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Daniel Hougendobler Date

Defining and Mapping the Global Access to Medicines Movement: A Proposal for a Dynamic Online Resource

By

Daniel Hougendobler
Master of Public Health

Department of Global Health

_____

Dabney Evans, PhD, MPH
Committee Chair

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Daniel Hougendobler

Bachelor of Arts
University of Notre Dame
2007

Thesis Committee Chair: Dabney Evans, PhD, MPH

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Abstract

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By Daniel Hougendobler

Despite the success of the Global Access to Medicines Movement (GAMM), there are few resources available for those new to the movement to understand its contours. As the movement shifts from targeting primarily access to existing medicines to encompassing research and development of new medicines, it becomes more important than ever to understand the ever-growing number of actors involved and where they fit into the policy space.

This project begins to close this gap by creating a proposal for an online resource that will (1) define the boundaries of the movement and (2) map a representative group of actors involved in the access to medicines movement.

The resource consists of three main parts: (1) a history of the Global Access to Medicines Movement from 1994 to the present, (2) a map of GAMM actors placing them according to their primary areas of policy focus, and, (3) proposed webpages briefly summarizing the work of each actor. The proposal also includes a website map.

In order to maximize the ability of GAMM to face the challenges and exploit the opportunities of the future, it must become more coordinated and coherent. This resource will serve as a point-of-entry for those new to GAMM, and a platform for education and collaboration for those already involved in the movement.

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Table of Acronyms & Abbreviations

ACTA	Anti-Counterfeiting Trade Agreement
AMF	Access to Medicines Foundation
AIDS	Acquired Immunodeficiency Syndrome
AMC	advance market commitment
ART	antiretroviral therapy
ARV	antiretroviral
AUTM	Association of University Technology Managers
BVGH	BIO Ventures for Global Health
CDC	U.S. Centers for Disease Control and Prevention
CPT	Consumer Project on Technology
d4T	Stavudine
DPP	Drug Pricing Project
EML	World Health Organization List of Essential Medicines
FDA	U.S. Food & Drug Administration
FDC	fixed-dose combination
FTA	free-trade agreement
GALF	Global Access Licensing Framework
GAMM	Global Access to Medicines Movement
GSP	Generalized System of Preferences
HAI	Health Action International
Health GAP	Health Global Acccess Project
HIV	Human Immunodeficiency Virus
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IGO	intergovernmental organization
IMF	International Monetary Fund
IP	intellectual property
IPR	intellectual property rights
KEI	Knowledge Ecology International
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NGO	non-governmental organization
NIH	U.S. National Institutes of Health
NTD	neglected tropical disease
PhRMA	Pharmaceutical Research and Manufacturers of America
PMTCT	prevention of mother-to-child transmission
PPP	public-private partnership
PRV	Priority Review Voucher
R&D	research & development
SPS	Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies
UC	University of California
TPP	Trans-Pacific Partnership

TRIPS	Trade-Related Aspects of Intellectual Property Rights
TTO	technology transfer office
UAEM	Universities Allied for Essential Medicines
UC	University of California
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organization

Introduction

From ushering in a 95% reduction in the cost of antiretrovirals (ARV) to achieving an unprecedented amendment to a World Trade Organization (WTO) agreement, over the past two decades global health activists have achieved remarkable success in their attempts to have global health recognized as a part of the intellectual property agenda (Kapczynski, 2008). However, despite the fact that most actors involved in global access to medicines would consider themselves to be a part of a movement, there has been little discussion of this movement's contours. As the Global Access to Medicines Movement (GAMM) shifts from targeting primarily access to existing medicines to encompassing research and development (R&D) of new medicines, it becomes more important than ever to understand the actors involved and where they fit into the policy space.

This project will begin to close this gap by creating an online resource that will (1) define the boundaries of the movement and (2) map a representative group of actors involved in the access to medicines movement.

For the purposes of this paper, GAMM will be defined as encompassing actors who advocate for the use of international laws, policies, and/or norms to overcome legal barriers to (1) access to existing medicines in resource-limited settings and/or (2) innovation for diseases predominantly impacting those in resource-limited settings.

This paper is designed to be converted into an online resource, allowing it to be updated as new organizations emerge and as existing organizations change focus. To facilitate translation into an online resource, hyperlinks have been used throughout the proposed webpages describing various actors.

This paper will be divided into three main sections. Section 1 will provide a brief history of the Global Access to Medicines Movement in order to provide context for the movement as it appears today. Section 2 will suggest a definition for GAMM and explore the boundaries of the movement. Section 3 will examine a select group of organizations and place them on a grid based upon their primary focus.

History of the Global Access to Medicines Movement

Beginnings: TRIPS and Antiretroviral Treatment

The history of the Global Access to Medicines Movement (GAMM) is closely tied to that of HIV/AIDS. Just as powerful new drugs were being developed to combat a disease that had until that point meant an automatic death sentence, the WTO established a new intellectual property regime that risked putting these drugs out of reach of the majority of those living with HIV/AIDS.

The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement was signed in 1994 as a core agreement of the newly-established WTO.[1] TRIPS most important provisions, in terms of access to medicines, were those that "harmonised patent terms for a minimum of 20 years and mandated the granting of patents in all fields of technology" ('t Hoen, 2009, p. 1). Before TRIPS, many countries had offered a diverse range of patent laws, often excluding certain types of technologies, such as drugs or food, from patentability altogether ('t Hoen, 2009). After TRIPS was ratified, all signatory countries had to bring their laws into compliance according to the WTO's timetable or risk WTO-imposed trade sanctions.

The TRIPS Agreement was pushed through primarily by governments of powerful countries, backed by influential industry actors (Sell, 2002). Because it was created under the auspices of the WTO, only states had a formal role in the negotiations (Sell, 2002). However, private sector lobbyists did have a large role in framing the discussion: "By wrapping themselves in the mantle of 'property *rights*,' they suggested that the rights they were claiming were somehow natural, unassailable and automatically deserved" (Sell, 2002, p. 490). These groups termed perceived violators of intellectual property rights as "pirates," even if the so-called pirates' actions were legal (Sell, 2002).

In the aftermath of the TRIPS Agreement, global health actors faced two primary challenges. One was to find ways to minimize the damage to global health caused by

[1] The predecessor of the WTO was the General Agreement on Tariffs and Trade (GATT), which was formed shortly after World War II.

the TRIPS Agreement. The other was to campaign against expansion of intellectual property rights (IPR) beyond that required by TRIPS, particularly through so-called "TRIPS-Plus" agreements—international trade agreements that attempted to impose intellectual property (IP) protections greater than those contained in TRIPS (Sell, 2002).

Groups quickly began to form as a consensus grew among HIV/AIDS activists that the TRIPS Agreement "was going to hurt many more people than it would help, at least in the short run" (Sell, 2002, p. 497). In response to the perceived threat, Health Action International (HAI) held the "first major [non-governmental organization (NGO)] meeting on health care and TRIPS" in 1996 (Sell, 2002, p. 500).

