Licensing to Promote Global Health Partnerships

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Introduction

The Global Forum for Health Research (www.globalforumhealth.org) recently published a two-volume report titled "Global Forum Update on Research for Health 2005". In summary, this report showed that there is a disparity in the research effort to improve healthcare between developed and developing countries. For example, there is high research effort in both rich and poor countries for diseases that affect large populations such as Hepatitis B and diabetes, but there is a low research effort for diseases that primarily affect poor countries, such as HIV/AIDS and tuberculosis. There is also a group of neglected diseases that exclusively affect people in poor countries, such as malaria, Chagas' disease, and leishmaniasis, and until very recently, very little research is focused on finding cures for such neglected diseases. The mortality rates from these diseases with high incidence in poor countries is staggering. Without a significant research effort, there will be very little innovation to develop effective interventions for these diseases, including better vaccines, drugs, diagnostics, and medical devices. Even with increased research effort, creative licensing approaches will need to be employed to manage research outcomes since these innovations do not carry with them the traditional promise of high financial returns, but rather, such innovations may help save the lives of millions around the world. In addition to numerous factors that lead to global health disparities, there is also an acknowledged need for better public health infrastructure, trained health workers to deliver healthcare services, disease surveillance, and policy formulations.

Over the last several years, a number of initiatives have emerged to stimulate the research effort to find better treatments for diseases in developing countries. These include the formation of product development public-private partnerships (PPPs) sponsored by philanthropic organizations. An Add-On session titled "Emerging Strategies and Structures in Global Health

Partnerships" at the Licensing Executives Society Annual Meeting 2005 in Phoenix, Arizona presented multiple perspectives on these initiatives and alliances to address global health challenges. This session was organized by several members of the Technology Managers for Global Health in collaboration with MIHR (Centre for the Management of Intellectual Property in Health R&D) and the LES Industry-University-Government Transactions Sector Committee, with the financial support of the Rockefeller Foundation. Usha Balakrishnan (MIHR-USA), Julie Tan (Health Canada), Gordon Comstock (University of Illinois at Chicago), and Tari Suprapto (Rockefeller University) were the primary organizers of the session. The speakers included representatives from the pharmaceutical industry, such as Pfizer; the PPPs, such as the Global Alliance for TB Drug Development, Aeras Global TB Foundation, the International AIDS Vaccine Initiative; early R & D drug development partnerships such as BioVentures for Global Health; professionals from academic institutions such as University of Illinois at Chicago, Boston University and University of Mississippi; as well as global health research sponsors including the Rockefeller Foundation, the Bill & Melinda Gates Foundation, NIH and NIAID. This document summarizes the speakers' remarks and the various discussions that followed their presentations.

Perspectives from the pharmaceutical industry

It was enlightening to learn about what the pharmaceutical industry is proactively doing to solve the global health inequity problem. There are various options involving IP that can be used by companies to expand access to medicines. Companies can out-license IP covering certain medicines, be it voluntary or compulsory. The patents can also be donated, however this means giving away the IP without any return, be it monetary or guaranteeing that the medicines reach the ones who need it the most. Companies can also refrain from filing or enforcing patents in countries with small or low-paying markets. Another option is to donate goods and services,

such as medicines, human resources, manufacturing facilities, and forming drug development partnerships with the pharmaceutical industry in the developing world.

Pfizer, for instance, donates and distributes medicines with training, education, and mentoring in collaboration with USAID. Heather Lauver, the Assistant Director for Global Operations for Pfizer's International Philanthropy Programs, said that donating goods and services in this way increases the sense of responsibility of getting drugs to the end-user as opposed to licensing or selling, where once the deal is done, the responsibility is transferred to the licensee or customer. One program is the International Trachoma Initiative, where the drug Zithromax is donated and delivered to those in need in Africa. Trachoma is a disease that causes blindness, thus perpetuating the cycle of poverty. This program has succeeded in reducing the infection rate of trachoma by 95%. Pfizer also has a program to fight HIV/AIDS by building research facilities, funding research and providing drugs, such as Diflucan, to AIDS patients at no cost. Future plans include the establishment of programs to combat malaria and respiratory illnesses.

