Whose rights matter? When patents stand in the way of access to medicines.

Portfolio Review prepared by Roxana Bonnell and Els Torreele
PHP Access to Medicines Initiative (AEMI)
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I. Defining the portfolio

The Public Health Program (PHP)'s access to medicines work began in 2007, with the funding of a few exploratory grants. The efforts were boosted in 2009 with the hiring of a director for the access to essential medicines initiative (AEMI). In 2010, in consultation with key players in the field, a new AEMI strategy was created for 2011-2014, with the following three objectives and focusing on developing countries:

1. To improve access to essential medicines at country level by making better use of the existing legal and policy frameworks.
2. ***Push back on emerging national and international policy and legal frameworks that hamper access to essential medicines, while promoting laws, policies and practices that protect public health and safeguard access to medicines.***
3. Foster new thinking and action on needs-driven pharmaceutical innovation, including access for the global south.

This portfolio review will focus on the second objective and look at grants and operational activities from 2010-2014 (annex 1a,b).

AEMI's strategic approach reflects the overall assumption behind PHP's access to medicines work, which is that while the long term solution to the chronic access to medicines crisis can only be addressed through a fundamental transformation of our medical innovation system (objective 3), there is a need on the short-medium term to preserve and broaden the policy space available for countries to increase affordable access to essential medicines, in particular in relation to intellectual property (IP) rights (objective 2), and ensure their effective implementation (objective 1).

As was laid out in a position paper presented jointly by PHP and the Information Program to the OSF global Board in June 2011 (Annex 2), IP rights are an important open society issue because they govern the ownership and control of knowledge. IP rights can serve to enable affordable access to information and ensure continued creativity and innovation or, alternatively, deny, delay, or distort access to knowledge and knowledge-based goods. IP rules determine the availability and price of vaccines, diagnostics, and medicines, as well as access to textbooks, research journals, tools, and data. OSF's interest in IP rights is motivated by concerns about the direction in which the global IP regime has evolved over the last two decades, in particular:

- A growing imbalance between the rights of IP holders and the public interest.
- IP policies that do not adequately address the interests of poorer countries.
- Deficiencies in transparent and democratic decision-making.

II. The Lay of the land in 2010

The defining international legal framework on intellectual property rights is the World Trade Organization's Trade Related aspects of Intellectual Property Rights (WTO-TRIPS) agreement, which came into force in 1995. Notwithstanding certain transition periods for low and middle income countries, all WTO members have had to extend the duration and scope of patent protection to the standards requested by industrialized nations, including 20-year patents on pharmaceuticals. By 2005, nearly all countries with pharmaceutical manufacturing capacity had adopted TRIPS-compliant domestic IP legislation which largely curtailed their capacity to produce and supply generic versions of new and patented medicines. This also included India, dubbed the "pharmacy of the developing world", on which most low and middle income countries had come to rely as a source of affordable medicines, thanks to its flexible IP regime that gave rise to a vibrant generic industry.

In the late 1990s and early 2000s, realizing the potential detrimental impact of IP on public health, and in particular on access to life-saving HIV medicines, AIDS activists and developing country governments successfully pushed back on even further extension of patent protections at WTO and WIPO (the World Intellectual Property Organization), through efforts which resulted in the Doha Declaration on TRIPS and Public Health and the WIPO Development Agenda. The 2001 Doha Declaration stated that *the TRIPS agreement 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*. Specifically, it referred to so-called TRIPS-flexibilities, legal provisions available under TRIPS, which countries can use to enable access to patented inventions, for instance compulsory licensing.

