

Script accompanying Usha Balakrishnan's Slide Presentation on Friday, March 9, 2007
Venue: AUTM 2007 Conference, San Francisco Marriott

Panel: Best Practices in Humanitarian Licensing of Intellectual Property

Moderator: Richard Wilder, Sidley Austin LLP

Speakers: Usha R. Balakrishnan, CARTHA

Alan Bennett, PIPRA & University of California-Davis

Labeeb Abboud, International AIDS Vaccine Initiative

Kevin Kuehm, Bayer Healthcare

Title of Usha's Talk: "Global Health Technology Transfer is NOT Business As Usual"

Good Afternoon! I thank Dick Wilder for giving me this opportunity to speak on this panel.

Tremendous efforts have been undertaken to study, develop, and share best practices in the area of humanitarian licensing approaches by practitioners like you, as well as academic scholars, student activist groups, research sponsors, philanthropic foundations, and many public and private sector organizations and NGOs such as MIHR and PIPRA.

In particular, because Steve Hansen from the American Association for the Advancement of Science had originally planned to be on this panel but could not participate today, I want to mention the work product of a Working Group of the AAAS called Science & Intellectual Property in the Public Interest or SIPPI for short. This group produced a wonderful paper in 2005 written by Amanda Brewster, Audrey Chapman, and Steve Hansen in Innovation Strategy Today. Titled "Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation," it is accessible on the AAAS website. Ashley Stevens had distributed this paper to all AUTM members at last year's AUTM conference in Orlando, which you will recall was focused on the theme of improving society and global health.

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My presentation today will cover two things in a personalized story format.

First, I will highlight some efforts of the Technology Managers for Global Health group. I will then highlight some managerial concerns relevant to humanitarian licensing provisions in university patent licenses. All I can share with you today are my perspectives based on my previous career in academic tech transfer. In my closing remarks, I will briefly share my ongoing work with CARTHA, a nonprofit that I launched six months ago.

Technology Managers for Global Health

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Celebrity attention, media coverage and more funding to global health projects have certainly created greater awareness.

However, beginning in 2002, I had to undergo my own struggle to assess what I could do as an everyday professional wanting to make a difference in global health fields.

There are numerous factors that contribute to global health disparities: poverty, lack of food, clean water, sanitation, lack of basic public health infrastructure and trained healthcare workers, and so many, many other factors. Nevertheless, new and effective interventions, such as better vaccines, drugs, diagnostics and medical devices can be critical to improving health around the world. Such interventions could save lives, reduce poverty, and help economies develop. In addition to the horrific number of deaths each year due to HIV/AIDS, malaria, and tuberculosis, there are also Chagas disease, leishmaniasis, and other diseases that kill or disable millions of people. Yet treatment options for so-called “neglected diseases” are inadequate or non-existent because there is little economic incentive for the private sector to develop new drugs.

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To address the formidable challenge of developing health products for neglected diseases, several global public-private product development partnerships or PDPs have been formed and supported by philanthropic organizations, as well as national governments and international organizations.

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My initial curiosity about PDPs, specifically the work of a nonprofit called MIHR, led me to form the AUTM Special Interest Group called Technology Managers for Global Health in 2003. TMGH is simply a collegial support network that meets annually at AUTM. About 40 participants have usually gathered energetically at each meeting. The rotating volunteers each year from within and outside AUTM have made all the difference to TMGH efforts.

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Our first annual meeting was held at AUTM 2004. This year is very special since we have as our guest speaker, Linda Harrar, an award-winning documentary producer. You’re all invited to participate at this 3:30 pm meeting which will be held right after this panel session today.

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The early efforts of TMGH focused on raising awareness and sharing experiences to foster a better appreciation and understanding of the nature of evolving practices and challenges in the context of global public health. Our global health technology transfer survey results were published in the AUTM Journal.

The work of academic technology managers – in evaluating inventions, licensing technologies, negotiating agreements, and facilitating partnerships -- does determine the trajectory for future development prospects. However, all of these activities need to be academically desirable, practically feasible, and economically viable. In the context of global public health, such approaches need to ensure fair access of such technologies for the world’s poor within an evolving framework of academic research and business opportunity, legal concerns, time and staff constraints, and ethical dilemmas. There are no easy, straightforward or standardized solutions in these cutting-edge professional practice realms.

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What can we do as technology managers? We can bring enormous creativity to our work and be effective change agents by undertaking proactive practice solutions and sharing them among colleagues. To create new opportunity for the development of academic inventions, we are in the business of business development, from a public benefit-oriented mentality. We deeply care about the aspirations of scientists and entrepreneurs, and strive to understand the goals of sponsors and licensees so that we can be effective cultural translators, good negotiators, and deal-makers. We can broaden networking efforts into larger communities-of-practice.

This has certainly been the exciting pattern of energetic outcomes with the work of TMGH.

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Teaming up with MIHR, TMGH produced the first booklet in May 2005 and distributed it to over 4,000 professionals.

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We contributed case studies for AUTM’s Better World Project reports.

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For our second booklet in 2006, we gathered and featured 4 case studies of PDP transactions.

Managerial Concerns

Let me now quickly highlight some managerial challenges with regard to “humanitarian licensing” approaches in university patent licenses.