One of the most critical components in providing medicines to developing countries is the supply chain. Unfortunately, ensuring that the supply chain is uninterrupted is one of the largest challenges as well. Corruption in low-income countries is a huge problem, such as smuggling and rebranding. Pfizer uses distinct packaging to label its drugs destined for donation to prevent the drugs from being diverted elsewhere. The company also deals with the regulatory affairs to fully register the drug in the country of destination, and pays the considerable costs for shipping the drugs to the port, including taxes and import duties. In order to ensure that the products reach the end users from the port, Pfizer establishes partnerships with non-profits and non-governmental organizations (NGOs) to create distribution channels. The supply chain is also needed to ensure that the drugs are delivered in a timely way to maintain their effectiveness,

especially in the case of anti-retroviral drugs for HIV/AIDS where 100% compliance is required to maintain critical efficacy.

Gordon Comstock from the University of Illinois at Chicago presented his work on a project called “Affordable Medicines for Africa” (AMFA), which is a non-profit initiative to manufacture, monitor quality and efficiently distribute medical products in Africa. This endeavor is meant to build the primary supply chain in Africa to avoid theft, counterfeiting, degradation of the drugs in transit and expiration of the drugs before they can be resupplied. A US $577M contract with President Bush’s Emergency Plan for AIDS Relief is funding an effort to establish a distribution channel. AMFA is coordinating with pre-existing African healthcare delivery systems established by NGOs and faith-based communities (e.g. missionary facilities), which also have the potential to provide education and training. AMFA is also making efforts to train the local pharmaceutical industry to manufacture high-quality products, as well as work with Africa’s largest pharmaceutical warehouse and distribution center. Other aspects of the initiative include working with the Ministry of Finance to lower tariffs on pharmaceuticals, which are currently at 40%, and to help move the products securely by training locals to recognize counterfeit drugs which may contain little to no active ingredient.

Perspectives from public-private partnerships (PPPs) and product development partnerships (PDPs)

Public-private partnerships (PPPs) are organizations that pursue a social mission by employing the best practices of the private sector and drawing upon the complementary skills and resources of the public and private realms. Many of these PPPs are also involved in developing appropriate products for various needs (e.g. neglected diseases), hence the term “product development partnerships” (PDPs). This part of the session had speakers from the Global Alliance for TB Drug Development (also referred to as the TB Alliance), the Aeras

Global TB Foundation, and the International AIDS Vaccine Initiative (IAVI), all of which presented case studies. At the time of the session, both Aeras and the TB Alliance had recently issued press releases concerning deals with pharmaceutical companies, which was very exciting for both the speakers and the participants. It was also evident that there was a great deal of positive communication between the PDPs and that they were supportive of each other.

The public health problems surrounding the individual diseases were presented to put the PPPs/PDPs' efforts into context. Dr. Gerald Siuta, Consultant for Business Development at the TB Alliance, showed that tuberculosis poses a serious public health problem by sheer numbers alone. About one-third of the world's population (~ 2 billion people) is infected with the bacteria responsible for tuberculosis, with about 2 million deaths annually. Current statistics indicate that there are 8-9 million new cases of active disease each year, and about 400,000 of them are multi-drug resistant (MDR-TB). Tuberculosis is also the leading cause of death in HIV-positive people, and about 12 million people are co-infected with TB and HIV. There is a significant need for new TB drugs as the current standard treatment involves administration of four drugs for a period of six to nine months and the few drugs used to treat MDR-TB are poorly tolerated. The antiretroviral agents for HIV interact with the TB drugs, making simultaneous therapy very difficult. Unfortunately, TB is an unattractive market for the private sector and there is very little commercialization of public sector research, resulting in no new anti-TB drugs in over thirty years.

Created in 2000, the TB Alliance is an international public-private partnership whose mission is to ensure equitable access to a faster and better cure for TB. The ideal drug would shorten the duration of TB treatment or otherwise simplify the completion of treatment, be effective against MDR-TB, improve the treatment of latent TB, and be compatible with antiretroviral agents against HIV. Another objective of the TB Alliance is to coordinate and catalyze TB drug development activities worldwide and ensure that these products are

affordable, adopted into existing treatment programs, and accessible to those who need them most (the TB Alliance's AAA Strategy). The TB Alliance utilizes an entrepreneurial, virtual R&D approach, where all the R&D is outsourced to public or private partners. Their deals include licenses, sponsored projects, co-development or co-investment partnerships, and any other arrangements that allow products to be developed and distributed. Their partners include the Korea Research Institute of Chemical Technology, the University of Illinois at Chicago, the University of Auckland in New Zealand, Chiron Corporation, GlaxoSmithKline, and most recently Bayer Healthcare AG. The Bayer partnership will conduct a global clinical trial (2,500 patients) to study the potential of Bayer's fluoroquinolone antibiotic, moxifloxacin, to shorten the standard 6-month treatment of TB. Moxifloxacin, approved for the treatment of bacterial respiratory and skin infections in 104 countries, has been shown to reduce treatment time by two months in *in vivo* studies and is safe to use with antiretroviral drugs. Bayer will donate the drug for the clinical trials, pay for the regulatory filings and ensure that the drug is sold at an affordable price for TB patients in the developing world. The TB Alliance will coordinate and help pay for the clinical trials and coordinate the data and results to facilitate registration of the drug.

