

Hudson Institute

The Patent Truth About Health, Innovation and Access

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Introduction

In November 2015, UN Secretary-General Ban Ki-moon launched the “High Level Panel on Access to Medicines” (HLP). The goal of the HLP is to “review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”¹ Sixteen panelists from around the world were appointed to carry out this mission. The HLP’s “terms of reference” below provide a much clearer view of what the Panel hopes to accomplish:

“Millions of people remain left behind when it comes to accessing medicines and health technologies that can ensure their health and wellbeing. Failure to reduce the costs of patented medicines is resulting in millions of people being denied access to lifesaving treatments for communicable diseases like HIV, TB, Malaria, and viral hepatitis, non-communicable diseases (NCDs) and rare diseases. This failure is affecting governments and individuals in all low-, middle- and high-income countries, where budgets are being stretched to capacity by treatment costs.”²

These “terms of reference” make it clear that the rationale and purpose of the HLP is “consistent with the findings and recommendations of the Global Commission on HIV and the Law,” an earlier United Nations report issued in July 2012. This Global Commission report stated that the “over-reach of intellectual property (IP) protections are impeding the production and distribution of low-cost generic drugs.” It concludes that “IP protection is supposed to provide an incentive for innovation but experience has shown that the current laws are failing to promote innovation that serves the medical needs of the poor.” Based on these findings, the Global Commission recommended the creation of a “new intellectual property regime for pharmaceutical products” and the suspension of TRIPS, a global treaty that encourages provision of essential medicines to low- and middle-income countries.³ It is obvious that the views of the HLP were based on this earlier UN work. Indeed, four of the HLP’s members also served on the Global Commission on HIV and the Law.

Given the importance of the global intellectual property regime in all areas of innovation and progress, this report will review and analyze the following premises of the HLP, which are:

1. Millions of poor people in low- and middle-income countries have been denied access to ARVs and other medicines;
2. Patents are the main cause of higher costs of medicines for poor people in low- and middle-income countries;

¹ United Nations Secretary-General’s High Level Panel on Access to Medicines, “United Nations Secretary-General’s High-Level Panel on Access to Medicines: The Process,” *HLPAM*, Last Updated: May 25, 2016. <http://www.unsgaccessmeds.org/the-process/>

² United Nations Development Programme and the Joint United Nations Development Programme on HIV and AIDS, *Terms of Reference: The United Nations Secretary-General’s High-Level Panel on Access to Medicines* (New York: UNDP HIV/AIDS Group, 2016): 2.

³ Joint United Nations Development Programme on HIV and AIDS, *Global Commission on HIV and the Law: Risks, Rights and Health* (New York: UNDP HIV/AIDS Group, 2012), 104.

3. The intellectual property system, including patents and voluntary licenses, limits research and disadvantages local producers in low- and middle- income countries.

These basic assumptions, drawing from the earlier Global Commission on HIV and the Law and the new High Level Panel on Access to Medicines, however, are not supported by global health research. Before examining them in more depth, it is helpful to review the origins and role of intellectual property in all sectors of an economy.

Intellectual Property and its Role

The protection of intellectual property rights is engrained in nations' legislative and regulatory systems throughout the world. Though intangible, intellectual property (IP) is a fundamental driver of human progress, fueling innovation, creative thinking and economic growth. The goal of protecting intellectual property rights—through copyrights, trademarks, and patents—has been to provide effective incentives for the risk, inventiveness, inquiry, diligence, and human energy necessary for creating new products, new processes and original artistic works. The security of private intellectual property rights for inventors and investors is fundamentally important to a public good: the sharing and flow of information and ideas, which in turn generate new inventions and innovations that drive technological advancements, economic development and economic growth.

In today's global economy, the role of intellectual property—and the case for its strong protection—is greater than ever. Industries that are characterized as being IP-intensive have higher productivity, support higher-paying jobs, have a faster rate of job growth, and drive exports.⁴ Moreover, by providing some legal certainty that investments of time and money can be recouped for successful endeavors, strong intellectual property protections encourage entrepreneurial activity and risk taking, which are critical to maintaining economic dynamism. More broadly, meeting critical challenges in global health, agricultural production and sustainability, provision of clean water, energy production and green technologies requires intensive thinking and research, financial commitment and technological advancement.

Unfortunately, the inventors of tomorrow's life-changing products face challenges in protecting their IP rights.

First, the costs for development of new technologies, and the increasing regulatory burdens, in manufacturing, software, pharmaceuticals and other services and products make patent protection more and more vital to society. In the United States, for instance, research and development of new pharmaceuticals require an average of ten years and billions of dollars in development costs—and testing must conform to specific standards set out by the Food and Drug Administration.⁵ New food products, medical devices, drugs, electronics, cars and other

⁴ U.S. Department of Commerce, "Intellectual Property and the U.S. Economy: Industries in Focus," *US Department of Commerce*, Published: March 10, 2012, <http://www.esa.doc.gov/reports/intellectual-property-and-us-economy-industries-focus>.

⁵ Christopher DeMuth and Christopher DeMuth Jr., "The FDA Nixes a Pathbreaking Drug for MS," *Hudson Institute*, Published: January 22, 2014, <http://www.hudson.org/research/10075-the-fda-nixes-a-pathbreaking-drug-for-ms>; PhRMA, *Biopharmaceutical Research and Development: The Process Behind New Medicines* (Washington DC: PhRMA, 2015).

consumer products must meet specific certifications, approvals, and compliance measures set by local, state and federal agencies before reaching the market.

Second, the time, effort and cost necessary to gain patents can be arduous. Statutes, court decisions regarding patents and regulations from the Patent and Trade office, are complex and extensive, making patent attorneys a necessary, but expensive, part of the patent application process. Further, according to the U.S. Patent and Trademark Office, the average time to process a patent application is over two years, which adds additional time to the work that must be done on the front end before filing an application.⁶

Third, once a patent is secured, the inventor must protect intellectual property rights both within and across borders. Roughly 95 percent of the world’s population—and, therefore, potential customer base—lives outside of the United States. But without strong, and strongly enforced, protections for IP rights in trade and other treaties, legal recourse for violations of intellectual property rights internationally is difficult.

Finally, intellectual property rights have been, and continue to be, under systematic assault. The intentional erosion of IP rights occurs passively, by failure to police piracy and counterfeiting, and actively, through advocacy against IP protections in trade agreements and multilateral bodies by NGOs, activist groups and many governments seeking to challenge the legal and moral underpinnings of intellectual property rights. Paradoxically, the transfers of high technology and advanced medicine these groups seek to promote are undermined as the incentives for innovation and information sharing are also undermined with weakened IP protections.

Premise One of the High Level Panel: Millions of People in Low- and Middle-Income Countries have been Denied Access to ARVs and Other Medicines

One of the main claims of the High Level Panel on Access to Medicines is that millions of people have been denied access to medicines. Everyone can agree that millions of people in the developing world are still suffering from poor health and are not receiving adequate health care. To narrowly attribute this complex and serious global health problem to patents and prices, as the HLP does, completely ignores the transformation in modern health care delivery in developing countries over the last twenty years and the dramatic improvements in health outcomes for poor people, even as intellectual property systems became stronger since the TRIPS agreement in 1994.