Global health activists had an important foothold in the compulsory licensing provision of the TRIPS Agreement. Articles 30 and 31 allow governments to circumvent patent protections and force the patent holder to grant a license if the government meets several requirements (World Trade Organization, TRIPS, 1994) Some of the most significant limitations include: (1) the government must first negotiate in good-faith with the patent holder, with certain exceptions, such as a "national emergency" or "cases of extreme urgency," (2) "any such use shall be authorized predominantly for the domestic market of the Member authorizing such use,"[2] (3) the government was required to provide "adequate remuneration" to the

[2] This provision would become a significant source of activist attention going into the Doha Round of WTO negotiations.

patent holder for the compulsory license, and, (4) the decision must be judicially reviewable (TRIPS 1994, Art. 31).

Compulsory licensing quickly became a key battleground for global health activists. In 1997, South Africa passed a new Medicines Act (Sidley, 2001). The Act allowed for "generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines" ('t Hoen, 2009, p. 21).

A group of 40 pharmaceutical companies brought suit to challenge the legislation ('t Hoen, 2009). After pressure from the pharmaceutical industry, "[T]he U.S. government threw its full weight behind the South African case to press South Africa to revoke the offending provisions of its law" (Sell, 2002, p. 501). In 1998, the U.S. government went as far as to suspend South Africa's Generalized System of Preference (GSP) trade benefits (Sell, 2002). In response, in 1999 ACT UP began targeting U.S. Vice President Al Gore's campaign events. On the day Gore announced his candidacy for president, a group of ACT UP activists disrupted his speech with "noisemakers and banners that read: 'Gore's Greed Kills'" (Sell, 2002, p. 503). The Clinton Administration dropped its objections to the law that same week (Sell, 2002).

At the 1999 World Health Assembly (WHA), global health activists, particularly the Consumer Project on Technology (CPT), Health Action International (HAI), and Médecins Sans Frontières (MSF), scored another important victory when, due in

large part to their activism, the WHA passed a revised drug strategy (WHA52.19) (Sell, 2002). The resolution called for Member States to "ensure that public health concerns are paramount in health and pharmaceutical and health policies" and "to explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs," among other provisions (World Health Organization, WHA52.19, Revised Drug Strategy 1999).

In 1999, MSF won the Nobel Peace Prize. It donated its $1 million prize to its Campaign for Access to Essential Medicines (Access Campaign) (Sell, 2002). Global health activists had begun to gain momentum, which they would carry into the next round of WTO negotiations.

GAMM Pushes Back: The Road to the Doha Declaration

In 1999, the leaders of the access movement met in preparation for the Seattle Round of WTO negotiations. The result of this conference was the "Amsterdam Statement," which called for, among other things, a WTO working group to study the issue of compulsory licensing (Sell, 2002). It also promoted an exception to the Article 31 restriction on export for countries without a domestic production capacity (Sell, 2002).

In response to the increased attention being placed on issues of global health, five large pharmaceutical companies offered steep price cuts on many of their key antiretrovirals (ARVs) (World Health Organization & UNAIDS, 2002). One company,

Boehringer Ingelheim, even agreed to provide Nevirapine for use in prevention of mother to child transmission (PMTCT) for free in developing countries (World Health Organization & UNAIDS, 2002). MSF remained unimpressed, calling the price reduction and donation program "a victory, but a small one, much like an elephant giving birth to a mouse" (Médecins Sans Frontières, 2000).[3] MSF feared, "The net effect of implementing this type of program could lead to a further consolidation of the AIDS drug market in the hands of a small number of multinational drug companies" (Médecins Sans Frontières, 2000).

In May of 2000, U.S. President Bill Clinton signed Executive Order 13155, signaling a significant shift in U.S. trade policy. The order stated that "the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals," so long as the law was consistent with the TRIPS Agreement (Exec. Order 13155, 2000).

Two events in 2001 dramatically raised awareness of access issues. First, on February 7th 2001, the New York Times ran a front-page story announcing that Cipla, an Indian generics manufacturer, had offered to supply MSF with a triple-cocktail antiretroviral therapy (ART) for $350, or less than $1 per day (McNeil, 2001). By highlighting the "true" cost of manufacturing drugs, Cipla's offer "shocked the world,

[3] The MSF website erroneously lists the date as May 11, 2001, but the context and reference to recent events make it clear that it should be dated 2000.

and completely transformed the global debate on treatment for HIV in Africa" (Sell, 2002, p. 510).

The second event was the impending March trial date for the lawsuit of 40 multinational pharmaceutical suing South Africa over the provisions of its Medicines Act ('t Hoen, 2009)[4]. The case earned the moniker "Big Pharma v. Nelson Mandela," and proved a significant misstep for the companies involved (Sell, 2002).

Demonstrators spread from South Africa to Brussels to protest the pharmaceutical companies' actions ('t Hoen, 2009). The companies' case "quickly became a high profile event marked by protestors, grim televised images of dying mothers and babies, street demonstrations, and extensive media coverage" (Sell, 2002, p. 511). The fact that the case took place in South Africa exacerbated the negative impact, as it "conjured up memories of apartheid" (Sell, 2002, p. 511). The companies, losing the support of their home countries and facing a "public relations disaster," dropped the lawsuit ('t Hoen, 2009; Sell, 2002, p. 511).

Activists at Yale University scored another significant victory when they pressured the University and Bristol-Myers Squibb, the holder of the exclusive license to Stavudine (d4T), an important ARV, to allow South Africa to import a generic version of the drug (Lindsey, 2001; Sell, 2002). This was an important event in its

[4] This was the same lawsuit that inspired ACT UP to protest with the slogan "Gore's Greed Kills," causing the U.S. government to withdraw its support.

own right, and also marked the beginning of the NGO Universities Allied for Essential Medicines (UAEM).

Against this backdrop, a group of 80 countries proposed an addendum to the TRIPS Agreement (Sell, 2002). The result, adopted on 14 December 2001, was the "Declaration on the TRIPS agreement and public health," more commonly known as the Doha Declaration. The Declaration itself is only about 500 words in length, but represented a radical reconception of the role of public health in the global intellectual property regime (World Trade Organization, 2001). One observer remarked that "NGO/developing country networking and coalitions" were "pivotal in the adoption of the Doha Declaration" ('t Hoen, 2009, p. 31).

First, the agreement recognized that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all," and "reaffirmed" TRIPS flexibilities as a tool for achieving these goals (Doha Declaration, ¶4). It then listed these flexibilities as (1) interpreting specific TRIPS provisions through the object and purpose of the agreement as a whole, (2) the right to compulsory licensing, (3) right to declare national emergencies, including in cases of "public health crises," and, (4) each country is "free to establish its own regime" for patent exhaustion (World Trade Organization, 2001, ¶5).

On the important question of Article 31(f)'s restriction on compulsory licensing primarily for domestic markets, the negotiators of the Declaration failed to reach an agreement. It acknowledged that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licenses," but concluded merely by calling for "the Council for TRIPS to find an expeditious solution…before the end of 2002" (World Trade Organization, 2001, ¶6).