Another PDP addressing the public health problems posed by tuberculosis is the Aeras Global TB Foundation, created in 1997, with the mission to develop and insure availability of new and effective TB vaccines to those who need them most. The current vaccine, BCG, has been used since the 1920s and fails to protect people beyond childhood. Aeras has also licensed technology from companies and academic institutions for sale of new TB vaccines to UN agencies, the Global Alliance for Vaccines and Immunization, and to developing and emerging economy countries. In addition, Aeras also provides process development, regulatory support, expertise, animal models and assays to their partners. In one particular case, Aeras used a market segmentation strategy where Aeras had a royalty-free, sublicensable, exclusive license to

import, distribute and sell in developing countries while the collaborator had a similar license to both manufacture and sell in developed countries and emerging economy countries. In another case, the partner agreed to provide the vaccine product at two different prices in the public and private markets. Aeras recently formed a partnership with GlaxoSmithKline (GSK) Biologicals to develop a tuberculosis vaccine that showed promising results in preclinical studies and appeared to have satisfactory safety and immunogenicity based on GSK's early clinical trials. Dr. Rita Khanna, the legal counsel for Aeras, commented that the more advanced the candidate is at the time of licensing, the less flexible the terms are. These deals often involve research collaborations as well. Key provisions in these agreements include intellectual property (ownership is usually based on inventorship, IP management, enforcement, and infringement), regulatory approval, manufacturing and termination.

It is evident that there is a need for vaccines in addition to drugs, especially protective vaccines that can prevent people from contracting diseases such as HIV. The International AIDS Vaccine Initiative (IAVI) is a PDP, founded in 1996 with the mission of ensuring the development of safe and accessible HIV vaccines. This means creating vaccines with speed and making them available and affordable to the developing world. IAVI utilizes a multi-pronged approach to reach its goals. IAVI conducts research & development to design, manufacture and test promising HIV vaccine candidates while securing adequate resources globally and promoting sustainable policies to accelerate HIV vaccine R & D with a focus on the developing world. For example, IAVI has set up clinical trial site infrastructure in Africa and India and has tested six vaccine candidates in the clinic during the past six years.

IAVI's R & D program is centered on pre-clinical and clinical collaborations for research to address key scientific challenges and for product development to advance promising candidates. The collaborators are from academia and industry. Some of the issues that are

consistently addressed in negotiations are financial terms, IP, and program management. The major challenges that IAVI faces are the science, third-party IP, manufacturing, and access. Labeeb Abboud, the general counsel for IAVI, spoke of a number of assumptions that underlie IAVI's engagement with the pharmaceutical and biotech industry to achieve its goals. One assumption is that development risks and lack of funding are obstacles to develop technology relevant to HIV vaccines. Another is that access can be ensured through various mechanisms, and that IAVI would obtain reasonable terms for third-party intellectual property. There are also several incentives for industry to partner with IAVI, which include the availability of early-stage funding, development of a technology platform, credibility to investors, and access to expertise and clinical trial sites.

In general, the IP terms for IAVI's research collaboration agreement would allow IAVI to manage the commercialization of the IP on behalf of all collaborators in developed and developing countries. The typical mechanism is for IAVI to have an option to an exclusive license to IP made during the course of the collaboration and an option to a non-exclusive license to the background IP. Revenue is shared amongst the collaborating parties, but no royalties are expected from sales in developing countries. If IAVI does not commercialize the IP, the other party may exercise march-in rights to further develop the product. Ownership of the IP is flexible, and is usually determined by inventorship. In IAVI's partnerships with industry, it is important that IAVI's partner be committed to developing and commercializing the technology in such a way that it is accessible to those who need it. Therefore, IAVI reserves march-in rights in the event that the development of the vaccine is abandoned, if the collaborating party fails to meet developmental milestones, or if it is priced unreasonably.

