The World Bank Legal Review

Volume 4

Legal Innovation and Empowerment for Development
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*The World Bank Legal Review* is a publication for policy makers and their advisors, judges, attorneys, and other professionals engaged in the field of international development with a particular focus on law, justice, and development. It offers a combination of legal scholarship, lessons from experience, legal developments, and recent research on the many ways in which the application of the law and the improvement of justice systems promote poverty reduction, economic development, and the rule of law.

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In 1994, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established minimum standards for the regulation of many forms of intellectual property (IP), including the right of patent owners to prevent unauthorized persons from using a patented process and making, using, offering for sale, selling, or importing a patented product or a product obtained directly by the patented process. All members of the World Trade Organization (WTO) were required to adopt TRIPS-compliant IP laws, with the exception of least-developed countries (LDCs), which have until 2016 to apply TRIPS provisions for pharmaceutical patents. The most comprehensive and influential international treaty on intellectual property rights, TRIPS is the global baseline for IP protection.

To successfully attract imported technology and to build the necessary preconditions for adapting the imported technology, developing countries needed a supportive environment that would facilitate such transfers, which included strong intellectual property protection and enforcement. To a large extent, this was the rationale behind the negotiation of TRIPS: technology would flow to those developing countries that adopted strong intellectual property protection and enforcement.

Developing countries view technology transfer as part of the bargain in which they agreed to protect intellectual property rights. TRIPS was crafted to create a common understanding of intellectual property rights globally and to provide its signatories (trading partners) with protections and certainties to ensure fair competition through a regime of IP rights. Articles 7 and 66.2 promote the practice of technology transfer, with the goal of ensuring that
technology holders are assured a favorable environment for investing in developing countries—and transferring their technology.³

The objectives section of Article 7 states 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.”⁴ The obligation for developed countries to provide incentives to enterprises and institutions to promote and encourage technology transfer to LDC members is found in Article 66.2.⁵ To ensure compliance, developed countries are required to submit reports on actions they have taken or plan to take in order to fulfill their commitments under this article.⁶

Despite the reference to technology transfer in Articles 7 and 66.2, TRIPS does not set out a universally recognized definition of technology transfer—leaving it open to legal and policy interpretation. There are many ways to transfer technology. Foreign direct investment, trade, and mobility of human resources are important sources of technology transfer and knowledge spillovers. Imports and exports, scientific collaborations, knowledge-sharing ventures, and capacity building help disseminate technology information from one source to another.⁷ Proprietary knowledge may be revealed during licensing agreements and joint ventures with local partners, thus giving rise to the transfer of technology.⁸ Additionally, foreign direct investment, a significant indicator of economic development and attractiveness of an economy, leads to technology transfer when multinational enterprises transfer information to their subsidiaries, some of which has the potential to “leak” into the host economy. The host country benefits via the experts, skills, and financial resources that are required to develop and make use of technology, as well as the development of human resources, higher wages, and improvement in corporate governance standards.⁹

³ TRIPS, supra note 1, Articles 7 and 66.2.
⁴ Id., at Article 7 (emphasis added).
⁵ Id., at Article 66.2 (“Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base”).
⁹ See Maria Maher, Hans Christiansen, & Fabienne Fortanier, Growth, Technology Transfer and Foreign Direct Investment (OECD 2011) (prepared for the OECD Global Forum on International Investment: New Horizons and Policy Challenges for Foreign Direct Investment in the
During the 37th Session of the Working Group on Trade and Transfer of Technology (WGTTT), Francis Gurry, the director general of the World Intellectual Property Organization (WIPO), discussed his organization’s work on innovation and technology transfer. During his presentation, Gurry quoted Sir Francis Bacon’s dictum that “knowledge is power,” extrapolating to propose that the sharing of “technological superiority” is a transfer of power. He considered what is required to entice companies to “do away with their competitive power” through technology transfer; in his view, the existence of suitable market conditions and market possibilities in the host country are vital for the transfer of technology to occur.

