

# I Strategy<sup>®</sup> P T O D A Y

An eJournal Sharing Creative and Innovative Ideas and Experiences in Intellectual Property Strategies and Management related to Global Development and Biotechnology in Agriculture, the Environment and Health

No. 12-2005

## Partnerships in Technology Transfer: An Innovative Program to Move Biomedical and Health Technologies from the Laboratory to Worldwide Application

*Luis A Salicrup, Rachelle F Harris and Mark L Rohrbaugh*



Published by



in collaboration with



and



<b>Published by</b>	<i>bio</i> Developments—International Institute Inc., Ithaca, NY in collaboration with Cornell University and The Biodesign Institute of Arizona State University.
<b>ISSN</b>	1534-6447
<b>Copyright</b>	© 2005. <i>bio</i> Developments—International Institute Inc., Ithaca, NY, USA  Sharing of <i>IP Strategy Today</i> through the Internet is encouraged. Reproduction for educational or other non-commercial purposes is authorized without prior permission from the copyright holder, provided the source is acknowledged. Reproduction for resale or other commercial purposes is prohibited without the prior written permission from the copyright holder.  <i>IP Strategy Today</i> is a registered trademark of <i>bio</i> Developments—International Institute, Ithaca, NY, USA.
<b>Editorial Board</b>	Anatole F. Krattiger, Editor-in-Chief, SWIFTT, Cornell University, Ithaca NY, USA Tanit Changthavorn, BIOTEC, Bangkok, Thailand W. Ronnie Coffman, Cornell University, CALS, Ithaca NY, USA John Dodds, Dodds & Associates, Washington DC, USA William H. Lesser, Cornell University, CALS, Ithaca NY, USA Darryl Macer, Eubios Ethics Institute, Tsukuba University, Japan Richard Mahoney, MIHR & Arizona State University, USA Peter W B Phillips, University of Saskatchewan, Canada
<b>Author's Addresses</b>	Luis A Salicrup and Mark L Rohrbaugh Office of Technology Transfer (OTT) National Institutes of Health (NIH) U.S. Department of Health and Human Services 6011 Executive Boulevard, Suite 325, Rockville MD 20852. USA <a href="mailto:salicrul@od.nih.gov">salicrul@od.nih.gov</a> and <a href="mailto:RohrBauM@OD.NIH.GOV">RohrBauM@OD.NIH.GOV</a>  Rachelle F Harris MIHR, the Centre for the Management of Intellectual Property in Health Research and Development Oxford Centre for Innovation, Mill Street Oxford, OX2 0JX. UK <a href="mailto:rachelle.harris@mihir.or">rachelle.harris@mihir.or</a>
<b>Citation</b>	Salicrup LA, RF Harris and ML Rohrbaugh. 2005. Partnerships in Technology Transfer: An Innovative Program to Move Biomedical and Health Technologies from the Laboratory to Worldwide Application. <i>IP Strategy Today</i> No. 12-2005. Pp. 1-12.
<b>Free Publication Orders</b>	For free downloads of this and future volumes of <i>IP Strategy Today</i> , please visit <a href="http://www.bioDevelopments.org">www.bioDevelopments.org</a>
<b>Free Subscriptions</b>	to <i>IP Strategy Today</i> , visit the above web site or write to: <i>IP Strategy Today</i> , Cornell Business and Technology Park, POBox 4235, Ithaca NY14852, USA.
<b>Submission of Papers</b>	Send an email to any of the Editorial Board Members (only electronic submissions are accepted)
<b>Instruction to Authors</b>	Please visit <a href="http://www.bioDevelopments.org">www.bioDevelopments.org</a>
<b>Editorial Policy</b>	The purpose of <i>IP Strategy Today</i> is to provide a forum to share creative, innovative and pragmatic analysis and ideas in intellectual property strategies and management issues, particularly as they affect the transfer of proprietary technologies to developing countries, developing countries access to proprietary technologies in agriculture, the environment and health, and the international exchange of genetic resources. Emphasis on the implications of biotechnology are specifically encouraged. Papers must have a problem solving orientation and demonstrate originality and innovation in thinking, analysis, methods or application. Issues related to research investments and management, bilateral and multilateral donor policies, extension, teaching, public-private partnerships are equally encouraged, as is interdisciplinary research with a significant IP and international development component. Manuscripts, review articles and working papers that offer a comprehensive and insightful survey of a relevant subject, consistent with the scope of <i>IP Strategy Today</i> , are welcome. All articles published, regardless of their nature, will be reviewed anonymously by members of the editorial board.
<b>Concept and Design</b>	<i>bio</i> Developments LLC (International Consultants), Interlaken, NY.
<b>Funding</b>	We are grateful to the Rockefeller Foundation, to the Department of Plant Breeding and to the International Program of the College of Agriculture and Life Sciences (IP/CALS) at Cornell University for support.
<b>Frontispiece</b>	© 2005. Geneva Foundation for Medical Education and Research ( <a href="http://www.gfmer.ch">www.gfmer.ch</a> ). Reproduced with permission. A photograph taken in Bangladesh by the Bangladesh Association for Maternal and Neonatal Health (BAMANEH).
<b>Disclaimer</b>	The views expressed are those of the authors and do not necessarily reflect those of their respective institutions, nor of the publishers, editors and donors of <i>IP Strategy Today</i> .

