Partnerships for Innovation and Global Health: NIH International Technology Transfer Activities

LUIS A. SALICRUP, *Senior Advisor for International Technology Transfer Activities, Office of Technology Transfer, National Institutes of Health, U.S.A.*

MARK L. ROHRBAUGH, *Director, Office of Technology Transfer, National Institutes of Health, U.S.A.*

ABSTRACT

Technological innovation is increasingly recognized as an important tool for improving global health. The Office of Technology Transfer of the U.S. National Institutes of Health (NIH OTT) has increased its licensing of technologies for the prevention and treatment of neglected diseases to partner institutions in developing regions of the world. Other efforts have focused on providing assistance to indigenous institutions in building their technology transfer capacity. In addition to helping to achieve the primary objectives of meeting global public health needs and strengthening local R&D capacities, NIH OTT expects such efforts to have a positive impact on national policies on intellectual property rights, and, ultimately, to increase multinational investments in developing countries, which will likely result in an even greater effort to develop accessible therapies for those in need.

1. NIH MISSION, INTERNATIONAL TECHNOLOGY TRANSFER, AND GLOBAL HEALTH

The mission of the U.S. National Institutes of Health (NIH), Department of Health and Human Services (HHS), is to support biomedical research that will reduce illness worldwide and extend healthy life. NIH's Office of Technology Transfer (OTT) works with institutes and centers at NIH and the Food and Drug Administration (FDA) to manage the patenting and licensing of inventions made by their intramural scientists. As part of this effort, NIH seeks to understand challenges that hinder the public availability of these inventions.

One might naturally ask why NIH, a domestic agency, should involve itself in international technology transfer. Enhancing technology transfer to developing countries, however, is an important humanitarian endeavor consistent with NIH's mission to improve health and save lives. Such transfers allow these countries to introduce technologies appropriate to their own regional needs, building more independence and enabling local and regional public health solutions.[1, 2, 3] Because many of these markets are not a priority for most companies in developed countries, technology transfer efforts can be extended outside the United States, consistent with humanitarian and economic goals.

By necessity, the NIH mission of NIH extends beyond U.S. borders. The U.S. works to improve health worldwide not only for humanitarian reasons but also because diseases do not observe national boundaries. Moreover, improved public health allows nations to better maintain economic growth and political stability.

One specific NIH goal for technology transfer is to "strengthen the capacity of developing countries to identify technologies and pursue their

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development into products, through education and technical assistance."[4] By extending R&D activities outside U.S. borders, we transfer technological know-how to developing countries. This learn-by-doing approach enhances technological capabilities[5] and facilitates the development of technologically capable partners, which, in turn, better leverages the value of technologies and extends scientific knowledge and practice. Overall, such technology transfer activities are likely to add value and provide social returns on existing inventions,[6] either by addressing U.S. market needs or by improving the health of people worldwide and preventing the spread of disease across U.S. borders.