Unfortunately, nearly 10 years after the Doha Declaration was signed, and with all except the least-developed countries fully adopting TRIPS, it was becoming clear that Doha was not delivering on its intent to protect public health. Intellectual property protection and monopoly pricing were increasingly becoming the key barriers to access to medicines, especially in middle income countries. Countries were openly and covertly pressured against the use of TRIPS-flexibilities (as painfully confirmed by Wikileaks), while various tactics were deployed to compel countries to accept more extensive IP protections and enforcement rules than required under TRIPS, referred to as TRIPS-plus provisions. Monopoly pricing and the resulting access challenges in particular impacted access to newer medicines such as 2nd line AIDS drugs, and those for treating cancer and hepatitis C as well as new formulations of existing medicines that would facilitate their use in resource poor settings (eg fixed dose combinations, heat-stable formulations, or pediatric forms).

Compared to the previous decade, the access to medicines movement in 2010 was a weakened and aging one, struggling to keep pace with these new, emerging policy threats. Since the successful price decrease of the first generation AIDS medicines, treatment activists including the historically strong civil society groups in Brazil, India, Thailand and South Africa shifted attention and energy to other challenges related to scaling up HIV treatment and literacy, including discrimination and poorly functioning health systems. And while major progress had been made to increase affordable access to AIDS drugs, for many other diseases the access to medicines challenge had remained unchanged.

Meanwhile, the global pharmaceutical industry lobby, along with the US, EU and Japanese governments protecting their interests, continued looking for ways to limit the impact of treatment activists' success and get stronger IP. In particular, they began pursuing IP enforcement mechanisms that would shift the responsibility for the protection of corporate and private IP "rights" from the IP holder to governments, by criminalizing IP infringements. This was the most

important emerging policy threat in 2010 as it sought to impose TRIPS plus provisions globally and went along with a “forum shifting”, shifting negotiations on IP enforcement rules from multilateral platforms like WTO and WIPO to a burgeoning number of less scrutinized bilateral or regional trade and investment agreements, and anti-counterfeiting legislation. Among the highest profile ones with potential impact on medicines access are: the EU-India Free Trade Agreement (EU-India FTA), the Anti-Counterfeiting Trade Agreement (ACTA, spearheaded by US, EU, and Japan with seven other countries), the Transpacific Partnership (TPP) agreement spearheaded by the US (with Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam), the East African Community Anti-Counterfeiting Trade Agreement, and most recently the Transatlantic Trade and Investment Partnership (TTIP) between the US and the EU.

With the globalization of patent rules and the increased focus on enforcement, mechanisms once used for achieving price drops for the first generation of AIDS medicines (i.e. generic production where patents did not apply) were no longer available, but the activism had not strategically stepped up to this challenge. In 2010, only a few civil society groups were still mobilized around actual access to medicines issues, and these were mostly international groups focusing on global policy issues at the World Health Organization (WHO), WTO and WIPO. At the national level, most civil society organizations were small, community-based, and poorly equipped to tackle access issues, which were perceived as too technical and complex. Most of the advocacy continued to focus on AIDS drugs, a continuation of earlier efforts, with limited global attention or traction. Importantly, several donors had also pulled out. Ford, MacArthur and Rockefeller Foundations that were instrumental in the first wave of access to medicines activism during the late 1990s and 2000s no longer funded IP-related work.

III. How we envisioned change happening, and what we supported

Firstly, because the access to medicines movement was strongly focused on AIDS treatment and had lost its focus, traction and leadership (especially as it concerned IP-related challenges), we considered it critical to start moving the access to medicines discussions beyond HIV-medicines. In addition to supporting, and possibly re-invigorating existing allies, we wanted to identify new partners and potential new access activists in other areas (which would include an effort to build more technical capacity). These included transparency groups, human rights groups interested in corporate responsibility, harm reduction groups and patient groups from other disease areas (eg non-communicable diseases like cancer).

Secondly, we choose to focus efforts on a small number of high profile agreements and negotiations involving the EU and the US, exposing how some of the specific provisions these powers are pushing for would have a detrimental impact on affordable access the medicines worldwide. These included various types of extensions of the monopoly rights, as well as mechanisms through which corporations can sue governments for introducing policies that would harm their investments (including health-promoting policies). The lack of transparency and democratic oversight displayed through the highly secretive negotiations was another area of attention.