# Partnerships in Technology Transfer:

## An Innovative Program to Move Biomedical and Health Technologies from the Laboratory to World-wide Application <sup>1</sup>

**Luis A Salicrup (PhD, MSM), Rachelle F Harris (MSc)<sup>2</sup> and Mark L Rohrbaugh (PhD, JD)**

*Office of Technology Transfer (OTT)*

*National Institutes of Health (NIH)*

*U.S. Department of Health and Human Services*

*6011 Executive Boulevard, Suite 325*

*Rockville MD 20852, USA*

<b>Executive Summary .....</b>	<b>2</b>
<b>1. The Role of Technology Transfer in Global Health .....</b>	<b>3</b>
<b>2. Innovation in Developing Countries .....</b>	<b>6</b>
<b>3. International Technology Transfer .....</b>	<b>7</b>
<b>4. Initial Results &amp; Lessons Learned .....</b>	<b>8</b>
<b>5. Next Steps .....</b>	<b>10</b>
<b>6. Conclusions .....</b>	<b>11</b>
<b>References.....</b>	<b>11</b>

---

<sup>1</sup> Salicrup LA, RF Harris and ML Rohrbaugh. 2005. Partnerships in Technology Transfer: An Innovative Program to Move Biomedical and Health Technologies from the Laboratory to Worldwide Application. *IP Strategy Today* No. 12-2005. Pp. 1-12.

<sup>2</sup> Former NIH/OTT International Intern. Currently at MIHR, the Centre for the Management of Intellectual Property in Health Research and Development, Oxford Centre for Innovation, Mill Street, Oxford, OX2 0JX. UK.

## Executive Summary

The mission of the U.S. National Institutes of Health (NIH), Department of Health and Human Services, is to support biomedical research to extend healthy life by reducing illness worldwide. As part of this effort, the NIH seeks to understand and overcome the obstacles hindering the public availability of inventions made by NIH scientists. This article reviews the results of initial efforts to narrow some of these availability gaps, the possible global benefits of NIH inventions, and future plans to evaluate models of successful international technology transfer activities.

The NIH Office of Technology Transfer (OTT) is the lead office managing the patenting and licensing of inventions made by scientists at the NIH and Food and Drug Administration (FDA). It is actively exploring ways to improve how technologies are transferred to developing countries, particularly by identifying biomedical research institutions, foundations, and companies in Latin America, Africa, Asia—as well as some of the transitional economies in Central and Eastern Europe—that have the interest and capacity to receive and develop new biomedical products and services.

By working with institutions in the above regions and with international organizations and private foundations, OTT has identified urgent technology transfer needs and opportunities related to HIV/AIDS, tuberculosis, malaria, dengue, rotavirus, meningitis, cancer, and diabetes. OTT has already transferred technologies or is currently negotiating licenses to begin transfers with institutions in India, Mexico, Brazil, Argentina, China, Korea, Indonesia, Egypt, South Africa, and other Sub-Saharan African countries.

This experience to date demonstrates that governmental or not-for-profit research institutions should transfer early stage biomedical technologies to institutions other than North American or European biotechnology and pharmaceutical companies. Of course, this should not be done haphazardly. NIH OTT learned a key lesson while expanding its licensing activities in developing countries: participating institutions should have some research and development (R&D) capability and clear national and regional public health objectives. When these two conditions are met, access to key technologies and models of successful product development by the NIH can enhance the prevention and care of infectious and non-communicable diseases. By encouraging technology transfer the NIH contributes to its long-term global mission of reducing the burden of diseases that are particularly devastating for people living in developing countries. The next possible steps include an evaluation study of this model of technology transfer and its impact on the translation of basic and applied research.

NIH OTT also recognized the lack of capacity building efforts to support development of a cadre of scientists and technology managers experienced in Intellectual Property Management (IPM) and other technology transfer-related matters. Overcoming this obstacle is necessarily a long-term project but also eventually a self-sustainable one. As a first step, OTT is working in partnership with other stakeholders in developing countries, the U.S., and Europe to assess the technology transfer capacity building and training needs of institutions in developing countries. As part of this effort we are identifying such competencies as the development and implementation of intellectual property management policies, the clinical development of technologies, and experience with public-private partnerships. OTT has also initiated an international technology transfer capacity building program to train scientists and managers from developing countries. The first phase will include transfers of staff from institutions in China, Brazil, and India. We plan to expand the program to relevant personnel in African, Latin American, and European institutions.

# 1. The Role of Technology Transfer in Global Health

There is a strong case for enhancing technology transfer to developing countries. It would allow them to develop technologies appropriate to their own regional needs, enabling sustainable local and regional solutions to public health needs (OECD 2003; Varmus *et al* 2003; Saya *et al* 2004). But one might question why the NIH should involve itself in international technology transfer. After all, the National Institutes of Health is a national institution. Moreover, the NIH should not risk leaking knowledge that might put the United States at a competitive disadvantage. There are good reasons, however, why the NIH mission extends beyond the borders of the United States.