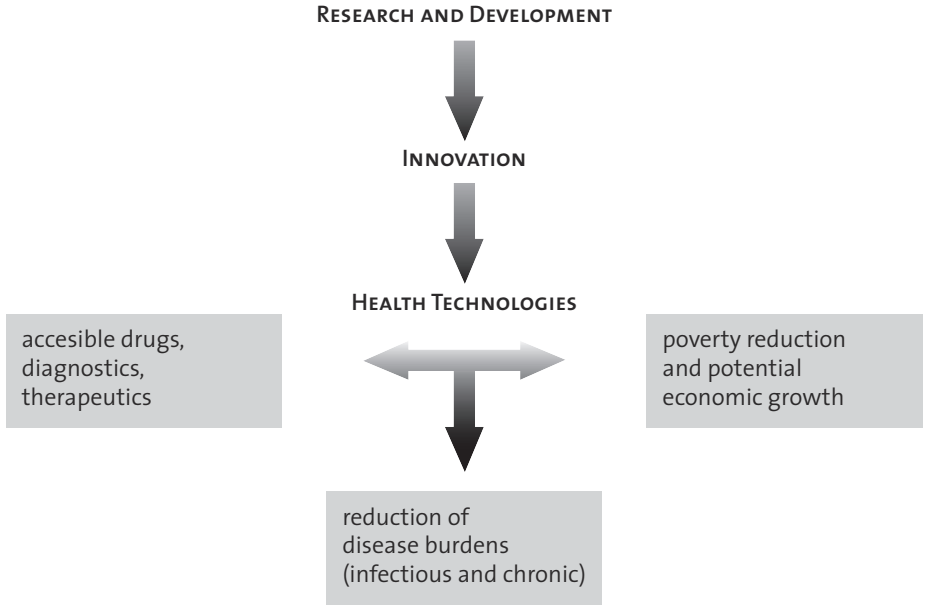
2. PARTNERSHIPS IN TECHNOLOGY TRANSFER

The most immediate incentive for OTT to engage in international activities is to help reduce the burden of disease globally. Developing countries stand to benefit from licensed NIH inventions, because when developed locally the technologies are more readily available to local markets. Such technology transfers may play a particularly important role in turning early-stage technologies into biomedical products in developing countries. Additional benefits accrue locally from the development of technologies for the developing world by indigenous institutions. These include enhanced local capacity in research and development, increased market competitiveness, the growth of an experienced work force, improvement of scientific excellence, and the consequential growth of the biotechnology infrastructure, all of which ultimately strengthen and stabilize developing countries' economies.[7] Figure 1 illustrates the potential impact of technology innovation on global heath.

The impact of globalization is not limited to international trade and economics.

Globalization also exacerbates existing public health challenges that in turn impact the national interests of industrialized nations. These challenges, though not limited to the developing world, can be addressed in part by the transfer

Figure 1: Potential Impact of Technological Innovation on Global Health



of technologies to developing countries. Indeed, the international community now widely recognizes that some diseases that once were contained within regional borders now threaten the United States in two ways:

- Emerging and reemerging infectious disease epidemics: With increased movement of goods, animals, and people, diseases spread rapidly across borders, posing direct threats to U.S. citizens. It suffices to mention epidemics of diseases such as HIV/AIDS, influenza, tuberculosis, cholera, and SARS, which threaten not only the regions where they originated but also the entire globe.[8]
- Risks from civil unrest: The spread of disease often fuels a cycle of poverty, suffering, and civil disorder. (Gaining access to drugs and medical technologies are genuine public welfare concerns in many developing countries.[9,10] Providing access to these countries will reduce the burden of disease and help improve the quality of life, thus diminishing the threat of unrest in volatile areas of the globe.)

While NIH focuses on making new methods of treating and preventing disease available to world markets, the agency also emphasizes the importance of making existing vaccines for pandemic diseases available to the countries in need For example, an effective vaccine for measles has been in use in industrialized nations for the past 40 years, but most of the developing world has only recently gained limited access to the vaccine.[11] In addition, the financial and logistical challenges of international efforts to provide antiretroviral drugs to treat HIV/AIDS in developing countries are well known.

Other diseases in developed countries remain serious public health burdens in developing countries. Malaria was virtually eradicated through the use of insecticides and antimalaria drugs in North America and Europe, while Africa, Asia, and Latin America saw the development of increasingly resistant mosquito vectors and malarial parasites. As malaria became a relatively low health risk in developed nations, the development of a malaria vaccine became a lower priority. This situation led the Bill and Melinda Gates Foundation to launch and support the Malaria Vaccine Initiative (MVI), an effort to address this serious shortcoming and accelerate vaccine development.[12] The foundation's efforts supplement ongoing research supported by NIH and other Non-Governmental Organizations (NGOs).