Expanding Into the Future

Although the Doha Declaration called for a solution by 2002, it was not until August 2003 that the question of Article 31(f) in cases of countries with insufficient domestic production capacity was addressed. The amendment, known as the 30 August decision, granted a waiver for least-developed countries lacking sufficient domestic manufacturing capacity, but only on a "drug-by-drug, case-by-case, country-by-country basis" ('t Hoen, 2009, p. 36) In 2005, this waiver was made permanent; however, because of the failure, as of April 2012, of the Doha round of WTO negotiations to reach consensus, the amendment has not come into force ('t Hoen, 2009).

Thanks in large part to the successes of the Global Access to Medicines Movement, drug prices have plummeted. By 2008, just seven years after Doha, "95% (by volume) of the global donor-funded ARV market was comprised of generics, primarily from India" ('t Hoen, Berger, Calmy, & Moon, 2011, p. 5). Thailand and

Brazil took out much publicized compulsory licenses, and 60 other developing countries made use of TRIPS flexibilities ('t Hoen et al., 2011).

Because India had become "the pharmacy of the world" for HIV/AIDS patients, "There was great concern in the public health community when India had to begin granting pharmaceutical patents in 2005 under its TRIPS obligations" ('t Hoen et al., 2011, p. 5). However, the reaffirmation of TRIPS flexibilities gave India the ability to create a Patents Act that included "public health safeguards," "strict patentability criteria and the possibility for anyone to oppose the granting of patents" ('t Hoen, 2009, p. 5).

However, many challenges remain. Free-trade agreements such as the Anti-Counterfeiting Trade Agreement (ACTA) and the EU-India Free Trade Agreement threaten to broaden intellectual property rights at the expense of public health. With lucrative pharmaceutical markets, but staggeringly large populations still in desperate poverty, middle-income countries are emerging as a key battleground for future access to medicines campaigns. Finally, an increasing awareness is emerging of the inequity of research and development spending.

The current state of GAMM is characterized by three significant trends. First, the movement is transitioning from an almost exclusive focus on HIV/AIDS to one that encompasses a far wider variety of diseases, including tuberculosis, malaria, and neglected tropical diseases (NTDs). Second, research and development is becoming

an increasingly important focus for campaigners. Finally, as issues of intellectual property continue to touch more areas of life, GAMM is increasingly seen as a part of a larger movement, which is termed an access to *knowledge* movement. This broader movement encompasses all the myriad ways in which intellectual property can impede equitable access (Kapczynski, 2008). It encompasses not only the access to medicines movement, but also, for example, open publishing, open-source software, challenging agricultural patents, and much more (Kapczynski, 2008).

Defining the Global Access to Medicines Movement

There are many ways of increasing access to medicines in the developing world. However, only a relatively small subset of these efforts is included in GAMM as defined here.

For the purposes of this project, GAMM will be defined as encompassing actors who advocate the use of international laws, policies, and/or norms to overcome legal barriers to (1) access to existing medicines in resource-limited settings and/or (2) innovation for diseases predominantly impacting those in resource-limited settings.

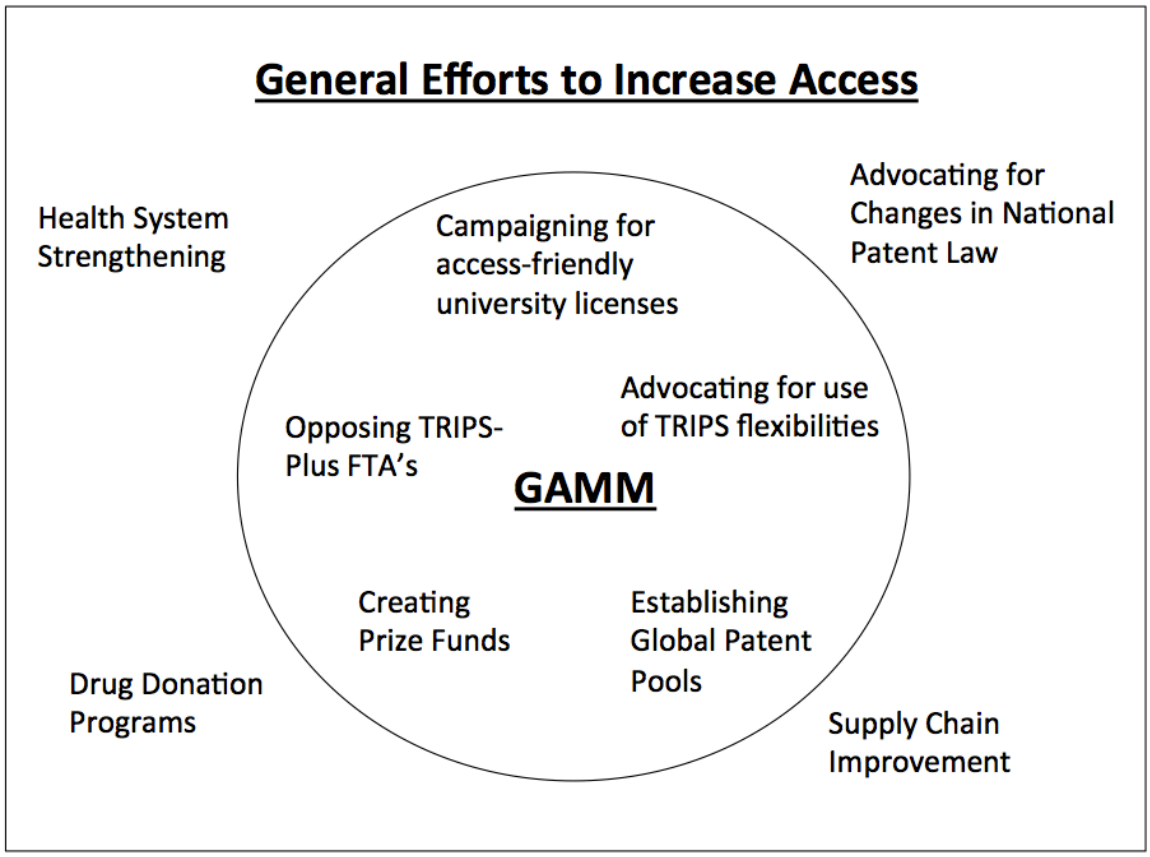
According to this definition, a pure drug donation program is not part of GAMM since it does not attempt to use law, policy, or norms to achieve its goal. Likewise, although health system strengthening is likely to result in greater access, it is not a part of GAMM. This definition also includes only those organizations that are

international or global in focus. Thus groups like the Treatment Action Campaign (TAC), although their work directly impacts access, are not included in this project.

On the other hand, actors that advocate for use of international law, such as TRIPS flexibilities, to increase access are a part of the movement. Even those that do not advocate for a change in the law, but attempt to create international norms to overcome legal barriers, such as the Medicines Patent Pool (MPP), are included within the definition.