A study in the *American Economic Review* shows that strengthening IP has resulted in *better* access to medicines in developing countries.⁷ Additionally, the Center for Global Development’s (CGD) recent book on global health lessons, recognizing that many people are still in basic need of healthcare, writes: “Since the turn of the 21st century, people in low- and middle-income

⁶ United States Patent Office, “General FAQs,” *USPO*, Updated: December 13, 2014, <http://www.uspto.gov/learning-and-resources/general-faqs#1202>.

⁷ Iain M. Cockburn, Jean O. Lanjouw, Mark Schankerman, “Patents and the Global Diffusion of New Drugs,” *American Economic Review* 106, 1 (2016): 136-164.

countries have experienced a health revolution...It is a revolution that keeps mothers and babies alive, helps children grow, and enables adults to thrive through and beyond their working lives.”⁸

The HLP seeks the replacement of the IP system, which has been accompanied by public-private partnerships and other global healthcare programs that have brought about the dramatic results discussed below.

To understand these results, it is important to look at the billions of people in developing countries who have been saved by access to medicines and other health and environmental technologies over the last sixty years. In the 1950s-60s, infant mortality rates in 34 low income countries averaged 165 per 1,000 births.⁹ By 2015, that number had fallen to an average of 49 per 1,000 live births in low-income countries.¹⁰ There were also dramatic reductions in maternal mortality and numerous diseases, along with increases in life expectancy in the developing world. Table 1 shows just some of the extraordinary progress that has been made against death and disease in poor countries.

How did these remarkable achievements come about? Since 1960, bilateral and multilateral aid agencies, non-profit foundations, private voluntary organizations, and pharmaceutical companies have sponsored large-scale vaccination and disease eradication programs along with water and sanitation improvements throughout the developing world. Innovative research and the availability of free or subsidized medicines for HIV, malaria, and TB therapies and Neglected Tropical Diseases (NTDs) were critical in achieving these results. In just 25 years, between 1990 and 2015, Development Assistance for Health (DAH)—funding provided by public and private donors—went from \$7.2 billion in 1990 to \$36.4 billion in 2015.¹¹

Added to this increase in DAH were low-and middle-income countries’ own government expenditures on healthcare. These expenditures rose from \$192.7 billion in 1995 to \$760 billion in 2013.¹² From 2000 to 2013 there was a steady annual increase of 8.5 percent. When the available data from DAH and low-and middle-income countries’ government expenditures on healthcare are combined, over \$7.5 trillion was spent on global health in low-and middle-income countries between 1990 and 2015.

In addition, private health spending by individuals in low-and lower-middle-income countries is substantial, but not well documented. In 2015, however, WHO data revealed that in over 50% of low-and lower middle-income countries, private expenditures on health as a percent of total national expenditures exceeded public expenditures.¹³ These countries account for approximately 42% of the world’s population including some of the poorest countries such as Bangladesh, Cambodia, Haiti, and Mali.

⁸ Amanda Glassman, Miriam Temin, *Millions Saved, New Cases of Proven Success in Global Health* (Washington, DC: Center for Global Development, 2016).

⁹ World Bank, *World Development Report 1984* (Washington, DC: World Bank, 1984).

¹⁰ Unicef, WHO, WB, UN, “Levels and Trends in Child Mortality” (Washington, DC: Unicef, 2015).

¹¹ Institute for Health Metrics and Evaluation, *Financing Global Health 2015: Development Assistance steady on the path to new Global Goals* (Seattle, WA: IHME, 2016), 92-93.

¹² *Ibid.*, 10.

¹³ World Health Organization, *World Health Statistics 2015* (Geneva: WHO Press, 2015), 125-135.

Table 1: Global Health Treatments and Health Outcomes Over Time

Global Health Areas	Treatment and Health Outcomes
HIV/AIDS treatment	People receiving ARV therapies increased from 690,000 in 2000 to nearly 16 million in 2015. ¹⁴
HIV testing	In 2015, PEPFAR supported HIV testing for 14.7 million pregnant women. ¹⁵
Malaria	Between 2001-2013, malaria mortality fell by 47%. ¹⁶
Tuberculosis	Between 2000-2012, 56 million people were treated for TB. ¹⁷
Polio	Incidence of polio was reduced by 99% globally. ¹⁸
Maternal mortality	In 1990, 420 mothers out of 100,000 live births died in childbirth; by 2011, this was 238. ¹⁹
Infant mortality	Since 1990, the global infant mortality rate has dropped 53 percent. ²⁰
Vaccinations	In the 1970s, 5% of the world's children had access to vaccines; today it is 80%. ²¹
Diarrhea	Twenty years ago, diarrhea killed 5 million children each year; the number today is 760,000. ²²
Lymphatic filariasis	Lymphatic Filariasis to be eliminated globally by 2020. ²³
Onchocerciasis	An estimated 78 million people treated for River Blindness in Africa; blindness prevented in 15 million children. ²⁴
Blinding trachoma	Blinding trachoma to be eliminated by 2020; Iran, Morocco, and Oman have reached elimination targets. ²⁵
Guinea worm	In 1986, there were 3.5 million cases occurring annually in Africa and Asia; by 2015, only 22 people had this disease. ²⁶
Schistosomiasis	The Egyptian Government declared schistosomiasis controlled for the first time since the Pharaohs reigned. ²⁷

¹⁴ World Health Organization, "Estimated numbers of people receiving antiretroviral therapy globally and by WHO Region and percentage coverage globally, 2000-2015," *WHO*, http://www.who.int/hiv/data/art_2003_2015.png?ua=1.

¹⁵ President's Emergency Plan for AIDS Relief, *2016 Annual Report to Congress* (Washington, DC: PEPFAR, 2016), 8.

¹⁶ Steven Radelet, "The Great Surge: The Ascent of the Developing World," (New York: Simon & Schuster, 2015).

¹⁷ World Health Organization, "World Health Statistics 2014," *WHO*, Published: May 15, 2014, <http://www.who.int/mediacentre/news/releases/2014/world-health-statistics-2014/en/>.

¹⁸ World Health Organization, "10 Facts on Polio Eradication," *WHO*, Updated: October 2015, <http://www.who.int/features/factfiles/polio/en/>.

¹⁹ Steven Radelet, "The Great Surge: The Ascent of the Developing World," (New York: Simon & Schuster, 2015), 74.

²⁰ UN Interagency Group for Child Mortality Estimation, *Levels and Trends in Child Mortality* (New York: United Nations Children's Fund, 2015), 1.

²¹ Steven Radelet, *The Great Surge: The Ascent of the Developing World* (New York: Simon & Schuster, 2015), 94.

²² *Ibid.*, 94.

²³ United States Agency for International Development, "About the Neglected Tropical Disease Program," *USAID*, Last Updated: June 16, 2014, <https://www.neglecteddiseases.gov/about/index.html>.

²⁴ Centers for Disease Control and Prevention, "Global NTD Programs," *CDC*, Updated: November 22, 2013, http://www.cdc.gov/globalhealth/ntd/global_program.html.

²⁵ World Health Organization, "Working to overcome the global impact of neglected tropical diseases: First WHO report on neglected tropical diseases," (Geneva: WHO Press, 2010).

²⁶ Carter Center, "Carter Center Announces Only 22 People had Guinea Worm Disease in 2015," *Carter Center*, Published: January 6, 2016, <https://www.cartercenter.org/news/pr/guinea-worm-worldwide-cases-Jan2016.html>.

