

## The value of intellectual property for access to medicines

Contribution I from the

European Federation of Pharmaceutical Industries and Associations  
International Federation of Pharmaceutical Manufacturers and Associations  
Pharmaceutical Research & Manufacturers of America  
Japan Pharmaceutical Manufacturers Association

02/26/16

---

### ABSTRACT

*Achieving Sustainable Development Goal (SDG) 3.8 on universal health coverage is a challenging but urgent task, requiring coherent, aligned global policies that enable coordinated action by governments, multilateral organizations, civil society and the private sector. The 2030 Agenda for Sustainable Development recognizes the importance of “the role of the diverse private sector, ranging from microenterprise to cooperatives to multinational corporations” to achieve the SDGs, and calls for a “revitalized global partnership” that includes the private sector.*

*The biopharmaceutical industry is at the center of global efforts to create access to medicines through its engagement in developing effective public policies, strengthening health systems, overcoming economic and poverty barriers, and driving biopharmaceutical innovation. Intellectual property (IP) protection is a proven and critical facilitator of access – both through encouraging investments to ensure that today’s medicines reach as many people as possible and providing incentives for R&D which leads to new medicines and vaccines. Therefore, mechanisms to improve access to medicines must acknowledge the critical role that industry and IP play in enhancing access to current and future medicines.*

*Cohesive, practical proposals to strengthen the impact of existing activities to increase access and improve the coherence of policies that expand incentives and capacity-building for R&D for unmet health needs include:*

- *Support for existing R&D models, and new approaches that advance innovative financing and collaboration;*
- *Developing and expanding policy incentives;*
- *Strengthening regional agreements relating to mutual recognition procedures for regulatory approvals;*
- *Bolstering and developing innovative R&D financing models to share the burden of costs associated with the discovery and development of medicines; and*
- *Supporting the Review on Antimicrobial Resistance and accelerating development of new antimicrobial agents to address a growing threat to global health.*

*Two related Contributions focus on systems barriers that impede access, and ways to scale-up effective access solutions.*

---

### CONTRIBUTION

- I. **Robust standards of IP protection enable access to today’s medicines and investments in R&D that lead to tomorrow’s cures.** This is substantiated by evidence and demonstrates

direct coherence between the “justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.” Moreover, any genuine commitment to improving access to medicine and advancing the UN SDGs *must* account for and sustain *both* access today and R&D for tomorrow.

**Access to medicines is about getting the world’s patients the medicines they need to live longer and healthier lives and is at the center of everything that the innovative biopharmaceutical industry does.** We invent and develop lifesaving and life-enhancing medicines through our intensive R&D efforts, reinvesting more of our net sales back into innovation than any other industry.<sup>1</sup> We also invest in providing our medicines to the world’s patients through appropriate doctor and patient outreach and education, local market investment and development, and local distribution, ultimately reaching billions of patients every year in nearly every country in the world, through a self-sustaining IP-based business model.

**To help improve access to medicine in meaningful ways, we need a holistic approach – one that acknowledges the many complex factors that contribute to meeting the challenge** (e.g., poverty; lack of health education; limited healthcare infrastructure; regulatory delays; shortage of trained healthcare workers; distance to hospitals or treatment centers; high taxes, fees, markups, etc.), and that does not politicize or overstate IP’s limited role in the access equation. (For example, the majority of drugs on the WHO Essential Medicines List are not patent-protected, yet hundreds of millions of people still do not receive them.<sup>2,3</sup>) An effective approach will embrace industry as a partner, harnessing our expertise, experience and resources as part of a collaborative effort.

**a. IP protection is a critical and proven enabler and facilitator of both long-term and short-term access to medicines.**

The role of IP as an incentive for innovation and long-term access is well established. Nearly every important medicine of the last century-and-a-half — including antibiotics, vaccines, HIV and HCV treatments, cancer and cardiovascular medicines — owes its existence to the R&D activities of the biopharmaceutical industry. Industry has developed 550+ medicines in the last 15 years for the world’s emerging health needs, including oncology, cardiovascular disease, and diabetes.<sup>4,5</sup> In the past 5 years, 182 novel drugs to treat major public health concerns have been approved by the US Food and Drug Administration (USFDA).<sup>6</sup> Today, industry continues to be instrumental in exploratory research, as well as in translating research into patient-ready treatments, including the 800+ medicines and vaccines that were in development during 2015 for a wide range of cancers.<sup>7</sup>