The following chart (see Figure 1) illustrates the scope of Global Access to Medicines Movement by including examples of activities that fall within and outside of GAMM. All actions listed on the chart are methods of increasing access, but only those within the circle are a part of the Global Access to Medicines Movement as defined.

Figure 1: The Global Access to Medicines Movement



Mapping the Actors

This following map is not meant to provide a comprehensive picture of every organization involved in the Global Access to Medicines Movement (GAMM). It is only meant to outline select key actors within the movement. For this reason, this document will focus primarily on the most prominent institutions.

To be included in the list, an organization must first be a part of GAMM, as previously defined. Once an organization is found to be a part of the movement, whether it is included in the analysis depends upon the balancing of several factors, including: (1) the amount of attention and money the organization devotes to access

and/or innovation issues, (2) how long the organization has been involved in access and/or innovation, and, (3) links and references to the organization's work in the academic literature and on the webpages of other prominent organizations. In a few cases, organizations that fill a unique niche have been included despite a relative lack of prominence in order to give a more complete picture of the movement.

Most organizations in the following list are involved to some extent in a wide variety of issues. In an attempt to determine what issues form the core of an organization's access work, a list of one to three "principal access & innovation project(s)" is provided for each non-governmental organization (NGO) and public-private partnership (PPP). For the pharmaceutical industry association and intergovernmental organization (IGO), a description of the most important policies and roles are provided. In determining what forms an organization's core projects, the following factors are considered: (1) percentage of expenditures devoted to a project (if available), (2) strength of the relationship between the project and the organization's mission statement, (3) prominence of the project on website and in the organization's literature, such as annual reports.

Overview

The primary actors involved in GAMM fall generally into three categories. First are NGOs, which are organizations not directly affiliated with government or industry. Second are pharmaceutical industry trade organizations, which are the collective lobbying arms of pharmaceutical companies. Third are PPPs, which are collaborative efforts between industry and NGOs. Finally, IGOs are organizations in

which many governments collaborate toward a particular goal. For example, the World Trade Organization (WTO) and United Nations are IGOs since its voting members are states.

Global Non-Governmental Organizations

NGOs have played a significant role in every aspect of GAMM. Their activities range from protests and direct advocacy to negotiations with universities and pharmaceutical companies. The following list provides examples of some of these organizations and their work.

Access to Medicines Foundation

Website*:* http://www.accesstomedicineindex.org/

Background

The Access to Medicines Foundation (AMF) is a Dutch non-profit. The goal of AMF is "to advance access to health care in developing countries by encouraging the pharmaceutical industry to accept a larger role regarding access to medicine in less developed countries." Its largest project is the Access to Medicines Index.

Principal Access & Innovation Project(s)

Access to Medicines Index

http://www.accesstomedicineindex.org/

The Access to Medicines Index (Index), published first in 2008 and revised in 2010, is AMF's flagship project. It provides a ranking of 20 pharmaceutical companies and seven generic manufacturers based on seven factors, each weighted separately: (1)

general access to medicine management, (2) public policy & market influence, (3) research & development, (4) equitable pricing, manufacturing & distribution, (5) patents & licensing, (6) capability advancement in product development & distribution, (7) product donations & philanthropic activities. Click here to learn more about the 2010 Index's methodology.

The Index has become an important tool for access campaigners. Much of this is due to its perceived legitimacy, bolstered by a number of high-profile signatories, including Bill Gates, Mary Robinson, and Carissa Etienne. The Index has also been featured in a number of influential publications, including the New York Times, the Financial Times, and Science Magazine. Pharmaceutical companies, too, have affirmed the legitimacy of the Index, publishing their ranking on their corporate websites and in annual reports.

Health Action International

Website: http://www.haiweb.org/

Background

Health Action International (HAI), a Dutch NGO, is committed to, among other objectives, "foster[ing] justice in healthcare worldwide by improving access to essential medicines" and developing networks to support this mission. It has regional offices spanning 4 continents, including Europe, Africa, Asia, and South America. The majority of HAI's 2011 global budget was devoted to access to medicines, with the majority of this money allocated to the Drug Pricing Project (DPP).

Principal Access & Innovation Project(s)

Drug Pricing Project

http://www.haiweb.org/medicineprices/

The DPP is a collaborative project between HAI and the World Health Organization (WHO) Department of Medicine Policy and Standards. The project aims to gather information both about the prices of private and government procurement of drugs in different settings, including all steps along the supply chain.

Along with the drug price data collection and publishing, HAI also undertakes policy education and advocacy efforts. For instance, between 2007 and 2009, HAI published a series of newsletters, *Medicine Pricing Matters*, on a variety of policy issues related to pricing and access. One newsletter highlighted a range of policy

guidelines for lowering the prices on essential medicines. Another advocated for the removal of taxes on essential medicines.

Essential Innovation and Intellectual Property

http://www.haiweb.org/02_focus_b.htm

HAI also sponsors a smaller project on innovation and access. This project consists primarily of a series of direct advocacy, policy briefs, and promoting new paradigms for innovation and access arguing, "Where the market fails, new approaches to pharmaceutical R&D are called for."

Health Global Access Project

Website: http://www.healthgap.org

Background

Health Global Access Project (Health GAP) is a non-profit based in the United States "dedicated to eliminating barriers to global access to affordable life-sustaining medicines for people living with HIV/AIDS." Health GAP is involved in a variety of issues from proposing global trade reform, advocating for International Monetary Fund (IMF) and World Bank debt cancellation to providing worldwide training in global access issues and activist tactics for achieving global health goals.

Principal Access & Innovation Project(s)

Access to Medicine

http://healthgap.org/trips.htm

Health GAP's Access to Medicine campaign is driven primarily by Brook Baker, an influential access activist. The campaign generates a great deal of policy papers, opinion pieces and fact sheets on topics as varied as leaking secret TRIPS-plus negotiations, writing to the Indian government suggesting the use of compulsory licenses, and analyzing and critiquing the licensing terms of ViiV, a GlaxoSmithKline/Pfizer co-venture, vs. those of the Medicines Patent Pool (MPP). The organization is also frequently involved in coordinating direct action campaigns.

Knowledge Ecology International

Website: http://www.keionline.org/

Background

Knowledge Ecology International (KEI) began as the Consumer Project on Technology (CPT). Founded in 1995 by Ralph Nader, CPT played an important role in the early days of the access to medicines campaign. CPT became KEI in 2006 and won the MacArthur Award for Creative and Effective Institutions in the same year.

KEI provides this list of its primary activities:

> KEI undertakes and publishes research and new ideas, engages in global public interest advocacy, provides technical advice to governments, NGOs and firms, enhances transparency of policy making, monitors actions of key actors, and provides forums for interested persons to discuss and debate Knowledge Ecology topics.

Led by James Love, one of the most influential figures in GAMM, the organization's focus spans from research & development to creative licensing and TRIPS flexibilities. KEI also maintains an active blog as well as the IP-health listserv, one of the most active and influential electronic forums for discussion of issues affecting GAMM.