Another approach to these public health challenges is for institutions, both national and international, to encourage and facilitate the relatively more technologically advanced developing countries to enhance their product commercialization capacity to meet local needs. Several research studies indicate that this is the best approach to combating long-term neglected diseases in poor countries in Sub-Saharan Africa, parts of Asia, Latin America and the Caribbean, and Eastern Europe.[13,14,15] Indeed, recent work by leading private foundations, such as the Gates and Rockefeller foundations, emphasizes developing countries' "*need for self-reliance and national production [of health technologies] to ensure that country-specific disease needs can be met.*"[16,17,18,19] Ultimately, such investment will provide less-developed countries with sustainable benefits.[20]

The World Intellectual Property Organization's (WIPO) Cooperation for Development Program is committed to tailoring the implementation of its IP strategies to the diverse infrastructures and needs of developing countries.[21] Similarly, the Organisation for Economic Co-operation and Development (OECD) concludes that "*the transfer of technology to developing countries is a key element so that countries can develop their own R&D infrastructure and capabilities to meet their own needs.*"[22] Developing countries that have reached a sufficient level of technological capacity are now encouraged to enhance their capabilities more dynamically by nurturing domestic assets and creatively blending domestic and foreign knowledge.[23]

NIH Office of Technology Transfer recognizes the significance of assisting U.S. and foreign institutions in the development of technologies as a means to make medicines more accessible to everyone. By working with local institutions, international organizations, and private foundations, OTT has identified technology transfer needs and opportunities related to HIV/AIDS,

pertussis, malaria, dengue, childhood diarrhea (rotavirus), meningitis, typhoid fever, cancer, and diabetes. Based on the extensive patent portfolio in neglected diseases (Table 1), OTT has already transferred technologies to public and private institutions in India, Mexico, Brazil, China, Korea, Egypt, and South Africa. The office expects to execute licenses in the near future with other institutions in Africa.

This experience demonstrates that governmental or not-for-profit research institutions should seriously consider transferring early-stage biomedical technologies to institutions in the developing world rather than focusing exclusively on pharmaceutical and biotechnology companies in the western world. Of course, this should not be done haphazardly. NIH OTT learned a key lesson while expanding its licensing activities with developing countries—licensee institutions should have at least some research and development capability, as well as clear national and regional public health objectives. When these two conditions are met, access to key technologies and models of successful product development are more likely to produce new products to improve public health. By encouraging technology transfer throughout the world, NIH contributes to its long-term global mission of reducing the burden of diseases that are particularly devastating for people living in developing countries.[24]

3. INTERNATIONAL TECHNOLOGY TRANSFER RESULTS AT NIH: LESSONS LEARNED

With the goal of global public health in mind, there are many different strategies and tools that can be utilized in the management of IP. For instance, commercialization licenses can involve the transfer of rights to utilize IP, not only in relation to patents, but also for unique biological materials such as cell lines and microorganisms to be used in production or as candidate vaccines, and any associated gene expression constructs. Patent rights can only be enforced in countries where patents have been obtained for compositions of matter (materials) or methods of producing or using a given technology. Thus, in order to enforce a patent in a particular country, the patented composition or method must be used or sold in that country (or in some countries, an unpatented product produced by a patented method can infringe the method patent when that product is imported into the country where the method patent is held). For example, if a live

Table 1: Examples of NIH Intellectual Property in Neglected Disease Areas

Disease/therapeutic Area	Distinct technologies	Issued patents	Patents pending
Dengue	27	20	40
Rotavirus	19	2	28
Human Papilloma virus (HPV)	28	23	46
Lyme disease	7	1	6
Tuberculosis	16	1	14
Malaria	36	64	39

Source: Salicrup and colleagues.[33]

attenuated virus developed for use as a vaccine has been patented only in the United States and European countries, a commercialization patent license could be given to one company for the United States and Europe and possibly another company (as a biological materials commercial license) for the rest of the world, where no patent is in force. Since many institutions, particularly government or academic laboratories, have not obtained patent protection in many, or any, developing countries, the biological materials commercialization license is an important commercialization incentive tool.[25]

