

3 Driving Innovation for Global Health through Multi-stakeholder Partnerships

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Introduction

Health is recognized as a public good and governments have a responsibility to ensure equitable health care provision. Yet, disadvantaged populations in low- and middle-income countries (LMICs) are less likely than others to have access to public sector health services. Inadequate health care infrastructures, distance to health facilities, insufficient numbers of trained health care workers, and low diagnostic capacity are among some factors contributing to this situation. Access to health care is further reduced when diseases urgently require action, as is the case with malaria, and tuberculosis (TB), but for which treatment options are inadequate or do not exist.

Multisectoral and cross-organizational partnerships¹ play a growing role in health research and development (R&D) as they help share the burden, risk, and expenses required to effectively address global health challenges. Public–private partnerships (PPPs) in the health sector have been growing in popularity, both in the provision of services and in developing new technologies. Initiatives such as WIPO Re:Search connect private sector with public sector entities to facilitate R&D and technology transfer necessary to support the development of new medicines, vaccines, and diagnostics that address some of the most challenging issues in global health today such as “neglected tropical diseases” (NTDs).² While the various initiative have their own specific characteristics, they share in common a general approach that borrows from private sector business models of organization while being largely noncommercial (i.e., not seeking a profit).

This chapter will review the multi-stakeholder partnership landscape in the context of the United Nations (UN) 2030 Agenda for Sustainable Development (2030 Agenda),

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¹ Multi-stakeholder, multisectoral, and cross-organizational partnerships can be public–private partnerships, but they do not necessarily include both public and private partners at the same time.

² Terminology can vary regarding these types of diseases; for example, “poverty-related neglected diseases” (PRNDs) is a commonly used and overlapping term. In many cases, the PNRDs are also NTDs, but WIPO Re:Search is anchored in the WHO list of NTDs. Therefore, this chapter employs the term NTDs.

as well as broader innovation incentive schemes, namely for NTDs. The chapter looks at some economic determinants of innovation and studies how different partnership models endeavor to address related challenges. WIPO Re:Search is presented as one recent initiative with the potential to create partnership networks that catalyze R&D in NTDs, malaria, and TB.

I The UN Sustainable Development Goals (SDGs)

In September 2015, The UN General Assembly adopted the 2030 Agenda “Transforming our World: the 2030 Agenda for Sustainable Development.”³ The 17 new Sustainable Development Goals (SDGs) and 169 Targets thereunder aim to end by 2030 all forms of poverty, hunger, inequality, and injustice, and to take action on climate change, global health, and education. The SDGs build on the success of the earlier Millennium Development Goals (MDGs), and are even more ambitious than their predecessor. Two of these goals are particularly relevant in the context of this paper.

First, Goal 3⁴, which is devoted specifically to health, is framed in broad terms that are relevant to all countries and all populations:⁵ “Ensure healthy lives and promote well-being for all at all ages.” SDG 3 is associated with 13 targets. Among other aspects, Goal 3 addresses the need to unite efforts to tackle NTDs.

The pressing need to address NTDs is reflected under Target 3.3, which calls on countries by 2030, “[to] end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.” This is a significant widening of the focus relative to MDGs in two ways: a shift from control to elimination, and explicit reference to TB, NTDs, hepatitis, and water-borne diseases in addition to HIV/AIDS, malaria, and “other diseases.”⁶

Second, Goal 17⁷ recognizes that a successful sustainable development agenda requires global partnerships between governments, the private sector, and civil society. In particular, two targets encourage multi-stakeholder partnerships:

“17.16 Enhance the Global Partnership for Sustainable Development, complemented by multi-stakeholder partnerships that mobilize and share knowledge, expertise, technology and financial resources, to support the achievement of the Sustainable Development Goals in all countries, in particular developing countries.

17.17 Encourage and promote effective public, public–private and civil society partnerships, building on the experience and resourcing strategies of partnerships.”⁸

In 2005 and 2006, the term “neglected tropical diseases” began to appear in peer-reviewed papers⁹ and has since come into popular use. Also in 2005, an original core

³ G. A. RES. 70/1 (Sept. 25, 2015).

⁴ *Id.*

⁵ World Health Organization [WHO], *Health in 2015: from MDGs to SDGs* (2015) http://apps.who.int/iris/bitstream/10665/200009/1/9789241565110_eng.pdf?ua=1.

⁶ *Id.*

⁷ G. A. RES. 70/1 (Sept. 25, 2015).

⁸ *Id.*

⁹ Peter J. Hotez, *The Neglected Tropical Diseases and the Neglected Infections of Poverty: Overview of Their Common Features, Global Disease Burden and Distribution, New Control Tools, and Prospects for Disease Elimination*, in *THE CAUSES AND IMPACTS OF NEGLECTED TROPICAL AND ZOONOTIC DISEASES: OPPORTUNITIES FOR INTEGRATED INTERVENTION STRATEGIES* (Institute of Medicine (US) Forum on Microbial Threats ed., 2011).

group of the thirteen major NTDs was proposed, which has since been expanded by the World Health Organisation (WHO) to a list of seventeen diseases. In their 2005 paper, Molyneux, Hotez, and Fenwick listed the following common features of NTDs:

- ancient afflictions that have burdened humanity for centuries;
- poverty-promoting conditions;
- associated with stigma;
- rural areas of low-income countries and fragile states;
- no commercial markets for products that target these diseases; and
- interventions, when applied, have a history of success.¹⁰

According to WHO, neglect occurs at many different levels: at the community level because the NTDs inflict social stigmas and prejudice; at the national level because the NTDs occur in remote and rural areas, afflicting populations that are marginalized; and at the international level because they are not perceived as posing an immediate global health threat.¹¹

The expressed consideration given to NTDs constitutes an opportunity to draw greater global attention and add them to a mainstream action plan. Since these targets cannot be achieved without R&D to develop new health technologies (e.g., new and improved medicines, vaccines, diagnostics),¹² multi-stakeholder partnerships are tools to achieve the objectives suggested in the Goal 17. These two goals should be seen as mutually reinforcing, especially because the burden of NTDs falls overwhelmingly in LMICs. In these countries, the commercial markets alone would not drive R&D for new products,¹³ or incentivize the investments necessary to optimize the use of existing medicines or to develop readily available, easy-to-use, reliable, and low-cost diagnostic tools. In a broader context, reducing the burden of diseases will also directly and indirectly affect many of the other SDGs by improving people's well-being and reducing their level of poverty.

II The Innovation Cycle and Incentives

At the outset, there are various approaches to encourage innovation with no single policy instrument alone appropriate under all circumstances. Therefore, the considerations below, relating to incentives spurring innovation, are in no way exhaustive.

“Push and pull mechanisms” can provide incentives for R&D in NTDs. “Push mechanisms” can, in general, be defined as incentives before R&D has started, such as up-front public funding, while “pull mechanisms” provide rewards to the final outcome of R&D, such as certain products. In other words, one category “pushes” capital into R&D investment, while the second “pulls” products into the market. Push mechanisms include tools such as grants and tax credits for R&D spending, while pull mechanisms create purchase funds and other tools to support markets for new products, or provide

¹⁰ David H Molyneux, Peter J Hotez, and Alan Fenwick, “*Rapid-Impact Interventions*”: *How a Policy of Integrated Control for Africa's Neglected Tropical Diseases Could Benefit the Poor*, PLoS MED (2005).

¹¹ WHO, *Neglected Tropical Diseases, Hidden Successes, Emerging Opportunities* (2006) http://apps.who.int/iris/bitstream/10665/69367/1/WHO_CDS_NTD_2006.2_eng.pdf.

¹² Policy Cures, *Measuring Global Health R&D for the Post-2015 Development Agenda* (2015) www.ghtcoalition.org/pdf/Measuring-global-health-R-D-for-the-post-2015-development-agenda.pdf.

¹³ *Id.*

incentives through streamlined regulatory review processes, such as priority review vouchers.¹⁴ In developed countries, combinations of “push” (to reduce R&D costs and generate research) and “pull” (generating market demand for products that result from the research) mechanisms provide some incentive for investment in R&D.¹⁵ The key difference is that, in the case of a “push” mechanism, innovation is supported at the outset, whereas in the latter case, it is the capacity of the market that is increased.¹⁶ A combination of push and pull mechanisms, if designed and implemented properly should, in general, facilitate the development of new health innovations.¹⁷ For example, pull mechanisms such as advance purchase commitments (APCs) have the potential to provide for a stable demand, thereby reducing risk and incentivizing investments in needed technologies. However, they also have their challenges since it is difficult to predict development in the future. To guarantee proper functioning, APCs require sometimes burdensome and bureaucratic monitoring mechanisms and they might still not be able to cope with changing market dynamics.¹⁸

The intellectual property (IP) rights system is considered a pull mechanism.¹⁹ It is seen as a useful incentive mechanism for governments to mobilize market forces toward innovation in certain areas.²⁰ The research-based pharmaceutical industry uses IP as a tool to help create market conditions in which product prices can cover the costs of doing business (including R&D, productions and liability insurance), so that private sector stakeholders will invest resources in product development and the marketing of new technologies. Such incentives are considered essential, among other reasons, due to the considerable financial and technical resources required for new product development, coupled with the high risk of failure, even at a late stage.²¹

The IP system is a useful mechanism when private motivation to innovate aligns with society’s preferences with regard to new technologies.²² It is debatable, however, whether the IP system can contribute to incentivizing inventions in areas where there is no profitable market. The same IP protection that is beneficial where a market helps to obtain a reasonable return on investment does not necessarily support an environment for R&D in unprofitable markets, even when the social or human need is great.