The Role of Pharmaceutical Intellectual Property and Technology Transfer in Developing Countries

Protection of Intellectual Property Is Critical

As Gurry implied, the private sector considers a variety of factors when deciding whether to engage in technology transfer. To create the necessary conditions to foster confidence to invest in and export new technologies, as well as to develop new technologies in collaboration with developing countries, there must be strong IP protection and effective enforcement in those countries. As an intellectual property–dependent industry, the pharmaceutical industry did not initially engage in technology transfer in developing countries where IP protection was lacking. With TRIPS, a framework was created that encourages the rapid dissemination of ideas and efficient technology transfer, both of which are critical for technology-intensive, high-risk sectors.

The pharmaceutical industry’s willingness to invest in critical value-added production and research and development (R&D) facilities in developing countries is directly linked to the strength and effectiveness of their IP systems. By safeguarding property against unauthorized commercial exploitation, effective IP protection provides predictability and, more important, the ability for a company to enter into license agreements and contracts. Because patents provide a legal basis for revealing proprietary information to subsidiaries and licensees, companies are less inclined to engage in technology transactions...
without effective IP protection.\textsuperscript{13} IP protection helps pharmaceutical companies justify investments in the inherently risky, costly, complex, and lengthy R&D and regulatory process, and ensure long-term foreign investor commitment to the local market.

Technology transfers that follow in the wake of strong IP protection also help curtail “brain drain” by generating a more qualified and technically advanced labor force that will be motivated to remain in their home countries. Brain drain is “the departure of educated or professional people from one country, economic sector, or field for another usually for better pay or living conditions.”\textsuperscript{14} When these skilled workers leave their home country in search of better opportunities in wealthier countries, the developing country fails to benefit from its considerable investment of public funds to educate the person who now brings his or her skills to the developed world.\textsuperscript{15} The loss of these workers negatively affects the developing country’s ability to absorb technology transfer, because knowledge of scientific and technical information is necessary to accomplish technology transfer and advance development.\textsuperscript{16} By providing companies with increased incentives—such as a supportive IP environment—to establish R&D facilities in developing countries, countries may entice local individuals to return or remain in country to capitalize on these opportunities.

IP plays an essential role in technological development and dissemination and provides incentives for innovation in developing countries. Developing countries have the potential to attract not only the transfer of existing technology but also the transfer of new technologies through stronger patent rights.\textsuperscript{17} Although the degree to which a country benefits from IP depends on the country’s relative strengths and socioeconomic characteristics, in countries with strong and effective IP regimes in place, there is a significant link between increased incentives for local innovation and the transfer of technologies that encourage local innovation and economic growth.\textsuperscript{18} By providing the right incentives and removing barriers to the timely launch of innovative medicines, the patients and the private sector benefit.

\textsuperscript{13} See Hoekman, Maskus, & Saggi, supra note 7.
\textsuperscript{18} Id., at 28.
Other Factors Conducive to Technology Transfer

Strong and effective IP protection and enforcement, generally a prerequisite for any out-licensing or joint-venture decision, is only one of many factors influencing a company’s decision to engage in technology transfer. Factors such as predictable regulatory standards, government commitment to education, a stable business environment, and alignment with the government’s economic development priorities play an essential role.

A reliable and predictable registration process for pharmaceutical products is important in providing motivations and incentives to engage in technology transfer.\(^{19}\) A heavily regulated sector, the pharmaceutical industry must meet rigorous standards involving safety, quality, and efficacy in order to ensure the welfare of patients. Therefore, when relying on local production, companies frequently transfer their technology to entities based in part on their capacity to meet international quality standards. This in turn contributes to the development of the local pharmaceutical industry.

