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NIH mission and global health

The mission of the US National Institutes of Health (NIH), Department of Health and Human Services, includes support for biomedical research to extend healthy life by reducing the burdens of illness worldwide. To this end, the NIH's Office of Technology Transfer (OTT) seeks to address gaps related to the availability of NIH inventions and to enhance the accessibility of its research to people around the world. With its leadership in biomedical research and innovation, as well as the management of technology commercialization across sectors, the OTT is in a key position to provide leadership in this area and to help other countries formulate appropriate technology-transfer procedures that are compatible with such activities in the developed world [http://www.iipi.org/activities/projects tech transfer.htm].

To illustrate the global reach of NIH international activities, Table 1 lists some of the countries with which it has executed grants and contracts. The OTT has already been successfully moving Public Health Services technologies to institutions in developing countries, such as China and Brazil, based on public-health needs and research and development (R&D) commercialization capabilities, but has found only a few institutions in even fewer countries to be familiar with the patenting or licensing process and/or able to enter

into negotiations. International property rights are considered a critical currency in technology transfer and innovation (Intellectual Property Rights: Implications for Development International Centre for Trade and Sustainable Development and United Nations Conference on Trade and Development, 2003). With its leadership in biomedical research, the NIH is in a position to play a significant role in international technology transfer. In presenting the NIH Roadmap Initiative, current NIH Director Dr. Zerhouni has stressed the need to position NIH in addressing the evolving public-health challenges of the 21st century. The Roadmap would target 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."

Table 1. Some of the countries that receive NIH grants and contracts

Thailand	Egypt	Canada	Costa Rica	
India	Kenya	Australia	Jamaica	
China	Ghana	Israel	Trinidad & Tobago	
South Korea	South Africa	Japan	Mexico	
Pakistan	Tanzania	UK	Brazil	
Indonesia	Mali	France	Argentina	
Nepal	Nigeria	Italy	Guatemala	
	Morocco	Spain	Chile	
		Russia	Colombia	
		Hungary		

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Technology transfer: a tool to move biomedical research in developing countries

With its significant role in technology transfer within the US for over 15 years, the OTT has both the expertise and the longstanding experience in moving technologies between the public and private sectors to commercialization in the US and abroad [http://www.iipi.org/activities/projects tech transfer.htm]. Indeed, 329 licenses have been executed to a foreign entity out of 2715 executed licenses or license amendments and, in fiscal year 2003, there were 19 foreign licenses executed out of a total of 221 (of which, 145 were new licenses and 76 were amendments). As some developing countries (such as China, India, Brazil, and South Africa) are now considered to be emerging economies, with areas of sophisticated technological (biomedical R&D) capabilities, there is increasing scope for intensifying technology transfers to such countries. In its routine functions relating to intellectual property, patents and licensing, and through its daily interactions with NIH scientists, universities and industries, the NIH has been at the forefront of this endeavor, making technologies accessible to the public. Its activities have resulted in the outcome of approximately 200 products, to-date through collaborations with stakeholders, including private industry, academia, governments, international organizations and private foundations. These include HIVAB (AIDS test kit, Abbott), Videx (ddI, BMS), Taxol (paclitaxel, BMS), Fludara (fludarabine, Schering), Hivid (ddC, Roche), and Havrix (hepatitis A, GSK).

The NIH has relatively strong portfolios in certain neglected infectious disease areas (shown in Table 2), which have not been fully used. Note that whilst there may be certain technologies available for these diseases, they may either be inaccessible to most developing-country markets due to cost of complicated delivery mechanisms (as in the case of Lyme disease), or may be obsolete (i.e. tuberculosis).

The OTT is increasingly active in exploring ways to enhance the process of transferring such technologies to developing countries and has been scaling up its international activities in recent months. Contacts are being developed worldwide with R&D institutions in developing countries, in both private and public sectors worldwide, in the drive to market these technologies to parties interested in entering developing-country markets. This has involved the proactive search for potential developing-country partners in key neglected disease areas, which include both communicable (i.e. HIV/AIDS, dengue and rotavirus) and non-communicable (i.e. cancer, diabetes) diseases.

Table 2. Examples of NIH intellectual property in neglected disease areas

Disease/therapeutic area	Technologies	Issued patents	Patents pending
Dengue	22	1	113
Rotavirus	12	4	36
Human papilloma virus	15	14	56
Lyme disease	6	1	18
Tuberculosis	10	2	24
Malaria	29	176	78

Initial results and lessons learned

Through ongoing analysis of its own portfolio and the needs and capabilities of developing countries, the OTT has found that there is a niche for intellectual technology transfer that does not jeopardize US techno-economic interests. Congruently, it aims at providing solutions to the most socioeconomically harmful diseases. The OTT has already transferred early-stage technologies to public and private institutions in India, China, and Mexico, whilst negotiations are in progress with countries such as Brazil, South Korea, Indonesia, and South Africa. Additionally, the OTT has become an important part of inter-institutional product developments, for example with the conjugated meningococcal vaccine (with the Program for Appropriate Technologies in Health-PATH; World Health Organization [WHO] and manufacturers in India for eventual distribution in Sub-Saharan Africa, the Middle East, Latin America, the Caribbean, and Eastern Europe). These licenses relate to diseases that lack a profitable market, and are of little to no interest to firms in developed countries, but—as we have already seen—can provide necessary medical solutions and the prospect of economic growth to developing countries.

The OTT has found that a holistic and flexible approach to international technology transfer is required, removing the possibility of developing the donor-recipient paradigm in which there are unequal partnerships, and consequent problems with trust, commitment, and reliability. It involves direct participation of local scientists and managers from indigent countries with whom we conduct development agreements as well as flexibility and determination on our part.

Future plans

Through its ongoing and intended activities in international technology transfer, the OTT has the potential to make a contribution to meeting the scientific, technological and health needs of developing countries by enabling their scientific and

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administrative staff to commercialize their home-grown technologies for the benefit of local and regional public health. As the OTT's interactions with developing countries mature and expand, the next steps include an evaluation study that will explore the needs and opportunities related to technology transfer and the capacity building/training needs of institutions in developing countries. Areas that impact technology-transfer outcomes will also be evaluated, such as policies related to intellectual property, regulations, clinical trials, intellectual property management capabilities, and legislation influencing public-private sector partnerships.

Some organizations hold training courses and workshops, and provide guidance in technology transfer, which may address important primary needs by providing some exposure to this field. The OTT has ongoing dialogue with different stakeholders in this area, including international organizations, regional agencies, private foundations, and professional societies.

The OTT has been and will continue to look for ways to provide input that is complementary to the missions of other organization missions (including international organizations, regional agencies, and private foundations) and to address the different needs and challenges associated with global health and technology transfer activities. In this way, we are systematically identifying and mapping ongoing work by such organizations, which will clarify the nature and scope of gaps in the capacity-building process and the international technology-transfer system. In turn, the OTT will use its experience to identify areas of greatest need and propose relevant solutions to bridge those gaps. We will also continue and enhance our contributions to hands-on training of managers and scientists in the processes of licensing, intellectual property management, and commercialization through internexchange programs and participation in international and regional seminars and workshops.

Conclusions

Up-scaling its activities in the above-described areas is helping the NIH meet an important part of its global mission to reduce the burden of diseases that have a devastating effect particularly on people living in developing countries, and thus to benefit public health. Moreover, it is expected that OTT's activities in international technology transfer will ensure public availability of new technologies, attract new R&D resources, obtain returns to public investment, and stimulate economic development.