Principal Access & Innovation Project(s)

Prizes to Stimulate Innovation

http://keionline.org/prizes

KEI is one of the leading organizations advocating for the use of prize funds as a tool for delinking research & development costs from the cost of the final product. These funds would work by granting developers of medicines and medical technologies—

in particular those that are beneficial to people living in resource-limited settings—a monetary prize in lieu of a monopoly. The drug could then be manufactured immediately in generic form (click here to learn more).

KEI campaigns for prize funds through a variety of methods including: writing academic articles; compiling lists of relevant literature; speaking at conferences and IGO/NGO meetings; and raising awareness through the website, blog and listserv.

Collective Management of IPR and Patent Pools

http://keionline.org/a2m

KEI has a long history of advocating for a patent pool for essential medicines. In fact the concept itself began with a presentation by James Love at the 2002 International AIDS Conference. Since then, KEI has been a strong proponent of pooling intellectual property rights, and particularly for the MPP.

KEI has provided much of the intellectual backing for evaluating patent pools, such as a cost-benefit analysis of the MPP, a survey of patent pools, and WHO briefing papers. The organization has also provided extensive feedback on the licenses negotiated by the MPP.

TRIPS Flexibilities and Compulsory Licensing

Finally, KEI is involved in researching and advocating for use of TRIPS flexibilities, particularly compulsory licensing. The organization was particularly engaged in the

2006-2007 controversy over Thailand's decision to grant compulsory licenses on two HIV/AIDS drugs. Another significant project is Mr. Love's document listing compulsory licenses worldwide.

Médecins Sans Frontières - Access Campaign

Website: http://www.msfaccess.org/

Background

Founded in 1999 in the wake of Médecins Sans Frontières (MSF) receiving the Nobel Peace Prize, the MSF Access Campaign is perhaps the most visible face of the Global Access to Medicines Movement. Since the early days of the movement it has been involved in nearly every aspect of the movement. The Access Campaign's reach has spread from campaigning for expanded use of TRIPS flexibilities, to advocating for research and development and innovative intellectual property management strategies.

It spearheaded the effort to have access to medicines included on the TRIPS agenda, culminating in the Doha Declaration. It also supported the creation of the MPP, with the current Executive Director of the Medicines Patent Pool, Ellen 't Hoen, acting as the Director of Policy and Advocacy at MSF's Access Campaign for the ten years immediately preceding her role at the MPP.

It has had a significant role in reducing drug prices, and its "Untangling the Web of Antiretroviral Price Reductions" report, in its 14th edition as of April 2012, is one of the most significant resources for those involved in procurement or advocating for lower prices for HIV/AIDS drugs. The report provides information about each antiretroviral drug, its therapeutic class, whether it is included on the WHO Model List of Essential Medicines (EML), the price of the medication and who is eligible for

the price, and a chart of originator vs. generic drug prices over time. It also provides some patent information as well as a "Spotlight on Access" section providing a narrative about the drug's benefits, patent situation and pediatric status, with an emphasis on ongoing access issues surrounding the drug (see, e.g., the page for ritonavir).

The Campaign is also involved in a large number of research and advocacy projects. It regularly produces reports, briefings, and peer-reviewed and other research articles on a variety of issues from "Ten Stories that Mattered in Access to Medicines in 2011" to a journal article addressing "The past, present, and future of affordable antiretroviral therapy in Africa." It also advocates more directly through opinion pieces and editorials; speeches, statements and letters; and by organizing events and presentations. Of all the NGO's included in this project, MSF's Access Campaign is directly involved in the greatest breadth of activities.

Principal Access & Innovation Project(s)

Overcoming Barriers to Access

http://www.msfaccess.org/our-work/overcoming-barriers-to-access

Here, the Access Campaign is focused primarily on confronting the barriers to access to medicines imposed by patents. MSF employs a variety of strategies to reach this end. First, it provides resources to educate people about the issues. Second, it advocates for particular solutions to access problems.

For example the campaign has advocated for a patent pool for medicines, against the Anti-Counterfeiting Free Trade Agreement (ACTA) and it has fought to prevent lawmakers from negatively impacting generic production in the name of fighting counterfeit or substandard drugs. Its campaigns are known for their use of creative animations to illustrate access issues, including for patent pools, counterfeit/substandard drugs, and evergreening.

Driving Innovation

http://www.msfaccess.org/our-work/driving-medical-innovation

The Access Campaign has expanded from its original focus on global access and now encompasses innovation. Some of its campaigns, such as that for a patent pool, are aimed both at access and innovation.[5]

However, some work is aimed exclusively at spurring research and development and innovation. For example, the Access Campaign has actively campaigned for innovation to be included on the WHO's agenda, including several statements and interventions at WHO negotiations.

The organization has also monitored advance market commitment (AMC)[6] efforts to evaluate whether they are fulfilling their function. The Access Campaign has

[5] The patent pool is designed to increase access by making it easier to obtain sublicenses to existing drugs and combinations from patent holders. However, it is also intended to spur innovation by allowing sublicensees to develop new fixed-dose combinations that respond to the particular needs of the developing world. This is discussed in more detail on the UNITAID page [insert internal link to UNITAID page].

worked to monitor these commitments and critique various aspects of particular programs.

[6] An AMC is a financial commitment to buy a certain amount of a product, once developed. It is meant to spur innovation into medicines that would not otherwise be developed due to market failure. In the case of neglected diseases, the market fails because the diseases affect primarily the poor who cannot afford the medicines, thus giving potential developers no way to recoup their investments. By guaranteeing a market, those offering an AMC hope to provide a financial incentive for researching and developing medicines whose development that would otherwise be financially impracticable.

Public Citizen

Website: http://www.citizen.org/

Background

Public Citizen describes itself as "the people's voice in the nation's capital." While the organization focuses primarily on issues affecting U.S. citizens, the access to medicines campaign is concerned with the effect of U.S. and international law on global access.

Principal Access & Innovation Project(s)

Access to Medicines Project

http://www.citizen.org/Page.aspx?pid=4955

The access project describes its role as largely an assistive one. It is tasked with "support[ing] civil society groups and public agencies with analysis and technical assistance to help overcome patent-based and other drug monopolies." It has done this in a variety of projects.

One is the access to medicines project aims to increase access to a Kaletra, an important fixed-dose combination (FDC) controlled by Abbott Labs. It has worked by raising awareness of what it terms Abbott's "abusive practices," compiling a list of country actions, and maintaining a list of developments. It has also started a project, similar to MSF's, which works to ensure that policies attempting to combat counterfeit or inferior quality drugs do not do so at the expense of access.

Finally, Public Citizen is engaged in a project to ensure that the Trans-Pacific Partnership (TPP) does not negatively impact access. This project provides the text of leaked trade negotiation documents and analysis as well as country-specific updates and analysis.

UNITAID

Website: http://www.unitaid.eu/

Background

UNITAID was established to increase treatment for HIV/AIDS, tuberculosis and malaria. It is funded primarily through airline levies placed on tickets bought in participating countries. It acts primarily to address market failures by creating a stable market through "large long-term orders" for key drugs.