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Aiming for collective benefit with a focus on outcomes for the poor *greatly alters* negotiative landscapes. All parties in a negotiation at least need to be somewhat aligned on

the objectives, and cross-sector perspectives need to be brought in, early on. We would definitely want to understand the desires of the inventing scientists, and then, for sure, include the perspectives of practitioners with direct roles in negotiating agreements. We must try to incorporate the valuable judgments of those who would have to sit across from each other at the negotiating table and those who would have the responsibility of concluding the deal in a timely manner while balancing a complex mix of business, legal, and regulatory constraints.

With regard to how wise it would be to standardize definitional issues in such licenses:

I'll leave it up to the lawyers on this panel!

I can observe though that in a globalized world, neither the world nor disease categories are so easily and neatly “carve-able” for licensing purposes any more. For example, there is the debate about the definitions of developed vs. developing countries, and the fact that not everyone residing within developing countries is necessarily poor, and chronic diseases such as diabetes are so universally prevalent now.

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There is tremendous energy and enthusiasm on the part of technology managers to make a difference, but we need additional resources and moral support to spur our interests and intellectual thinking to advance global health causes in practical ways.

Since I no longer work at a university, I can raise some issues boldly from my current vantage point, on behalf of my family of colleagues, on behalf of those who have so critically contributed to the work of TMGH, and most importantly, on behalf of the interests of less-advantaged populations.

We need to address the practical reality of who pays the salaries of university technology managers. These positions are usually paid from a portion of earned licensing income. Given this current equation, the growing insistence on royalty-free provisions will simply not achieve sustainable outcomes at university locations over the long run. While signing a humanitarian licensing deal may mean a lot to a university overall in terms of its PR value, close examination of its impact within technology licensing offices of various sizes needs to be examined further. How can we expect university licensing offices to pay for technology managers, to file and maintain speculative patents, and then license the patents royalty-free?

With regard to the global health field itself, it is such a hugely complex, vast, and dynamic field! Someone has got to fund the growth of tech transfer professionals who are serving society’s interests in these arenas. We can ask how and where the discretionary income from a few lucrative university tech transfer deals is being spent and how the priorities for

professional development are being determined. But, it will still likely be the case that the added costs of being engaged in global health issues cannot be absorbed by current budgets.

** In my own case, without the grant support from the Rockefeller Foundation and the Kauffman Foundation, I would not be here today.**

There are other broader concerns. I don't believe there are any campuses that currently reward their technology managers for "doing global good." In addition, it is important to examine how the participatory role for technology managers is being defined on campuses within the mix of scientists, researchers, students, administrators, and governing bodies?

In my own case, as a junior technology manager in 1992, I was fortunate to get to participate and contribute to the discussions with genome researchers when the Ethical, Legal, Social Implications of ELSI programs of the NIH were launched at the University of Iowa in conjunction with the establishment of the Human Genome Center there. An interdisciplinary course -- with biomedical scientists, philosophers, ethicists, lawyers, AND technology managers -- is what enhanced my learning and appreciation for these issues. It is perhaps time for something like that to be routinely fostered to advance global health tech transfer practice.

CARTHA & Closing Remarks

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Okay, I'm now ready to move on to CARTHA. In addition to neglected diseases, our world has so many other public health challenges emerging with diabetes, cancer, heart disease, mental health disorders, the threats from pandemic flu and climate change. In this larger context, humanitarian licensing approaches are simply one tool to deal with more equitable sharing of protected IP rights. Even if such approaches are routinized in agreements, someone needs to take on the responsibility to design practical steps to activate these humanitarian licensing provisions. And, even if IP issues were fully resolved, even if drugs were made fully available, the challenges in global health are so huge and so daunting.

Global Health Technology Transfer is Not Business as Usual. To make a difference in these fields, new business development frameworks and partnership practices need to be fostered in ways that advance global health causes as well as academic innovation management & tech transfer practice.

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To leverage partnerships and innovations & create opportunities for advancing global good, my vision with CARTHA is to build & empower a network of *Collaborative Doers*. With an action-oriented framework, I'm engaged in several initiatives.

For example:

- How can we adapt invention assessment tools to prompt inventors to reveal upfront whether their inventions may have applications in developing countries?
- How can we find seed funding to routinely “activate” humanitarian licensing provisions by offering incentives to prospective development partners?
- With so many universities now setting up global health centers, how can we additionally help in “globalizing” contact networks and increase practitioner-academic collaborations so that our universities can play an expanded role in transforming global health tech transfer practice, training, and research environments within and outside of the US?

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As I see it, our collective challenge is to find practical ways to extend the beneficial impacts of science and technology to wider settings. New health research efforts and innovations arising from such research have great potential to improve and save lives, but they need to be applied to the problems of poor populations around the globe as well as more developed countries. Even with increased research effort -- no matter where it takes place – we will need to employ creative approaches to manage innovations that do not carry with them the traditional promise of high financial returns.

We have to therefore put technology managers’ roles within an accountability framework.

Without the base of scientific excellence and capacity made possible through our US government, without the Bayh-Dole Act which allowed for formal managerial frameworks like tech transfer to be born, without the collective resources of so many professionals and philanthropists, without the human creativity and resilience we find in tough, resource-constrained communities, we could not possibly imagine to think today – in ambitious ways – to construct novel partnership arrangements between the public and private sector, and foster global networks to harness science and innovations to improve global health.

When Global Health Tech Transfer is Not Business as Usual, let’s prepare ourselves to help in new ways to develop and jointly implement practical solutions to advance global health causes!

Thank you.