²⁷ Jon Alterman, *Egypt and U. S. Health Assistance* (Washington, DC: CSIS, 2012), 4.

Due to increases in per capita GDP accompanied by significant poverty reduction throughout the world, people in poor countries have had access to medicines through large-scale donor and government campaigns *and* their own disposable incomes. In 2012, 12.7 percent of the world's population lived at or below \$1.90 a day, down from 37 percent in 1990 and 44 percent in 1981. In October 2015, the World Bank announced that, for the first time, the number of people living in extreme poverty around the world would fall below ten percent.²⁸

The progress in combatting infectious diseases has brought about an epidemiological transition as well. Communicable diseases are no longer the major cause of death in developing countries since people are living long enough to develop non-communicable diseases like cancer, cardiovascular disease, and stroke. In 2012, the WHO found that the top two causes of death in lower middle income countries were ischemic heart disease and stroke, the same as high-income countries. In low-income countries, the WHO found that the top two causes of death were lower respiratory infections and HIV/AIDS, while stroke and ischemic heart disease were numbers four and five.²⁹

Without any demographic surveys or supporting data, the HLP ignores the billions of people who have had access to medicines and other healthcare technologies over the past 60 years. In 1960 the world's population was 3 billion. It increased to 7.3 billion in 2015, a growth of 4.3 billion people between 1960 and 2015, with 49% living in low- and lower-middle income countries.³⁰ This extraordinary growth--the largest in human history--would never have occurred without access to medicines and trillions of dollars from both public and private institutions and individuals.³¹ Even the Director General of the WHO, Dr. Margaret Chan, reaffirmed that progress in global health is continuing at an even faster pace than before. She announced on May 19, 2016: "...dramatic gains in life expectancy have been made since 2000...life expectancy increased by 5 years between 2000 and 2015, the fastest increase since the 1960s."³²

In his request for submissions to the HLP, UN Secretary General Ban Ki Moon charged respondents to submit "evidence-based recommendations" that would remedy a situation in which millions were denied access to medicines. The Secretary General and his high level panel have not provided the full picture on their most basic assumption behind this initiative.

If the Secretary General and his high level panel had looked at the track record of affordable life-saving medicines and technologies available to the developing world, they would have seen that the most important problems impeding access to medicines and better health for poor people are not patents and prices. The high level panel, however, excludes consideration of any other

²⁸ The World Bank, "Poverty: Overview," *The World Bank Group*, Updated: March 13, 2016, <http://www.worldbank.org/en/topic/poverty/overview>.

²⁹ World Health Organization, "Fact Sheet No. 310: The top 10 causes of death," *WHO*, Updated: May, 2014, <http://www.who.int/mediacentre/factsheets/fs310/en/>.

³⁰ World Bank, "Population, total," *World Bank*, Accessed: 6/23/16, <http://data.worldbank.org/indicator/SP.POP.TOTL>.

³¹ Esteban Ortiz-Ospina and Max Roser, "World Population Growth," *OurWorldInData.org*, Published: June 1, 2016, <https://ourworldindata.org/world-population-growth/>.

³² World Health Organization, "Life Expectancy increased by 5 years since 2000, but health inequalities persist," *WHO*, Published: May 19, 2016, <http://www.who.int/mediacentre/news/releases/2016/health-inequalities-persist/en/>.

barriers to access to medicines and healthcare delivery. The U.S. Department of State criticizes the HLP's "narrowly focused mandate" and the HLP's description of the problem which, according to the State Department, "suggests predetermined outcomes," and concern that the final report "may be imbalanced and of limited use, or even counterproductive."³³ The European Commission further raised concern that "such a narrow starting point also ignores all the efforts and verifiable progress that have been made on the link between patents and access to medicines in the last 15 years."³⁴

The next section addresses the HLP's second basic premise by providing the evidence on known and proven barriers to access to medicines.

Premise Two of the High Level Panel: Patents are the Main Cause of Higher Costs of Medicines for People in Low- and Middle-Income Countries

In a landmark 2001 article published in the *Journal of the American Medical Association* (JAMA), Amir Attaran and Lee Gillespie-White analyzed the role of patents in access to medicines.³⁵ Over 15 years ago, their findings disputed the same arguments that the High Level Panel on Access to Medicines is making in 2016. The research looked at whether patents on anti-retroviral drugs in Africa were impeding access to lifesaving treatment for the 25 million Africans with HIV. Attaran and Gillespie-White examined the patent status of 15 drugs for treating HIV in 53 African countries and found that patents were not a barrier to HIV treatment.

Their conclusions were further substantiated in an article published by *Health Affairs* in 2004. Attaran found that access to HIV treatment had little relation to the patent status of various drugs. He determined that: 1) "Pharmaceutical companies usually did not seek patents in developing countries, even when they legally had the option;" and, 2) "Patents are an infrequent determinant of access to essential medicines." In fact, patents and patent applications existed for only 1.4 percent of essential medicines in the African survey.³⁶

Attaran and Gillespie-White urged the global health community to resolve the ongoing conflict over patents and direct its energies towards the more relevant challenges of poverty, weak healthcare systems, taxes, and poor supply systems in developing countries.

These conclusions were echoed again in 2006, when 16 institutions from around the world formed the International Policy Network (IPN) and published a report on intellectual property, innovation and health. The report found that the most important advances in pharmacology, from vaccines to ARVs, were originally made with wealthy markets in mind. The IPN conclusions however, differed markedly from the findings of the HLP by noting that "Lower income countries have benefited enormously from this technology transfer and will continue to do so in

³³ Ann Blackwood, *Submission to the Secretary General's High-Level Panel on Access to Medicines* (Washington, DC: United States Department of State, 2016).

³⁴ Xavier Prats Monné, *Submission to the Secretary General's High-Level Panel on Access to Medicines* (Belgium: European Commission, 2016).

³⁵ Amir Attaran and Lee Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa," *JAMA* 286, 15 (10/17/01), 1886-1892.

³⁶ Amir Attaran, "How Do Patents And Economic Policies Affect Access to Essential Medicines in Developing Countries," *Health Affairs* 23, 3 (05/2004), 155-166.

the future.”³⁷ The report also concluded that lower income countries have often not benefitted from modern drugs due to their own policy failures that impede access to medicines. These include:

- Excessive tariffs and taxes on imported medicines that inflate the cost of medicines by up to one-third and price the poor and sick out of the market for life-saving treatments. When combined with VAT taxes on medicines, government imposed levies account for an additional 55% in India; 40% in Sierra Leone; 34% in Nigeria; and 29% in Bangladesh.³⁸
- In a two year effort, researchers found that taxes and mark-ups “frequently contribute more to the final price than the actual manufacturer’s price, e.g., in Indonesia’s public sector, patients paid 11 times the procurement price.”³⁹
- Weak healthcare systems hinder the effective distribution of drugs. While insufficient hospitals and medical staff are obvious weaknesses, insufficient infrastructure including poor roads, unreliable electricity, and poor water and sanitation are key constraints as well;⁴⁰
- The intervention of international public health authorities is no guarantee that medicines will be widely distributed. The WHO’s “3 by 5” HIV/AIDs program failed to achieve its targets, and may have even increased drug resistance.⁴¹

These policy failures reflected some earlier views of the WHO in understanding the real reasons for poor access to medicines. In 2006, the director of the organization’s HIV Division publicly stated: “Africa has been the hardest hit by the AIDS epidemic... it is very obvious that the elephant in the room is not the current price of drugs...The real obstacle is the fragility of the health systems... You have infrastructure that is dilapidated, and supply chains that don’t exist.”⁴² In 2010, the International Treatment Preparedness Coalition of South Africa listed a number of key barriers to access, including “long delays for routine services; unsafe and unhygienic conditions; low salaries; deterioration of facilities, and shortages of basic materials—have had negative impact on the quality and effectiveness of HIV treatment services.”⁴³

Sadly, these serious weaknesses, having nothing to do with patents and prices, prevail to this day. A May 21, 2016 editorial in the *Lancet* found that “efforts to strengthen the health

³⁷ International Policy Network, *Civil Society Report on Intellectual Property, Innovation, and Health* (London: International Policy Network, 2006), 59.