Consider the mission of the NIH:

“Science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.”<sup>1</sup>

The agency achieves this mission by pursuing the following goals to:

1. foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to advance significantly the Nation's capacity to protect and improve health;
2. develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease;
3. expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
4. exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.” (*ibid.*)

Furthermore, one NIH goal for technology transfer is specifically to “strengthen the capacity of developing countries to identify technologies and pursue their development into products, through education and technical assistance”<sup>2</sup>. Extending R&D activities outside US borders transfers technological know-how as developing countries learn-by-doing and gain technological capabilities (Bell and Pavitt 1993; Hobday 1995). Facilitating the development of technologically capable partners better leverages the value of technologies and extends scientific knowledge and practice. Overall, such activities are likely to add value and provide social returns on existing inventions (Saha *et al* 2004). Social returns are realized on the public sector's vast financial investments in biomedical R&D, either directly by serving US markets or indirectly by improving the health of people worldwide and preventing the spread of disease across US borders.

A number of studies document the existence of major global health disparities, with the greatest burdens borne in the developing world (Gwatkin and Guillot 2000). One primary reason is the lack of access to advanced technologies that address emerging, re-emerging, and chronic diseases in major parts of the developing world. It is also well known that this problem persists largely because there are no incentives in the developed world to provide technological solutions (e.g., drugs, vaccines, diagnostics) for these problems.<sup>3</sup> Figure 1 highlights the main disease burdens in developing countries.

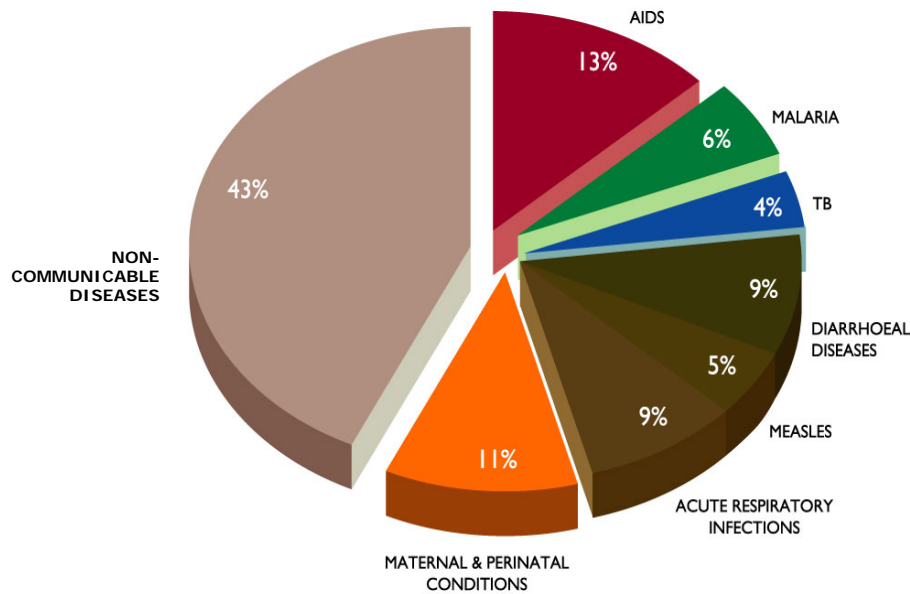
---

<sup>1</sup> NIH Almanac, [www.nih.gov/about](http://www.nih.gov/about)

<sup>2</sup> Government Performance and Results Act (GPRA 2003). <http://www.ftc.gov/opp/gpra/>

<sup>3</sup> The cost of R&D for new drugs is estimated to be between \$650 and \$800 million, including opportunity costs and absorbing the costs of failures (Kettler 2000; Di Masi *et al* 1991). For instance, out of the nearly 1,400 new drugs that were registered between 1975 and 1999, only 1% (13 drugs) was for tropical diseases (Olliaro and Trouiller 1999, DNDi Working Group and MSF 2003). However, 95% of the annual 17 million deaths worldwide from infectious and communicable diseases occur in developing countries (OECD 2002).

**Figure 1: Health: A Key to Prosperity—Success Stories in Developing Countries**



Globalization can disseminate these diseases across continents through the rapid migration of human populations, a dynamic that poses new challenges to the United States. Indeed, it is now widely recognized by the international community that diseases that once were contained within regional borders now threaten the United States in two ways:

- Emerging and re-emerging 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 SARS. The epidemics of diseases such as HIV/AIDS, influenza, tuberculosis, and malaria in certain parts of the world threaten not only the regions where they originate but also the entire globe (Global Health Council, [www.globalhealth.org](http://www.globalhealth.org)).<sup>4</sup>
- Risks from terrorism: Access to drugs and medical technologies are genuine public welfare concerns in many developing countries (Oxfam 2000; CMH 2001). Indeed, the spread of disease often fuels poverty, suffering, and civil disorder. Providing access to needed medical technologies will reduce the burden of disease and improve the quality of life in volatile areas of the globe, diminishing the unrest that fuels the growth of terrorism.

The burden of disease on the social fabric of societies has led the US and many other Western countries to treat disease in developing countries as a serious economic and security issue. Countries ravaged by disease are more likely to be unstable politically and to require more foreign assistance; they are also less likely to develop economically into strong international trading partners (Folkers and Fauci 2001; Institute of Medicine 1997; and NIC 2000).

Despite this great need, pharmaceutical firms have few incentives to invest in products to treat and prevent diseases that primarily afflict poor countries because of low returns on investments in high-risk and costly biomedical R&D.<sup>5</sup> This is clearly illustrated by tuberculosis. A new generation of drugs has not

<sup>4</sup> At the same time, chronic diseases such as cardiovascular diseases and diabetes, which historically have primarily been diseases of the developed world, are also increasing in developing countries.