In addition to commercial licenses under either type of license, an institution can grant rights on a geographic basis, either exclusive, coexclusive or nonexclusive, in another country or to multiple countries within a geographic region, continent, or throughout the world. A strategy for a particular technology may be to permit multiple institutions around the world, each with a different geographic market segment, to develop the technology in parallel. This strategy is used to increase the opportunity for introduction of a product in multiple regions nearly simultaneously with the aim of meeting public health needs with less delay. Each regional producer may want to tailor the product slightly differently to meet the public health and regulatory demands of the region it represents. Finally, with this type of strategy, there will be back-up institutions to meet worldwide needs if one of the regional producers is delayed significantly or fails to produce the product.

By law and policy, NIH favors nonexclusive licensing to promote market competition, unless an exclusive or coexclusive license is a necessary incentive for one or two parties, respectively, to bring a product to market. Thus, when an exclusive license is not needed to encourage commercialization in a given country or region, nonexclusive licensing, regionally or worldwide, will allow multiple parties to compete in the market to develop a product. Like the regional strategy with multiple codevelopers, nonexclusive licensing within a given market has similar advantages.

When framing a marketing strategy for international product development, all of these mechanisms can be utilized in complex ways to provide the appropriate incentives for each country or region. Otherwise, the licensing terms for institutions serving the public health needs of developing countries are comparable to NIH OTT licenses to institutions in developed countries. Royalty fees are negotiated on a case-by-case basis, depending on such factors as the marketing plan, market size, potential use for the public interest, and the need to license additional technologies. In developing markets, some of these factors (for example, market size and public health interests) may play a greater role in determining the license terms than licenses for markets in OECD countries. This paradigm allows OTT to fulfill its statutory requirement to favor U.S. small businesses and to use exclusive licensing strategies as a commercialization incentive only as needed and supported by the market players.[26]

In recent years, NIH has increased its filing of patents for globally important vaccines and therapeutics in countries like China, India, Brazil, and Mexico so that the exclusive or coexclusive patent license mechanism is available for use as an incentive, as needed, to develop such products. This is particularly important for technologies where no unique biological materials are needed for commercialization and biological materials licensing is thus not an option. Additionally, NIH makes efforts to transfer know-how and critical documentation for manufacturing and marketing approval (when available) to help institutions in developing countries expedite their commercialization plans.

Through an ongoing analysis of its own portfolio and the needs and capabilities of developing countries, OTT has found that a niche exists for international technology transfer that is consistent with U.S. technological, public health, and economic interests. Such transfers, moreover, can provide solutions to the most socio-economically harmful diseases. OTT has already transferred early-stage technologies to public and private institutions in India, Brazil, China, Korea, Egypt, South Africa, and Mexico (see Table 2), and negotiations are in progress with institutions in Brazil, China, Argentina, India, Egypt, and Nigeria. For example, OTT licensed a vaccine conjugation technology to PATH, a nonprofit global health organization, to

develop a conjugated meningococcal vaccine in collaboration with the World Health Organization (WHO). PATH and WHO selected the Serum Institute in India to manufacture the vaccine for eventual distribution in Sub-Saharan Africa, the Middle East, Latin America and the Caribbean, and Eastern Europe. Another license agreement involves the transfer of NIH materials for the development of a conjugated vaccine against typhoid fever to the International Vaccine Institute (IVI) in Seoul, Korea, which plans to sublicense manufacturing to public and private entities in Indonesia and India for ultimate distribution of the product in Asia.