Principal Access & Innovation Project(s)

The Medicines Patent Pool Foundation

http://www.medicinespatentpool.org/

Going beyond its typical purchasing function, UNITAID decided to attempt to correct a particular market failure by establishing the MPP in 2009. The goal of the MPP is "to make newer medicines available in patient-adapted form, at lower prices, for low- and middle-income countries." It is targeted exclusively at treatment for HIV/AIDS.

The MPP is intended to improve both access to and innovation for antiretroviral therapies. The basic problem the MPP attempts to address is that separate patent holders often hold patents for key antiretroviral therapies in FDC form. This means that when a generic company wants to manufacture an FDC, it must often negotiate with several patent holders, thus increasing transaction costs and uncertainty.

The MPP attempts to overcome the problem of access to existing FDCs by creating a centralized license repository. The MPP attempts to convince patent holders, generally multinational pharmaceutical companies, to grant licenses to the MPP, which in turn will sublicense the drugs to generics manufacturers. If the MPP's strategy is successful, generic manufacturers will only need to obtain licenses from a single entity in order to produce an FDC.

The MPP uses the same method to stimulate innovation to help overcome the acute lack of FDCs designed to meet the needs of those living in developing settings. For instance, there is little market in the rich world for formulations that are heat-stable (because of the ease of ensuring a cold-chain in the rich world) or designed for pediatric use (due to the rich world's nearly complete success in preventing mother-to-child transmission). Originator pharmaceutical companies have little financial motive to develop these types of formulations. However, generics manufacturers, which often market their drugs predominantly in developing markets, do have incentive to develop them. By lowering transaction costs, the MPP hopes to make it easier for generics companies to develop "patient-adapted" forms of antiretrovirals (ARVs).

As of April 2012, the MPP had successfully negotiated licenses with Gilead Sciences and the U.S. National Institutes of Health (NIH). It had also signed sublicense agreements with three generics manufacturers.

Beyond its licensing efforts, another initiative of the MPP is "Patent Status of ARV's" database it maintains on its website. This database is intended to provide an easy way of checking whether a patent has been granted in a particular country and, if so, whether it remains valid, has been successfully challenged, a challenge is pending, or if the patent has expired.

Universities Allied for Essential Medicines

Website: http://essentialmedicine.org/

Background

Universities Allied for Essential Medicines (UAEM) began with the 2001 Yale d4T campaign and has expanded rapidly since. It now has 55 U.S. chapters registered, and international chapters spanning six continents. It describes its mission as "promot[ing] access to medicines for people in developing countries by changing norms and practices around university patenting and licensing" as well as promoting university research that "meets the needs of the majority of the world's population and "empower[ing] students to respond to the access and innovation crisis."

In 2006 it promoted the Philadelphia Consensus, which called for universities to ensure "equal access" to health-improving inventions, undertake "research for neglected diseases," and to "measure[e] research success by impact on human welfare." It was signed by, among many others: nine Nobel Laureates; public health and policy experts such as Jeffrey Sachs, Paul Farmer, and Jim Yong Kim; and several prominent scientists.

Principal Access & Innovation Project(s)

University Technology Transfer

Ensuring equitable licensing terms for technology created at universities continues to be UAEM's primary focus. This project is designed to pressure universities to

ensure that drugs developed at their institutions are licensed so as to ensure that, according to UAEM's mission, "people regardless of income have access to essential medicines and other health-related technologies."

UAEM used a variety of strategies to attain this goal. It has developed the Global Access Licensing Framework (GALF) that provides a list of principles that university technology transfer offices (TTOs) should adhere to in order to ensure that their licenses maximize global access to the drug or device being licensed. The GALF language was recently included in an April 2012 WHO report. UAEM also provides resources for chapters that wish to apply pressure to their TTOs (see, e.g., the 2011 Global Access to Medicines Month toolkit, available here).

UAEM has achieved a number of notable successes since the d4T campaign at Yale including convincing the Association of University Technology Managers (AUTM) to endorse a "Nine Points" plan for promoting global access and pressuring universities to create specific global access licensing plans at University of British Columbia and Emory University. In 2009, UAEM successfully convinced AUTM to create the "Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies" (SPS), which was endorsed by NIH and the U.S. Centers for Disease Control and Prevention (CDC), among others. Most recently, in March of 2012, UAEM successfully pressured the University of California (UC) to adopt a revised set of University Licensing Guidelines, which "instructs administrators

across the UC system to prioritize global health when licensing university medical research."

Neglected Disease Research

UAEM also pressures universities to prioritize research for neglected diseases. It has organized academic symposia on the issue of neglected disease research and another on patent pools for innovation. It has also published a number of academic papers advocating for greater emphasis on neglected disease research.

Pharmaceutical Company Advocacy Groups

Although many pharmaceutical companies have access projects, most attempts to affect law, policy, or norms occurs through the companies' lobbying groups. As the most influential international pharmaceutical lobbying organization, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) will be used to represent the views of the pharmaceutical industry. Two PPPs sponsored by the pharmaceutical industry are also addressed in the following section.

International Federation of Pharmaceutical Manufacturers and Associations

Website: http://www.ifpma.org/

Background

IFPMA, based in Geneva, Switzerland, is an influential pharmaceutical lobbying group with membership consisting of most of the largest pharmaceutical companies as well as influential associations such as the U.S.-based Pharmaceutical Research and Manufacturers of America (PhRMA).

Principal Position(s) on Access & Innovation

IPFMA's foundational assertion is that intellectual property rights (IPR) are essential for stimulating future innovation. These rights create a "key incentive for innovators to recoup their significant R&D investments." "The vast majority of medicines available today," it claims, "would not exist without the incentive provided by intellectual property rights." In this view, efforts that result in weaker intellectual property rights (IPR) are ultimately counterproductive. Even if they

boost access in the short-term, ultimately they will result in less innovation and therefore poorer health outcomes.

IFPMA therefore emphasizes projects such as health system strengthening over weakening IPR. Unlike many GAMM NGOs, IFPMA disfavors compulsory licensing stating, "While compulsory licenses are possible under TRIPS, they are only an option; they are certainly not the solution to access problems." It argues that frequent use of compulsory licensing would hurt innovation by "weaken[ing] the IP framework and thereby undermin[ing] the system that underpins the ability of the private sector to undertake essential R&D."

IFPMA suggests that factors other than excessively strong IPR are to blame for the lack of access in the developing world. For instance it argues, "Poverty is the single biggest barrier to improving healthcare in the developing world."

IFPMA suggests voluntary mechanisms such as voluntary licensing and non-assert declarations as solutions that will boost access while retaining the incentive for innovation it believes strong IPR provides. Voluntary licenses are agreements by an originator company to allow a generics company to manufacture a version of its patented drug, usually in a developing country setting. A non-assert declaration is a statement by a patent or license holder that it will not assert its rights under certain conditions (for instance in a developing country so long as certain quality standards

are met). IFPMA also promotes non-IP solutions such as drug donation programs, capacity building, and preferential pricing.