<sup>5</sup> The so-called 10/90 Gap, by which is meant that 90% of the world's drugs reach only 10% of its population (Kettler 2000; Olliaro and Trouiller 1999).



reached the market for over thirty years, largely because the disease has ceased to be a priority for wealthy nations, whose ability to pay high prices for drugs enables companies to recoup their steep investments.<sup>6</sup>

Similar challenges also exist for drugs and vaccines that have been developed for pandemic diseases where the introduction of such products to developing world markets has been delayed significantly. For example, the first polio vaccines were introduced in the West in the 1950s, and only now fifty years later health officials foresee the eradication of this virus in the near future. An effective vaccine for hepatitis B virus (HBV) was introduced in the West in the 1970s, but most of the developing world has no access to the vaccine. In addition, the financial and logistical challenges of international efforts to provide anti-retroviral drugs to developing countries are well known.

Consequently, some of the relatively more technologically advanced developing countries should enhance their R&D capacity and expertise in product commercialization to meet local needs. A wealth of research indicates 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.<sup>7</sup> Indeed, recent work by well-respected think tanks, academics, private foundations, and policy-makers emphasizes developing countries' "need for self-reliance and national production [of health-care products] to ensure that country-specific disease needs can be met" (Saha *et al* 2004; OECD 2002).<sup>8</sup> Similarly, the Organization for Economic Co-operation and Development (OECD) states strongly 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" (OECD 2002). Developing countries that have reached a certain level of technological capacity are now encouraged to foster dynamic capabilities, to nurture domestic assets by creatively blending domestic and foreign knowledge (Lall 1992, 1996; Hobday 1995).

These policy recommendations are supported by extensive research showing that innovation capability and international technology transfers are key elements of maintaining and expanding national shares in the global economy (Romer 1993; Ariffin and Bell 1999; Bell and Albu 1999). Technology transfer refers to "any process by which one party gains access to another's technical information and successfully learns and absorbs it into its production process" (Maskus 2003, p. 3). Facilitating further research and development, transfers ensure the wide application of scientific discoveries, methods, procedures, techniques, and equipment for promoting health and social development. The NIH uses a variety of mechanisms to facilitate such transfers: patenting and licensing inventions, scientific publications to share knowledge, transfers of unique biological materials, and scientific collaborations for basic and applied research. A major channel is the licensing of patent-pending or patented inventions, which "typically involves the purchase of production or distribution rights and the underlying technical information and know-how" (Maskus, 2003, p. 4). Patents directly facilitate this kind of knowledge transfer.

---

<sup>6</sup> It is only in remote cases—those in which an acute threat is posed to the United States—that exceptions are made and vaccines and therapeutics are produced under government subsidy.

<sup>7</sup> The report of the Organization for Economic Co-operation and Development (OECD) from the "Conference on Biotechnology for Infectious Diseases: Addressing the Global Needs (OECD 2002)" strongly recommends this view, clearly articulating 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."

<sup>8</sup> "Grand Challenges in Global Health," (Varmus *et al* 2003). The Panel analyzing these "Grand Challenges" suggested seven overarching goals and challenges. All of these were related to developing new and better technologies, such as effective vaccine technologies, efficient vaccine and drug-delivery systems, diagnostic tools, therapeutics, bio-available nutrition systems (via genetic modification of plants), etc. This view was reiterated by Dr. Elias Zerhouni and a former Director of the National Cancer Institute (Varmus *et al* 2003). Furthermore, one of the key messages from world leaders at the World Summit for Sustainable Development (WSSD), held in 2002 in Johannesburg, South Africa, was the need to build capacity of the Science & Technology (S&T) enterprise in the developing world for its own sustainability.

## 2. Innovation in Developing Countries

A positive side effect of increased technology transfer to developing countries is the worldwide reduction of poverty, which in turn reduces the spread and impact of disease (OECD 2003; CMH 2001)<sup>9</sup>. Approximately one third of the world's population is "technologically deprived," and only 15% of the global population provides almost all technological innovations (Juma *et al* 2001). Clearly this imbalance needs to be addressed. Collaboration between countries and across sectors in technological areas outside of national core competencies is one way to reduce this inequality. It will enable the transfer of technological knowledge and its application into under-invested areas. We should act quickly to transfer relevant expertise and scientific knowledge to developing country institutions that can transform it into health-related products for areas neglected by developed country innovators.

Thus Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) states as an objective for the global system that,

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

Reiterating this point, Article 66(2) speaks directly "to the disparity in innovation capacity and access to technology between developed and developing countries" by supporting technology transfer from developed country WTO Members to least-developed country Members "in order to enable them to create a sound and viable technological base." (Taylor and Cayford 2003). This is stated again in TRIPs Article 67 on Technical Cooperation:

"In order to facilitate the implementation of the Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favor of developing and least developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations of protection and enforcement of intellectual property rights as well as on the prevention of their abuse."