³⁸ *Ibid.*, 30.

³⁹ Susanne Gelders, Margaret Ewen, Nakae Noguchi, Richard Laing, *Price, Availability, and Affordability: An International Comparison of Chronic Disease Medicines* (Cairo: WHO Press and HAI, 2006), viii.

⁴⁰ International Policy Network, *Civil Society Report on Intellectual Property, Innovation, and Health* (London: International Policy Network, 2006), 7.

⁴¹ *Ibid.*, 8.

⁴² Patricia Reaney, “Creaking Health Systems Hampering AIDS Battle,” *Reuters*, July 21, 2006, <http://www.hst.org.za/news/creaking-health-systems-hampering-aids-battle-who>.

⁴³ International Treatment Preparedness Coalition, *Missing the Target 8: Rationing Funds, Risking Lives: World Backtracks on HIV Treatment* (New York: ITPC, 2010), 61.

workforce over the past decade have fallen severely short of expectations.” In order to meet the Sustainable Development Goals (SDGs), “the global needs-based shortage of healthcare workers will be more than 14 million by 2030... without them, other efforts will be in vain.”⁴⁴ The editorial makes no mention that patents and prices have been the key inhibiting factors for access to medicines and medical technologies.

Had the HLP considered the most important factors behind access to medicines and had it properly consulted with UN member states, their panel might have pursued more meaningful solutions than eliminating the intellectual property system. The U. S. Department of State’s submission to the Secretary General’s High-Level Panel emphatically stated that the HLP occurred “almost entirely without UN Member State involvement or input.”⁴⁵ Although the Secretary General called for “the involvement of all relevant UN agencies,” those most involved in the broad subjects of health and trade, such as WHO, WIPO, and the WTO were not consulted prior to its establishment.⁴⁶

These agencies, whose job it is to provide expertise in the areas of global health, intellectual property, and trade--not surprisingly--have a completely different perspective on intellectual property. In a joint report published in 2012, the WHO, WIPO, and WTO found that the “appropriate licensing of patents can help build partnerships and enable innovation through cooperation to bring new medical technologies to fruition. ...Public sector entities can use patents expressly to leverage public health outcomes.”⁴⁷ Director of Global Health, Global Challenges Division of WIPO, Tom Bombelles, questioned the HLP’s assertion that there is a “policy incoherence” between IP rights and access to medicines. He pointed out, quite simply, that “Coherence exists in the recognition that without productive innovation there is nothing to have access to.”⁴⁸

Some of the major misunderstandings in the HLP’s statements regarding patents, prices and access to healthcare have to do with prices. In 2004, MSF published *Untangling the Web of Price Reductions*, a reference guide that compared prices of widely used patented and non-patented ARV drugs.⁴⁹ In 2004 these non-patented ARVs were referred to as “copy drugs” because they had not undergone bioequivalence testing and other rigorous approval requirements to ensure that they were true generics, i.e. drugs that are equal to patented drugs in safety, efficacy, and quality. There were no true generics on the market then, and the copy price range included those charged across multiple manufacturers, mainly in India.

⁴⁴ “No health workforce, no global health security,” *The Lancet* 387, 10033 (5/21/16): 2063.

⁴⁵ Ann Blackwood, *Submission to the Secretary General’s High-Level Panel on Access to Medicines* (Washington, DC: United States Department of State, 2016).

⁴⁶ *Ibid.*

⁴⁷ World Health Organization, World Intellectual Property Organization, and World Trade Organization, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property, and Trade* (Geneva: WHO, WIPO and WTO, 2012), 13.

⁴⁸ Catherine Saez, “Special Feature: UN High Level Panel On Access to Medicines-First Reactions, Process Explained,” *Intellectual Property Watch*, January 2, 2016, <http://www.ip-watch.org/2016/02/01/special-feature-un-high-level-panel-on-access-to-medicines-first-reactions-process-explained/>.

⁴⁹ Medecins Sans Frontieres, *Untangling the Web of Price Reductions: A Price Guide for the Purchase of ARVs for Developing Countries* (Geneva: MSF, 2004), 11-14.

Table 2: Drug Prices for Patented and Non-Patented Single Dose HIV/AIDs Drugs, April 2004

Drug	Patented Drug Price (US, \$pp/py)	Average Copy Drug Price (US, \$pp/py)	Copy Price Range
Nelfinavir	\$942	\$1519	\$1132-1789
Ritonavir	\$83	\$311	\$204-394
Saquinavir	\$956	\$1022	\$1022
Abacavir	\$887	\$979	\$803-1314
Lamivudine	\$69	\$72	\$55-171
Indinavir	\$400	\$402	\$321-467
Efavirenz 600mg	\$347	\$412	\$347-462
Efavirenz 200mg	\$500	\$414	\$329-462
Zidovudine	\$212	\$208	\$140-292
Didanosine 100mg	\$310	\$263	\$146-\$415
Stavudine 40 mg	\$55	\$47	\$26-77
Stavudine 30 mg	\$48	\$41	\$21-60
Nevirapine	\$438	\$150	\$80-256

Table 2 shows the prices of thirteen drugs from the MSF reference guide published in 2004. Over half of the patented drugs are less expensive than the average copy drug price. Of the remaining drugs, only Nevirapine is significantly higher-priced than its copy. However, Nevirapine's German manufacturer, Boehringer Ingelheim Pharmaceuticals, offered this drug free of charge to developing countries for use in mother-to-child transmission prevention programs.⁵⁰ It should also be noted that the patented drug prices include a ten percent transportation cost, while copy drug manufacturers do not include such costs in their list prices. Copy drug prices are manufacturers' prices for products shipped only upon receipt of an Irrevocable Letter of Credit. Thus, the copy drugs were even more expensive than the patented.

Most importantly, however, in 2004, all of the patented drugs had been approved for standards of quality, safety and efficacy by stringent drug regulatory authorities like the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). However, the backbone of the WHO's "3 by 5" program was the copy drug Triomune (a combination of Nevirapine, Stavudine, and Lamivudine), produced by Cipla, an Indian drug company, which was not approved by the Drugs Controller General of India. In its permission to manufacture Triomune, the Drugs Controller General warned Cipla that "No reference in the advertisements or medical literature is made that the government has approved the drug."⁵¹ Stringent regulatory authorities refer to copy drugs as substandard products and, according to the US Pharmacopeia, there is no faster route to drug resistance than through the use of substandard drugs. The WHO estimated that "up to 25% of the medicines consumed in poor countries are counterfeit or substandard."⁵²

⁵⁰ PRNewswire, "Boehringer Ingelheim Offers Viramune (Nevirapine) Free of Charge to Developing Economies for the Prevention of HIV-a Mother-To-Child," *Presseportal*, July 7, 2000. <http://www.presseportal.de/pm/6631/154546>

⁵¹ Asliwini Kumar, Drugs Controller General to Cipla Limited, Mumbai Central, July 26, 2001.