In order to better understand the issues surrounding incentives for innovation, the development of new medicines requires a closer look. Innovation in health can be presented as a cycle, which goes from R&D of new, basic compounds to the testing and development of new products, up to the delivery of these products, and then

¹⁴ WHO, World Intellectual Property Organization [WIPO] & World Trade Organization [WTO], *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property, and Trade* (2012) www.wto.org/english/res_e/booksp_e/pamtiwhowipowtweb13_e.pdf.

¹⁵ OECD, COHERENCE FOR HEALTH: INNOVATION FOR NEW MEDICINES FOR INFECTIOUS DISEASES, THE DEVELOPMENT DIMENSION (2009).

¹⁶ WIPO, *World Intellectual Property Report 2011: The Changing Face of Innovation* (2011) www.wipo.int/edocs/pubdocs/en/intproperty/944/wipo_pub_944_2011.pdf.

¹⁷ OECD, *supra* note 12.

¹⁸ Andrew Farlow, *The Global HIV Vaccine Enterprise, Malaria Vaccines, and Purchase Commitments: What is the Fit?* (2005) www.who.int/intellectualproperty/submissions/Farlow.pdf.

¹⁹ WIPO, *supra* note 16.

²⁰ *Id.*

²¹ WHO, WIPO & WTO, *supra* note 14.

²² WIPO, *supra* note 16.

re-investing in R&D to start the cycle anew.²³ A well-functioning innovation cycle can be dynamic and self-sustaining.²⁴ In a highly profitable market there are continuous efforts to develop new products by multiple players. In less profitable markets, there may be fewer players but developers try to maintain a portfolio of candidates that they may push simultaneously depending on their priority setting system, including the availability of resources.

This scheme applies principally to developed countries and the diseases that are common among the global population.²⁵ The innovation cycle does not function optimally where the disease burden falls disproportionately on poor populations in developing and least developed countries. For these countries, where the economic demand is weak – but not the human need – there is little financial incentive to develop new or modified interventions appropriate to the disease burden.²⁶ As the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) describes it: for diseases that predominantly affect disadvantaged patients in developing countries, there is a critical gap in the availability of incentives that fuel the conventional innovation cycle.²⁷

This illustrates a critical reality: the current market-driven innovation cycle works better for some countries and diseases than for others.²⁸ Incentive mechanisms need to be designed and deployed effectively to make the innovation cycle work for developing countries which will overcome the lack of market incentives.²⁹ IP rights will tend to be more important for highly profitable markets and less important for markets that depend on government procurement to meet the needs of the poor. In other words, the IP system is not in itself an incentive to innovate; the incentive for commercial investment in innovation stems from the existence of an economically viable market.³⁰

This gap has inspired an array of practical initiatives across territorial boundaries to find new ways of combining the diverse inputs, infrastructure, and resources needed for product development, typically making use of collaborative structures.³¹ Incentives for R&D vary with the nature of the market. There are six factors that affect success in new product innovation, of which IP is only one.³² However, IP will almost always have some

²³ WHO Comm'n on Intellectual Prop. Rights, *Public Health: Innovation and Intellectual Property Rights* (2006) www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1.

²⁴ Kamil Idris & Hisamitsu Arai, *THE INTELLECTUAL PROPERTY-CONSCIOUS NATION: MAPPING THE PATH FROM DEVELOPING TO DEVELOPED* (2006).

²⁵ WHO, *supra* note 23.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ Roy Widdus, *Product Development Partnerships on “Neglected Diseases”: Intellectual Property and Improving Access to Pharmaceuticals for HIV/AIDS, Tuberculosis and Malaria*, in *NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 205* (Pedro Roffe et al. eds., 2006).

³¹ *Id.*

³² Richard Mahoney, *Product Development Partnerships: Case Studies of a New Mechanism for Health Technology Innovation*, 9 *HEALTH RES. POL'Y AND SYS.* 33 (2011). The six factors are: 1. The design and execution of research and development programs from preclinical studies to licensure; 2. Analysis and planning for the marketing and distribution of new technologies in individual developing countries; 3. Analysis and planning for the procurement and supply of new health technologies by the global health community; 4. Planning and implementation of manufacturing capabilities; 5. Establishment and implementation of regulatory systems to ensure safe and effective products; 6. Establishment and implementation of intellectual property rights (IPR) management systems.

value, since new inventions may be useful not only for the target product but also for other products that may have highly profitable markets.

III Costs of R&D in Health

Developing a pharmaceutical product and bringing it from a laboratory to market takes a long time, is expensive, and involves the burden of complying with stringent regulatory approval processes, all of which result in a small number of successful outcomes.³³

The topic of the true costs of medical research and development is much debated with numerous studies providing varying estimates, depending, in part, on what costs are included or excluded. The cost estimate of bringing a medicine to market will depend on, for instance, whether only the direct cost of developing an individual medicine is considered, or whether the global R&D costs of a company or institution are also considered.³⁴ For example, research by the Tufts Center for the Study of Drug Development³⁵ assessed the cost of developing a prescription medicine that gains market approval at US\$2.6 billion.³⁶ Lower estimates were put forward by the Deloitte Centre for Health Solutions in the United Kingdom, which estimated the cost in 2014 at \$1.4 billion³⁷ and the Drugs for Neglected Diseases initiative (DNDi), a product development partnership (PDP), estimated its own costs of development to range from EUR 6–20 million for an improved treatment, and EUR 30–40 million for a new chemical entity (NCE).³⁸

What is less controversial is that the cost model of pharmaceutical development represents a “J curve,” i.e., the closer to registration the higher the costs.³⁹ Bringing the product to registration reflects not just direct costs but the risk of failure.⁴⁰ Traditionally, the costs have been borne by a company from revenues of existing products.⁴¹ An entity without a formidable revenue stream could not support the risk of failure.

R&D costs also depend greatly on the type of medical innovation in question.⁴² For example, there is a big difference between a medicine based on a new chemical entity (NCE) not previously used in any pharmaceutical product and an incremental modification of an existing medicine. However, even for NCEs the stated costs differ widely.

³³ WHO, WIPO & WTO, *supra* note 14.

³⁴ Clive Cookson, *Studies Fuel Criticism of High Drug Development Costs*, FIN. TIMES, April 9, 2015, www.ft.com/content/6a57fcd4-bdcd-11e4-8cf3-00144feab7de?mhq5j=e5.

³⁵ Press Release, Tufts Ctr. for the Study of Drug Dev., Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion (November 18, 2014). http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.

³⁶ Dollar (\$) amounts mentioned herein refer to U.S. dollars.

³⁷ Deloitte Centre for Health Solutions, *Measuring the Return from Pharmaceutical Innovation 2014*, DELOITTE (2014), <https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/measuring-the-return-from-pharmaceutical-innovation-2014.html>.

³⁸ Drugs for Neglected Diseases Initiative, *An Innovative Approach to R&D for Neglected Patients: Ten Years of Experience & Lessons Learned by DNDi* (2014), www.dndi.org/wp-content/uploads/2009/03/DNDi_Modelpaper_2013.pdf.

³⁹ Thomas Bombelles et al., *Neglected Tropical Disease Research: Rethinking the Drug Discovery Model*, 7 FUTURE MEDICINAL CHEMISTRY 7, 693–700 (2015).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² WHO, WIPO & WTO, *supra* note 14.

Often, on top of R&D, manufacturing facilities are costly. For instance, the production of vaccines and biologics includes significant fixed costs due to the very specific character of these products. The expenses linked to establishing and gaining regulatory approval for a manufacturing facility for products with a small profit margin will discourage companies from entering this domain.⁴³

High costs of pharmaceutical innovation are confronted with the challenge of ensuring that these innovations reach those who need them. Affordability, acceptability, and accessibility are priorities for any public health policy.

Experience gained over the last few decades has shown that for products where there are no profitable markets that could justify R&D investments, collaborations between pharmaceutical companies and nonprofit entities are essential to progress. Such public-private partnerships are especially important for the development of products directed to neglected diseases.

IV Collaborative Models to Address NTDs

According to WHO, NTDs are communicable diseases⁴⁴ that prevail in tropical and subtropical conditions in 149 countries, affecting more than a billion people, who are mainly living in poverty and without adequate sanitation. NTDs cost developing countries billions of dollars every year.⁴⁵ Over the past twenty years, a range of new collaborative innovation models have been created to tackle the need for innovation in the field of NTDs.

In May 1974, the World Health Assembly (WHA) called upon the WHO to intensify activities in tropical disease research.⁴⁶ This WHA resolution eventually led to the creation of the Special Programme for Research and Training in Tropical Diseases, which is hosted at the WHO and is sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and WHO. This partnership is committed to R&D and a dynamic collaboration to achieve innovations for NTDs in a new environment of private and public partnerships.⁴⁷

The emergence of donor organizations, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria; the GAVI Alliance; and the Bill and Melinda Gates Foundation, led to an era of partnerships launched in the early 2000s.⁴⁸ New partnerships endeavored to address the mismatch between the need for health technologies for NTDs and the lack of engagement of the commercial sector that shied away from the costs and risks because of the low market potential.⁴⁹

⁴³ *Id.*

⁴⁴ WHO, *Neglected Tropical Diseases Summary*, WHO (2017) www.who.int/neglected_diseases/diseases/summary/en/.

⁴⁵ *Id.*

⁴⁶ World Health Assembly Res. 27.52.