The NIH recognizes all the potential benefits to be gleaned from participating in international technology transfer and is also acutely aware of the potential losses in its absence, particularly for developing countries with dire needs and technological shortfalls (see Maskus 2004 for a concise review of this area). NIH OTT is working to complement the activities of organizations such as the Centre for the Management of Intellectual Property in Health Research and Development (MIHR), which was established with start-up funding from the Rockefeller Foundation to address issues in intellectual property management that can enhance technology transfer and innovation in developing countries. Moreover, as the office responsible for patenting and licensing inventions made by scientists working at the NIH and the Food and Drug Administration (FDA), NIH OTT is actively exploring ways to improve the process of transferring technologies to developing countries. In particular, OTT has identified (and continues to identify) biomedical research institutions, foundations, and companies in Latin America, Africa, Asia, and some of the transitional economies of Central and Eastern Europe that have the interest and capacity to receive and further develop new technologies. In collaboration with these partners, OTT has identified urgent technology transfer needs and opportunities related to HIV/AIDS, tuberculosis, malaria, dengue, rotavirus, meningitis, cancer, and diabetes. OTT has already transferred technologies or is currently negotiating licenses to begin transfers with institutions in India, Mexico, Brazil, Argentina, Chile, China, Korea, Indonesia, Egypt, South Africa, and other Sub-Saharan African countries.

---

<sup>9</sup> Evenson and Westphal 1995; UNCTAD 2003; Maskus 2003; Hoekman, Maskus and Saggi 2004; IAC 2004.



### 3. International Technology Transfer

One goal of NIH OTT is to address availability gaps for NIH and FDA inventions and to make these technologies more accessible to people around the world. With its leadership in biomedical research and innovation, as well as its management of technology commercialization across sectors, the U.S. is in a prime position to lead and help other countries formulate appropriate technology-transfer procedures in the developed world<sup>10</sup>. And as a leader in biomedical research, the NIH OTT can play a significant role in international technology transfer. In presenting the NIH Roadmap Initiative, NIH Director Dr. Elias Zerhouni stressed the need to position NIH for the evolving public-health challenges of the 21<sup>st</sup> Century. The Roadmap emphasizes the enhancement of “public-private partnerships [which] have become a model for advancing science and communicating results of medical advances to improve the quality of life for all people.” (Zerhouni, 2003).

With its large portfolio and 15 years of experience in technology transfer, the NIH OTT is also well positioned to move technologies to the private sector for commercialization in the US and abroad.<sup>11</sup> Out of a total of 2800 executed licenses or license amendments, about 410 licenses have been executed to a foreign entity. In FY 2004, there were 32 foreign licenses (27 new and 5 amendments) executed out of a total of 276 (of which 196 were new licenses and 80 were amendments). There are even more opportunities for international technology transfer because some developing countries, such as China, India, Brazil, and South Africa, have become emerging economies with expertise in advanced technological (biomedical R&D) capabilities.

NIH has been at the forefront of this endeavor. It has made technologies accessible to the public through its management of intellectual property, patents, and licensing and by utilizing its daily interactions with NIH scientists, universities, foundations, and companies worldwide. Its technologies have been put to use in approximately 200 marketed products and services, in part through collaborations with governments, private industry, academia, international organizations, and private foundations. These include HIVAB (AIDS Test Kit/Abbott and others); Videx (ddI/BMS); Taxol (paclitaxel/BMS); Fludara (fludarabine/Schering); Havrix (hepatitis A vaccine/GSK); and Synagis (monoclonal antibody to respiratory syncytial virus (RSV)/MedImmune).

NIH has already developed a relatively strong portfolio for some neglected infectious diseases (shown in Table 1), but these technologies have not yet been fully exploited. It should be noted that while there may be technologies on the market for these diseases, they may be either obsolete, inaccessible to most developing-country markets due to cost, or involve complicated delivery mechanisms.

For technologies with a worldwide market, such as those related to HIV/AIDS, the NIH OTT has adopted license terms in the last few years that require companies in North America or Europe to provide a marketing plan for making products available to developing countries. Usually these plans are due shortly after receiving their first market approval. Since these technologies are in their early stage, none of the licenses governed by these terms have yet reached this milestone.

---

<sup>10</sup> eg. IIPi, [http://www.iipi.org/activities/projects\\_tech\\_transfer.htm](http://www.iipi.org/activities/projects_tech_transfer.htm)

<sup>11</sup> Indeed, approximately 15% all active NIH licenses have been executed with institutions outside the US.

<sup>11</sup> Hoekman, Maskus and Saggi 2004; CIPR 2001; Ernst&Young 2000; Rivette and Kline 2000; Falconi and Salazar 1999; Juma & Clark 2002; IIPi ([http://www.iipi.org/activities/projects\\_tech\\_transfer.htm](http://www.iipi.org/activities/projects_tech_transfer.htm)). OTT has already been successfully moving PHS technologies to institutions in developing countries, such as China and Brazil, based on public-health needs and R& D and commercialization capabilities, but only a few institutions in even fewer countries are familiar with the patenting or licensing process and/or are able to enter well-prepared into technology transfer transactions and negotiate terms and conditions. IPR is considered a critical currency in technology transfer and innovation generally: Intellectual Property Rights: Implications for Development ICTSD and UNCTAD, 2003.

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

Disease/Therapeutic Area	Distinct Technologies	Issued Patents	Patents Pending
Dengue	22	1	113
Rotavirus	12	4	36
Human Papilloma Virus (HPV)	15	14	56
Lyme disease	6	1	18
Tuberculosis	10	2	24
Malaria	29	176	78

Several inventions have also arisen out of the NIH Natural Products Screening Program, which screens natural products from countries outside the US for activity against cancer or infectious diseases.<sup>12</sup> Under the terms of the collection agreement, if NIH scientists make an invention, any commercialization license must require the licensee to reach mutually agreeable terms with the source country or region as to how benefits from commercialization will be shared.<sup>13</sup> The most successful to date is Calanolide A, an antiretroviral drug for treating HIV/AIDS, originally identified by NIH and Sarawak scientists in a tree native to Sarawak, Malaysia. In 1995, NIH OTT licensed this invention to Medichem with a requirement that they enter into an agreement with the government of Sarawak regarding benefits sharing. NIH OTT does not otherwise dictate or mediate the terms of these agreements. The sharing agreement between Medichem and Sarawak provided for the founding of a joint venture, Sarawak-Medichem, in Malaysia. The drug is in Phase II clinical trials.