⁵² World Health Organization, *Public Health: Innovation and Intellectual Property Rights* (Geneva: WHO Press, 2006), 106.

From 2004, when ARVs were being used by less than one million people to 2015, when ARVs were being used by nearly 16 million people, ARV prices for most categories of drugs have decreased.⁵³ Many of the single drug first line treatments in Table 2 have been reformulated into Fixed Dose Combinations (FDCs) with greatly increased adherence factors, since the single dose ARVs often required a patient to take up to a dozen pills per day.

The decrease of ARV prices over time can also be identified by examining the U.S. Government’s global HIV/AIDS program, the President’s Emergency Plan for AIDS Relief (PEPFAR). Started in 2004, PEPFAR directly covers the majority of all patients on ARV therapy around the world.⁵⁴ It also funds one-third of the Global Fund to Fight HIV/AIDS, TB and Malaria’s operating budget, indirectly funding an indeterminate number of additional patients. PEPFAR maintains rigorous yearly records regarding the cost of treatment and only procures products that have been FDA-approved, including both patented and generic drugs. Table 3 shows PEPFAR’s costs per patient per year for 2010 and 2014:

*Table 3: PEPFAR Costs PPY for
2.5 Million Patients in 2010 and 6.7 Million Patients in 2014*

Category	PEPFAR Costs Per Person Per Year for 2.5 Million Patients in 2010 ⁵⁵	PEPFAR Costs Per Person Per Year for 6.7 Million Patients in 2014 ⁵⁶
Treatment, all patients	\$436	\$315
Treatment, pediatric patients	\$489	\$341
Treatment, adult patients	\$431	\$312
Second-line patients	\$942	\$657
First-line patients	\$402	\$286
Patients in lower-income countries	\$467	\$442
Patients in middle-income countries	\$366	\$80

All of PEPFAR’s treatment costs declined over the four-year period from 2010 to 2014. Costs for second line treatments went down as well. PEPFAR expends “approximately 39% of the annual cost of AIDS treatment on ARV drugs.”⁵⁷ Thus, against an increased population coverage

⁵³ World Health Organization, “Estimated numbers of people receiving antiretroviral therapy globally and by WHO Region and percentage coverage globally, 2000-2015,” *WHO*, http://www.who.int/hiv/data/art_2003_2015.png?ua=1

⁵⁴ Avert, “Funding for HIV and AIDS,” *Avert.org*, Updated: October 27, 2015, <http://www.avert.org/professionals/hiv-around-world/global-response/funding>.

⁵⁵ PEPFAR, *Report to Congress on Costs of Treatment in the President’s Emergency Plan for AIDS Relief* (Washington, DC: PEPFAR, 2010), 1.

⁵⁶ PEPFAR, *Report to Congress on Costs of Treatment in the President’s Emergency Plan for AIDS Relief* (Washington, DC: PEPFAR, 2014), 3.

⁵⁷ PEPFAR, *Report to Congress on Costs of Treatment in the President’s Emergency Plan for AIDS Relief* (Washington, DC: PEPFAR, 2010), 3.

of 2.5 million patients in 2010 to 6.7 million in 2014, its costs in all categories have dramatically decreased. If prices were a barrier to access to medicines in the world's largest AIDS treatment program, then they would have been reflected in Table 3. Instead, this table shows that when patient coverage nearly tripled after 2010, overall treatment prices for AIDS patients significantly decreased.

As noted, the UN Secretary General states that “millions have been denied access to medicines and medical technologies,” and he points to patents and prices as the central barriers.⁵⁸ Had he consulted with the member states of the UN, civil society associations, non-governmental organizations, and UN specialized agencies on their extensive research and past publications on the issues of public health, innovation, and intellectual property rights, he would have determined--as the U. S. Department of State did in its submission to the HLP--that: “The Panel’s work overlaps with efforts taking place [in other UN] forums.”⁵⁹ He would have also seen that this issue has been extensively debated throughout the UN system since 2001, and the value of innovation and the intellectual property that fuels it has been well-established by these global health stakeholders.

Premise Three of the High-Level Panel: The Intellectual Property System Limits Research and Disadvantages Drug Manufacturers in Low- and Middle-Income Countries

The High Level Panel on Access to Medicines primary premise purports that the intellectual property system limits the innovation that serves the medical needs of the poor. This assertion blatantly ignores the lifesaving drugs and vaccines that have dramatically reduced infant mortality and increased life expectancy in low-income countries. But nowhere is the importance of innovation and drug development for the poor more clear than in the case of HIV/AIDS over the last 35 years.

In the history of therapeutic medicine, there has not been a comparable period during which so much innovation resulted in so many new products—which principally benefited the poor in markets far away from those of the manufacturers. In the United States, between 600,000 and 900,000 people were living with HIV in 1989, while approximately 5-10 million people were living with HIV around the world, most in lower income countries.⁶⁰ In just over ten years, the number of people living with HIV around the world had grown to approximately 37 million while the number in the United States was just under one million people.⁶¹ At the beginning of

⁵⁸ United Nations Development Programme and the Joint United Nations Development Programme on HIV and AIDS, *Terms of Reference: The United Nations Secretary-General’s High-Level Panel on Access to Medicines* (New York: UNDP HIV/AIDS Group, 2016), 2.

⁵⁹ Ann Blackwood, *Submission to the Secretary General’s High-Level Panel on Access to Medicines* (Washington, DC: United States Department of State, 2016).

⁶⁰ SD Holmberg, “The estimated prevalence and incidence of HIV in 96 large US metropolitan areas,” *Am J Public Health* 86, 5 (5/1996): 642-54; PS Rosenberg, “Scope of the AIDS epidemic in the United States,” *Science*, 270, 5240 (11/1995): 1372-5; World Health Organization, “Global Statistics,” *Weekly Epidemiological Record* 62, 49 (1987): 372; J. Chin, P.A. Sato, J.M. Mann, “Projections of HIV Infections and AIDS Cases to the Year 2000,” *Bulletin of the World Health Organization* 68, 1 (1990): 1-11.

⁶¹ Joint United Nations Programme on HIV/AIDS, *Report on the Global AIDS Epidemic* (Geneva: UNAIDS, 2004), 202.

the crisis, an HIV/AIDS diagnosis was a death sentence, and only Zidovudine, developed in 1987 by GlaxoWellcome, could slow the progression of HIV.

Despite the fact that the majority of the end users of ARV drugs for people living with HIV were citizens in low- and middle-income countries, including some of the poorest in the world, the U.S. pharmaceutical industry invested in the development and manufacture of these drugs and the FDA designed a new approval system for bringing more safe and effective generic drugs into the marketplace. The FDA has approved 37 ARVs for the treatment of HIV.⁶² PhRMA, the association of U.S. pharmaceutical companies, reported in 2014 that its members had 44 medicines and vaccines for HIV/AIDS treatment and prevention in development.⁶³ Today, nearly 16 million people around the world have extended life spans due to the historic innovative developments of the pharmaceutical industry. Millions more, at risk of contracting opportunistic infections like TB, are also eligible for prevention and treatment through global HIV/AIDS programs.