IP protection is time-limited, but the benefits are long term; the goal of patent law is to transfer innovation to the public by making the details of patented inventions broadly available. This promotes research by others into areas outside of the claims of the original patents, which avoids overlap of R&D, optimizes inventions and accelerates further innovation. Strong IP protection is not only a primary incentive for the discovery and development of new medicines but also the optimization of existing medicines, including those which may address the unmet medical needs of local populations. Additionally, IP protection helps to foster innovation within developing markets, all of which improves access through innovation.<sup>8</sup>

Increasingly recognized is IP’s key role in facilitating access to today’s medicines (short-term):

- Strong IP protection creates a framework for rapid dissemination of ideas and efficient technology transfer,<sup>9</sup> resulting in faster launch and faster access to new medicines in developing countries<sup>10</sup> and the introduction of many medicines that would not otherwise be available in those countries (in either brand or generic form).<sup>11</sup>
- Innovator launch of a medicine in a developing country “materially improves access to that medicine [by a factor of 7, on average] compared to instances or time periods when a generic provider” launches.<sup>12</sup>
- Patient compliance and health outcomes improve when mechanisms such as local IP incentivize innovators to develop a local market, as compared to generic launches.<sup>13</sup>
- Those living in economies with fair to strong IP regimes are 30% more likely to benefit from access to new technologies as compared to those in weak IP environments, as companies are encouraged to introduce new products faster.<sup>14</sup>

Measures that develop robust IP systems and build capacity, including international agreements on IP norms and/or resource-sharing, and bilateral or regional cooperation agreements, will facilitate access and should be pursued.

**b. IP is also indispensable to the creation of generic medicines, which would not exist without originator IP-protected medicines, and which in the long term help to lower healthcare costs and make certain medicines more accessible.**

The mutually reinforcing nature of robust IP law and the existence of the generic drug industry is often overlooked. The generic business model relies for its lower cost base on an R&D cycle funded and conducted by innovators, without which there would be no medicines to copy.

**c. With its proven role in facilitating access to medicine – both in the long-term as an incentive for innovation and in the short-term as an incentive to develop markets – IP is too limiting a focus to address ongoing challenges to access to medicines.**

Industry shares the UNHLP’s ultimate goal of improving access to medicine and tackling the challenges that have complicated access. Given the role of IP in providing proven incentives for innovation and in financing the development of local markets and infrastructure, any approach which weakens IP is counterproductive to the ultimate goal of creating sustainable access to medicines and other health technologies.

**d. New mechanisms to improve access to medicines should be pragmatic, politically feasible, acknowledge the critical role that industry and IP play in providing access to current and future medicines, and respond to the realities of the global health landscape to achieve our shared goals.**

To improve access, the UNHLP should consider solutions based on accurate, evidence-based assessments. Collective efforts should address the complex factors that serve as barriers to access. Poverty remains the single biggest barrier in developing countries and emerging markets, followed by inadequate health systems and a lack of resources to provide quality, essential healthcare coverage. Any genuine effort to tackle the problem must take a holistic approach, with measures designed to address all factors, and include the right partners with the right expertise and capabilities.

Industry has embraced a holistic approach, implementing innovative programs that are designed to enable access to medicines by overcoming these structural barriers, in

collaboration with governments, multilateral organizations and other stakeholders. Industry efforts, guided by SDGs 1 (end poverty), 3 (ensure health, promote well-being), and 9 (foster innovation) have aimed to improve both the affordability and accessibility of medicines and vaccines by strengthening local economies and health infrastructure and employing innovative approaches to address patients' ability to pay for medicines. Specific examples are outlined in Submissions II and III.

One approach is tiered or differential pricing, both across and within countries. Companies using these approaches must make independent determinations regarding the adoption of any pricing policies, commercial arrangements and individual negotiations with governments and others. Examples of tiered pricing implementation include the provision of vaccines through the GAVI Alliance and the competitive market for medicines to fight HIV/AIDS.<sup>15</sup> Public reports show that industry is using this approach with a broader range of products in more countries.<sup>16</sup> For example, the [Novartis Access program](#) offers a price of \$1 per treatment per month for a basket of patented and off-patent medicines targeting non-communicable diseases to public sector healthcare providers in LMICs. Bayer implements a comprehensive tiered pricing approach for its contraceptives and in January 2016, announced that it will [halve the price of its contraceptive implant Jadelle®](#) until 2023 to meet the growing need for long-acting contraceptives for women in developing countries.