The presence of a highly skilled workforce is vital to the development, application, utilization, and integration of new technology\(^{20}\) and makes the investment climate more attractive for foreign investors. Due to their depth of knowledge, these highly trained and educated workers are essential for technology transfer to occur. Through improvements in education and in the operating environment, developing countries are encouraged to promote the knowledge, experience, and skills necessary to enable workers to bring economic value and a competitive advantage to technical companies. These companies, in turn, provide education and training and may bring new information, skills, and technology to host nations.

A country’s relative political, economic, and social stability will influence a company’s decision whether to transfer technology and is often considered a precondition for technology transfer to occur.\(^{21}\) Long periods of stability lead to stronger and more successful partnerships because stability lowers the risk of doing business in an unfamiliar environment and provides companies with increased confidence to implement long-term business strategies and assurance that their goals will be sustainable. Economic reforms and other efforts that promote trade, investment, nondiscriminatory policies, legal frameworks, and national infrastructure add to the attractiveness of a country with regard to technology transfer.\(^{22}\) As governments begin to understand the interrelationship between health care and economic outcomes, investment in health care systems and infrastructures will become a high priority.\(^{23}\)

\(^{19}\) See Technology Transfer: A Collaborative Approach to Improve Global Health (IFPMA 2011).

\(^{20}\) See Barton, supra note 15.

\(^{21}\) See Technology Transfer, supra note 19.

\(^{22}\) See Maher, Christiansen, & Fortanier, supra note 9.

\(^{23}\) See Technology Transfer, supra note 19.
By aligning themselves with a system that promotes technology transfer, developing countries are more likely to create medicines and technologies that address their public health needs and enable local and regional solutions. Technology transfer arrangements can create strong alliances and collaborations that can be leveraged for long-term commercial and economic advantage. A supportive environment that encourages these transactions is a win-win situation for both the private sector and the developing country. The R&D activities of companies can enhance economic and social progress in developing countries. In turn, the development of a robust and dynamic innovation system in a developing country will expand commercial opportunities for companies.

Examples of Technology Transfer in the Pharmaceutical Industry

A goal of technology transfer, in the context of pharmaceuticals, is to promote access to new medicines and technologies for diseases that affect a local population. Access to medicines in developing countries is a high-priority issue in the global health sector, including for multinational pharmaceutical companies. Technology transfer can directly affect research for neglected tropical diseases (NTDs) that primarily occur in developing countries. Many forms of collaboration and alliances have been developed to promote research and treatment of these diseases, and many include a technology transfer element. These types of arrangements, which are becoming more frequent, demonstrate that solutions to societal issues can be found through partnerships and the sharing of knowledge without undermining IP rights.

Pfizer’s Research Partnership with Drugs for Neglected Diseases Initiative

According to the World Health Organization (WHO), NTDs affect more than 1 billion people each year and are endemic in 149 countries. For NTDs such as leishmaniasis and human African trypanosomiasis (HAT), infections occur among the poorest people in rural areas. To accelerate the elimination or

control of these diseases, Pfizer entered into an agreement with Drugs for Neglected Diseases initiative (DNDi) in 2009, in which Pfizer agreed to provide DNDi with access to a Pfizer library of proprietary compounds to screen for new potential targets against leishmaniasis, Chagas disease, and HAT. This arrangement, which partners Pfizer’s research infrastructure with DNDi’s neglected disease expertise, maximizes the chances of identifying promising starting points for drug discovery programs. Although Pfizer owns the IP on these compounds, any novel leads are a candidate for licensing agreements with regard to NTDs. The Pfizer-DNDi partnership demonstrates that the burden of finding solutions to diseases endemic to developing countries does not rest with a single entity. Through the transfer of technology, duplication of research and repetitiveness of efforts are minimized, resulting in a more streamlined and focused approach that draws on the complementary strengths of each organization. The collaboration has identified promising leads, and DNDi will continue research, development, and commercialization based on these leads.