The story of how pharmaceutical companies and the FDA encouraged and sustained innovation, drug development and widespread treatment of HIV/AIDS is an important one. As mentioned, the WHO promoted the Indian copy drug Triomune as the backbone of its “3 by 5” program in 2003. Those who supported Triomune referred to it as a generic drug when in fact it was not, because there was no reference or innovator drug and no process of rigorous review. In May 2004, the WHO abruptly began de-listing ARVs that it had pre-qualified for its HIV/AIDS program. From May to September, it recalled 36 ARVs of various dosage forms and strengths. WHO released a public explanation that stated: “What is missing [from certain drugs] is proof of bioequivalence.”⁶⁴ Non-bioequivalent ARVs are a leading cause of drug resistance and force patients to move from first line to more expensive second and salvage line therapies, often requiring periods of hospitalization. The WHO’s de-listings prompted a global crisis to the nascent ARV treatment programs that had closely followed its recommendations.

At the beginning of this crisis in May 2004, the United States FDA stepped in to mitigate the consequences. Any firm in any country that wished to file its ARV drug for approval by the FDA and for classification as a generic drug was welcome to do so. Moreover, ARV drugs submitted in this way would be moved to the front of the line or “fast tracked” and application fees would be waived. Since all ARVs were under existing patents by the originator companies in 2004, the FDA had to offer patent-holders the opportunity to present a legal challenge to those companies that wanted to reproduce their patented drugs. U.S. pharmaceutical companies that had developed these drugs, and held their patents, were assured they could not be sold in developed countries and did not challenge the patents. At the time of the serious and growing HIV pandemic, this allowed non-research based companies to produce generic ARVs. Now that that they were FDA-approved, PEPFAR, the world’s largest ARV treatment program, could procure

⁶² U.S. Food and Drug Administration, “Antiretroviral Drugs Used in the Treatment of HIV Infection,” *U.S. FDA*, Updated: June 1, 2016, <http://www.fda.gov/ForPatients/Illness/HIVAIDS/Treatment/ucm118915.htm>.

⁶³ PhRMA, *Medicines in Development: HIV/AIDS* (Washington, DC: PhRMA, 2014).

⁶⁴ World Health Organization, “WHO statement on removal of two AIDS medicines from list of prequalified products,” *World Health Organization*, Published: June 17, 2004, http://www.who.int/mediacentre/news/statements/2004/statement_aidsprequal/en/; World Health Organization, “Three AIDS medicines will be removed from prequalification list this week,” *World Health Organization*, Published: August 4, 2004, <http://www.who.int/mediacentre/news/releases/2004/pr53/en/>.

ARVs from India with significant savings. The FDA Commissioner announced: “It is estimated that the FDA’s actions are allowing PEPFAR to spend \$150 million more each year on patients’ access to care.”⁶⁵

Due, in part, to the FDA’s “fast track” program developed in 2004, India jump-started itself onto a path of global dominance in generic ARV therapies without fear of legal challenge from patent-holders. Today, the majority of people living with HIV are beneficiaries of India’s generic drugs. In fact, the country’s generic manufacturing infrastructure is so vast that non-governmental organizations like Medecins Sans Frontieres refer to it as “the pharmacy of the developing world.”⁶⁶ In 2012, “more than 50% of its \$10 billion annual generic medicine production was exported.”⁶⁷

The idea underlying the HLP premise that generic production of off-patent, lower cost ARVs is the solution to better access to medicines, is not guaranteed, at least in the case of India. Despite its ARV product capacity, India cannot even supply its own citizens with ARV therapies. In 2014, *Reuters* reported that, of India’s “2.1 million HIV/AIDS patients, only about 750,000 people depend on free distribution of drugs through government-run centers.”⁶⁸ The lack of a developed healthcare infrastructure, rather than patents and pricing, is keeping ARVs out of the hands of patients.

The FDA and pharmaceutical industry approach helped increase medicines quickly for the increased demand of the HIV/AIDS pandemic by maintaining the IP system which was critical to producing the complex and expensive lifesaving ARV drugs and without having to resort to compulsory licenses. The system worked for this dire global pandemic as pharmaceutical companies continued their commitment to the UN’s Millennium Declaration and the TRIPS Agreement on the transfer of production technology to developing countries.

Research-based companies have issued 165 voluntary licenses to developing countries for the production of ARVs, anti-malarials, and TB drugs, and they have participated in the Medicines Patent Pool (MPP), a UN-backed organization founded in 2010 to increase access to medicines through partnerships with patent holders in patent pools.⁶⁹ The voluntary licenses serve as an incentive for local manufacturers to produce needed medicines for their own populations and export them to other developing countries.

Pharmaceutical companies also engaged in “royalty-free license transfers.” Eleven such licenses were issued for products like the ARV drugs Maraviroc and Efavirenz as well as licenses to the

⁶⁵ USFDA, “FDA Marks 100th HIV/AIDS Drug Authorized for Purchase Under PEPFAR,” *FDA*, October 6, 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm185416.htm>.

⁶⁶ Mihir Mankad, “India: The Pharmacy of the Developing World,” *Save the Children*, February 16, 2015, <http://blogs.savethechildren.org.uk/2015/02/india-the-pharmacy-of-the-developing-world/>.

⁶⁷ Simon Reid-Henry and Hans Lofgren, “Pharmaceutical companies putting health of world’s poor at risk,” *The Guardian*, July 26, 2012, <http://www.theguardian.com/global-development/poverty-matters/2012/jul/26/pharmaceutical-companies-health-worlds-poor-risk>.

⁶⁸ Zeba Siddiqui and Aditya Kalra, “Poor patients in India facing HIV/AIDS drug shortages,” *Reuters*, September 4, 2014, <http://in.reuters.com/article/india-pharmaceuticals-aids-idINKBN0GZ0L120140904>.

⁶⁹ Medecins Sans Frontieres, *Untangling the Web of Price Reductions: A Price Guide for the Purchase of ARVs for Developing Countries* (Geneva: MSF, 2012), 91.

Drugs for Neglected Disease Initiative (DNDI). Merck & Co. alone granted five royalty-free licenses for its ARV Efavirenz to South African generic manufacturers. All but one of the five South African manufacturers donate a percentage of their net sales to the Msizi (Cares) Trust, a charitable trust established to fight against HIV/AIDS in South Africa. Merck & Co. has also extended royalty-free licenses to pharmaceutical firms in India.⁷⁰

Eli Lilly & Company has transferred multi-drug resistant tuberculosis (MDR-TB) production technologies to companies in South Africa, India, Russia, and China. The transfers were accompanied by engineering staff to assist with training in the use of the manufacturing technologies in each of the four countries, as well as quality control staff to ensure that production output met standards of known quality, safety and efficacy. The value of these transfers was estimated at \$70 million.⁷¹

Additionally, pharmaceutical companies entered into public-private partnerships and sponsored ten clinical trials for tropical and other diseases in low income countries.⁷² Often, these trials were conducted in collaboration with WHO, and were for HIV/AIDS, TB, malaria, Neglected Tropical Diseases, and MCH conditions. These important trials provided the scientific data for the development and production of new and improved treatments for diseases that affect people in poor countries. While the health care needs of developing countries are still vast, they are dramatically better than in years past through the initiatives described above - medicines patent pools, voluntary licensing, local capacity building, public-private partnerships, donations and subsidized medicines. These proven examples have shown what works in increasing access to medicines while maintaining a strong IP system to encourage and ensure the innovation needed to develop the drugs to treat the life-threatening diseases of today and dreaded pandemics of the future.