⁴⁷ WHO, *Making a Difference: 30 Years of Research and Capacity Building in Tropical Diseases* (2007) http://apps.who.int/iris/bitstream/10665/43689/1/9789241595575_eng.pdf.

⁴⁸ Mahoney, *supra* note 32.

⁴⁹ Cheri Grace, *Product Development Partnerships (PDPs): Lessons from PDPs Established to Develop New Health Technologies for Neglected Diseases*, HUMAN DEV. RES. CTR. (2010).

The move toward a more cohesive international response to NTDs started to emerge in 2003 at WHO under the leadership of then Director General Dr. J. W. Lee.⁵⁰ A turning point in efforts against NTDs was achieved after the first Global Partners' Meeting convened by WHO in 2007⁵¹ – an initiative outside any formally structured partnership that resulted in a shared commitment to support WHO's strategies, goals, and targets.⁵²

In 2010, WHO released its first report on NTDs, entitled “Working to overcome the global impact of NTDs.”⁵³ This paper has had a significant impact and since then the World Bank, pharmaceutical companies, philanthropic foundations, bilateral aid agencies, endemic countries, and other public and private sector organizations have increased their support to respond to the challenges posed by NTDs.⁵⁴

In 2012, WHO published “Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases,” a roadmap that sets out implementation targets for the control, elimination, or eradication of seventeen NTDs by 2020.⁵⁵ This gave rise to further strengthening global efforts in the field of NTDs.

Drawing inspiration from the WHO Roadmap and previous developments, the Bill and Melinda Gates Foundation, the United States Agency for International Development (USAID), the United Kingdom's Department for International Development, the WHO, DNDi, and the Governments of Mozambique, Tanzania, Brazil, as well as thirteen pharmaceutical companies met in 2012 in London, where they pledged to unite in their efforts in supporting the control, elimination, or eradication of ten NTDs.⁵⁶ The resulting London Declaration on Neglected Tropical Diseases (London Declaration)⁵⁷ was a significant step in the efforts to accelerate progress toward eliminating or controlling NTDs. It recognized that existing tools were having a major impact, but that several NTDs required new or improved medicines and diagnostics. Its partners committed to ensuring supplies of drugs, and to advancing R&D through partnerships, funding, and technical support. The London Declaration has been endorsed by 80 organizations, and led to the donation of 7.9 billion tablets and a pledge of more than \$17.8 billion in drug

⁵⁰ Lorenzo Savioli et al., *Neglected Tropical Diseases: The Development of a Brand with No Copyright. A Shift from a Disease-Centered to a Tool-Centered Strategic Approach*, in THE CAUSES AND IMPACTS OF NEGLECTED TROPICAL AND ZOONOTIC DISEASES: OPPORTUNITIES FOR INTEGRATED INTERVENTION STRATEGIES: WORKSHOP SUMMARY (2011).

⁵¹ Some 200 participants attended the meeting, including representatives of WHO Member States, United Nations agencies, the World Bank, philanthropic foundations, universities, pharmaceutical companies, international nongovernmental organizations, and other institutions dedicated to contributing to control neglected tropical diseases. WHO, *First Global Partners' Meeting on Neglected Tropical Diseases*, www.who.int/neglected_diseases/partners_meeting/en/.

⁵² WHO, *Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases – A Roadmap for Implementation: Executive Summary* (2012) [www.who.int/neglected_diseases/NTD_RoadMap_2012_Full version.pdf](http://www.who.int/neglected_diseases/NTD_RoadMap_2012_Full_version.pdf).

⁵³ *Id.*

⁵⁴ Amber Cashwell et al., *BRICS in the Response to Neglected Tropical Diseases*, 92 BULLETIN OF THE WORLD HEALTH ORG. 385 (2014).

⁵⁵ WHO, *supra* note 52.

⁵⁶ *Uniting to Combat Neglected Tropical Diseases, Country Leadership and Collaboration on Neglected Tropical Diseases: Third Progress Report of the London Declaration* (2015) <http://unitingtocombatntds.org/sites/default/files/document/UTCNTD%20FULL%20REPORT.pdf>.

⁵⁷ *Uniting to Combat Neglected Tropical Diseases, London Declaration on Neglected Tropical Diseases* (2012) http://unitingtocombatntds.org/sites/default/files/resource_file/london_declaration_on_ntds.pdf.

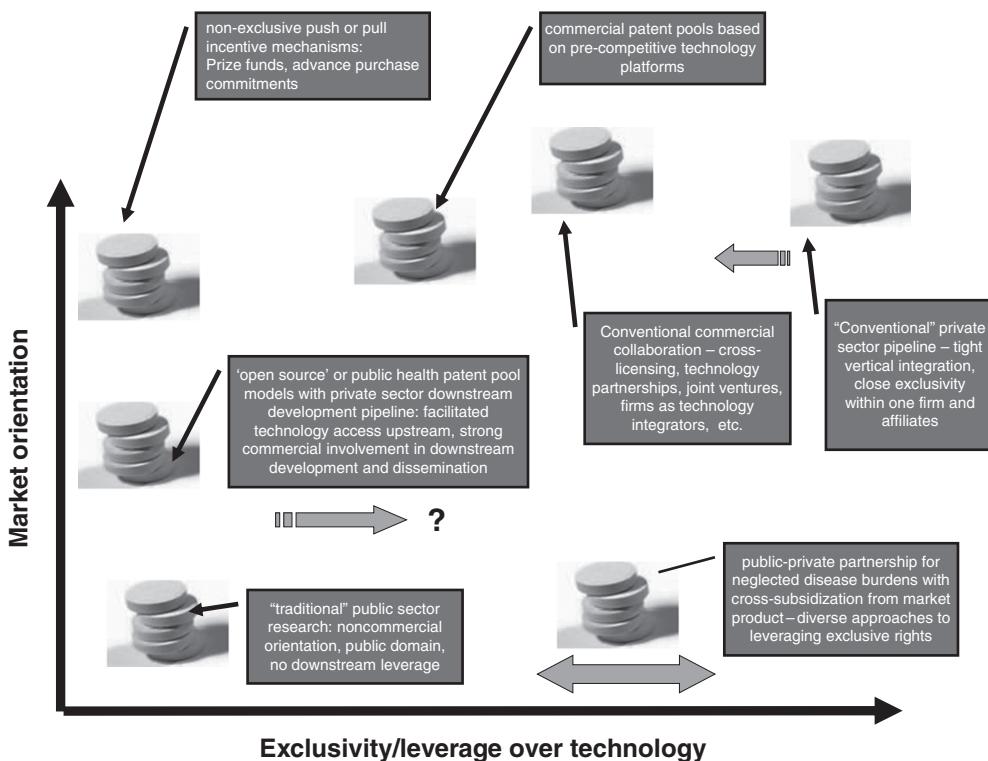


Figure 3.1. Mapping market incentives and leverage over technology in innovation structures. Source: Antony Taubman, *A Typology of Intellectual Property Management for Public Health Innovation and Access: Design Considerations for Policy Makers*, 4 OPEN AIDS J. 1, 4 (2010).

donations by 2020.⁵⁸ The London Declaration in many ways confirms that the partnership route between industry, public sector, nonprofit, and philanthropic organizations is a key component in the arsenal of R&D.⁵⁹

According to the eighth annual G-FINDER report, one of the most comprehensive reports on public and private funding into R&D for NTDs, \$3.4 billion was invested in NTDs R&D in 2014.⁶⁰ This was the largest investment in NTDs R&D in the history of the G-FINDER survey.⁶¹

In sum, a variety of innovation models are used in the development of health technologies (see Figure 3.1). The London Declaration and WIPO Re:Search are just some of the examples of more novel structures which include a multitude of actors from public and private sectors. What they all have in common is that they are neither situated in an entirely noncommercial context nor do they apply a rigid, highly exclusive and entirely private model of technology development.

⁵⁸ UNITING TO COMBAT NEGLECTED TROPICAL DISEASES, <http://unitingtocombatntds.org/>.

⁵⁹ David Torstensson, *FIGHTING TROPICAL DISEASE: IT'S NOW A COMMON CAUSE*, PHARMEXC.COM, (Feb. 8, 2012), www.pharmexec.com/fighting-tropical-disease-its-now-common-cause.

⁶⁰ *Global Funding of Innovation for Neglected Diseases: G-FINDER*, POLICYCURES (2015) <http://policycures.org/gfinder.html>.

⁶¹ *Id.*

What is clear in areas such as NTDs is that neither private nor public entities are capable of resolving global health challenges alone. Public institutions and research centers are sometimes confronted with limited financial resources. At the same time, private sector entities might be careful about initiating internal pharmaceutical R&D programs when there are no commercial prospects for such products. Industry can be expected to require some form of risk sharing before investing in such programs.

By contrast, partnerships such as Medicines for Malaria Venture (MMV), which have been generously funded are able to operate independently. They may cooperate with private companies as contractors and engage them for work, so that the companies take few risks and invest little themselves. These partnerships can use industry skills (especially in manufacturing, clinical trials, and regulatory affairs) that are important for progress and which the public sector may not wish to build up on its own. The key could be partnership and finding the right “meshing” of capabilities to make an effective mechanism.