**GlaxoSmithKline’s Vaccine Development Initiative with the Oswaldo Cruz Foundation**

In 2009, GlaxoSmithKline (GSK) announced a partnership with the Oswaldo Cruz Foundation (Fiocruz) to develop and manufacture vaccines for public health needs in Brazil. The agreement created an R&D collaboration program at Fiocruz to develop a vaccine for dengue fever, a mosquito-borne viral infection that is the leading cause of serious illness and death among children in Asian and Latin American countries and for which no specific treatment is available. With approximately half of the world’s population at risk of contracting dengue fever, this joint R&D initiative will enhance Brazilian capacity to improve the health of patients by protecting them against this disease.

GSK also partnered with Fiocruz in 2009 to provide access to the technology behind GSK’s 10-valent conjugate vaccine for pediatric pneumococcal disease, or Synflorix. Under the agreement, GSK supplied Fiocruz with Synflorix until the technology transfer was complete; the vaccine has since been incorporated into Brazil’s national immunization program. In sharing knowledge and technology between the two organizations, scientists from GSK and Fiocruz work across facilities in Brazil and Belgium to protect

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28 See Pfizer and DNDi Advancing International Research Efforts in the Fight against Neglected Tropical Diseases, DNDi Press Release (Nov. 18, 2009).
29 See GSK and Brazil’s Fiocruz Form Partnership for New R&D Effort and Increased Vaccine Access, GSK Press Release (Aug. 17, 2009).
30 Id.; World Health Organization, Dengue and Severe Dengue, Fact Sheet No. 117 (Jan. 2012).
31 Id.
32 See GSK and Brazil’s Fiocruz, supra note 29.
33 Id.
children from diseases such as pneumonia, meningitis, and bacteremia.\textsuperscript{34} The two organizations extended their partnership in 2010, enabling scientists at Fiocruz and GSK’s Tres Cantos facility in Spain to share new ideas, know-how, and research on diseases such as malaria, tuberculosis, Chagas disease, and leishmaniasis.\textsuperscript{35}

In collaborations such as these, the transfer of technology and expertise drives discovery and development efforts to produce new and innovative medicines to treat diseases that affect people in developing countries. Antonio de Pádua Risolia Barbosa, deputy director of production at the Immunobiological Technology Institute, or Bio-Manguinhos unit, of Fiocruz, states, “Besides our own innovation and development, we have partnerships with local and global organizations, and we use technology transfer to accelerate the viability of the products for the population.”\textsuperscript{36}

\textbf{WIPO Re:Search—Sharing Innovation in the Fight against NTDs}

Recognizing the need for progress in neglected disease research and understanding that such research is the collective responsibility of the entire global health community, WIPO Re:Search was formed in 2011 through the efforts of several of the world’s leading pharmaceutical companies, WIPO, and BIO Ventures for Global Health (BVGH).\textsuperscript{37}

WIPO Re:Search provides three services:

- A comprehensive platform/database, hosted by WIPO, of patent and other proprietary information (for example, clinical trial results, regulatory status) on compounds and technologies available for licensing for NTD research
- A partnership hub, managed by BVGH, providing a forum where interested parties can learn about available licensing opportunities, available funding for research, and networking opportunities in their research fields
- A range of specific supporting activities, such as facilitating licensing agreements and dispute resolution\textsuperscript{38}

WIPO Re:Search aims to promote the transfer of knowledge through the facilitation of nontraditional partnerships and by encouraging organizations to share proprietary information publicly. WIPO Re:Search also offers researchers in developing countries access to research facilities and scientists

\textsuperscript{34} Id.

\textsuperscript{35} See GlaxoSmithKline and Fiocruz Extend Innovative Collaboration to Research and Develop New Medicines for Neglected Tropical Diseases, GSK Press Release (Nov. 12, 2010).

\textsuperscript{36} Patricia Van Arnum, \textit{Technology Transfer in Global Health Initiatives}, 7(4) Pharmaceutical Technology Sourcing and Management (Apr. 6, 2011).


working in leading pharmaceutical companies and laboratories, an important step in the technology transfer process. The structure of the consortium demonstrates that solutions to societal issues can be solved through partnerships without undermining IP.