In addressing research & development into neglected diseases, IFPMA points out that "the research-based pharmaceutical industry is the third largest funder of R&D into [neglected tropical diseases] in the world, after the U.S. National Institutes of Health and the Bill & Melinda Gates Foundation." It also points to the partnerships developed between industry and other groups to increase research and development. Two of these will be discussed in the section on public-private partnerships.

Public-Private Partnerships

There is a trend toward developing partnerships between industry and governments, NGOs, and IGOs. Two of these, BIO Ventures for Global Health (BVGH) and Re:Search, are most relevant to GAMM since they represent an attempt to change international norms and, some would argue, act as a counterpoint to the initiatives of many of the NGOs which, in industry's view, undermine IPR.

BIO Ventures for Global Health

Website: http://www.bvgh.org/

Background

BVGH attempts to use a "dual lens" approach to better health outcomes by involving experts from industry as well as global health. It attempts to overcome the "two main barriers to biotech involvement in global health." First, it works to find solutions to the "financial realities that keep many innovator companies from focusing on neglected diseases with low market potential." It also attempts to provide options to overcome industry's "lack of information about how they can apply their expertise and technologies to global health." Since the first barrier is most relevant to GAMM, it will be addressed below.

Principal Access & Innovation Project(s)

Global Health Innovation Quotient Prize

This innovative program represents an attempt to stimulate innovation into a drug or device where little financial incentive exists to develop it. It stimulates investment by creating a financial prize for development, thus guaranteeing entities

that achieve results a way to recoup their investments. Unlike a pure prize fund, the IQ Prize provides milestone awards as a way of reducing risk. Taking the example of a medical device, funds are awarded at proof of concept, when the prototype is built and evaluated, when the device is clinically validated (by far the largest payout), and again when the device obtains regulatory approval. This reduces risk by providing shorter term and more predictable benchmarks than a lump-sum prize.

Priority Review Vouchers

BVGH also advocates for the use of U.S. Food and Drug Administration (FDA) Priority Review Vouchers (PRVs) and facilitates their use and trade. The FDA grants PRVs to companies that are granted approval for a new product that treats one of a list of neglected tropical diseases. A PRV entitles the company to accelerated review of another drug the company is developing, or the voucher can be sold or transferred to another company. Rather than the standard 10 month review period, FDA aims to conclude priority review within 6 months. Although this may seem a minor concession, experts have estimated that an ARV is worth between $50 million and $500 million USD.

BVGH facilitates the PRV system in two main ways. First, it educates companies and provides resources to companies interested in the process. Second, BVGH is in the process of developing an online marketplace for trading PRV.

Advance Market Commitments

Finally, BVGH advocates for the use of AMCs. It has assisted the World Bank and the Global Alliance for Vaccines and Immunizations to develop the first AMC – targeted at developing a pneumococcal vaccine.

BVGH also partners with Re:Search.

Re:Search

Website: http://www.wipo.int/research/en/

Background

The World Intellectual Property Organization's Re:Search, which began life as a GlaxoSmithKline "knowledge pool" for neglected tropical diseases, aims to share intellectual property and "know-how" related to neglected diseases, malaria, and tuberculosis.

Principal Access & Innovation Project(s)

Re:Search operates as a searchable database of information consisting of proprietary information including patents and associated "know-how" related to drugs, vaccines, and medical devices. Participants are divided into three groups: (1) providers, (2) users, and, (3) supporters. Providers are those who contribute knowledge to the pool, users are those who are granted access for research, development or manufacture purposes, and supporters are entities that neither provide or use the knowledge from the database, but wish to express their support.

Users who wish to license from Re:Search must contact the relevant provider(s) directly. However, all licenses are granted on a non-exclusive basis. Providers may withdraw their intellectual property from Re:Search at any time.

Intergovernmental Organizations

Like pharmaceutical companies, IGOs are often both actors and targets of action. Although many IGOs are involved in GAMM, this section will focus on three organizations that are especially important. Although the WTO plays a significant role in GAMM, it does not fall within

World Health Organization

Website: http://www.who.int

Background

The WHO is the organ of the United Nations responsible for human health. Its primary responsibilities include: "providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends."

Role in Access & Innovation

WHO plays a number of important roles in GAMM. From serving as a venue for important symposia to publishing standards for essential medicines, WHO is an indispensible actor in GAMM.

The WHO's most important role is that of norm-setter. Currently the most salient norm created by WHO is codified in the "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property" (Global Strategy), which was

adopted at the 2008 World Health Assembly (WHA). This rest of this discussion will focus on the relevant provisions of this resolution.

The Global Strategy identifies eight elements needed for ensuring better health outcomes: (1) "prioritizing research and development needs," (2) "promoting research and development needs," (3) "building and promoting innovative capacity," (4) "transfer of technology," (5) "application and management of intellectual property to contribute to innovation and promote public health," (6) "improving delivery and access," (7) "promoting sustainable financing mechanisms," and, (8) "establishing monitoring and reporting systems." Elements 1 – 5 are especially important to GAMM and so will be discussed further. It is important to note that this resolution was granted legitimacy through formal adoption at the World Health Assembly, at which every WHO member is given a vote.

Elements 1, 2 and 3 propose ways in which research capacity can be improved and promoted. Element 1 calls for greater research into the research needs of the developing world, with special emphasis on identifying research gaps. It also calls for an explicit policy of prioritization and for making use of traditional knowledge. Element 2 first suggests supporting national governments in efforts to expand their research capacities and form partnerships, with a particular focus on expanding the research capacity of developing countries. It also focuses on the need for greater coordination between biomedical and health research. Finally Element 2 calls on governments to promote "greater access to knowledge and technology relevant to

meet public health needs of developing countries." Element 3 outlines ways to develop and expand the innovative capacity, again focusing especially on developing countries.

Elements 4 and 5 focus on ensuring access to health-related technology that has already been developed. Element 4 focuses on improving mechanisms for technology transfer, including exploring the use of patent pools. This element also calls for use of TRIPS flexibilities to facilitate technology transfer. Finally, Element 5 explicitly calls for the use of TRIPS flexibilities, calling on governments to:

> consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003

In important language related to TRIPS-plus provisions, it also calls on governments to "take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection" than mandated under TRIPS. It also calls on governments to make use of the 30 August decision to export pharmaceuticals to countries with insufficient manufacturing capacity.

Although this resolution speaks in generalities, it has significant moral force. By providing a framework for action, and representing an international consensus on contentious issues, the Global Strategy will continue to be an important document for GAMM.

World Intellectual Property Organization

Website: http://www.wipo.int

Background

Like the WHO, the World Intellectual Property Organization (WIPO) is an organ of the United Nations. WIPO's role is "to promote innovation and creativity for the economic, social and cultural development of all countries, through a balanced and effective international intellectual property system."