Perspectives from early R& D drug development partnerships, biotech companies and start-ups

The need for global health equity has created a number of partnerships across multiple sectors and also created the need to creatively manage IP worldwide. Usha Balakrishnan, the executive director for MIHR-USA, called out for new ways of thinking about how to evaluate inventions, license IP, form partnerships in drug development, and build appropriate capacity and other infrastructure in developing countries. Ms. Balakrishnan also emphasized the importance of raising awareness for global health-related issues amongst fellow IP, licensing and business development managers. One way she has done so is by founding a collegial network called the Technology Managers for Global Heath (TMGH) in 2003 as a special interest group within the Association for University Technology Managers (AUTM). With financial support from the Rockefeller Foundation, TMGH in collaboration with MIHR, produced and widely distributed a booklet titled "Global Health Partnerships and Academic Technology Transfer" in May 2005. TMGH has grown to over 200 interested participants, meets at the AUTM Annual Meeting, and in the spirit of collaborating to promote global health equity, has now reached across to organizing workshops at AUTM, LES and the Biotechnology Industry Organization (BIO).

Academic institutions can certainly play an important role in addressing the global health problem. Research in academia is not financially driven, and funding is available for developing world diseases. In fact, half of the deals done by private-public partnerships involve academic institutions. Promoting global health-relevant technologies is increasingly being addressed by academic licensing professionals. Following the call to action, "Global Health is the Next Frontier for Technology Transfer", presented by Dr. Maria Freire, President & CEO of the Global Alliance for TB Drug Development, during her acceptance speech as the recipient of AUTM's 2002 Bayh-Dole Service award, AUTM's 2006 Annual Meeting in Orlando is

dedicated to the theme of global health and improving society. Most offices of university technology transfer and licensing operate fairly autonomously allowing for potential creativity in licensing solutions for global health purposes. The key issues are how to learn to establish and implement practical mechanisms and partnering strategies that allow for an optimal balance: (a) to enhance both the economic and social impact of university licensing; (b) to extend the economic and social impact of innovations to broader global settings; and (c) for assuring fair access to the world's poor within an evolving framework of licensing practices, legal concerns, business opportunity, and time constraints.

Ashley Stevens, the Director of the Office of Technology Development at Boston University proposed a number of licensing approaches that could be utilized by academic institutions, which include (i) structure two-tier pricing (different prices for developed versus developing countries), (ii) require a development milestone involving developing countries, (iii) require cost-plus pricing in developing countries, (iv) refrain from patenting in developing countries or (v) grant a non-exclusive license to the patent rights without royalties, (vi) exclude developing countries from the primary license, (vii) grant a license to a developing country's pharmaceutical/biotech company, (viii) require public sector development in return for private sector rights, mandatory sublicensing, and non-assert provisions for developing countries. A number of case studies were presented, such as the licensing of certain anti-fungal compounds to the Institute for OneWorld Health (a PDP) for Chagas' disease and Bristol-Myers' agreement to produce generics in developing countries due to public protests from the licensor's (Yale University) student population regarding fair access.

Mark Rohrbaugh, the director of the Office of Technology Transfer for the National Institutes of Health (NIH) also talked about NIH's role in promoting global health research via intramural research, research collaborations and the licensing of inventions. Most of the technologies that come out of the NIH are novel, fundamental research discoveries and research

tools. NIH also commercializes biological materials via tangible materials licenses, which works well for countries that do not have IP regulations. Only a few of NIH's licensed products are in developing country markets, but NIH's licenses often contain a "White Knight" clause requiring public good where products are provided at cost. More recently, NIH has required submission of commercialization plans for other countries upon first US or EU regulatory approval and has licensed directly to institutions in developing countries. In fact, collaborations with institutions in developing countries has revealed needs and technologies related to neglected diseases, and NIH has already transferred technologies to, or has negotiations in process with a number of organizations in developing countries. Some of these licenses are non-exclusive, or utilize a market segmentation strategy, and quite a few are done with PDPs. NIH is also making efforts to promote international technology transfer by helping to build local technology transfer expertise and collaborate with others to facilitate transfer of technologies for neglected diseases.

Other sectors can also be involved in finding and developing new solutions. The biotechnology industry sector can help by developing faster and cheaper point-of-care diagnostics, safer and more effective vaccines, improved delivery systems, sequencing the genomes of pathogens, and creating recombinant drugs or therapeutic biologics. The main question is how to stimulate more innovation within the biotech industry that would lead to appropriate technologies for the developing world.