Users of WIPO Re:Search are granted royalty-free licenses to IP for research and development, anywhere in the world, of products and technologies or services for the sole purpose of addressing public health needs for NTDs in LDCs. Users are also granted royalty-free licenses to make or have made such products, technologies, or services. These licenses also allow users to sell these products in LDCs royalty-free. Users are allowed to retain ownership of and apply for registration of IP as they deem fit, but are encouraged to license through WIPO Re:Search new IP rights generated under an agreement made pursuant to membership in the consortium.\(^{39}\)

WIPO Re:Search leverages expertise to develop new products and technologies, improves research productivity, allows the monetization of technologies and IP assets that would otherwise go unused in the organization’s own business, and makes more efficient use of research investments by enhancing the exchange of mutually beneficial knowledge. Through information-sharing consortiums such as WIPO Re:Search, products and technologies can be brought to market faster and more efficiently.

The consortium has received the commitment of more than 50 private and public organizations dedicated to accelerating R&D for NTDs, malaria, and tuberculosis, including Pfizer, GlaxoSmithKline, AstraZeneca, DNDi, Fiocruz, Medicines for Malaria Ventures (MMV), PATH, and the Walter Reed Army Institute of Research (WRAIR).\(^{40}\) Although the commitment and willingness of these partners to transfer technology through WIPO Re:Search is a step toward addressing the R&D challenges that affect the developing world, sustained elimination of these diseases is possible only with a commitment by individual countries to ensure access to safe water, proper waste disposal and treatment, basic sanitation, and improved living conditions.\(^{41}\)

### ViiV Healthcare—Joint Venture between Pfizer and GSK

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), the growth of the global AIDS epidemic appears to have stabilized, and the annual number of new HIV infections has been steadily declining.\(^{42}\) However, approximately 34 million people worldwide continue to live with HIV,\(^{43}\) and

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40. Id.

41. See World Health Organization, Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases, supra note 27.

42. See UNAIDS, Report on the Global AIDS Epidemic 16 (UNAIDS 2010).

more than 7,000 people are newly infected every day.\textsuperscript{44} Discrimination and stigmatization remain, and many people continue to lack access to the antiretroviral (ARV) medicines and health care support they require; only one-third of the 15 million people living with HIV in low- and middle-income countries who need treatment are receiving it.\textsuperscript{45}

To further efforts to deliver advances in treatment and care for people living with HIV, Pfizer and GSK created a joint venture and established a new specialist HIV company, ViiV Healthcare, in 2009.\textsuperscript{46} ViiV Healthcare is focused solely on the research, development, and commercialization of HIV medicines and has a single, sustainable, not-for-profit price for each ARV that it makes available to a wide range of patients in LDCs and sub-Saharan Africa—a total of 69 countries, representing 80\% of all people living with HIV/AIDS worldwide.\textsuperscript{47} ViiV Healthcare extends royalty-free voluntary licensing of its innovative drugs to generic manufacturers producing and distributing therapies to people living with HIV in LDCs, low-income countries, and all of sub-Saharan Africa. As of 2012, ViiV Healthcare had granted 11 voluntary licenses for its ARVs.\textsuperscript{48}

By combining the research efforts and knowledge of Pfizer and GSK, ViiV Healthcare will achieve more for those whose lives are affected by HIV than either company could have achieved alone. Various ViiV initiatives, such as the ViiV Healthcare Effect, strive to strengthen education, support services, local health care capacity, and capabilities through education and collaboration.\textsuperscript{49}

\textit{Pfizer’s Global Health Fellows}

Since 2003, more than 300 Pfizer colleagues have participated in the Global Health Fellows Program, an international corporate volunteer program that places Pfizer colleagues in short-term assignments with international development organizations in emerging markets.\textsuperscript{50} The objective of the program is to strengthen the ability of health care providers in these countries to care for their patients. Through Pfizer’s partnership with more than 40 organizations, colleagues are provided the opportunity to transfer their professional medical and business expertise to optimize local supply chains and business functions