Above all, efforts to improve access to medicine should not exclude any stakeholders. The UN acknowledges “the role of the diverse private sector, ranging from microenterprise to cooperatives to multinational corporations” to achieve the SDGs.<sup>17</sup> In addition to the UNHLP, several other important efforts to address access to medicines (e.g., the Global Fund; GAVI Alliance; London Declaration Alliance on NTDs; global polio eradication; and the Ebola response) have active industry cooperation. While there is more to be done, industry must be recognized as an indispensable partner, with its expertise, experience and resources as part of a collaborative effort to address barriers to access.

## **II. Addressing unmet medical needs for diseases of poverty**

Industry has embraced innovative approaches to increase access to medicines and address unmet medical needs where the return on R&D investment may be too low to enable adequate allocation of resources. Many of these activities have potential to be scaled up if the scientific and financial risks that can help initiate and accelerate R&D are shared.

Product development partnerships (PDPs), innovative financing mechanisms, licensing, mechanisms like the Medicines Patent Pool (MPP), and non-assert declarations have helped industry products reach hundreds of millions of people in under-resourced settings.

- a. PDPs:** The industry is increasingly collaborating in PDPs, which involve companies providing technological innovations as well as development and distribution expertise to the partnership. Participating companies take IP into account, yet these measures do not pose a barrier to drug development. Public sector partners help fund development costs and the medicines and vaccines resulting from the partnership are dispensed to patients in need through implementation programs.

IFPMA members have worked with [Medicines for Malaria Venture](#), [TB Alliance](#), [Pediatric HIV Treatment Initiative](#), [International Partnership for Microbicides](#), and [Drugs for Neglected Diseases Initiative](#) since their inception and participate in [WIPO Re:Search](#), [Yale University Open Data Access \(YODA\)](#), the [TB Drug Accelerator](#) and [NTD Drug Discovery Booster](#). (Additional examples are found in the [IFPMA Developing World Health Partnerships Directory](#).) These PDPs help bring complementary expertise to bear on unmet medical needs; distribute costs (and minimize risks) of development; and ensure medicines reach patients faster.

- b. Innovative financing for R&D:** Recognizing the limited incentives for R&D for a number of disease areas, industry is exploring innovative financing mechanisms that can help share the burden of costs, while expanding access to medicines. The [Global Health Innovative Technology Fund \(GHIT\)](#) is the world's first product development fund which facilitates international partnerships that bring Japanese innovation, investment, and leadership to the fight against infectious diseases in LMICs. The GHIT has invested USD54 million, funded 53 partnerships, and supported 6 clinical trials in LMICs, with two additional trials set for 2017.<sup>18</sup>
- c. Licensing and non-assert declarations:** These IP-based tools enable local manufacturers to produce and sell generic versions of patented products and increase access when certain conditions apply, including:
- A therapy area with limited alternative generic therapies available
  - Sustained external funding to make licensed products attractive for generic companies
  - Sufficient political will to make the therapy area a public health priority
  - An effective health system to absorb more products
  - Products which are easy to manufacture and not complex
  - Appropriate generic partners are available and willing.

[Licensing agreements can increase access to medicines](#) by reducing prices while fostering development of new medicines and formulations (see examples: [Boehringer Ingelheim](#), [Bristol-Myers Squibb](#), [Janssen](#), [Lilly](#), [Merck KGaA \(Darmstadt, Germany\)](#), [Roche](#), [ViiV](#), etc.). Some of these agreements can be facilitated by an intermediary platform. For instance, [industry's collaboration with the MPP](#) has increased access while preserving R&D incentives for much needed new medicines.

---

## PROPOSALS

We strongly recommend a holistic approach to improving access to medicines – which includes robust IP protections and enforcement – to maintain and improve access to today's medicines and provide incentives for tomorrow's cures. The following proposals to enhance access to medicines will positively impact health outcomes and advance human rights.

- 1. *Support existing R&D models, as well as new approaches to innovative financing and collaboration***

Access initiatives are expanding and the impact of those initiatives largely depends on continued collaboration. Increased support from governments, multilateral partners, and the international community will be an important driver for existing R&D models and innovative financing and collaboration approaches. Examples of successful existing models include: Drugs for Neglected Diseases initiative, the TB Alliance, Medicines for Malaria Venture, WIPO Re:Search, YODA, the TB Drug Accelerator and the NTD Drug Discovery Booster.