Even though a lot of attention is given to the role of the industry, public sector entities continue to have a significant impact on the innovation cycle in health R&D.⁶² Researchers from public sector organizations, including private universities and institutes, are usually involved in early-stage drug development, but they also play an important role in the innovation cycle at subsequent stages.⁶³ The public sector plays a critical role in the delivery phase of health products; governments are usually the main procurer as well as being involved in the distribution and delivery of such products.⁶⁴ Moreover, the private sector’s expertise, know-how, state of the art facilities, networks, manufacturing capabilities, capital investment, and market development experience allow important projects to be undertaken or continued when, otherwise, they might not be possible. In that sense, the public and private sectors collaborate and interact throughout the product development and delivery cycles.

In recent years, there has been a rapid global expansion and acceleration of one of these forms of collaborations – PPPs for public health.

V Public–Private Partnerships (PPPs) for Public Health

Partnerships between public and private actors can lead to enormously positive outcomes for well-defined public health goals. They are a powerful mechanism for addressing difficult problems by leveraging the ideas, resources, networks and/or expertise of diverse partners⁶⁵ who engage in PPPs to make sure that health innovations are affordable, available, and accessible to people around the world.

Various definitions of “public–private partnerships” have been prepared but there does not seem to be a clear consensus around what a PPP really is (beyond the fact that public and private entities collaborate in some manner) and what its essential elements are.⁶⁶ However, four points stand out as broadly applied to all PPPs in health:

⁶² WHO, WIPO & WTO, *supra* note 14.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Michael R. Reich, *Public–Private Partnerships for Public Health*, 6 NATURE MED. 617 (2000).

⁶⁶ Jeffrey Barnes, *Designing Public–Private Partnerships in Health*, SHOPS (2011), www.abtassociates.com/reports/PPP_Primer.pdf.

- they integrate public sector and private sector approaches, and generally use industry practices in their R&D activities;
- they manage neglected diseases R&D portfolios and target one or more neglected diseases;
- they are created to pursue public health objectives rather than commercial gains; and
- they ensure that the developed products are distributed at the lowest possible sustainable price.⁶⁷

Another definition, which avoids the difficulty of having to judge the private partners' commitment to the social mission, was formulated by Jeffrey Barnes in his report for USAID: "A PPP in health is any formal collaboration between the public sector at any level (national and local governments, international donor agencies, bilateral government donors) and the nonpublic sector (commercial, nonprofit, and traditional healers, midwives, or herbalists) in order to jointly regulate, finance, or implement the delivery of health services, products, equipment, research, communications, or education."⁶⁸ This definition includes the elements of a formal agreement and recognizes the capacity of private partners to strengthen any health system component. Barnes argues that successful partnerships show that partnering must take account of, and accommodate, the profit motive.⁶⁹

In the context of addressing health problems in LMICs, Roy Widdus and Pedro Roffe enumerate four main categories of such partnerships:

- product development partnerships (PDPs);
- partnerships for improving access to pharmaceuticals;
- global coordination and financing mechanisms; and
- partnerships for strengthening health systems.⁷⁰

R&D supported by PDPs may lead to patentable inventions, proprietary (trade secret) data, and technical know-how, all of which the PDP needs to manage in its agreements with collaborators. Indeed, PDPs in general, have two interconnected long-term objectives: creating a new product and ensuring that it is as widely and affordably available as possible. It should be noted that PDPs apply different IP management strategies depending on the particular project in order to best advance their social and development missions.

PDPs, by working together, have the potential for exchanging and transferring valuable knowledge and skills. Robust exchanges of know-how among public and private sector players also expedites the translation of knowledge about diseases of the poor while also reflecting national sensitivities, changing contexts, and the concomitant desire for economic growth.⁷¹ Dissemination of technology and knowledge provides opportunities for

⁶⁷ WHO, *Public Health, Innovation and Intellectual Property Rights; Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (2006) www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

⁶⁸ Barnes, *supra* note 66.

⁶⁹ *Id.*

⁷⁰ Widdus, *supra* note 30.

⁷¹ Carlos M. Morel et al., *Health Innovation Networks to Help Developing Countries Address Neglected Diseases*, 309 *SCIENCE* 401 (2005).

regions, firms, and institutions that are comparatively less developed to close the technology gap and to develop their own innovative capacity.⁷²

Over the last two decades, many PDPs aiming to address gaps in health innovation have been established. The targeted commitments and investments from private and public partners have reduced the burden of several NTDs, but significant gaps remain. Concurrently, there have been profound changes in the world of intellectual property management⁷³ and research on NTDs, malaria, and TB over the last two decades, and these changes have led to the environment in which WIPO Re:Search was founded and currently operates.

VI WIPO Re:Search – Overview

The WIPO is one of a number of stakeholders contributing to the fight against NTDs, in areas where WIPO has a comparative advantage. A PPP-like structure was eventually chosen as the most effective form. The engagement is anchored in WIPO's role as the specialized agency of the UN serving as the global forum for IP services and information. As such, WIPO is uniquely positioned to help organizations work toward creating a truly global view and understanding of the IP system, including the flexibilities to implement the patent system at the national level, to provide information on patents (including information on the patent status of key medicines and vaccines in developing countries), and to lend its expertise on patent law and its interplay with public policy.⁷⁴ Most importantly, however, WIPO has been able to leverage a concerted approach by many pharmaceutical companies to openly share their intellectual property assets for the development of NTD, malaria, and TB solutions.

WIPO's Director General, Mr. Francis Gurry, considers PPPs to be most effective vehicles for implementing policies agreed to by WIPO Member States.

“Public–private partnerships can deliver on the objectives set by member states. They provide access both to intellectual resources and to financial capital that do not exist in the public sector. [...] In each case the private sector is also contributing financial resources.”⁷⁵

Critically for a UN agency, public–private partnerships do not affect the Organization's intergovernmental character. Member States still drive the Organization and establish its normative program.⁷⁶

In October 2011, a new Consortium of WIPO Re:Search – *Sharing Innovation in the Fight Against Neglected Tropical Diseases* – was launched by WIPO jointly with BIO Ventures for Global Health (BVGH) and thirty-one initial WIPO Re:Search Members. The World Health Organization (WHO) serves as a technical adviser to WIPO on

⁷² Jennifer Brant and Balaji Parthasarathy, *The Dynamics of Global Technology and Knowledge Flows* (Innovation and Intellectual Prop. Series, Research Paper No. 4, 2015).

⁷³ Krattiger et al. (eds.), *INTELLECTUAL PROPERTY MANAGEMENT OF HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES* (2007).

⁷⁴ WHO, WIPO & WTO, *supra* note 14.

⁷⁵ Cathy Jewell, *Harnessing the Power of the Private Sector – An Interview with Francis Gurry*, 5 WIPO MAG., Oct. 2015, at 2.

⁷⁶ *Id.*

NTDs, malaria, and TB. The Consortium’s goal is to catalyze the development of medical products for NTDs, malaria, and TB through innovative research partnerships and knowledge sharing. Central to the value of WIPO Re:Search is the sharing of IP assets in a highly efficient manner with low transaction costs. To this end, the Consortium has created an open innovation platform through which public and private sector entities can share IP to eventually benefit patients in LMICs.

WIPO Re:Search is a reflection of the hope of WIPO, BVGH, and its partners that public–private collaboration under the aegis of a UN agency can provide a valuable and concrete contribution to improving the R&D landscape for NTDs, malaria, and TB.⁷⁷ WIPO’s sponsorship of this initiative supports WIPO’s mandate from its Member States as expressed in the WIPO Development Agenda (DA) recommendations,⁷⁸ specifically:

- facilitating access to knowledge and technology for developing countries including Least Developed Countries (LDCs);
- promoting the transfer and dissemination of technology to the benefit of developing countries, including LDCs;
- encouraging Member States, especially developed countries, to urge their research and scientific institutions to enhance cooperation and exchange with research and development institutions in developing countries, especially LDCs; and
- cooperating with other intergovernmental organizations to provide developing countries, including LDCs, upon request, advice on how to gain access to and make use of intellectual property-related information on technology.⁷⁹

Indeed, various WIPO DA recommendations under Cluster A (“Technical Assistance and Capacity Building”) and Cluster C (“Technology Transfer, Information and Communication Technologies (ICT) and Access to Knowledge”) are being realized in a tangible manner through this initiative. For instance, Recommendation 26 requires WIPO “to encourage Member States, especially developed countries, to urge their research and scientific institutions to enhance cooperation and exchange with R&D institutions in developing countries, especially LDCs.” One of the key goals of WIPO Re:Search is to ensure such an ongoing exchange. Furthermore, WIPO DA recommendation 2 asks WIPO to establish voluntary funds specifically for LDCs, and accord high priority to finance activities in Africa to promote, *inter alia*, the legal, commercial, cultural, and economic exploitation of intellectual property in these countries. As we will see later in this chapter, WIPO Re:Search fellowships for researchers from LMICs, until now mainly from Africa, contribute to the implementation of this objective.

WIPO Re:Search is a voluntary endeavour open to all *bona fide* private and public entities, including intergovernmental institutions. It comprises institutions from all relevant sectors, including public, private, academic, and civil society. WIPO Re:Search has a cooperative, voluntary character, with various groups and institutions collaborating toward a common set of principles and objectives. Even though WIPO Re:Search

⁷⁷ *Id.*

⁷⁸ WIPO, *The 45 Adopted Recommendations under the WIPO Development Agenda* (last visited April 10, 2016), www.wipo.int/ip-development/en/agenda/recommendations.html.

⁷⁹ WIPO Re:Search *Guiding Principles* (June 8, 2011) www.wipo.int/export/sites/www/research/docs/guiding_principles.pdf.

enables partnerships between private and public institutions, it is not a PDP itself. To date, it has facilitated mainly early stage research and addresses possible barriers to products moving into PDPs, if the PDPs wish to develop them further.