Table 2: Examples of NIH OTT Interinstitutional and Multiprong License Strategies

Technology	License type	Licensee(s)	Manufacturer	Technology distribution region
Conjugated Meningitis Vaccine	Nonexclusive patent	PATH/WHO, public and private institutions in South Africa and Nigeria (applied)	Serum Institute in India, public and private entities in Mexico and South Africa	Sub-Saharan Africa, Middle East, Asia, Latin America and the Caribbean
Human-Bovine Rotavirus Vaccine	Nonexclusive, coexclusive, or exclusive patent	Public and private institutions in Brazil, India, China, U.S.	Multiple companies; public entities in Brazil, China, India, U.S.	Latin America and the Caribbean, Asia, Africa, Middle East
Typhoid Fever Conjugated Vaccine	Nonexclusive biological materials	IVI	Biopharma in Indonesia, Serum Institute in India	Southeast Asia
Dengue Tetravalent Vaccine	Internal evaluation for Brazil (applied), nonexclusive for India and certain Latin American countries	Public institutions in Brazil, private institutions in India	Public institutions in Brazil, two companies in India, one company in U.S.	Latin America and the Caribbean, Asia
Varicella Vaccine	Commercial evaluation license	Public and private institutions in Egypt	Public entity in Egypt	Africa and the Middle East

Source: Adapted from Salicrup and colleagues.[34]

In some cases, a multiprong licensing strategy can be developed for the same technology that utilizes different license types to multiple institutions in different countries based on institutions' needs and market dynamics. For example, OTT is licensing technology related to the development of a human-bovine rotavirus reassortant vaccine to several public and private institutions in Brazil, China, India, and the United States.[27] Depending on the country and geographic region, the license is exclusive, coexclusive, or nonexclusive. The degree of exclusivity was determined by the needs of the prospective licensees and the market dynamics in each country. Surprisingly, not all nonprofit institutions were willing and able to accept a nonexclusive licensing arrangement. By granting exclusive rights only when needed to spur commercialization in world market segments, the strategy allows the market to drive the degree of exclusivity. This strategy also increases the likelihood that the technology will be developed in parallel from multiple sites for eventual worldwide distribution from multiple companies and institutions. In the case of an effective human-bovine rotavirus vaccine, such a goal is critical to significantly reducing childhood deaths from this infection, throughout the developing world, without unnecessary delays.[28, 29]

NIH OTT has found that international technology transfer requires a holistic and flexible approach—a donor-recipient paradigm that eschews unequal partnerships and the consequent challenges with trust, commitment, and reliability. Local scientists provide scientific support for the licensing strategy, and business managers directly participate in negotiations with NIH OTT as it pursues agreements with as much flexibility as possible to meet local needs. Hopefully, this strategy of enhancing technology transfer to emerging markets will build international capacity and capabilities. It should also provide regional, multilateral, and philanthropic organizations with more options to work with licensee companies to distribute products at a lower cost in developing countries and emerging markets.

4. CAPACITY BUILDING AS A TOOL FOR SUSTAINABLE ECONOMICAL AND SOCIAL DEVELOPMENT

NIH OTT also recognizes the relevance of assisting in the development of a cadre of scientists and technology managers experienced in IP management and other matters related to technology transfer. Overcoming this obstacle is necessarily a long-term project but also, eventually, a self-sustainable one.[30] As a first step, OTT is working in partnership with other stakeholders throughout the world to assess the technology transfer and training needs of institutions in developing countries. Moreover, OTT has initiated an international technology transfer capacity building program to train scientists and managers from developing countries. The first phase will include training of staff from institutions in China, Brazil, Argentina, India, South Africa, Philippines, Chile, Mexico, and Hungary. Future expansion of the program is envisioned for relevant personnel from additional institutions in Africa, Latin America, Asia, and Eastern and Central Europe.