There are significant barriers to overcome, mainly because there are lots of unknowns. The developing world is an unfamiliar market with high risk and low expected returns, and the funding for R & D is limited. The amount of information is relatively small; there is a lack of experience in dealing with the developing world and a lack of reliable information on how to find partners and funding sources, test, purchase, and distribute products. Another obstacle is the lack of technical and scientific expertise in the diseases relevant to the developing world. One solution is to take a market-based approach, where capable innovators respond to incentives

other than R & D funding and build markets that are competitive with economic opportunities, which is what BioVentures in Global Health (BVGH) is trying to do, as presented by Wendy Taylor, co-founder and VP of Strategy and Operations of BVGH.

BVGH is an offshoot of BIO with the support of the Gates Foundation and the Rockefeller Foundation, and its mission is to break the barriers of development of treatments for neglected diseases. Its efforts include developing business cases to dispel the myth that least developed country markets are unviable as well as to develop scenarios for market size and development costs. BVGH is also developing new market incentives by creating advance market commitments, where companies commit to guarantee minimum price for certain volumes of sales. In addition, BVGH is working on co-development models and outreach to raise awareness and obtain more information. It is also focusing on ways to catalyze private sector R&D by supporting biotech investment in particular disease opportunities, seeking out relevant products and technologies and to see how biotech companies can use their own technology to develop treatments for neglected diseases.

Perspectives from global health research sponsors

The Rockefeller Foundation has a Health Equity program, which is designed to be at the intersection of biomedical science and public health. In the 1980s, this program funded research for neglected diseases. At present, the program's primary goal is to establish product availability for the poor and one of the ways is to spur the formation of product development partnerships (PDPs). The PDPs are non-profit entities that utilize a portfolio management strategy to expand product pipelines. Priorities are based on health inequities, social demand, and maturity of the science in order to ensure availability and adoption of the technologies by the countries that need them. Chad Gardner, Associate Director for Health Equity showed that the Rockefeller Foundation is aware of what is needed for the PDPs to succeed. Availability requires R & D to

ensure product existence and design for acceptability, manufacturing capability and capacity, IP systems to support affordable production, national-level regulatory approvals, and appropriate mechanisms and networks for procurement and distribution. Effective adoption requires education and training of health providers, affordable pricing, policy research to fully understand the demand, education of the end users, and disease surveillance to understand health burden and need.

The Bill and Melinda Gates Foundation recently awarded US $450M in grants to fund 43 research projects directed towards global health solutions, and not simply to advance science. This initiative is named the Grand Challenges in Global Health. This initiative and global health programs funded by the foundation have a global access strategy that is based on two core principles: 1) global health solutions must be made available at affordable prices to those most in need in the developing world and 2) the knowledge made through discovery must promptly be made available to the broader scientific community. Therefore, a great deal of thought must be given to the potential activities, obstacles and needs beyond the proposed project itself.

There are a number of key elements to implement this *Global Access* strategy. First, due diligence is needed to confirm appropriate ownership or rights to the necessary IP via legal documentation (e.g. license agreements) and to ensure that the organizations directly involved with the grant project are viable organizations, meaning that there are executives, a pipeline, and means of fundraising. It is essential that there be adequate structures and strategies to manage the project, the technologies, and other related rights. Second, the foundation asks its grantees to make a commitment to support the *Global Access* strategy, which may entail conducting certain activities, such as providing reports or refrain from certain actions, such as granting exclusive licenses and filing for patent protection. This commitment may extend past the term of the grant to achieve the intended health solution. Third, the nature and the scope of the grantee's commitments will depend on the particular project being funded and other facts. Fourth, the

grantee will be required to provide an IP management plan and report inventions and licenses. Fifth, the foundation does not take ownership of the technologies, but limited march-in rights remain a possibility. Sixth, grantees are required to submit a written *Global Access* strategy document to outline their plan and maximize output. Erik Iverson, the associate general counsel to the Global Health Group of the Gates Foundation, stated that the foundation will work with each grantee to develop appropriate global access commitments. The foundation also aims to balance its charitable objectives with the grantee's need to market the technologies outside the developing countries, preserve market competitiveness, and promote IP rights.