As of December 2016, WIPO Re:Search has enjoyed more than five years of success and growth; it comprises 109 Members with BVGH having facilitated over 100 collaborations.⁸⁰

VII Structure and Governance

The membership of WIPO Re:Search, includes three groups of key players: Providers, Users, and Supporters:

- **“Providers”** share their IP assets, materials, or services with other WIPO Re:Search Members for licence or use;
- **“Users”** are Members that have entered into licence agreements with Providers to utilize these IP assets (and/or materials and/or services) made available by Providers;
- **“Supporters”** are Members that encourage the facilitation of R&D of products for NTDs. Supporters may voluntarily offer to provide support, services, or assistance of any kind to the Consortium or its Members in order to facilitate achievement of the principles and objectives of the Consortium.

WIPO Re:Search is open to those that agree to the WIPO Re:Search Guiding Principles, as is mentioned in the opening lines: “The Consortium is a voluntary endeavour open to all *bona fide* private and public entities.”⁸¹ In addition to pharmaceutical companies, Members of WIPO Re:Search include universities, PDPs, research centers, associations and national IP offices from all over the world.⁸² A notable component to the development of new and better treatments for NTDs is the emphasis on the inclusion of research centers in developing countries.⁸³

Many of the Members participate both as a Provider and User, and have uploaded data in the database, participated in the hosting arrangements, and entered into collaborations.

The Consortium has three major components:

- The **Database**, hosted by WIPO, providing information about IP available for licensing from a Provider, as well as services, technology, or materials which can be accessed and/or licensed by anyone, anywhere, for free;
- The **Partnership Hub**, managed by the Partnership Hub Administrator (BVGH) in cooperation with WIPO, where Members and other interested parties can learn about the Consortium, available licensing and research collaboration opportunities, networking possibilities, and funding options;
- A range of specific **supporting activities**, led by WIPO in cooperation with BVGH, facilitate the negotiation of licensing agreements and address technical matters such as identifying research needs and opportunities, among others, with technical advice from WHO.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

⁸³ WIPO Re:Search Members, www.wipo.int/research/en/about/members.html.

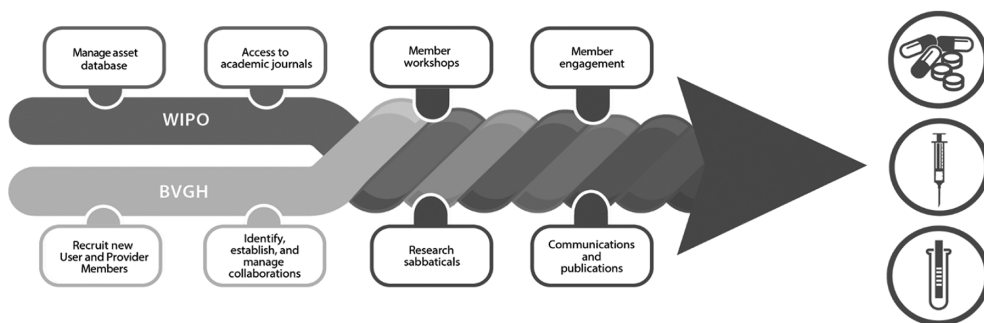


Figure 3.2. WIPO Re:Search based on the collaboration between WIPO and BVGH.
 Source: BIO Ventures for Global Health.

As the Secretariat of WIPO Re:Search, WIPO manages the Database, coordinates regular communication between WIPO, BVGH, and Members, and organizes the annual or biennial meeting of members.⁸⁴ BVGH is the Partnership Hub Administrator and facilitates connections and collaborations between Members, recruits new Members, and communicates the Consortium's activities and achievements.⁸⁵ WIPO and BVGH work closely together as depicted in Figure 3.2.

VIII Funding

WIPO finances the WIPO Re:Search Secretariat function, whereas the Partnership Hub relies on funding from the private sector Members. To date, additional support for the Partnership Hub has not been obtained from other sources such as philanthropic foundations, nor from European and North American bilateral donors.

Additionally, WIPO Re:Search activities are supported by Funds-in-Trust (FIT) from the Government of Australia and Japan. Research fellowships for developing country scientists are supported by the government of Australia, while certain communications and training activities have been funded by the government of Japan.⁸⁶

Beyond the funding for the fellowships, the FIT programs are also dedicated to supporting the capacity-building activities. For example, the Government of Japan has sponsored training programs on successful technology licensing for the African Network for Drugs and Diagnostic Innovation, which were offered to fourteen scientists and technology managers from research institutions from ten African countries.⁸⁷ The support of the government of Japan has also enabled the organization of other training activities for

⁸⁴ Thomas Bombelles et al., *WIPO Re:Search: Sharing Innovation in the Fight Against Neglected Tropical Diseases* (2015) www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_8.pdf.

⁸⁵ Roopa Ramamoorthi et al., *WIPO Re:Search: Accelerating Anthelmintic Development through Cross-Sector Partnerships*, 4 *INT. J. FOR PARASITOLOGY: DRUGS & DRUG RESISTANCE* 220 (2014); Symposium, *Anthelmintics: From Discovery to Resistance* (2016); Symposium, *Global Challenges for New Drug Discovery Against Tropical Parasitic Diseases* (2014).

⁸⁶ Bombelles et al., *supra* note 84.

⁸⁷ WIPO, *The First Five Years of the WIPO Japan Funds-in-Trust for Industrial Property (Japan FIT/IP) for Africa and Least Developed Countries (LDCs): A Productive Collaboration with the Japan Patent Office (JPO)* (2013) www.wipo.int/export/sites/www/cooperation/en/funds_in_trust/docs/japanfitip_jpo_firstfive_years_en.pdf.

WIPO Re:Search members, particularly from LMICs, at the margins of annual meetings and elsewhere (Geneva in 2012, New York in 2014, as well as Manila in 2015 and 2016).

IX Database

One of the fundamental resources of WIPO Re:Search is its Database. The information therein on IP and other assets, which are available for licensing from the WIPO Re:Search partners, is intended to be of potential use for NTDs, malaria, and TB, or for application to related R&D.

Providers of uploads to the Database include pharmaceutical companies and many other public and private sector research institutions from all over the world. Interested researchers can access and use those resources to meet their needs. In particular, this can help scientists from developing countries to identify technologies that may be of interest to them.⁸⁸ The central element of WIPO Re:Search, however, is to provide a framework for building collaborations beyond the database, through the services of BVGH as an intermediary, bringing users and providers together.

X Services Beyond the Database

Over the years, WIPO Re:Search has expanded from its original ambition of facilitating research collaborations between pharmaceutical companies and academic researchers. The Consortium now also facilitates agreements between pharmaceutical companies and biotech startups, as well as bilateral collaborations between academic institutions.⁸⁹

To establish a collaborative opportunity, BVGH (in its role as Partnership Hub Administrator) studies scientific literature published by Members' scientists, identifies areas of potential collaboration, and contacts the researchers to suggest partnership ideas.⁹⁰ In other words, it acts as a matchmaker that connects users who have specific research plans and needs with Provider Members holding assets that fulfil those needs (see Figure 3.3). After BVGH builds the initial link, Providers and Users must come together to define the conditions of the collaboration. A clearly defined mission becomes the critical underpinning of all collaborations.⁹¹

WIPO Re:Search may also help its Members at a later stage. Bringing a product through preclinical, clinical, and regulatory filing activities is an inherently expensive endeavour that requires significant expertise. As an exploratory possibility for further services, if a WIPO Re:Search partnership shows potential for future development, BVGH could help the participating Members identify sources of funding as well as support with the expertise needed to transit the potential product through the pipeline to the market and those who need it the most.⁹²

⁸⁸ Richard Mahoney, *Strategic Review of WIPO Re:Search*, GLOBAL CHALLENGES REP. (2015) www.wipo.int/export/sites/www/research/en/docs/wipo_research_external_review.pdf.

⁸⁹ Ramamoorthi et al., *supra* note 85.

⁹⁰ *Id.*

⁹¹ William B. Mattes, *Divided We Fall*, in COLLABORATIVE INNOVATION IN DRUG DISCOVERY: STRATEGIES FOR PUBLIC AND PRIVATE PARTNERSHIPS 11 (Rathnam Chaguturu ed., 2014).

⁹² Ramamoorthi et al., *supra* note 85.

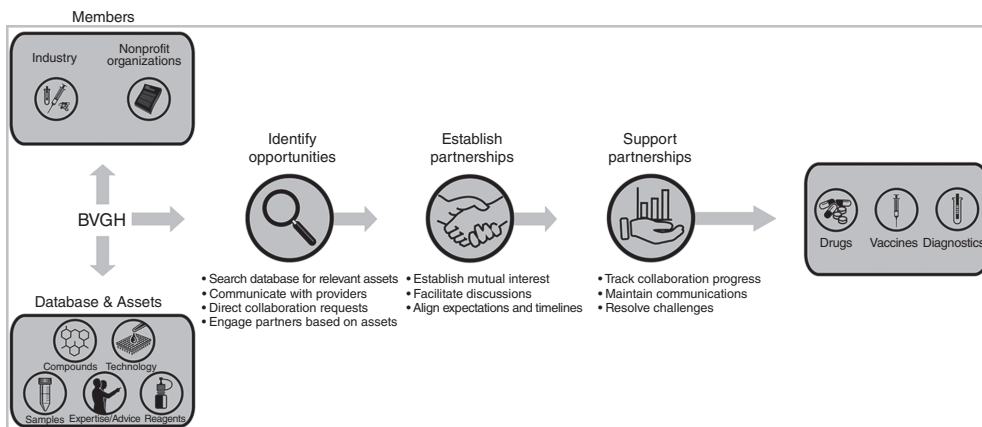


Figure 3.3. The Partnership Hub – facilitating collaborations.