Table 4 lists some examples of the healthcare research and institutional capacity building efforts undertaken by pharmaceutical companies since the MDGs began in 2000.⁷³ The projects indicate a long-term commitment by the private sector towards improving access to affordable medicines. The WHO has also been a partner in some of these initiatives

Supplementing these direct efforts, pharmaceutical companies have made indirect contributions towards the development of new drugs and vaccines. In 2006, the U. S. Congressional Budget Office estimated that the cost of developing a new drug was \$802 million. Of this total, 43% or \$335 million was spent on the preclinical phase and \$467 million was spent on the clinical trials

⁷⁰ Merck & Co., "Merck & Co., Inc. and Drugs for Neglected Diseases initiative Collaborate to Find Treatments for World's Most Neglected Tropical Diseases," *Merck & Co.*, Published: November 4, 2012, <http://www.merck.com/licensing/our-partnership/dndi-partnership.html>.

⁷¹ Jeremiah Norris, Carol Adelman, Yulya Spantchak, and Kacie Marano, *The Pharmaceutical Industry's Contributions to the United Nations Millennium Development Goals* (Washington, DC: Hudson Institute, 2013), 9.

⁷² Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22, 2 (2003): 151-85.

⁷³ Jeremiah Norris, Carol Adelman, Yulya Spantchak, and Kacie Marano, *The Pharmaceutical Industry's Contributions to the United Nations Millennium Development Goals* (Washington, DC: Hudson Institute, 2013), 12.

and FDA approval process.⁷⁴ Since foreign manufacturers, like those in India, Bangladesh, Brazil, Kenya, South Africa, Tanzania, Zimbabwe, and others, bypass the preclinical drug development phase, they are able to cut costs. A rough estimate of these savings, for India alone, shows that \$335 million per generic ARV, when multiplied by the number of FDA-approved generic drugs in India, will equal total savings of approximately \$10 billion for the Indian pharmaceutical industry and the Indian government purchasing drugs for its citizens.⁷⁵

Table 4: Research Facilities and Institutional Capacity Building Supported by Companies and Foundations since 2000

Company	Country	Facility
Bristol-Myers Squibb	Uganda	Baylor College of Medicine/Bristol Myers Squibb Children's Clinical Center for Excellence
Abbott	Tanzania	Hakara Health Institute
Pfizer, Inc.	Uganda	Infectious Disease Institute, Managed by Makerere University
Pfizer, Inc.	Nigeria	Institute of Human Virology
Bristol-Myers Squibb	United States, Texas	Baylor International Pediatric AIDS Initiative
Pfizer, Inc.	Nigeria	Glaucoma Patients Association of Lagos State
Novartis	Singapore	Institute for Tropical Diseases
GlaxoSmithKline	Spain	Basic Research Centre in Tres Cantos
AstraZeneca	Bangalore	Bangalore Infectious Disease Research Institute
Novartis	Italy	Vaccine Research and Development Institute
Merck & Co., Inc.	Uganda, Kenya, Zambia, and South Africa	Vaccine/Immunization Training Centers
Merck & Co., Inc. and Bill & Melinda Gates Foundation	Botswana	Pediatric AIDS Hospital and Outpatient Clinics

In addition to the preclinical savings to Indian manufacturers, many such manufacturers rely on the clinical trials data generated during the FDA approval process by U. S. manufacturers. As part of the FDA's "fast track" process, approval applications submitted by Indian firms were not required to include clinical trial data. The FDA, however, did require Indian manufacturers to submit data which showed that the Indian products had bioequivalency to the patented product. The clinical trials conducted by Cipla for Triomune were, in contrast to traditional FDA trials, conducted over a short period of time, with small sample sizes, and no control groups.⁷⁶

Development costs for new drugs against difficult viruses and bacteria are now estimated at \$2.6 billion, and it takes ten years, from the pre-clinical phase to FDA approval, before a new drug

⁷⁴ Congressional Budget Office, *A CBO Study: Research and Development in the Pharmaceutical Industry* (Washington, DC: CBO, 2006), 20.

⁷⁵ Medecins sans Frontieres, *Untangling the Web of Antiretroviral Price Reductions* (Geneva: MSF, 2012), 20, 23.

⁷⁶ Asliwini Kumar, interviewed by Jeremiah Norris, Fixed Dose Combination ARVs Conference, Botswana, March 2004.

can reach the market.⁷⁷ This should help the High Level Panel, and others who want to eliminate the current system of innovation and drug development, understand the complexity and high costs of producing ARVs and new therapies for the world's pandemics. With regard to this complexity, it should be noted that Indian manufacturers have had difficulties complying with FDA standards in the production of generic ARVs and other drugs. The FDA has “banned at least 36 manufacturing plants in India, from sending products to the U. S.” and products sent to Africa have been found to be “of lower quality than the same medicines the companies sell at home and outside of Africa.”⁷⁸

Conclusions

Clearly, from the research in this report, the current intellectual property system has not denied millions of poor people access to ARVs and other medicines. Patents have not been a cause of high cost drugs for the poor, or led to limited drug research, or disadvantaged local producers. On the contrary, as this paper has shown, the intellectual property system has encouraged innovation that has *saved* millions of lives by providing the poor with access to lifesaving therapies. The current system has allowed generic substitutes to be quickly produced by local producers and at low-cost to help meet the demand for high quality, safe, and effective drugs to treat patients around the world.

The main barriers—cited by specialized agencies in the UN, numerous civil society organizations, and other stakeholders using scientific research—are not patents and prices. They are the endemic problems of poverty described in this report. They include lack of good governance, poor physical infrastructure and distribution systems, a shortage of healthcare facilities and providers, insufficient public health spending, corruption, taxes and tariffs on medicines, and the lack of policies that promote economic growth and incentives for individuals and businesses to develop new technologies so their countries can grow and prosper.

One must wonder then why the HLP was formed, since it does not address any of the relevant problems of access to medicines and healthcare. Instead, the HLP focuses on the narrow issue of patents and prices that have been debated for decades in the UN system. The reality is, however, that some 95 percent of drugs on the WHO Essential Medicines List (EML) are already off-patent, and the remaining 5 percent are ARVs which India can produce at affordable costs with FDA approval, thus helping to ensure their safety and efficacy.⁷⁹ So, there is no need to have compulsory licenses for drugs on the EML. The largest global HIV/AIDS program, PEPFAR, is purchasing its ARVs primarily from Indian companies, and treatment costs for both first and second line treatment have gone down even while the number of patients has gone up.

The notion that pharmaceutical companies do not develop drugs for markets other than their own has been dispelled with numerous examples. Oral Rehydration Salts (ORS), a treatment for diarrhoeal diseases, which the *Lancet* proclaimed “possibly the most important advance[ment] of

⁷⁷ PhRMA, *Policy Solutions: Delivering Innovative Treatments to Patients* (Washington, DC: PhRMA, 2016), 3.