NIH OTT, in collaboration with technology transfer offices at NIH Institutes and Centers, regularly invites individuals with particular expertise and experience with various aspects of technology transfer to give seminars at NIH. These experts include biotechnology and pharmaceutical business people, lawyers, technology transfer managers, governmental technology transfer experts, representatives of charitable foundations and NGOs dedicated to supporting product access in the developing world, representatives from nonprofit and for-profit institutions involved in commercialization efforts, and public health officials from throughout the world. Topics have included licensing strategies and terms, patents, public/private partnerships, MTAs, policy issues, and international agreements. As part of their internship at OTT, international trainees attend these lectures as they are able. OTT is currently discussing how to enhance the participation in these training and presentation sessions of both technology managers from institutions in developing countries and scientists and administrators from "resource limited"

institutions in the United States. Additionally, as part of the Curriculum Planning Workgroup of the Technology Managers for Global Health, a special interest group within the Association of University Technology Managers, NIH OTT participated in the design and development of an educational booklet geared to serve as a resource tool for technology managers of institutions in developing countries.[31]

OTT is working with the Patent Facilitation Centre at the Indian Ministry of Science & Technology, the Bi-National S&T Endowment Fund (generally called the Indo-U.S. science and technology fund), the South African Council for Scientific & Industrial Research (CSIR), and the Developing Countries Vaccine Manufacturers Network (DCVMN) to develop and implement short courses, seminars, and workshops on issues pertaining to IP management that are geared to training technology managers from several universities and from research and development centers in India, South Africa, Tanzania, Egypt, Brazil, Mexico, Argentina, Chile, China, Vietnam, and Thailand.

Information and access to knowledge has been recognized as a crucial step in enhancing capacity in developing countries. NIH OTT and the technology transfer offices from several universities in the United States recently developed and implemented a database of neglected-disease technologies available for licensing from these institutions. This database is already available at the OTT Web site with discussions underway with other potential hosts.[32] The database should be an important resource and capacity building tool for technology managers of universities and research centers in developing countries for identifying more readily such technologies and for coordinating work with the licensor institutions. The expectation is that other universities and non-profit institutions with technology licensing opportunities in the area of neglected diseases will eventually join this initiative to provide information at a single Web site while retaining licensing from the institution owning the technology.

5. INNOVATION, R&D COLLABORATIONS: NEXT STEPS

As NIH OTT's relationship with institutions in developing countries matures and the relationships between the office and those institutions expand, the next steps may include an evaluation study to explore the needs and opportunities related to technology transfer and training for people from institutions in developing countries. This evaluation would explore areas that affect technology transfer outcomes, such as IP policies, regulations, clinical trials capacity, IP management capabilities, and policies influencing public/private sector partnerships (PPPs). Thus, OTT has the potential to contribute to the scientific, technological, and health needs of developing countries by improving its own ability to bring to market technologies that will benefit local and regional public health.

NIH OTT is committed to contributing expertise and sharing ideas, strategies, and practices mutually with other organizations, in both developing and developed nations, to advance the goals of international technology transfer. Such coordination can only enhance the individual efforts of each of the institutions involved. In addition, OTT will continue to learn from partners throughout the world about creative alternative solutions to the challenges of transferring biomedical technologies to benefit global health.

6. CONCLUSIONS

Building on a strong track record, NIH OTT is expanding its efforts at licensing technologies to institutions in developing countries, and it continues to work with other stakeholders to help build technology transfer infrastructures. These activities are helping NIH to fulfill an important goal of its global public health mission: to reduce the devastating disease burden on people living in developing countries. Bringing biomedical inventions to populations in less-developed regions of the world can be achieved through various technology licensing models that fit the specific competencies of the research and development infrastructure of the particular countries. Moreover, it is expected that OTT's activities

in global technology transfer will promote well-recognized, good licensing practices that meet regional and national health priorities and standards. As a result, these activities should enhance public availability of new technologies, attract new biotechnology R&D resources, obtain returns on early-stage public investment, and stimulate economic and social development. ■

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LUIS A. SALICRUP, *Senior Advisor for International Technology Transfer Activities, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD, 20852, U.S.A. salicrul@mail.nih.gov*

MARK L. ROHRBAUGH, *Director, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD, 20852, U.S.A. mark.rohrbaugh@nih.hhs.gov*

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