\textsuperscript{44} See UNAIDS, 2011–2015 Strategy: Getting to Zero (UNAIDS 2010).
\textsuperscript{45} See UNAIDS, supra note 42, at 7.
\textsuperscript{46} See ViiV Healthcare Launches: A New Specialist HIV Company Dedicated to Delivering Advances in HIV Treatment and Care, ViiV press release (Nov. 3, 2009).
\textsuperscript{48} Id.
\textsuperscript{49} The ViiV Healthcare Effect is a portal that introduces the company’s approach to partnerships and showcases best practices throughout the world. It provides users the opportunity to hear directly from people creating new solutions on the ground and to learn what has worked and how those efforts can be applied or expanded to support more communities. See ViiV Healthcare Effect website, www.viivhealthcarefffect.com (accessed Mar. 2012).
and improve health prevention approaches. This program demonstrates that technology transfer encompasses expertise and technical skills.

**WHO’s TDR Career Development Fellowship Program**

In 1975, the Special Programme for Research and Training in Tropical Diseases (TDR), sponsored by the United Nations Children’s Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank, and WHO, was established as a scientific collaboration to coordinate, support, and influence global efforts to combat diseases affecting disadvantaged populations.  

TDR founded the Career Development Fellowship on Clinical Research & Development in 2009 with the support of the Bill & Melinda Gates Foundation. Researchers and public health professionals from disease-endemic countries are awarded a 12-month training opportunity with pharmaceutical companies in order to receive specialized in-house training to acquire experience in clinical trial management, R&D project management, regulatory compliance, and good practices. By focusing on human resources development and capacity building, individual fellows are able to maintain their existing capabilities, strengthen their potential, and obtain new skills that are not normally taught in academic centers. Once the fellowship has been completed and the fellows return to their home countries, they have the opportunity to assume a leading role in the global effort on R&D, thereby enhancing the developing country’s capacity for product development. In 2009, Pfizer hosted two developing-world clinical researchers as part of the TDR program. In 2011, Eisai, a major Japan-based pharmaceutical company, welcomed a TDR clinical research fellow whose goal is to build the health care capacity of developing countries; Eisai provides the fellow with the opportunity to learn about drug development from the US and Japanese perspective. Upon completion of the fellowship, the fellow returned to his home country, Colombia, to develop and arrange local and regional academic meetings to educate his counterparts in the study of tropical and neglected diseases.

**Looking toward the Future: Navigating an Evolving Landscape**

The world today is quite different than it was a few decades ago; trade, as well as scientific and education research systems, is highly globalized, and an


55 Id.
increasing number of developing countries are becoming more technologically sophisticated. According to the World Bank’s *Global Economic Prospects* report, however, “the world economy has entered a very difficult phase characterized by significant downside risks and fragility,” with developing-country growth expected to decline to 5.4 percent and 6.0 percent versus 6.2 percent and 6.3 percent in June 2011 projections.\(^\text{56}\)

Developing countries should be encouraged to identify new drivers of growth, one of which is technology transfer. Although technology transfer can be a time-consuming and complex process, given the right incentives and strong interest by developing countries in increasing their access to international technologies, companies from developed countries can assist LDCs in achieving sustained economic change and growth in domestic productivity. Intellectual property, in particular, helps realize the model necessary to transfer technology and should be viewed as a vital tool that can aid in social and economic progress. As countries develop their own assets, they will have greater incentives to respect the IP framework and implement and enforce strong IP regimes that will aid in the facilitation of new types of positive partnerships.

Although not all countries are equally prepared to integrate complex technology into their production chains, the level of complexity on the technology transfer spectrum varies, beginning with knowledge and skills training as the most basic form. Therefore, the transfer of technology should be encouraged in all regions of the developing world, because building local capacity can play a major role in moving LDCs to the next stage of development and significantly affect the pace of innovation within these countries.