biomedical research.[5] The authors noted that, although common, patents in this field are not typically used to restrict access to the knowledge and tangible materials that biomedical scientists require.

The authors cite a number of reasons, including the fact that firms generally do not threaten infringement litigation against academic research institutions (a *de facto* research exemption), in part because such academic use may improve their invention, because they wish to maintain good will and to ensure access to future academic inventions, and also because the damages are likely to be very small. According to the authors:

> "Our research thus suggests that 'law on the books' need not be the same as 'law in action' if the law on the books contravenes a community's norms and interests."

These findings are consistent with another recent major survey of 19 of the 30 US universities with the largest number of DNA patents. Their results showed that the licensing of DNA patents at US academic institutions has not led to the decline in academic cooperation and technology transfer that many observers have feared.[6] In fact, based on responses, the study demonstrated that in most cases the licensing behavior of universities allows for collaboration and sharing of DNA-based inventions among academic institutions.

The study investigated the patenting and licensing behavior for four main types of DNA-based inventions:

- DNA sequences that encode therapeutic proteins
- DNA sequences that are phenotypic markers only
- DNA sequences comprising genes encoding drug targets
- DNA discoveries or inventions representing research tools

The authors discovered that most universities base their decisions to patent and strategies for commercializing the invention on a determination of the level of protection necessary to induce an interested company into investing in the further development, testing, manufacture, marketing and sales of a product embodying the technology. Thus, in the case of a fully sequenced gene that encodes a therapeutic protein, where the utility and the development risks are both generally acknowledged to be high, survey respondents generally agreed that they would patent and license such inventions exclusively. However, in the case where the gene encoded is simply a target for drug discovery, few would consider even patenting such a discovery since researchers would be free to screen their compound libraries against the target while the patent application was pending and to use any resulting

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[5] Walsh, J. P. Cho, C. Cohen, W. M. 2005. "View from the Bench: Patents and Material Transfers." *Science* 309: 2002 – 2003.

[6] Pressman, L. Burgess, R. Cook-Deegan, R. M. McCormack, S. J. Nami-Wolk, I. Soucy, M. & Walters, L. 2006. "The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey." *Nature Biotechnology* 24: 31-39.

information without fear on infringement. In addition, it has become commonplace for universities, when licensing their inventions, to reserve the right for their own faculty, as well as researchers at other non-profit entities, to use the patented invention. The study confirmed that university technology managers take a nuanced approach to patenting and licensing, seeking only enough intellectual property protection to facilitate the commercial development of the invention.

This market sensitivity is also reflected in data on patent trends. The number of DNA patents has shown a fairly dramatic and steady decline since their peak in 2001 (from about 4,500 to around 2,700 in 2005). Patent prosecution, maintenance and management costs that are typically between $20,000 and $30,000 per patent militate against patenting inventions that are unlikely to recover those costs and encourage considerable selectivity in which inventions are patented. As Pressman et al. point out, "these practices are designed pragmatically to accommodate both economic goals, such as revenue generation and new company formation, and social goals, such as ensuring utilization and availability of federally funded inventions."

Establishing Licensing Principles to Promote Access

These results are not surprising to persons currently involved in technology licensing activities as practiced at major research universities. To some extent the practices of university technology transfer managers reflect the salutary effects of guidance that the National Institutes of Health has issued on patenting of research tools and genomic inventions as well as the formation of professional norms and standards of behavior encouraged by groups such as the Association of University Technology Managers. Universities share certain core values that can and should be maintained to the fullest extent possible in all technology transfer agreements, chief among these are the protection of academic freedom and open pursuit of scientific inquiry. When crafting agreements with industry, a balance must be struck between the business needs of our licensing partners to generate returns on their investments and the shared values of our respective academic institutions.

Recognizing the need to clearly articulate a set of technology licensing principles that strikes the appropriate balance, a group of university research officers, licensing directors and a representative from the Association of American Medical Colleges met in July 2006 to brainstorm about critical societal, policy, legislative and other issues in university technology transfer.[7] Our aim was and is to encourage our colleagues in the academic technology transfer profession to analyze each licensing opportunity individually, but with certain core principles in mind.

The participating universities released a white paper, "In the Public Interest: Nine Points to Consider in Licensing University Technology."[8] The paper seeks to capture the shared perspectives of the participating university research officers and licensing directors on policy issues related to university technology transfer, in particular, with respect to ensuring that licensing activities are "in the public interest and for society's benefit." These considerations are put forth in an aspirational, rather than proscriptive, sense to encourage others in the profession to set a higher standard by stretching the boundaries of conventional licensing practices and sharing with the greater technology transfer community the insights that they gain in doing so.

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[7] The participating universities included: 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).

[8] "In the Public Interest: Nine Points to Consider in University Licensing," March 6, 2007. http://www.autm.org/aboutTT/Points_to_Consider.pdf

The nine points identified in the white paper (see Appendix for the full elaboration of each point) included:

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

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

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

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

Point 5: **Ensure broad access to research tools**

Point 6: **Enforcement action should be carefully considered**

Point 7: **Be mindful of export regulations**

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

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**

In Conclusion

We recognize that many of these points are already being practiced. In fact, the "Nine Points" have been endorsed by a growing number of institutions and professional organizations around the world. We applaud the participating institutions' efforts to articulate these important principles and urge their adoption and application by the wider community of universities. . 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.

We believe that patent policy, as well as practice, should be guided by the goal of promoting innovation and, in turn, improvements in human welfare. That view drove Yale's interest in helping to draft the "Nine Points" guidelines, which recommend that universities refrain from patenting genomic inventions that will serve primarily as research tools. Yale has long taken a balanced approach to patenting, taking into account the nature of the invention, its relevance to research, and the extent to which patent protection would be necessary to give a commercial partner adequate incentive to develop the product completely. We have taken a similar approach to licensing, especially by insisting upon the right to make the invention available to researchers at Yale and other academic institutions.

We do not think that gene patents are having a significant negative impact on academic research. There have been thoughtful analyses of problems that could arise, and there have been anecdotal reports and two comprehensive studies of this issue, cited earlier in my testimony, that concluded that patents are not slowing the pace of research for several reasons. Universities take a nuanced approach to patenting and they are increasingly making specific provision for research uses of inventions in licenses. There is evidence that a "de facto research exemption" exists because companies rarely prosecute academic investigators for research uses that may be infringing.

Yale and other universities have a major stake in ensuring that access to research tools is not compromised (the "Nine Points" document is evidence of that); we also recognize that circumstances may change as the fields of genomics and proteomics continue to advance. I am confident that the scientific community, working with the National Institutes of Health, the Association of

University Technology Managers, the Association of American Medical Colleges and others, will continue to monitor whether gene patents are interfering significantly with research. My colleagues and I are grateful for the Subcommittee's interest in this topic.

APPENDIX

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

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.

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.

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.

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.

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.[9] Without delving more deeply into the very real issues of

[9] 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

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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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.