Our overall theory of change to counter the TRIPS-plus and IP enforcement agenda was that a combination of civil society pressure at the global level, with targeted advocacy in key middle income countries like India, Brazil, Thailand and South Africa, would result in multiple and strong voices that could raise awareness of the dangers of the IP enforcement agenda to access to medicines, and serve as an effective push back against it.

Specifically, we believed that:

1) Support to global activists would highlight and seek to reverse the negative actions of the US and EU governments, heavily influenced by the pharmaceutical lobby, to build ever higher patent protections on medicines;
2) Support to national level advocates in middle income countries in which the access challenges related to monopoly pricing were most pronounced would build outrage, leading to (re)engagement and (re)commitment of political leadership in those countries to put in place needed legislation promoting increased access to medicines, and push back on demands that would negatively impact access;
3) Documenting the negative impact of the policies and using this evidence for advocacy purposes, as well as exposing the ways in which the pharmaceutical industry exerts its influence on policy making, which often leads to unaccountable, non-transparent decision making and corrupt systems would contribute to swaying policy makers to oppose the IP enforcement agenda;
4) Building a new generation of access to medicines activists, and broadening the movement beyond HIV, was essential to achieving both short and long term impact.

AEMI considered its main tool to be strengthening and amplifying civil society's advocacy to push back on the IP strengthening and enforcement agenda, which included in some cases that civil society experts provide direct advice to (developing country) governments. While we did not distinguish "fealty" versus "concept" at that time, we consider our approach to be a combination of both.

Pursuing this goal, we supported a small number of well-established civil society organizations ("fealty" organizations: KEI, TACD, IP-Watch, Lawyers Collective, Public Citizen, HAI-Europe, TWN, CEHURD, TAC – see annex 3 for more details), several coming out of the HIV/AIDS movement and often working at a global level. These groups had been advocating around IP and access to medicines for years, and had been among the first to point out the threats of the IP enforcement agenda beyond HIV. In fact, most of these groups are not only advocating for access to medicines but have a much broader vision on balancing IP in the context of global development and medical innovation, and/or were concerned about the transparency and accountability of global (IP) policy making. This means that only a portion of our grants have supported countering the TRIPS-plus and IP-enforcement agenda, as several of these groups are also spearheading a broader access to medical innovation agenda (as does AEMI). Moreover, several of these grantees were co-funded with the Information Program, whose copyright reform portfolio also aims at pushing back against overly aggressive IP enforcement regimes, which are being pursued through the same trade agreements.

Complementary to the fealty grants, AEMI supported capacity strengthening and policy advocacy through project grants in a number of mostly middle income countries where civil society and/or our National/Regional Foundation Partners expressed interest to engage on these issues (see annex 4 for more details). This included supporting existing allies and identifying and building the capacity of new partners in Brazil, Argentina, Peru, Thailand, Vietnam, Burma, South Africa, India, East Africa in particular Uganda and Kenya (with OSIEA), Kyrgyzstan (with SFKg), Kazakhstan (with SFK), and Ukraine (with IRF).

In addition to technical assistance to grantees (provided through OSF staff or consultants), we engaged in a series of broader capacity strengthening efforts. For instance we supported several short courses (1-2 weeks) on Human rights, Intellectual Property and Access the Medicines organized by Law Faculties at three African Universities and targeting lawyers, activists and civils servants. We also held several civil society training and strategy workshops on access to

medicines which included technical and advocacy training on IP and IP enforcement, and we piloted an access to medicines fellowship program in which six individuals from the EECA were coached for 18 months to become activist leaders in the field of access to medicines. While in the EECA region, access to HIV treatment barriers were largely not IP-related, access to expensive hepatitis C treatment was identified by health activists as a huge concern as early as 2009. For that reason, the training and related grantmaking in the EECA region focused to a large extent on hepatitis C treatment access barriers, which became the basis of a growing international of hepatitis C treatment activism movement.