The NIH OTT is exploring more ways to enhance the process of transferring technologies to developing countries. In a drive to market these technologies to parties interested in entering developing-country markets, contacts are being developed worldwide with R&D institutions in developing countries, in both the private and public sectors. We are proactively searching for potential partners in developing countries for key neglected diseases, including both communicable (i.e. HIV/AIDS, dengue, and rotavirus) and non-communicable diseases (i.e. cancer, diabetes).

## 4. Initial Results & Lessons Learned

Commercialization licenses can involve the transfer of rights to utilize intellectual property as well as unique materials in some cases. The NIH OTT has utilized both types of licenses as incentives to develop products for the developing world. Intellectual property rights can only be enforced in countries where a patented technology is used to manufacture a product or in countries where the product is sold. Thus, in countries where the patent owner has not sought patent protection, as is often the case in many developing countries, a biological materials license agreement can be an important incentive in providing the institutions with some level of market protection the transfer of technologies. In addition, NIH OTT has utilized geographic exclusivity or co-exclusivity as an incentive for a licensee to develop a product for a particular regional market. When an exclusive license is not needed to encourage commercialization, non-exclusive licensing, regionally or worldwide, will allow multiple parties to compete in the market to develop a product.

<sup>12</sup> See <http://www.nci.nih.gov/search/results.aspx>

<sup>13</sup> See <http://ttb.nci.nih.gov/nploc.html> for model Letter of Collection Agreement used by the Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, NIH.

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 less-industrialized countries would be comparable to NIH OTT licenses to institutions in industrialized countries. Royalty fees are negotiated on a case by case basis, depending on factors such as the marketing plan, market size, and the need to license additional technologies. Using this paradigm allows the OTT to fulfill its statutory requirement to favor small U.S. businesses for the U.S. market and to use exclusive licensing strategies only as needed.

Through an ongoing analysis of its own portfolio and the needs and capabilities of developing countries, OTT has found that a niche exists for technology transfer that does not jeopardize US 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 and Mexico, and negotiations are in progress with institutions in Brazil, China, India, Korea, Indonesia, Egypt, and South Africa to facilitate inter-institutional, international product development (see Table 2). For example, NIH licensed a vaccine conjugation technology to the Program for Appropriate Technologies in Health (PATH) to develop a conjugated meningococcal vaccine in collaboration with the World Health Organization (WHO). India will 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 to the International Vaccine Institute (IVI), in Seoul, Korea, which plans to sublicense manufacturing to an Indonesian company to distribute the product in Asia.

In some cases, OTT has adopted a multi-prong strategy that licenses the same technology under different license types to multiple institutions in different countries. For example, NIH OTT is licensing technology related to the development of a human-bovine vaccine to institutions in Brazil, China, India, and the U.S. (*Federal Register* 2004a and 2004b). Depending on the country and geographic region, the license is non-exclusive, co-exclusive, or exclusive. The degree of exclusivity was determined by the needs of the prospective licensees in each country. By granting exclusive rights only when needed to spur commercialization and segment the world market, the strategy allows the market to drive the degree of exclusivity and thus increase the likelihood that the technology will be developed for worldwide distribution. In the case of an effective human-bovine vaccine, such a goal is very important because it would greatly reduce childhood deaths related to rotavirus infection in developing countries.

This approach is a viable means to circumvent the problems of market failure or delayed market entry that occur when Western companies have little or no interest in bringing technologies to less profitable markets. Such an approach also has other potential advantages, such as a product that costs less than that made by a Western-based company, an opportunity for economic growth and capacity building in developing countries, and the ability to modify the geographic scope of licenses to successful licensees if for some reason a regional producer is unsuccessful. However, there will still be the challenge of providing such products to the least developed countries. The extreme poverty of the people may make it impossible for them to purchase even inexpensive products. But if international interest and funds exist to provide products to these least developed countries, then at least lower cost producers will already be established in developing countries to fill this need. Hopefully, this strategy of enhancing TT to emerging markets will ultimately provide regional/multilateral and philanthropic organizations with more options to distribute products at a lower cost in lesser- developed countries.

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 and managers directly participate in negotiations with the NIH OTT as it pursues agreements with flexibility and determination.

**Table 2: Examples of NIH OTT Inter-Institutional or Multi-Prong License Strategies**

<b>Technology</b>	<b>License Type</b>	<b>Licensee (s)</b>	<b>Manufacturer</b>	<b>Technology Distribution Region</b>
Conjugated Meningitis Vaccine	Non-exclusive patent	PATH/WHO	Serum Institute-India	Sub-Saharan Africa, Middle East, Asia, Latin America & the Caribbean
Human-Bovine Rotavirus Vaccine	Nonexclusive, co-exclusive or exclusive patent	Public & Private institutions in Brazil, India*, China*, US*	Multiple companies & public entities in Brazil, China, India, U.S. & Mexico	Latin America, the Caribbean, Asia, Africa, Middle East
Typhoid Fever Conjugated Vaccine	Nonexclusive biological materials	IVI*	Public & private institutions in Indonesia and India	South-East Asia
Dengue Tetravalent Vaccine*	Exclusive patent for Brazil, nonexclusive for other Latin American countries	Public & Private Institutions in Brazil and India	Butantan Institute-Brazil Biological E-India	Latin America, the Caribbean, Asia
ddl—antiretroviral for HIV/AIDS	Nonexclusive patent	Private Institution in Mexico	Protein, SA-Mexico	Latin America

\* Applied.

