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The Implications of the Medicines Patent Pool and Gilead Licenses on Access to Treatment

Briefing Paper

On 12 July, 2011 the Medicines Patent Pool (MPP) and Gilead Sciences, Inc. (Gilead) announced they had entered into a licensing agreement to improve access to anti-retrovirals (ARVs) and Hepatitis B (HBV) treatment in developing countries.

After analysing the licenses, ITPC[1] and I-MAK[2] believe that within the broader context of reforming the patent system under the trade agenda, the outcome is a serious setback for the global movement on access to medicines.

We also believe the terms agreed by the MPP raise grave potential for a conflict of interest over its role as an independent arbiter for increasing global access to medicines.

While we appreciate and respect the efforts of UNITAID and the MPP to improve access to medicines, we are duty bound to raise our legitimate and serious concerns about the process, terms and implications of the agreement between the MPP and Gilead.

Our demands for resolving the issues arising from this matter are included at the end of this note.

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[1] The International Treatment Preparedness Coalition (ITPC) is a global network of community organizations, local NGOs, researchers and activists united to promote access to treatment for people living with HIV.

[2] The Initiative for Medicines, Access & Knowledge (I-MAK) is a team of lawyers and scientists increasing access to affordable medicines by challenging unmerited patents, increasing patent transparency and reforming the patent system.

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Summary of Key Issues:

- Exclusion of civil society and PLHIVs from the negotiation process and analysis of agreements resulting in an assumed 'global mandate'.
- A serious conflict of interest issue, namely the 5% fee to be paid by Gilead to the MPP for identifying licensees and administering the licenses;
- The MPP has effectively enabled and validated new uses of known products leading to the potential weakening of stricter patentability criteria in countries like India;
- The requirement of royalties to be paid on any new uses of existing products, even where patent rights do not exist;
- The introduction of a 'global patent system' – even though Gilead does not appear to have patents for TDF in almost every country in the license, through this agreement they can extract rents without such rights;
- The exclusion of middle-income countries with high HIV/AIDS populations from the licenses;
- Gilead's control of active pharmaceutical ingredient production;
- Licenses only granted to manufacturing entities in India;
- Restrictive conditions governing the ability of licensees to supply non-licensed territories under a compulsory license;
- The transfer of know-how and technology under the license mirrors the earlier TDF licenses, thereby raising questions over the quality of the technology transfer;
- Royalty free grant back licenses to Gilead for any improvements made by licensees to API or licensed products.

Our Key Demands:

- The Patent Pool Governance Board and Expert Advisory Group (EAG) censure these licenses as not being a significant improvement to the status quo;
- A moratorium must be placed on current negotiations with Bristol Myers Squibb and Boehringer-Ingelheim until a broad technical consultation is held with representatives for the affected communities to discuss the future and reform of the MPP's mandate;
- An explanation from the MPP on the conflict of interest issues resulting from the payment terms agreed between the MPP and Gilead;
- The EAG should comprise civil society lawyers with expertise in IP issues and PLHIVs who act in the interests of patients on issues of access to medicines;
- To improve transparency and accountability of the MPP, updates of future negotiations and draft license agreements should be shared with interested civil society for comment and consensus building before any license/agreement is approved.

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On 12 July, 2011 MPP announced an agreement with Gilead for licensing its antiretroviral (ARV) drugs, tenofovir disoproxil fumarate (TDF), emtricitabine (FTC), elvitegravir (EVG), cobisitat (COBI) and a combination pill comprising all four drugs known as the 'Quad'. UNITAID, as the main funder of the MPP, welcomed the deal. However, what has largely gone unnoticed is that Gilead appears to have simultaneously, and separately, extended the licenses agreed with the MPP to four existing licensees for TDF - Ranbaxy, Matrix, Strides and Hetero. [3] Since the MPP has yet to add any new generic licensees, this raises important questions over the future role of, and the existing need for, the MPP.

The media, following the press announcements by the MPP, has largely reported the agreement between Gilead and the MPP as an important and positive step for resolving access problems to ARVs. The White House's Office of Science of Technology Policy has issued a statement supporting the licensing agreements. On the civil society side, there has been a reaction of applause and disappointment. A statement by the Thai Network of People Living with HIV/AIDS felt the agreement between the MPP and Gilead was 'one step forward and two steps back'. The Latin-American civil society groups were frustrated at being excluded from the licenses after having lent previous support to the MPP.

The MPP released a detailed Q&A about the Licenses and the gains they claim will ensue.[4] But what do the licenses really say?

Analysis of the Licenses

After analysing the licenses, ITPC and I-MAK believe that the deal struck by Gilead and the MPP is a serious setback to the global access to medicines movement, especially within the broader intellectual property (IP) and trade policy context. Equally significant, we believe the terms agreed by the MPP raise the potential for a grave conflict of interest over its role as an independent arbiter for public health and access to medicines for people with HIV and Hepatitis B.

The following terms of the licenses are of particular concern:

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[3] See *Gilead Expands Access Program for Medications in the Developing World*, 12 July 2011 available at http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle&ID=1584101&highlight=

[4] The Medicines Patent Pool/Gilead Licenses, Medicines Patent Pool at http://www.medicinespatentpool.org/content/download/490/2895/version/1/file/The+Medicines+Patent+Pool+Q%26A+Gilead+Licences+Final.pdf

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Conflict of Interest:

In the Agreement between Gilead and the MPP, for the MPP's effort in identifying new licensees **and** administering the licenses entered into with generic manufacturers, Gilead has agreed to pay the MPP 5% of all sublicensee revenue up to a maximum of $1 million dollars per year.