## **2. *Develop and expand policy incentives for neglected diseases***

New policy incentives should be developed and existing ones strengthened to enable companies to dedicate greater resources to developing, adapting, and providing access to medicines for neglected diseases. Examples include priority review vouchers,<sup>19</sup> market exclusivity periods,<sup>20</sup> and R&D tax credits. The US Patent and Trademark Office's program of awards for "patents for humanity" provide accelerated examinations, re-examinations or appeals in exchange for patents that help improve technology access for the poor.<sup>21</sup> U.S. legislative initiatives, such as the MODDERN Cures Act and the Dormant Therapies Act, also provide models that support innovation.<sup>22,23</sup>

## **3. *Strengthen regional agreements relating to mutual recognition procedures for regulatory approvals in LMICs, which expedite access to both innovator and generic medicines***

Regional agreements relating to mutual recognition procedures for regulatory approvals (e.g., the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, the European Union Mutual Recognition Procedure, and now the African Medicines Regulatory Harmonization Program) should be implemented to facilitate access to medicines in LMICs. Active and transparent communication between international regulatory bodies, national governments and industry will facilitate mutual recognition.

## **4. *Bolster and develop innovative R&D financing models to share the burden of the cost of discovery and development of medicines***

Mobilizing commitments from a diverse range of partners is necessary to sustain innovative financing models to expand access to medicines and improve health outcomes. Recognizing the need for additional R&D incentives for some disease areas, this recommendation will help explore strategies to overcome one of the principal barriers to access. The GHIT has demonstrated how new financing models can be implemented.

## **5. *Support the Review on Antimicrobial Resistance and coordinate the leadership efforts of key stakeholders and establish regulatory frameworks and innovative financing for new antibacterial agents***

Antimicrobial resistance is a serious public health challenge, with implications for treating diseases from tuberculosis to common surgeries; a streamlined and coordinated approach across sectors is critical. Close collaboration with key stakeholders is vital to explore how IP can act as an accelerator for innovation to deal with this emerging threat.

---

<sup>1</sup> Hector Hernandez et al., "The 2014 EU Industrial R&D Investment Scoreboard," Publications Office of the European Union Luxembourg, 2014, <http://iri.jrc.ec.europa.eu/documents/10180/354280/EU%20R%26D%20Scoreboard%202014>.