Critical partnerships in the efforts to push back on the emerging threats, while also promoting the law reform needed, included joint efforts with UNDP, Médecins Sans Frontières (MSF), OSF national/regional foundations and the Information Program. With UNDP, AEMI organized policy workshops with decision makers in Kenya, Uganda, Tanzania, Kazakhstan and Ukraine. MSF was a key thought and advocacy partner at the global level, and mobilizer for some of the country level efforts through its local offices in South Africa, India and Brazil. OSF national/regional foundations played a key role in identifying partners on the ground, co-funding and monitoring the grants, while also helping to outline challenges and opportunities to the policy agenda. The Information Program served as a thought partner and co-funder in strategy and activities, mostly at the global level (and with fealty grantees).

IV. Our progress and challenges

We have seen a degree of progress resulting from our efforts over the past five years:

- Civil society has successfully influenced key language and provisions in the EU-India FTA and the TPP drafts (neither have been finalized), helping to ensure these agreements safeguard space to protect access to medicines. Additionally, much of the IP enforcement agenda has been stalled, with the European Parliament voting against ACTA in 2012, and East African governments pressured to revise problematic proposed enforcement provisions.
- Patent law reform efforts in South Africa and Brazil and reform implementation in Argentina and India have also seen important steps forward. Even in Kyrgyzstan the IP law reform was recently passed into law by Parliament (Jan 2015).
- Civil society collaboration looks different today. The movement has moved beyond an HIV/AIDS focus to include advocacy for overcoming IP/price barriers for access to Hepatitis C medicines, as well as to cancer drugs and the new biological medicines. Increased attention to these very expensive medicines has reinvigorated the movement, introducing a renewed sense of urgency. We also see that some groups have started to reach out beyond medicines and health, to forge important partnerships with groups, such as trade watch activists and consumer advocates.

The progress is certainly significant and has delayed, and in some cases stopped, harmful processes that would have further impaired access to medicines. We also believe that the groups we have supported were by and large the right ones, with a few notable exceptions (e.g. HAI-Africa, SEATINI, APN+, University of Pretoria –mainly because of a lack of capacity and commitment). Yet the IP environment remains threatening and very challenging for medicines access. We are winning some battles, but a question we ask ourselves is whether we are making enough progress in the bigger picture. Key challenges for us over the last five years have included:

- *Limited strategic long term vision and, in some cases, poor leadership within civil society.* Work in this portfolio continues to put activists in a reactive mode. There are many concomitant threats, and in particular in the case of trade agreements, the power imbalance between well-resourced trade negotiators and corporate lobbies versus a thinly spread civil society that scrambles to keep up with the rapid pace of the secret negotiations puts them at a constant disadvantage. Activists are always moving to put out the latest fire in the ongoing negotiations, meaning that much less time and attention can be paid to getting out in front of the action, to create a proactive strategy. Several organizations have not recovered from much of their intellectual leadership leaving and/or moving into other positions over the last ten years. In part linked to the highly technical nature of the legal work, the ability of groups, both new and old ones, to engage politically and frame the IP-battles into a broader political ecology, remains weak. This was particularly evident in our grantmaking in Brazil and in the EAC region. Our support for training and technical assistance hasn't been as pivotal as hoped in strengthening and building new confident leadership and strategic capacity, including political skills. The movement, even if small, is also somewhat fragmented, with the leading organizations each setting out their own priorities, not necessarily agreeing to a joint overall strategy. Our efforts to catalyze such joint priority setting have not been particularly successful.