## 5. Next Steps

As NIH OTT's interactions with developing countries mature and expand, the next steps may include an evaluation study to explore the needs and opportunities related to technology transfer and capacity building for developing country institutions. This evaluation would explore areas that impact technology transfer outcomes, such as policies related to intellectual property, regulations, clinical trial capacity, intellectual property management (IPM) capabilities, and legislation influencing public-private sector partnerships (PPPs). Thus, OTT has the potential to contribute to both the scientific/technological and the health needs of developing countries by enhancing their own ability to bring to market technologies that will benefit local and regional public health.

Some institutions are providing guidance in technology transfer or organizing training courses and workshops to address important primary training needs. OTT maintains an ongoing dialogue and has already partnered with different stakeholders in this area, including international organizations, regional agencies, private foundations, and professional societies. Moreover, OTT has also initiated an international capacity building program to train scientists and managers from developing countries in different areas of technology transfer. The program's first phase will include staff visiting from China, Brazil, and India. NIH OTT is seeking to expand the program to relevant personnel from institutions with R&D capabilities in Africa, Latin America, and Eastern Europe.

NIH OTT will continue to look for ways to complement the efforts of other organizations' missions in this area by addressing the different needs and challenges associated with global health and technology transfer activities. OTT is committed to sharing ideas, strategies, and successes with other organizations in an effort to mutually learn from each other about alternative creative solutions to technology transfer problems. OTT is systematically reviewing the ongoing work of such organizations, which will clarify the nature and scope of the gaps in the capacity-building process and in the international technology trans-

fer system. In turn, OTT will use its experience to identify areas of greatest need and to propose relevant solutions for bridging those gaps. OTT anticipates that it will continue a degree of hands-on training for managers and scientists in licensing, IP management, and commercialization by participating in intern exchange programs and international and regional seminars and workshops.

## 6. Conclusions

Building on a strong track record, NIH OTT is further enhancing its activities in technology licensing to developing countries and continues to work with many institutions to help build technology transfer infrastructures. This activity is helping NIH to meet an important part of its global public health mission: to reduce the devastating disease burden on people living in developing countries. Moreover, it is expected that OTT's activities in international technology transfer will ensure wider public availability of new technologies, attract new R&D resources, obtain returns on public investment, and stimulate economic development.

## References

- Ariffin N. and M Bell. 1999. Firms, politics and political economy: patterns of subsidiary-parent linkages and technological capability building in electronics TNC subsidiaries in Malaysia. In *Industrial Technology Development in Malaysia* (Eds Jomo KS, G Felker and R Rasiah). Routledge: UK.
- Bell M and K Pavitt. 1993. Technological accumulation and industrial growth: contrasts between developed and developing countries. *Industrial and Corporate Change* 2(2):157–210.
- Bell M and M Albu. 1999. Knowledge systems and technological dynamism in industrial clusters in developing countries. *World Development* 27(9):1715–1733.
- CIPR. 2001. Integrating Intellectual Property Rights and Development Policy. Commission on Intellectual Property Rights. DFID: London. <http://www.iprcommission.org>
- CMH. 2001. Commission on Macro Economics and Health (CMH) of the World Health Organization (WHO): Macro economics and health: Investing in health for economic development. Report of the Commission of Macroeconomics and Health, <http://www.cmhealth.org>
- Di Masi JA, RW Hanson, HG Grabowski and L Lasagna. 1991. Cost of Innovation in the Pharmaceutical Industry. *Journal of Health Economics* 10: 107-142.
- DNDi Working Group and MSF. 2003. Intensified Control of Neglected Diseases: WHO Report of an International Workshop. Berlin, December 10-12, 2003 [www.who.int/lep](http://www.who.int/lep)
- Ernst & Young. 2000. Management and Evaluation of Patents and Trademarks. Consultants' Analysis Report for the Danish Patent and Trademark Office, December 2000. [www.european-patent-office.org/news/epidosnews/source/epd\\_3\\_02/10\\_3\\_02\\_e.htm](http://www.european-patent-office.org/news/epidosnews/source/epd_3_02/10_3_02_e.htm)
- Evenson RE and LE Westphal. 1995. Technological Change and Technology Strategy. In *Handbook of Development Economics*, Vol. 3. (Eds. Behrman J and TN Srinivasan). pp. 2209-2299. Elsevier Science B.V.: The Netherlands.
- Falconi C and S Salazar. 1999. Identifying the Needs for Managing Intellectual Property In Latin America. Workshop Report, Costa Rica, 23-24 September 1999. ISNAR: The Hague.
- Federal Register 2004a. Vol. 69, pp.57335-57336 (Sept. 24).
- Federal Register 2004b. Vol 69, pp. 34381—34382 (June 21).
- Folkers GK and AS Fauci. 2001. The AIDS Research Model: Implications for Other Infectious Diseases of Global Health Importance. *JAMA* 286:458-461.
- Gwatkin DR and M Guillot. 2000. The Burden of Disease among the Global Poor: Current Situation, Future Trends, and Implications for Research and Policy. Health, Nutrition and Population Series. The World Bank: Washington, DC.
- Hobday MG. 1995. Innovation in East Asia: The Challenge to Japan. Paperback Edition. Cheltenham, UK: Edward Elgar, 224p.