- 
- <sup>2</sup> R. Laing, *The Patent Status of Medicines on the WHO Model List of Essential Medicines* (Geneva: World Health Organization, World Trade Organization & World Intellectual Property Organization, 2011).
- <sup>3</sup> Amir Attaran, "How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries?," *Health Affairs* 23, no. 3 (May 1, 2004): 155–66, doi:10.1377/hlthaff.23.3.155.
- <sup>4</sup> US Food and Drug Administration, "Summary of NDA Approvals & Receipts, 1938 to the Present," *About FDA*, January 18, 2013, <http://www.fda.gov/aboutfda/whatwedo/history/productregulation/summaryofndaapprovalsreceipts1938tothepresent/default.htm>.
- <sup>5</sup> Pharmaceutical Research and Manufacturers of America (PhRMA), "Medicines in Development," *PhRMA*, 2015, <http://www.phrma.org/innovation/meds-in-development>.
- <sup>6</sup> Center for Drug Evaluation and Research, "New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products," *US Food and Drug Administration*, February 8, 2016, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm>.
- <sup>7</sup> American Association for Cancer Research, "Medicines in Development for Cancer" (PhRMA, 2015), <http://phrma.org/sites/default/files/pdf/oncology-report-2015.pdf>.
- <sup>8</sup> See, e.g. Federica Angeli, "With the Help of a Foreign Ally: Biopharmaceutical Innovation in India after TRIPS," *Health Policy and Planning* 29, no. 3 (2014): 280–91.
- <sup>9</sup> Rozelle Laha, "Pfizer, IIT-Delhi Join Hands for Healthcare Innovations," *Hindustan Times*, November 30, 2015, <http://www.hindustantimes.com/education/pfizer-iit-delhi-join-hands-for-healthcare-innovations/story-1HRLSmVqxYsHF3eYavxt2L.html>.
- <sup>10</sup> See, e.g. Ernst R. Berndt and Iain M. Cockburn, "The Hidden Cost of Low Prices: Limited Access to New Drugs in India," *Health Affairs* 33, no. 9 (2014): 1567–75; Iain M. Cockburn, Jean O. Lanjouw, and Mark Schankerman, "Patents and the Global Diffusion of New Drugs" (National Bureau of Economic Research, 2014), <http://www.nber.org/papers/w20492>; Margaret Kyle and Yi Qian, "Intellectual Property Rights and Access to Innovation: Evidence from TRIPS" (National Bureau of Economic Research, 2014), <http://www.nber.org/papers/w20799>;
- <sup>11</sup> *Ibid.*; see also Michael P. Ryan, "Pharmaceutical Foreign Direct Investment, Technology Transfer, Health Competitiveness, and the Jordan-United States Free Trade Agreement," *George Washington University Law School, Creative and Innovative Economy Center*, May 2007.
- <sup>12</sup> Charles River Associates, "The wider value delivered to patients, healthcare systems and competitors when innovators launch new products" (Charles River Associates, April 2013).
- <sup>13</sup> *Ibid.*
- <sup>14</sup> Global Intellectual Property Center (GIPC), "Infinite Possibilities: IP as a Development Tool: Supplementary Statistical Analysis to the U.S. Chamber International IP Index" (US Chamber of Commerce, 2016), [http://www.theglobalipcenter.com/wp-content/themes/gipc/map-index/assets/pdf/2016/GIPC\\_IPIndex\\_Annex.pdf](http://www.theglobalipcenter.com/wp-content/themes/gipc/map-index/assets/pdf/2016/GIPC_IPIndex_Annex.pdf).
- <sup>15</sup> See, e.g., Jeffrey L. Sturchio, "Partnership for Action: The Experience of the Accelerating Access Initiative, 2000–04, and Lessons Learned." In *Delivering Essential Medicines: The Way Forward*, edited by Amir Attaran and Brigitte Granville, 116–41. Royal Institute of International Affairs. London: Chatham House, 2004. [http://www.who.int/hiv/amds/AAI\\_chapter6.pdf](http://www.who.int/hiv/amds/AAI_chapter6.pdf); Brenda Waning, Margaret Kyle, Ellen Diedrichsen, Lyne Soucy, Jenny Hochstadt, Till Barnighausen and Suerie Moon, "Intervening in Global Markets to Improve Access to HIV/AIDS Treatment: An Analysis of International Policies and the Dynamics of Global Antiretroviral Medicines Markets," *Globalization and Health* 6, no. 9 (2010), doi: 10.1186/1744-8603-6-9
- <sup>16</sup> Access to Medicine Foundation. *The Access to Medicine Index 2014*. 4th ed. Haarlem, The Netherlands: Access to Medicine Foundation, 2014. [http://www.accesstomedicineindex.org/sites/2015.atmindex.org/files/2014\\_accesstomedicineindex\\_fullreport\\_clickablepdf.pdf](http://www.accesstomedicineindex.org/sites/2015.atmindex.org/files/2014_accesstomedicineindex_fullreport_clickablepdf.pdf).
- <sup>17</sup> United Nations, "Transforming Our World: The 2030 Agenda for Sustainable Development" (United Nations, 2015), <https://sustainabledevelopment.un.org/content/documents/21252030%20Agenda%20for%20Sustainable%20Development%20web.pdf>.
- <sup>18</sup> Global Health Innovative Technology Fund, "About the GHIT Fund," *GHIT Fund (Global Health Innovative Technology Fund)*, 2016, <https://www.ghitfund.org/about/organization/partners/en>.
- <sup>19</sup> Henry G. Grabowski, David B. Ridley, and Jeffrey L. Moe, "Developing Drugs For Developing Countries," *Health Affairs* 25, no. 2 (March 2006): 313-324, doi: 10.1377/hlthaff.25.2.313.

---

<sup>20</sup> See, e.g., Aaron S. Kesselheim, “Using Market-Exclusivity Incentives to Promote Pharmaceutical Innovation,” *New England Journal of Medicine* 363, no. 19 (November 4, 2010): 1855–62, doi:10.1056/NEJMhle1002961.

<sup>21</sup> Office of Policy and International Affairs, “Patents for Humanity,” *United States Patent and Trademark Office*, (2015), <http://www.uspto.gov/patent/initiatives/patents-humanity>.

<sup>22</sup> Leonard Lance, “H.R.3116 - 113th Congress (2013-2014): MODDERN Cures Act of 2013,” *Legislation*, (January 9, 2014), <https://www.congress.gov/bill/113th-congress/house-bill/3116>.

<sup>23</sup> Orrin Hatch, “S.3004 - 113th Congress (2013-2014): Dormant Therapies Act of 2014,” *Legislation*, (December 11, 2014), <https://www.congress.gov/bill/113th-congress/senate-bill/3004>.