- *Many of the organizations we support remain institutionally weak.*

  Part of the problem is lack of management skills and/or acknowledgment of the importance of developing a stronger organizational basis, confounded with a severe dearth of funding. Over the last five years, OSF has been the sole funder of the IP-related work for many of the grantees (they sometimes have other donors funding other activities related to access to medicines, but not IP). We have heard from many grantees that it is hard to find time to plan strategically or focus on institutional strengthening, when staff, including campaigners, have to spend much of their time fundraising. AEMI, sometimes in collaboration with the Information Program, funded fundraising assistance or organizational strengthening to some of the grantees (e.g. KEI, IP Watch, HAI-Africa, ABIA), with little resulting. TAC in South Africa is another critical organization in funding crisis.

- *Creative partnerships in this space have been difficult to identify.*

  Our challenge is that many potential partners are either influenced directly or indirectly by the pharmaceutical industry lobby (e.g. bilateral development cooperation donors such as DFID and EU-DG-Dev and many patients groups, in particular in the field on non-communicable diseases), have an agenda to promote the use of IP and set global standards (WIPO), fundamentally believe that market forces and IP are the key drivers of innovation for needed medicines (the Bill & Melinda Gates Foundation), or have a clear approach to steer away from all IP related work (the Global Fund for AIDS, TB and Malaria and the Clinton Health Access Initiative). Since the establishment in 2006 of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), the World Health Organization (WHO) has developed reports and action plans to address the health innovation crisis, yet most observers doubt whether this process will ever get sufficient traction to move the needle on the current IP-framework as it relates to health.

  We did proactively reach out to a number of new potential partners, including human rights and transparency groups. In 2012, seeking to expose pharmaceutical industry marketing and lobbying practices and its consequences on medicines access, we spoke

to a number of corporate responsibility (CR) groups utilizing human rights mechanisms to hold corporations to account. We wanted to understand if there was potential interest and traction to include a focus on pharmaceutical industry behavior in their ongoing efforts. These groups were hesitant to take on the pharmaceutical industry, noting that the public sees the industry as a good corporate actor that delivers promised cures, making advocacy very difficult. They also pointed out that human rights mechanisms did not provide ways to penalize corporations, making it easy, especially for transnational companies to gain legitimacy by engaging in selected CR actions (e.g. drug donations, nominal price reductions), without actually changing any behavior and in fact undermining efforts to address the health innovation and access problem at a more fundamental level. Overall it has remained difficult to find a productive angle to use the human rights frame to overcome IP barriers and advance access to medicines beyond rhetoric and highly critical reports (eg the 2013 Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines).

We also explored partnerships with anti-corruption groups, as we knew that medicines procurement processes, because of high and elastic medicines pricing, are prone to corruption. However, a strategic convening bringing together medicines and anti-corruption activists from Ukraine, Kenya and South Africa did not lead to the hoped for cross-pollination. We also partnered on various occasions with UNDP, particular in East Africa and EECA and more recently also in Burma. The main challenge with UNDP, whose HIV/AIDS unit has been quite vocal on the need to use TRIPS-flexibilities and counter TRIPS-plus, was to motivate their thinking, involvement and commitment beyond convening one-off meetings to longer term efforts to influence decision making.

- *Exposing the health impact or the conflicts of interest around the IP enforcement agenda does not suffice to alter the power dynamics that dominate this policy area.* While several grantees (and other partners, including academic groups and high level commissions such as WHO's IGWG) have documented time and again the negative impact of increased IP protections on people's access to medicines and government budgets, or exposed how the pharmaceutical lobby is exerting direct pressure on IP-related policy making and implementation, this evidence does not naturally translate in more public interested oriented policy making.
- *Difficulty to sustain attention and momentum in relation to trade agreements and legal reform.* Most of the negotiations and reform efforts discussed in this review have been going on for five or more years. Human and financial resources are stacked against health advocates. The pharmaceutical industry lobby is one of the better organized, most strategic and wealthiest, able to outspend and outstaff access activists at every turn. Trade negotiators and IP policy makers are not typically knowledgeable or interested in health or medicines issues, and health policy makers are generally not at the table of these discussions. Trade delegations are huge, the negotiated texts highly technical, cumbersome and wide-ranging, and negotiations are shrouded in secrecy, making getting even basic details highly problematic and time consuming. Activists struggle to continue high level engagement over the years it takes to influence the outcome.