The various programs and products of charitable organizations such as the Gates Foundation and the Rockefeller Foundation that are directed towards global health research require an appropriate legal framework. This framework should adequately address the external legal requirements of a charitable funder, such as federal tax rules (including IP issues addressed by the IRS) as well as the foundation's internal mission and goals. Most foundations, universities, PDPs, hospitals, and medical research organizations are 501(c)(3) organizations, meaning that they are corporations or legal entities that are exempt from income tax, and can receive tax-deductible donations and grants. These organizations are formed and operated for public benefit and charitable purposes, including education, scientific, or literary goals. At the same time the organization should not benefit privately from its works. It is also crucial that all 501(c)(3) entities find the appropriate balance between public and private benefit.

Robin Krause, an attorney with Patterson, Belknap, Webb & Tyler was involved in the initial set up of a Gates Foundation-sponsored PDP, IAVI. She observed that from a purely legal perspective, there is no difference between a university and a PDP, but the reality is that there is a perception that universities are more protected. In fact, the operations of a university are broader than PDPs – even a university-generated blockbuster product is only a small portion of the university's entire activity. Regardless, scientific research as a charitable activity must be

carried on in the public interest, which means that the results are available to the public on a timely and non-discriminatory basis, the research is performed for a governmental body, and is directed toward benefiting the public by either publishing in a trade publication, aiding economic development of a geographic area, or discovering a cure for a disease.

There are also basic federal tax rules governing exploitation of IP rights of or by a 501(c)(3) entity, where the public must be the primary beneficiary of said exploitation of IP rights, and any commercialization should not be contrary to industry norms, the terms should satisfy arms-length standards, and provide for reasonable compensation and economic benefit without being excessive. The organization must document why the compensation is deemed reasonable. PDPs are of great interest to the IRS as they have IP, revenue-generating abilities, and interest from the private sector. Overall, these legal and tax requirements may be reflected in the terms of the grant administered by the charitable funder, such as the *Global Access* strategy adopted by the Gates Foundation as described above.

The National Institutes of Allergy and Infectious Diseases, an organization that is part of NIH, also funds global health research as it covers diseases such as HIV/AIDS, malaria, tuberculosis, enteric diseases, and vaccine development. NIAID has a Global Health Plan, which promotes international outreach by encouraging capacity-building in the host country and has training programs for technology transfer. The funding for projects outside the U.S. has increased steadily to about US $400M for 2005, and over time a number of international research networks have been built.

Traditionally, NIH has supported product development through grants, cooperative agreements, contracts, SBIRs, and CRADAs. According to Mukul Ranjan, an officer in the Office of Technology Development of NIAID, there are now new models for product R&D. These include an increased emphasis on research resources (e.g. reagent repositories, genomic databases, animal models, support for clinical trials), a vaccine research center, vaccine

production contracts, and partnership programs. The vaccine production contracts provide resources to facilitate development of candidate vaccines into testable products, manufacturing of GMP-quality pilot lots as well as reagent-grade vaccines for testing in non-human primates, preclinical safety evaluations, and IND preparation. NIAID also puts CRADAs in place for vaccine development, which is directed towards early-stage and high-risk research and encourages collaboration to identify strong leads. NIAID also interacts with industry by granting awards to private sector companies (i.e. SBIRs, and STTRs), and providing support for PDPs to address barriers to development, mainly through a cooperative agreement mechanism with a focus on preclinical activities.

Conclusion

The LES Add-On session described in this article brought together people from various sectors, which led to interesting discussions with the speakers and amongst the attendees. It was noted that there was a need to bring more people from the biotech and pharmaceutical industry to provide their unique perspective and expertise, which would be very instrumental in developing innovative licensing activities to promote the creation of global health solutions in collaboration with university and PDP managers. One way to address this would be to design future LES workshops with a program content that would be of interest to the health care industry, perhaps by having a scientist communicate the importance and progress of his or her work in laymen's terms, or have legal practitioners provide specific frameworks under which licensing provisions could be constructed and negotiations could be undertaken in more creative ways.

It is also important to have open and transparent communication across the multiple sectors involved, and to know what other organizations are doing to encourage synergy and complementarity of skills and experience. Other suggestions included the sharing of *Global Access* strategy documents and obtaining feedback from the IP managers or licensing personnel

of the institutions who received a grant from the Grand Challenges for Global Health initiative from the Gates Foundation. Overall, it was incredibly encouraging to see a diverse collection of people come together and share their experiences and perspectives so generously with each other. These dialogs will be continued in other sessions planned at future conferences, including a workshop at the 2006 Spring LES/AUTM Meeting in Philadelphia.