Role in Access & Innovation

Largely concerned with technical issues, WIPO rarely wades squarely into the contentious policy issues surrounding access to medicines. However, its member states often debate these issues within WIPO, with much of the debate occurring in the Standing Committee on the Law of Patents. WIPO also occasionally publishes white papers outlining areas in which IP and public health intersect. WIPO also provides valuable technical advice and support to organizations working in GAMM, such as the MPP. It also hosts the Re:Search database.

The Role of the World Trade Organization

Website: http://www.wto.org/

Background

Role in Access & Innovation

Although the WTO's policies impact nearly every aspect of GAMM, WTO itself is not an actor in the movement as previously defined. Rather it serves as a forum for discussion between states. However, given the importance of the WTO's policies, a brief summary of the three most significant policies is provided here.

TRIPS

TRIPS created a set of minimum IPR standards below which national governments may not go. The two most significant provisions are a mandatory 20 year patent term and a requirement that countries to grant product patents for drugs. However, TRIPS left open significant flexibilities—for example compulsory licensing (so long as the drug was manufactured for domestic use) and the ability of national governments to set and enforce patentability provisions in national law.

Doha Declaration

The Doha Declaration reaffirmed the flexibilities contained in TRIPS and called for a solution to the problem of compulsory licensing for countries lacking sufficient manufacturing capacity. It also allowed each country to create its own laws surrounding patent exhaustion "without challenge."

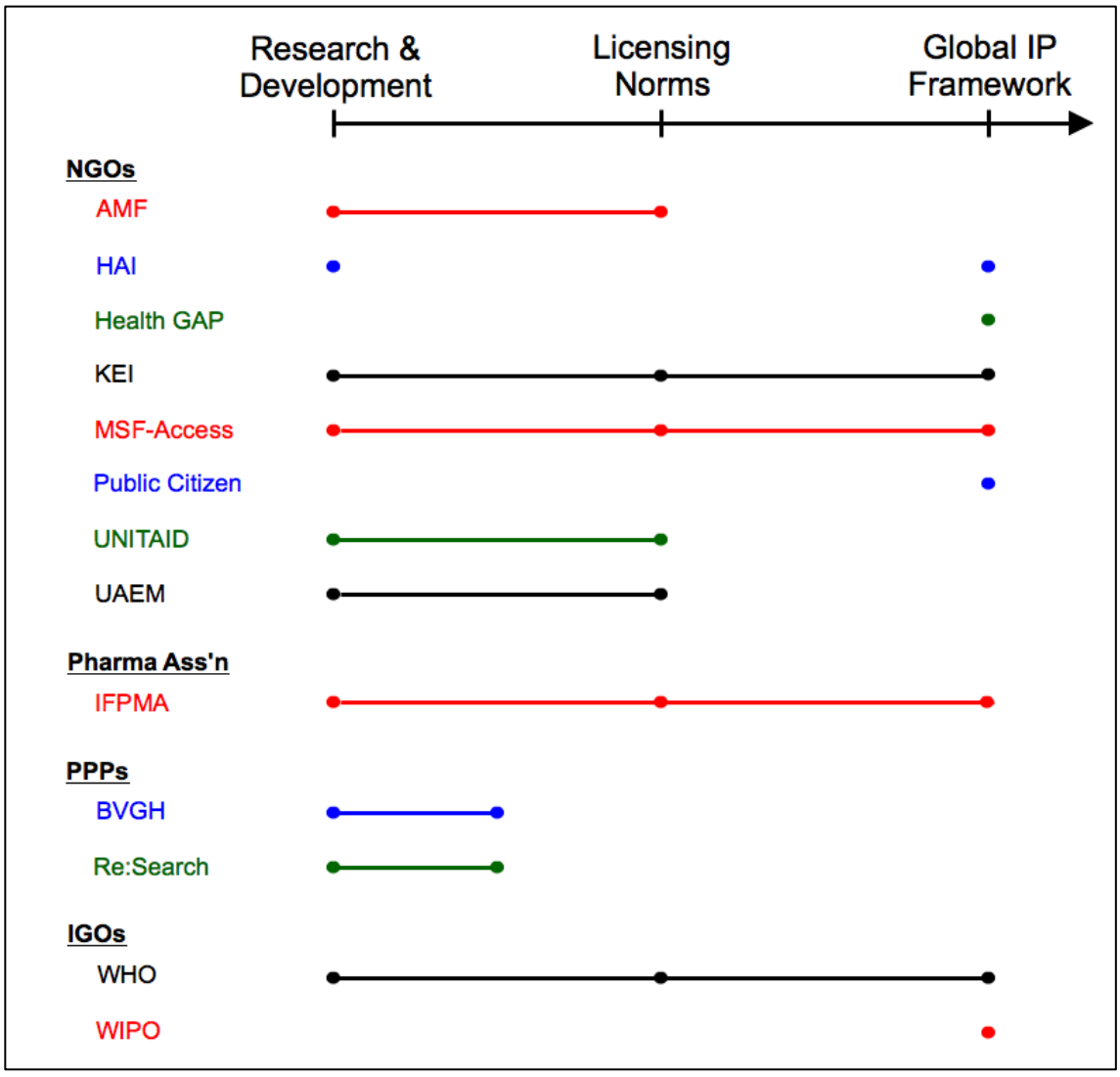
August 30 Decision

The 30 August Decision constituted the resolution of the question of compulsory licensing for countries lacking sufficient manufacturing capacity. The TRIPS Agreement had allowed compulsory licensing only for domestic consumption, but this rule was waived by the 30 August Decision, subject to certain restrictions. In 2005, the waiver was made permanent, although the amendment has never entered into force.

Summary

The following chart (see Figure 2) provides an overview of the organizations involved in GAMM and their primary areas of focus. Most actors are involved to some degree in all three areas; however, this chart captures only those areas at the core of the actor's work.

Figure 2: Map of Selected GAMM Actors



Conclusion

GAMM has achieved a great deal in the past 18 years and continues to evolve. The number of actors involved continues to increase in both number and diversity. PPPs are becoming increasingly important players as NGOs and IGOs realize the importance of pharmaceutical industry collaboration, and access and innovation for neglected diseases are gradually placed on pharmaceutical companies' agendas.

Increasing collaboration is essential if GAMM is to successfully face emerging challenges and exploit new opportunities. As the movement expands, it is becoming clear that every aspect is interdependent. By defining the movement and mapping and describing GAMM actors, this project aims to become a tool for increasing collaboration and for introducing new actors to the movement.

Further research is needed to use the mapping of actors to identify areas in which the movement is able to coordinate, and those areas in which coordination fails to occur. Understanding these coordination failures and their causes is crucial to creating a unified, coherent movement that maximizes its efficacy.

The Global Access to Medicines Movement has been notable for its fluidity and rapid change. This document offers a snapshot of GAMM as it exists in April 2012. For it to be a truly useful document over the long term, it will need to become a dynamic resource. The website map (Figure 3, *infra*) offers a suggested structure for

converting this document into an electronic resource that can be updated and expanded as the movement inevitably evolves.

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Appendix

Figure 3: Website Map