V. Lessons learnt and reflections moving forward

1. The biggest challenge we continue to face moving forward is striking the right balance between supporting the long term solution to the access to medicines crisis, which is a

fundamental transformation of our medical innovation system, with the shorter term goal of preserving national level IP policy space to increase affordable access to essential medicines as highlighted in this portfolio review (and promoting more efforts to actually make use of them). We believe continued action on a couple of fronts in preserving and broadening policy space will remain important.

- India has been at the forefront of the access to medicines battle, having been one of the rare countries to adopt many of the pro-public health flexibilities allowed under WTO TRIPS. India has used these safeguards, for instance, implementing stringent patentability criteria to avoid evergreening, as in the case of the cancer drug imatinib (Gleevec®), and through issuing a compulsory license to overcome abuse of monopoly rights, as in the case of the cancer drug sorafenib (Nexavar®). In the EU-India FTA negotiations, Indian government officials managed to withstand EU pressures and preserve these safeguards. The Indian supreme court, after years of legal battle between Novartis and patient advocates (represented by the Lawyers Collective) also upheld the denial of a patent on imatinib, thereby confirming the legality of the anti-evergreening policy framework. Recent events in India, however, are concerning with Prime Minister Modi indicating his willingness to rethink India's approach to IP, under pressure from the US and business groups on both sides. A high level joint US-India working group on IP has been established after Modi's visit to the US in November 2014, and more recently a government committee has been formed to review India's IP policy and make recommendations on IP reform. The committee's work will need to be closely followed, evaluated and reacted to.
- The US-EU trade and investment agreement, TTIP, also deserves special attention and monitoring, as it is expected to further regulatory harmonization in various fields of importance to medicines, including IP protections and price regulation, and will again seek to create a new global standard for all future trade agreements. Another highly contentious issue is the probable inclusion of Investor State Dispute Settlement (ISDS) mechanisms, which would allow companies to sue governments for introducing policies that would harm their investments. TTIP does offer the opportunity to more strategically partner with transparency groups that challenge the secrecy of these negotiations, including pointing out that members of the US Congress and of the European Parliament do not have access to the negotiating texts (in an unprecedented move in response to such pressure, the European Commission published a draft text in January 2015).
- The current struggles around accessing the new hepatitis C medicines provide an excellent example of the key importance of preserving space within the IP regime for access to medicines, and elevate access to medicines from a problem of poor people in developing countries to an issue that concerns us all. We will want to continue to support civil society utilizing TRIPS flexibilities options, such as patent oppositions and compulsory licensing around these medicines, specifically tying those efforts to advocacy around the ongoing IP patent reform and the trade negotiations, as well as the need for new innovation models.
- Given Brazil and South Africa's unique history and special role in access to medicines advocacy, IP reform efforts in both countries will need continued support. Getting progressive legislation in place and implemented in either country, would serve as a powerful example for other middle income countries, significantly boosting civil society advocacy efforts and progressive government plans. Adopting these reforms and applying them to increase affordable access to the new hepatitis C drugs would be a powerful case in point.

2. We have spent a lot of time contemplating civil society's role and capacity in this field and how best to strengthen and support it. While we would have liked to see even greater strategic vision coming out of the grantees, including more diverse collaborations (eg with transparency groups, with other patient groups), we recognize that repopulating and growing a movement takes time, and that capacity is strengthened over time through experience and partnership. Some aspects of capacity we continue to think about include:

- While some technical expertise is undoubtedly needed, we have found that in these ultra political environments, it is not the technical arguments that make a difference. The position of many negotiating teams and government officials is seemingly pre-determined, and ideologically-driven, no matter the evidence presented. Given this situation (and building on the feedback which we received from the corporate responsibility groups mentioned above), we have started to refocus some of our training and grant support efforts to work more upstream and engage in changing the overall narrative and framing around medicines pricing and innovation, rather than more training on technical IP issues. In this line of work, we want more people to question why medicines are so expensive, and why the pharmaceutical industry is not producing the medicines we need (despite even increasing IP protections), leading to louder and broader demands for governments to take clear action to ensure health needs-driven medical innovation that leads to affordable priced medicines that are generally accessible. Again, the extremely expensive hepatitis C medicines are a clear mobilizing factor in this respect, especially in Europe.
- The question of how to support grantees to be more politically strategic and confident remains a big challenge, and one that we don't have a clear answer to. What we learned from the fellowship project we piloted, the organization of the EECA annual courses, as well as some of the activities in Latin America, is that a particularly effective approach is peer to peer learning. We actively seek to incorporate more peer to peer exchange in our future work. In addition to this, some OSF national/regional foundations recognize the challenge civil society has in operating more politically across their programming efforts, and are starting to initiate some thinking on ways to address this, as well as facilitating advocacy linkages across the social justice spectrum, and we look forward to engaging more on this.

3. We recognize the importance of cultivating more strategic partnerships for our work, including at the donor level. This is an area we didn't prioritize as highly as what we should have over the last five years. This was partly because it is a complicated, challenging environment, with few obvious allies. And probably also because our ambitions overall in AEMI outweighed our capacity to engage.

- Donor partnership has been non-existent in this field. The three big foundations funding IP related efforts previously, withdrew in late 2000s for reasons that at least in part seem to have related to the controversial nature of challenging IP (in the business world). Over the last five years, OSF has largely been the sole support for civil society efforts to preserve and broaden the IP space for access to medicines (in addition to MSF's own advocacy in this space, and with whom we partner strategically). The recent attention to access to hepatitis C medicines has brought a couple of new potential funders into the arena, including the AIDS Fonds and UNITAID. UNITAID, within its market dynamics framework, recently started supporting civil society efforts to advocate for and utilize TRIPS flexibilities as an additional way to help shape markets. While it is good to see some of our grantees receiving additional funds, it is not yet clear what UNITAID hopes to see as an outcome of this (uneasy?) coupling of market dynamics and TRIPS flexibilities,

and for the moment these efforts remain limited to HIV/AIDS drugs. In an initial scoping, it has proven challenging to think of what other donors to potentially approach, and how to frame the issues to speak to them (if not IP, maybe the innovation angle? Or medicines prices?). Human rights donors have not traditionally engaged on access to medicines, beyond HIV/AIDS discrimination issues. In a recent AEMI team retreat, we discussed our lack of engagement with donors over the last years, and confirmed the importance of prioritizing cultivating donors as we move forward.

- Possible alliances with transparency groups, in particular in relation to holding corporations to account, remain an area of interest that deserve further exploration, including within OSF (for instance, OSEPI, OSJI (anti-corruption), the Fiscal Governance Program)
- We are interested in creating new thought leadership and close allies in academia and the think tank world. To foster new thinking on medical innovation, we have reached out to economists, to help highlight the economic reality and cost inefficiencies of the current medicine innovation model. A small meeting is planned with leaders in the field in the first half of 2015.

V. Questions we continue grappling with

- What is the right balance between fighting the defensive agenda of pushing back against the continued expansion of IP rights to safeguard policy space to increase access to medicines on the short term, versus the longer agenda of reforming the medical innovation system (knowing that the alternatives are not yet well-defined). What questions should we be asking ourselves to help us get to the right balance?
- Which strategic civil society (or social movement) partnerships should we prioritize in broadening the field?
- Are there additional/different approaches to strengthening civil society strategic (political) advocacy capacity on these issues that we have not yet considered and should?
- Should we (have) engage(d) more on this issue with global institutions such as WHO, WTO, WIPO, the World Bank, the Global Fund for AIDS, TB and Malaria, UNITAID, etc? Are there others worth considering?