XI Research Capacity Building and Knowledge Transfer

Collaborations built through WIPO Re:Search do not focus only on developing medicines, vaccines, or diagnosis. Of equal importance is capacity building, which is regarded as one of the important long-term contributions of the Consortium.

Capacity building can be defined as an approach to the development of sustainable skills, organizational structures, resources, and commitment to health improvement in health and other sectors, to prolong and multiply health gains many times over.⁹³ Building research capacities in LMICs is crucial to empowering individuals, institutions, organizations, and nations. This can be done, *inter alia*, by research and advanced training for individual researchers at state-of-the-art research institutions, usually located in developed countries. Potential gains from such partnerships have included increased access to new ideas and best practices, technical expertise, and resources; wider coverage and impact of research benefits; and an increased probability of sustainability, recognition, and advantage of the research partnerships.⁹⁴

Moreover, building medical research capacity contributes to international development. A strong research base can help developing countries in various ways, including dealing with local health challenges such as NTDs that may be not otherwise be addressed by researchers from elsewhere. Further, this will strengthen their role in global research and reduce the need for future development assistance, developing health solutions that are more relevant to the local context, and encouraging scientists to stay and work in their home country rather than move abroad, thereby reducing “brain drain”⁹⁵

WIPO Re:Search supports capacity building by providing opportunities for developing country scientists to work in laboratories of pharmaceutical companies and developed country research centres. To assist in the development of product development skills in the developing world, WIPO Re:Search has established several training opportunities for

⁹³ NSW HEALTH DEPARTMENT, A FRAMEWORK FOR BUILDING CAPACITY TO IMPROVE HEALTH (2001).

⁹⁴ Mary Ann Lansang and Rodolfo Dennis, *Building Capacity in Health Research in the Developing World*, 82 BULLETIN OF THE WORLD HEALTH ORG. 764 (2004).

⁹⁵ HOUSE OF COMMONS SCIENCE AND TECHNOLOGY COMMITTEE, BUILDING SCIENTIFIC CAPACITY FOR DEVELOPMENT, 2012–13, HC 377 (UK).

researchers from African Member institutions, such as research fellowships described in the section below. Through such experiences, the participating scientists gain the skills and knowledge essential to move their projects forward. Such an approach helps to maximize existing investments in health research made by some developing countries.⁹⁶ (See Appendix I.)

Indeed, these capacity-building opportunities facilitated through WIPO Re:Search foster international collaboration and cooperation, and increase the skills and capabilities of laboratories across the region, thus allowing these institutes and researchers to be active contributors to the global movement to eliminate the health inequalities of the developing world.⁹⁷

Those Member institutions and companies that host researchers from LMICs can benefit in terms of knowledge and know-how transfer. Even though they may already have the assets and expertise needed to systematically discover and develop medicines, they can still benefit from the direct and in-depth knowledge of the pathogens' biology and understanding of disease mechanisms that NTD researchers have – expertise that is essential to develop treatments for these diseases.⁹⁸

XII IP and Access

Effective IP management through voluntary licensing is an essential tenet of WIPO Re:Search. Because the sharing occurs in the framework of a formal agreement, more information, including patent and related registered rights, know-how, manufacturing processes, and regulatory data and the corresponding physical materials such as propriety compounds and technologies are shared within the collaboration. This vision is reflected in the WIPO Re:Search Guiding Principles, which stipulate, *inter alia*, that the Members believe there are opportunities to use IP innovatively and to encourage both public and private sector R&D of health solutions that are particularly needed by the world's poorest populations. Moreover, they are convinced that an open innovation framework for the sharing of IP, as well as technology and research materials not protected by IP rights, can facilitate such R&D into new products for NTDs.

Each WIPO Re:Search partnership is governed by its own specific agreement; however, it is expected that these agreements will embody the spirit of the WIPO Re:Search Guiding Principles. The Guiding Principles are incorporated into all collaboration agreements.

The WIPO Re:Search Guiding Principles can broadly be summarized as follows:

- Members will provide royalty-free licences for R&D related to NTDs, malaria, and tuberculosis;
- Members will provide a royalty-free licence for any product developed through WIPO Re:Search that is used and sold in LDCs;
- Members will consider the issue of access and affordability to these products for all developing countries, including those that do not qualify as LDCs; and
- Users will retain ownership of any new IP developed, but are encouraged to make new inventions available to other Members of WIPO Re:Search.

⁹⁶ Morel et al., *supra* note 71.

⁹⁷ Ramamoorthi et al., *supra* note 85.

⁹⁸ Jennifer Dent, Katy M. Graef, and Paddy Shivanand, *Open Innovation to Bolster Research and Development for Neglected and Emerging Infectious Diseases*, 1 J. MED. DEV. (2015). Available at <http://ojs.whioice.com/index.php/jmids/article/view/119/99>.

XIII Status of Collaborations

By December 2016, 109 collaborations between WIPO Re:Search Members were established. The research collaborations covered fourteen diseases among which malaria is the most common focus of collaborations. While the collaborations focus on basic research and drug, vaccine, and diagnostic development, drugs are the most common focus of collaborations established each year, and compounds are the most commonly shared asset each year. During 2012–2013, the majority of established collaborations involved, respectively, a for-profit and nonprofit Member. Those involving only nonprofit Members became the majority from 2014 onward. Thirty-two collaborations include a Member from a developing country, among which twelve Members are African Members. A total of forty collaborations are ongoing and four collaborations have advanced to the next stage of development.

Conclusions: Successes and Challenges

WIPO Re:Search Members trust that partnerships will not only accelerate product development but are also a key means to ensure access. From the beginning, it was clear that significant scientific and technical know-how as well as IP that private partners bring to partnerships will be determining factors for the success of this initiative.

With over one hundred collaborations in four years,⁹⁹ WIPO Re:Search contributes to the important goal of tackling NTDs, malaria, and TB. In its short existence, the partnerships facilitated by WIPO Re:Search have focused on early stage research. However, the value a partnership delivers takes time to be fully realized. Considering that developing a medicinal product and bringing it to the market is a long and complex process, this should not be discouraging. In fact, many Member researchers are already seeing their product discovery projects advance due to access to industry assets.¹⁰⁰ The progress in the WIPO Re:Search mission can be traced via the monthly Partnership Hub's newsletter¹⁰¹ and in its Annual Reports.¹⁰²

The capacity-building experiences of the six selected researchers discussed above who participated in WIPO Re:Search fellowships are presented in a WIPO Global Challenges Report.¹⁰³ This paper highlights the long-term impact of such collaborations, and their potential to facilitate R&D in NTDs. In particular, the selected researchers from Africa have emphasized the empowering nature of the fellowships as well as the fact that skills, knowledge, and know-how gained have profoundly contributed to their research.

WIPO Re:Search currently faces a number of opportunities and challenges. In 2015, Dr. Richard Mahoney, an independent health specialist and researcher engaged by

⁹⁹ See the list of collaborations at www.wipo.int/research/en/collaborations/.

¹⁰⁰ *Id.*

¹⁰¹ See, e.g., BIO VENTURES FOR GLOBAL HEALTH, Partnership Hub Mid-Year Report 2017, <https://bvgh.org/wp-content/uploads/2017/09/2017-BVGH-Partnership-Hub-Mid-Year-Report.pdf>.

¹⁰² See, e.g., BIO Ventures for Global Health, *2015 Partnership Hub Mid-Year Report: Catalyzing Partnerships for Global Health* (2015), www.wipo.int/export/sites/www/research/en/docs/bvgh_midyear_research_report_2015.pdf.

¹⁰³ Ania Jedrusik, *Sharing Innovation and Building Capacity to Fight Neglected Tropical Diseases: A Selection of WIPO Re:Search Fellowship Stories*, GLOBAL CHALLENGES REP. (2016) www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_11.pdf.

WIPO, prepared a report entitled “Strategic Review of WIPO Re:Search,” that identified its successes and challenges and provided a set of recommendations for future action.¹⁰⁴ He found that WIPO Re:Search had emerged at a time when companies were willing to relax IP considerations in order to facilitate R&D. As a result, WIPO Re:Search was able to create new R&D markets for underutilized assets and a global network of stakeholders for technology R&D in the target fields. He recommended some areas for improvements to the network infrastructure and the funding base, as well as a strategic governance reorientation, through the creation of an Advisory Committee to assist WIPO, BVGH, and all Members to define the future direction and goals of the project.¹⁰⁵

WIPO Re:Search was founded on the belief that the sharing of IP assets and knowledge transfer can be used creatively to stimulate research and development into new health solutions for NTDs, malaria, and TB, while ensuring access for the most disadvantaged populations. Indeed, with the effective structure of WIPO Re:Search, combining the strength of a UN agency with an energetic nonprofit, namely, BVGH, that manages the Partnership Hub, and coupled with vibrant members of the Consortium, WIPO Re:Search has demonstrated that IP does not have to be a barrier to research on NTD technologies.