- Hoekman B, K Maskus and K Saggi. 2004. Transfer of Technology to Developing Countries: Unilateral and Multilateral Policy Options. Working Paper No. 3332. The World Bank: Washington DC.
- Interacademy Council. 2004. Inventing a better future A strategy for building worldwide capacities in science and technology. Inter Academy Council, Amsterdam, The Netherlands.  
<http://www.interacademycouncil.net>
- Institute of Medicine. 1997. America's Vital Interest in Global Health: Protecting Our People, Enhancing Our Economy, and Advancing Our International Interests, Board of International Health, National Academy Press, Washington, D.C.: <http://www.nap.edu/>
- Juma C and N Clark. 2002. Technological Catch-Up: Opportunities and Challenges for Developing Countries.  
[www.supra.ed.ac.uk/Publications/Paper\\_28.pdf](http://www.supra.ed.ac.uk/Publications/Paper_28.pdf)
- Juma C, K Fang, D Honca, J Huete-Perez, V Konde, SH Lee, J Arenas, A Ivinson, H Robinson and S Singh. 2001. Global Governance of technology: meeting the needs of developing countries. *International Journal of Technology Management* 22(7/8):629-655.
- Kettler H. 2000. Narrowing The Gap between provision and need for medicines in developing countries. Office of Health Economics (OHE): London.
- Lall S. 1992. Technological capabilities and industrialization. *World Development* 20(2):165-186.
- Lall S. 1996. Learning from the Asian Tigers: Studies in Technology and Industrial Policy. London: Macmillan.
- Lasker R, R Miller and E Weiss. 2001. Partnership Synergy: A Practical Framework for Studying and Strengthening the Collaborative Advantage. *The Milbank Quarterly* 79:179-206.
- Maskus K. 2003. Transfer of Technology and Technological Capacity Building. ICTSD-UNCTAD Dialogue. 2nd Bellagio Series on Development and Intellectual Property. 18-21 Sept. 2003.  
<http://www.ictsd.org/pubs/dloguepapers.htm>
- Maskus K. 2004. Encouraging International Technology Transfer. Intellectual Property Rights and Sustainable Development. May 2004. UNCTAD-ICTSD : Geneva.
- National Intelligence Council. 2000. The Global Infectious Disease Threat and its Implications for the United States, David F. Gordon, Washington, DC, [http://www.fas.org/irp/infectious\\_disease\\_paper.html](http://www.fas.org/irp/infectious_disease_paper.html)
- OECD 2002. Conference on Biotechnology for Infectious Diseases: Addressing the Global Needs. Rapporteurs' Report. Lisbon, October 7-9, 2002.
- OECD.2003. Conference on Biotechnology for Infectious Diseases: Addressing the Global Needs Rapporteurs' Report (2003), <http://www.oecd.org/dataoecd/53/20/2500434.pdf>
- Olliaro P and P Trouiller. 1999. Drug development output: what proportion for tropical diseases? *Lancet* 354  
[http://www.accessmed-  
msf.org/prod/publications.asp?scntid=3082001227213&contenttype=PARA&](http://www.accessmed-msf.org/prod/publications.asp?scntid=3082001227213&contenttype=PARA&)
- Oxfam 2000. Cut the Cost Report. Oxfam: Oxford.
- Rivette KG and D Kline. 2000. Rembrandts in the Attic: Unlocking the Hidden Value of Patents. Harvard Business School Press: Boston MA.
- Romer P. 1993. Idea gaps and object gaps in economic development. *Journal of Monetary Economics* 32:531-555.
- Saha R, K Satyanarayana and CA Gardner. 2004. Building a "Cottage Industry" for Health (and Wealth) The New Framework for IP Management in India. *IP Strategy Today* No. 10-2004. Pp. 23-58.  
[www.bioDevelopments.org/ip](http://www.bioDevelopments.org/ip)
- Taylor M and J Cayford. 2003. American Patent Policy, Biotechnology and African Agriculture. Resources for the Future: Washington DC. <http://www.rff.org/rff/Documents/RFF-RPT-Patent.pdf> (p.12)
- UNCTAD. 2003. UNCTAD's Commission on Science and Technology for Development (CSTD). Papers, workshops and meetings of the 6<sup>th</sup> session 2003. <http://stdev.unctad.org/un/6thsession.html>
- Varmus H, R Klausner, E Zerhouni, T Acharya, AS Daar and PA Singer. 2003. Grand Challenges in Global Health. *Science* 302(5644):398-399.
- Zerhouni E. 2003. The NIH Roadmap. *Science* 302(5642):63-72.



***IP Strategy Today***

**An eJournal Sharing Creative and Innovative Ideas  
in Intellectual Property Strategies and Management  
related to Global Development and Biotechnology in Agriculture, the Environment and Health**

ISSN  
1534-6447

Free electronic distribution  
US\$ 35 for printed version

[www.bioDevelopments.org](http://www.bioDevelopments.org)