⁷⁸ Anna Edney, “India’s Poor Quality Drugs End up In Africa, Study Finds,” *Bloomberg*, September 17, 2014, <http://www.bloomberg.com/news/articles/2014-09-17/india-s-poor-quality-drugs-end-up-in-africa-study-finds>

⁷⁹ Reed F. Beall, *Patents and the WHO Model List of Essential Medicines: Clarifying the Debate on IP and Access* (Geneva: WIPO, 2016), 1.

diarrhoeal diseases, which the *Lancet* proclaimed “possibly the most important advance[ment] of the 20th Century,”⁸⁰ was a patented drug in which the right-holder never challenged its production for mass distribution by NGOs and aid donors. Over twenty years ago, diarrhea killed 5 million children each year. Today, that number is less than a million.⁸¹ U.S. foundations and healthcare companies have created public-private partnerships that have tackled pandemics and tropical diseases with tremendous success. While improvements can still be made in global health policy to increase access to medicines and better healthcare, the achievements to date have been remarkable.

Looming beyond patents and prices, however, is the larger agenda of the HLP and other advocacy groups. Their mission is to establish an alternative drug development system from the existing system that relies on government sovereignty in issuing patents and setting the standards and approval processes for drugs entering the public domain. In addition, the HLP and other advocates want to remodel the funding mechanism for drug development that would de-link research and development costs from drug patents and pricing. All innovation, proprietary information and processes, and clinical trials would be “global public goods” governed by the UN in one form or another.

A resolution at the World Health Assembly (WHA) in May 2016 called for the WHO to develop a plan and a pooled fund for drug research and development.⁸² This plan is to be presented at the 2017 WHA and policy-makers will have a year to consider this idea. The problems with de-linking R&D costs from drug patents and pricing are many.

First, this idea ignores the very basis for innovation and progress which does not occur without the “fire of interest that fuels man’s genius,” as Abraham Lincoln described the value of patents. Without the incentives for innovation and protection of those incentives, discovery and development are hindered. How does the UN decide which new drug to invest in? Or which market to enter? The complex system of drug development does not lend itself to interagency task forces of member states with no knowledge or stake in pharmaceutical markets or distribution.

Second, the idea ignores the costs of research and development and creating a centralized regulatory system that would need to approve any new drug developed by a new UN/WHO method. As discussed in this report, the cost of bringing a new drug to market is now \$2.6 billion. Research and development costs are estimated at 43 percent of this cost or some \$1.3 billion. If the new system were approved, the UN would need to raise \$1.3 billion for the development of one drug, which does not include the costs for clinical trials, regulatory approval, and global monitoring of safety and efficacy. The WHO is tasked with the management of this program. For the United States, this would mean carrying a large portion of drug research and development costs. As one of the largest funders of the WHO, the United States paid 25 percent

⁸⁰ Amy Yee, “The Power, and Process, of a Simple Solution,” *New York Times*, August 14, 2014.

⁸¹ Steven Radelet, *The Great Surge: The Ascent of the Developing World* (New York: Simon & Schuster, 2015), 94.

⁸² World Health Organization, *Follow-Up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination* (Geneva: World Health Organization, 2016).

of its assessed budget in 2014/2015.⁸³ Since the US is the main source of new research and development on global blockbuster drugs already, this new program would lead to the duplication of regulatory efforts and increased costs.

Third, and most importantly, this idea ignores the entire goal of stringent drug regulatory agencies whose purpose is to approve drugs on their certifiable standards of safety, quality, and efficacy. When the WHO entered the “prequalification” business in 2002, it issued a careful disclaimer that stated: “Inclusion in this list does not constitute an endorsement, or warranty of the fitness, of any product for a particular purpose, including in regard of its safety and/or efficacy in the treatment of HIV/AIDS.”⁸⁴ This helps explain why the WHO had to de-list 36 ARV drugs that had been “prequalified” and distributed to WHO member states because it had not verified their bioequivalency. India became the “pharmacy to the developing world” which gave Indian firms licenses to produce generics without fear of legal challenge from right-holders, making them eligible for procurement by US foreign aid agencies. For non-FDA approved drugs, the National Bureau of Economic Research found that some of India’s poor quality drugs ended up in Africa. These drugs often lack enough of their key active ingredients compared to the same drugs sold in countries like Russia and China.⁸⁵

Table 5: Comparison of FDA and WHO Regulatory Procedures as of June 10, 2004

FDA	WHO
Compulsory drug approval	Voluntary prequalification
Drugs approved before market entry	Drugs prequalified after market entry
Independent clinical trials required	No trials required
Guaranteed quality, safety, efficacy	Quality but disclaimers on safety/efficacy
Can fine and close plants	No authority to fine or close plants
Post-marketing surveillance for safety	Not required
Consistent set of professional examiners	Examiners rotate among UN member states
Published standards for innovator/generic drugs	No known standards for copy drugs
Manufacturers’ can be sued	No legal basis for malpractice
FDA under juridical authority of U.S. Congress, guided by 120 years of legal precedence and case law	Prequalified operated by WHO Office of Essential Drugs & Medicines, majority of funds earmarked/managed by donor states

Before the UN and WHO dive into drug development, regulation, and monitoring, it would be useful for UN member states to consider these organizations’ capacity and track record. UN member states should also review some of the differences between drug regulatory agencies in

⁸³ World Health Organization, “Request for payment for the biennium 2014-2015—United States of America,” *World Health Organization*, http://www.who.int/about/resources_planning/invoices/2014_2015/usa_en.pdf

⁸⁴ World Health Organization, “General Information on the WHO List of Prequalified Medicinal Products,” *World Health Organization*, http://apps.who.int/prequal/info_general/notes_registry.htm.

⁸⁵ Anna Edney, “India’s Poor Quality Drugs End Up in Africa, Study Finds,” *Bloomberg*, September 14, 2014, <http://www.bloomberg.com/news/articles/2014-09-17/india-s-poor-quality-drugs-end-up-in-africa-study-finds>.

developed countries (e.g. the U.S. FDA and European countries) and those of the UN and its specialized agencies like the WHO.⁸⁶

UN member states who value innovation, progress and development should carefully examine the HLP's mandate and its larger agenda for centralizing drug development, regulation, and funding while dismantling the global intellectual property system. The record is clear on the achievements in global health and the real issues affecting access to medicines.

In her article titled "To Increase Access to Medicines Don't Make IP the Scapegoat," Kristina Lybecker wrote about the HLP: "Contrary to the 'incoherence' described by the Panel, the relationships seem quite logical: strong intellectual property rights are essential for robust biomedical innovation."⁸⁷ She went on to note the conspicuous absence of the rights of the innovators in the deliberations of the HLP: "And what about the innovators? Apparently the outcome [of the High Level Panel] will include no commitment to the interests of those who create the technologies that enhance and extend life. It's difficult to place much credibility in the Panel's efforts if they don't consider the source: innovators."⁸⁸

⁸⁶ Mary Pendergast, lecture to Children's AIDS Fund, "Comparison of FDA and WHO Regulatory Procedures," June 10, 2004.

⁸⁷ Kristina M. Lybecker, "To increase access to medicines don't make IP the scapegoat," *The Hill*, 5/10/16. <http://thehill.com/blogs/congress-blog/healthcare/279168-to-increase-access-to-medicines-dont-make-ip-the-scapegoat>

⁸⁸ Ibid.

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