As the understanding of the role of IP management evolves, industry has realized that it could do more to address the “access” side of the “innovation-access continuum.”¹⁰⁶ Access essentially begins with the way IP is managed during the invention, research, and product development stages through creative licensing practices. Given that NTDs, malaria, and TB represent a noncompetitive space for companies’ commercial interests, and given WIPO’s expertise in IP, and its long-standing relations with private sector inventors, this specialized UN agency was a natural venue to establish the multisectoral, public–private sector Consortium. Finally, having “prenegotiated” the minimum licensing terms, enshrined in the Guiding Principles,¹⁰⁷ that any institution that joins the Consortium needs to endorse, the transaction costs of entering into IP and knowledge sharing have been reduced significantly. This is a particularly important component of the way the Consortium operates and explains, in part, why so many collaborations were initiated within the framework of WIPO Re:Search.¹⁰⁸

Now that the Consortium has demonstrated its initial success, new questions arise to move into the next, more mature phase. What is the longer-term vision of WIPO Re:Search? What are the next steps to ensure that WIPO Re:Search is able to build on its successes? What resources are required, especially for WIPO and BVGH as the administrator of the Partnership Hub, to support the ongoing expansion of WIPO Re:Search? These topics will keep the WIPO Secretariat, BVGH, and the Members busy as they continue the efforts to identify ways of maintaining the Consortium’s success while simultaneously enabling and driving its future evolution.

¹⁰⁴ Mahoney, *supra* note 88.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *WIPO Re:Search Guiding Principles* (June 8, 2011) www.wipo.int/export/sites/www/research/docs/guiding_principles.pdf

¹⁰⁸ Collaboration agreements are the tangible results of WIPO Re:Search’s work. The full list of collaboration agreements is available at www.wipo.int/research/en/collaborations/collaborationagreements.html.

Appendix A: WIPO Re:Search Fellowships

WIPO Re:Search has provided opportunities for research fellowships of six developing country scientists at Member facilities, supported by funds-in-trust from the Government of Australia. WIPO Re:Search sought gender balance in the fellowships and half of the fellows were women. This is especially important since in some LMICs, female scientists face social, cultural, and economic barriers to the participation in “Women in Science, Technology, Engineering and Mathematics (STEM)” fields. WIPO Re:Search supports women from such places in realizing their potential and gaining recognition in their field.

A short summary of each of the six fellows and their current research follows here.¹⁰⁹

Dr. Fidelis Cho-Ngwa, Head of the Pan-African ANDI Centre of Excellence and Associate Professor of Biochemistry and Molecular Biology at the University of Buea in Cameroon, works on onchocerciasis (river blindness) which affects 25 to 40 percent of Cameroonians.

Dr. Cho-Ngwa developed an interest in onchocerciasis research and in 2013, Dr. Cho-Ngwa was invited to spend three months at Novartis facilities in Basel, Switzerland. Having extensive experience in onchocerciasis, he travelled to Basel with clear goals in mind. Dr. Cho-Ngwa wanted to acquire in-depth knowledge and skills required to use high-performance liquid chromatography and mass spectrometry techniques in order to extract, purify, and identify active natural product compounds for filarial diseases. Novartis’ state-of-the-art equipment combined with the host’s strong support made Dr. Cho-Ngwa’s plan possible.

Dr. Wellington Oyibo, Director of Research and Innovation, University of Lagos, Nigeria, is a medical parasitologist who previously worked on onchocerciasis; however, during the past ten years he has focused on malaria. Dr. Obiyo’s rich experience in malarial diagnostics includes his participation in a WHO platform focusing on the use of malaria rapid diagnostic tests (RDTs) together with quality assurance of these tests. Dr. Obiyo joined the program convinced about a possibility to merge his diagnosis-oriented approach and Novartis’ expertise in drug development. “They are producing medicines, but you have to be able to test a patient before the treatment,” he remarked. “I wanted to explore if as a pharma company they had an interest to get into diagnosis.” Dr. Obiyo hopes to obtain a malaria antibody that is able to dislodge or disrupt the interaction in which malarial parasites attach to the blood vessels.

Dr. Olfat Hammam is a pathologist who specializes in schistosomiasis pathology. She works at the Theodor Bilharz Research Institute in Giza, Egypt and has academic training in Egypt and Germany. WIPO Re:Search supported Dr. Hammam in completing her fellowship at Stanford University, Palo Alto, California. Her choice was a result of a careful investigation and preparatory work by BVGH, and Dr. Hammam saw the Stanford lab as a perfect match. Dr. Michael Hsieh, with whom she was invited to work, has extraordinary expertise in schistosomiasis and other NTDs. In addition, he specializes in animal models for research – something that she wanted to explore in depth. Dr. Hammam sees the fellowship at Stanford as having provided an important boost to her research.

¹⁰⁹ Jedrusik, *supra* note 104.

Dr. Christian Agyare is a professor at the Department of Pharmaceutics, Kwame Nkrumah University of Science and Technology (KNUST), Kumasi, Ghana, specializing in investigating medicinal plants for their potential to treat infectious, including neglected, diseases. In October 2013, Dr. Agyare travelled to the Center for Discovery and Innovation in Parasitic Diseases (CDIPD), University of California, San Francisco, to start a ten-month fellowship. “My collaboration started with Dr. Conor Caffrey from CDIPD, which was made possible by WIPO Re:Search. The collaboration has continued with a project on parasites responsible for NTDs,” Dr. Agyare explained.

Dr. Agyare’s initial idea was to perform the extraction and purification of compounds from the anti-parasitic products in Ghana and then to travel to California to further examine their activity. However, new demands on his time arose in Ghana, and instead of returning to California himself, one of his students, Ms. Gertrude Kyere-Davies, who at the time was pursuing a degree in pharmaceutical microbiology, was invited to the University of California to continue Dr. Agyare’s research. While in the CDIPD labs, Ms. Kyere-Davies learned various methods for growing the organisms and how to safely store them. She was glad that she could continue the work with the same team because of the complexity of the research and the need for time to obtain tangible results.

Dr. Krupa Naran was a doctoral fellow at the Institute of Infectious Diseases and Molecular Medicine, University of Cape Town, South Africa. As she has stated, “At the time when I went to AstraZeneca our lab just started doing some initial drug discovery in tuberculosis. On the biology side, it meant setting up different assays [investigative procedures aimed at the assessment of the composition of a substance] to try to figure out which would be the best drug to treat TB.” During the fellowship, the experts at AstraZeneca supported her in developing new skills and knowledge relating to assay development and beyond. Dr. Naran reported: “I have gained incredible knowledge and experimental skills in areas such as the culturing of nonreplicating bacteria, kill kinetics, and intracellular assays, all of which forms the basis of our drug discovery program.”

References

- Barnes, Jeffrey, *Designing Public–Private Partnerships in Health*, SHOPS (2011), www.abtassociates.com/reports/PPP_Primer.pdf.
- BIO Ventures for Global Health, *2015 Partnership Hub Mid-Year Report: Catalyzing Partnerships for Global Health* (2015), www.wipo.int/export/sites/www/research/en/docs/bvgh_midyear_research_report_2015.pdf (last visited Nov. 18, 2017).
- BIO VENTURES FOR GLOBAL HEALTH, *Partnership Hub Mid-Year Report 2017*, <https://bvgh.org/wp-content/uploads/2017/09/2017-BVGH-Partnership-Hub-Mid-Year-Report.pdf> (last visited Nov. 18, 2017).
- Bombelles, Thomas (Interview by Hannah Coaker), *Neglected Tropical Disease Research: Rethinking the Drug Discovery Model*, 7 *FUTURE MEDICINAL CHEMISTRY* 7 (2015).
- Bombelles, Thomas, Jennifer Dent, Meghana Sharafudeen, Philip Stevens, Katy M. Graef, and Anatole Krattiger, *WIPO Re:Search: Sharing Innovation in the Fight Against Neglected Tropical Diseases* (2015), www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_8.pdf (last visited Nov. 18, 2017).

- Brant, Jennifer and Balaji Parthasarathy, *The Dynamics of Global Technology and Knowledge Flows*, (Innovation and Intellectual Prop. Series, Research Paper No. 4, 2015).
- Cashwell, Amber, Anupama Tantri, Ashley Schmidt, Greg Simona, and Neeraj Mistrya. *BRICS in the Response to Neglected Tropical Diseases*, 92 BULLETIN OF THE WORLD HEALTH ORG. (2014).
- Cookson, Clive, *Studies Fuel Criticism of High Drug Development Costs*, FIN. TIMES, April 9, 2015, www.ft.com/content/6a57fcd4-bdcd-11e4-8cf3-00144feab7de?mhq5j=e5.
- Dent, Jennifer, Katy M. Graef, and Paddy Shivanand, *Open Innovation to Bolster Research and Development for Neglected and Emerging Infectious Diseases*, 1 J. MED. DEV. (2015) Available at <http://ojs.whoice.com/index.php/jmids/article/view/119/99> (last visited Nov. 18, 2017).
- Deloitte Centre for Health Solutions, *Measuring the Return from Pharmaceutical Innovation 2014*, DELOITTE (2014) <https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/measuring-the-return-from-pharmaceutical-innovation-2014.html> (last visited Nov. 18, 2017).
- Drugs for Neglected Diseases Initiative, *An Innovative Approach to R&D for Neglected Patients: Ten Years of Experience & Lessons Learned by DNDi* (2014) www.dndi.org/wp-content/uploads/2009/03/DNDi_Modelpaper_2013.pdf (last visited Nov. 18, 2017).
- Farlow, Andrew, *The Global HIV Vaccine Enterprise, Malaria Vaccines, and Purchase Commitments: What is the Fit?* (2005) www.who.int/intellectualproperty/submissions/Farlow.pdf note 14.
- Grace, Cheri, *Product Development Partnerships (PDPs): Lessons from PDPs Established to Develop New Health Technologies for Neglected Diseases*, HUMAN DEV. RES. CTR. (2010).
- Hotez, Peter J., *The Neglected Tropical Diseases and the Neglected Infections of Poverty: Overview of Their Common Features, Global Disease Burden and Distribution, New Control Tools, and Prospects for Disease Elimination*, in THE CAUSES AND IMPACTS OF NEGLECTED TROPICAL AND ZOONOTIC DISEASES: OPPORTUNITIES FOR INTEGRATED INTERVENTION STRATEGIES (Institute of Medicine (US) Forum on Microbial Threats ed., 2011).
- HOUSE OF COMMONS SCIENCE AND TECHNOLOGY COMMITTEE, BUILDING SCIENTIFIC CAPACITY FOR DEVELOPMENT, 2012–13, HC 377 (UK).
- Idris, Kamil, and Hisamitsu Arai, THE INTELLECTUAL PROPERTY-CONSCIOUS NATION: MAPPING THE PATH FROM DEVELOPING TO DEVELOPED (2006).
- Jedrusik, Ania, *Sharing Innovation and Building Capacity to Fight Neglected Tropical Diseases: A Selection of WIPO Re:Search Fellowship Stories*, GLOBAL CHALLENGES REP. (2016), www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_11.pdf (last visited Nov. 18, 2017).
- Jewell, Cathy, *Harnessing the Power of the Private Sector – An Interview with Francis Gurry*, 5 WIPO MAG., Oct. 2015.
- Krattiger, Anatole, Richard T. Mahoney, Lita Nelsen, Jennifer A. Thomson, Alan B. Bennett, Kanikaram Satyanarayana, Gregory D. Graff, Carlos Fernandez, and Stanle P. Kowalski (eds.), INTELLECTUAL PROPERTY MANAGEMENT OF HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES (2007).
- Lansang, Mary Ann, and Rodolfo Dennis, *Building Capacity in Health Research in the Developing World*, 82 BULLETIN OF THE WORLD HEALTH ORG. (2004).
- Mahoney, Richard, *Product Development Partnerships: Case Studies of a New Mechanism for Health Technology Innovation*, 9 HEALTH RES. POL'Y AND SYS. (2011).
- Mahoney, Richard, *Strategic Review of WIPO Re:Search*, GLOBAL CHALLENGES REP. (2015), www.ip-watch.org/weblog/wp-content/uploads/2015/10/WIPO-GlobalChallenges-ReSearch-Review-Oct-2015.pdf (last visited Nov. 18, 2017).
- Mattes, William B., (Rathnam Chaguturu ed.), *Divided We Fall*, in COLLABORATIVE INNOVATION IN DRUG DISCOVERY: STRATEGIES FOR PUBLIC AND PRIVATE PARTNERSHIPS (2014).

- Molyneux, David H., Peter J Hotez, and Alan Fenwick, “*Rapid-Impact Interventions*”: *How a Policy of Integrated Control for Africa’s Neglected Tropical Diseases Could Benefit the Poor*, PLoS MED (2005).
- Morel, Carlos M., Tara Acharya, Denis Broun, Ajit Dangi, Christopher Elias, N. K. Ganguly, Charles A. Gardner, R. K. Gupta, Jane Haycock, Anthony D. Heher, Peter J. Hotez, Hannah E. Kettler, Gerald T. Keusch, Anatole F. Krattiger, Fernando T. Kreutz, Sanjaya Lall, Keun Lee, Richard Mahoney, Adolfo Martinez-Palomo, R. A. Mashelkar, Stephen A. Matlin, Mandi Mzimba, Joachim Oehler, Robert G. Ridley, Pramilla Senanayake, Peter Singer, and Mikyung Yun, *Health Innovation Networks to Help Developing Countries Address Neglected Diseases*, 309 SCIENCE (2005).
- NSW HEALTH DEPARTMENT, A FRAMEWORK FOR BUILDING CAPACITY TO IMPROVE HEALTH (2001).
- OECD, COHERENCE FOR HEALTH: INNOVATION FOR NEW MEDICINES FOR INFECTIOUS DISEASES, THE DEVELOPMENT DIMENSION (2009).
- POLICY CURES, *Global Funding of Innovation for Neglected Diseases: G-FINDER* (2015) <http://policycures.org/gfinder.html> (last visited Nov. 18, 2017).
- POLICY CURES, *Measuring Global Health R&D for the Post-2015 Development Agenda* (2015) - www.ghtcoalition.org/pdf/Measuring-global-health-R-D-for-the-post-2015-development-agenda.pdf (last visited Nov. 18, 2017).
- Ramamoorthi, Roopa, et al., *WIPO Re:Search: Accelerating Anthelmintic Development through Cross-Sector Partnerships*, 4 INT. J. FOR PARASITOLOGY: DRUGS & DRUG RESISTANCE (2014).
- Symposium, *Anthelmintics: From Discovery to Resistance* (2016); Symposium, *Global Challenges for New Drug Discovery Against Tropical Parasitic Diseases* (2014).
- Reich, Michael R., *Public–Private Partnerships for Public Health*, 6 NATURE MED. 617 (2000).
- Savioli, Lorenzo, Antonio Montresor, and Albis F. Gabrielli, *Neglected Tropical Diseases: The Development of a Brand with No Copyright. A Shift from a Disease-Centered to a Tool-Centered Strategic Approach*, in THE CAUSES AND IMPACTS OF NEGLECTED TROPICAL AND ZOONOTIC DISEASES: OPPORTUNITIES FOR INTEGRATED INTERVENTION STRATEGIES: WORKSHOP SUMMARY (2011), www.ncbi.nlm.nih.gov/books/NBK62524/ (last visited Nov. 18, 2017).
- Taubman, Antony, *A Typology of Intellectual Property Management for Public Health Innovation and Access: Design Considerations for Policy Makers*, 4 THE OPEN AIDS J. 1 (2010).
- Torstensson, David, *Fighting Tropical Disease: It’s Now a Common Cause*, PHARMEXEC.COM (Feb. 8, 2012), www.pharmexec.com/fighting-tropical-disease-its-now-common-cause.
- Tufts Ctr. for the Study of Drug Dev., Press Release, Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion (November 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (last visited Nov. 18, 2017).
- Uniting to Combat Neglected Tropical Diseases, *Country Leadership and Collaboration on Neglected Tropical Diseases: Third Progress Report of the London Declaration* (2015) <http://unitingtocombatntds.org/sites/default/files/document/UTCNTD%20FULL%20REPORT.pdf>.
- Uniting to Combat Neglected Tropical Diseases, *London Declaration on Neglected Tropical Diseases* (2012) http://unitingtocombatntds.org/sites/default/files/resource_file/london_declaration_on_ntds.pdf (last visited Nov. 18, 2017).
- UNITING TO COMBAT NEGLECTED TROPICAL DISEASES, <http://unitingtocombatntds.org/> (last visited Nov. 18, 2017).
- World Health Organization [WHO], *Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases - A Roadmap for Implementation: Executive Summary* (2012), www.who.int/neglected_diseases/NTD_RoadMap_2012_Fullversion.pdf.
- WHO, *First Global Partners’ Meeting on Neglected Tropical Diseases*, www.who.int/neglected_diseases/partners_meeting/en/ (last visited Nov. 18, 2017).

- WHO, *Health in 2015: from MDGs to SDGs* (2015), http://apps.who.int/iris/bitstream/10665/200009/1/9789241565110_eng.pdf?ua=1 (last visited Nov. 18, 2017).
- WHO, *Making a Difference: 30 Years of Research and Capacity Building in Tropical Diseases* (2007), http://apps.who.int/iris/bitstream/10665/43689/1/9789241595575_eng.pdf (last visited Nov. 18, 2017).
- WHO, *Neglected Tropical Diseases Summary*, WHO (2017), www.who.int/neglected_diseases/diseases/summary/en/ (last visited Nov. 18, 2017).
- WHO, *Neglected Tropical Diseases, Hidden Successes, Emerging Opportunities* (2006), http://apps.who.int/iris/bitstream/10665/69367/1/WHO_CDS_NTD_2006.2_eng.pdf (last visited Nov. 18, 2017).
- WHO, *Public Health, Innovation and Intellectual Property Rights; Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (2006), www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf (last visited Nov. 18, 2017).
- WHO Comm'n on Intellectual Prop. Rights, *Public Health: Innovation and Intellectual Property Rights* (2006), www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1 (last visited Nov. 18, 2017).
- WHO, WIPO & WTO, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property, and Trade* (2012), www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf (last visited Nov. 18, 2017).
- World Intellectual Property Organization [WIPO], *The 45 Adopted Recommendations under the WIPO Development Agenda*, www.wipo.int/ip-development/en/agenda/recommendations.html (last visited April 10, 2016).
- WIPO, *The First Five Years of the WIPO Japan Funds-in-Trust for Industrial Property (Japan FIT/ IP) for Africa and Least Developed Countries (LDCs): A Productive Collaboration with the Japan Patent Office (JPO)* (2013), www.wipo.int/export/sites/www/cooperation/en/funds_in_trust/docs/japanfitip_jpo_firstfiveyears_en.pdf (last visited Nov. 18, 2017).
- WIPO RE:SEARCH, www.wiporesearch.org/ (last visited Nov. 18, 2017).