This arrangement with Gilead raises a serious conflict of interest, particularly concerning the ability of the MPP to be impartial when negotiating licenses for the betterment of public health. It also suggests, whether intentionally or not, that the MPP is essentially an **agent**, receiving a 'finders-fee' for attracting new licensees, and doing Gilead's bidding.[5] One such targeted licensee is CIPLA, a company that has to date refused to enter into licenses with Gilead, preferring to successfully challenge its patents.

In the past, where civil society organisations around the world (e.g. Thailand, U.S, South Africa and Brazil) acting on behalf of PLHIVs have sought to increase access to medicines by pushing for licenses through legal action or a compulsory license application, they have done so without financially benefiting themselves or taking an 'administrative fee' from the pharmaceutical company in question.

This form of financial incentive discredits the MPP, and in our view affects the trust of the communities we work in. It also means that patients will inevitably have to swallow the increased prices elsewhere on Gilead products (where generics are not permitted) as Gilead looks to recoup this expense. This will likely happen in the middle-income countries excluded from the licenses. Using the MPP as a 'trojan horse', Gilead is strategically attempting to gain favour in the public health world and in India to ensure its patents are granted.

We are also concerned that many organisations have chosen not to publicly raise concern about this clause in the Agreement for fear of offending colleagues at the MPP as well as highly respected officials at UNITAID. This is particularly so given that the UNITAID Patent Pool Initiative Implementation Plan of 2009, which was approved by the Executive Board, recommended that rather than operate on a 'fee-for-service' model the patent pool be *"fully-subsidized for establishment, on-going*

[5] Such a relationship is arguably contrary to the terms of the Gilead and MPP Agreement (see Section 9.1).

annual operations and future scale up."[6] The decision of the MPP to accept a 'fee-for service' model with Gilead -- and for UNITAID to accept this model -- despite appearing to be fully subsidised by UNITAID requires some explanation. [7]

We raise this as a legitimate question concerning the judgment of the MPP and UNITAID in light of the approved implementation plan and the MPP's position as a non-profit organisation created to defend the global demand for more affordable access to medicines.

New Uses of Known Products Permitted:

In relation to elvitegravir (EVG) and cobisistat (COBI) the terms of the licenses state that they will cover these products for **any use** that is consistent with the label approved by the FDA, or any use another regulatory agency approves these drugs for.

This provision is broad enough that should either of EVG and/or COBI be approved for a second use, such as Hepatitis C (HCV) or tuberculosis (TB), licensees will still be bound to pay royalties to Gilead for such use – the cost of which would be borne by patients and public health programmes. It means any subsequent patents on new uses of EVG and COBI would extend the term of the licenses.

With respect to TDF, the license extends royalty payments by licensees for its use in relation to HBV. Although the patents for TDF in relation to HIV also claim utility in relation to HBV, thereby not necessarily requiring any additional new use patents, the issue of concern is that the MPP allowed for royalties to be paid on such a second therapeutic use.

In the bigger picture, this means that the MPP has accepted new uses of these known products. As a result, ***the MPP has effectively validated new use patents*** for all other companies that might enter the pool, or set a precedent for doing so, going against the very policy of using TRIPS flexibilities advocated by public health IP commentators, the World Health Organization/UNAIDS, organisations that represent people living with HIV/AIDS and People Living with HIV/AIDS around the world (PLHIVs).

This outcome poses a significant problem if one considers other scenarios, e.g. with other candidates for the patent pool. For example, Abbott Laboratories has a patent

[6] UNITAID Patent Pool Initiative – Implementation Plan, November 2009, page 61. It is worth noting that despite the transparency policy of the MPP, the implementation plan was never made publicly available for review by civil society.

[7] According to Article 6.1 of the Memorandum of Understanding between the MPP and UNITAID, UNITAID will provide the MPP with an amount of US$4,427,951 to facilitate its activities for the first year of collaboration and provided UNITAID is satisfied with the MPPs performance, it shall approve funding for an additional four years based on the revised revenue and cost estimates for the period 2010-2015.

application[8] pending in India for a method of using ritonavir for treating HCV. The claims include co-adminstering ritonavir with telepravir (the recently approved product of Vertex/Johnson & Johnson called Incivek) for HCV. If Abbott were to join the pool, it would be well within its rights to request the same 'any use' language the MPP has agreed with Gilead for any potential second use of ritonavir. Such an agreement would implicitly give validation to Abbott's second use patent in relation to HCV and require any potential use of ritonavir by licensees in the pool to pay royalties. This would be the case even though ritonavir, the base compound, was never patented in India for HIV.

This brings India's patent law under the microscope, something Gilead and other companies are desperately trying to change in order to safeguard TDF and other patents.

While civil society groups work tirelessly to ensure free-trade agreements, like the Trans-Pacific Partnership Agreement and EU-India Free Trade Agreement, do not include new use patents or intellectual property (IP) provisions that hinder access, it is regrettable that the MPP has undermined and negotiated away this critical position of global advocates. It is worth noting here that the issue of access to medicines is broader than just HIV/AIDS. By conceding ground on new uses on existing products, this could harm efforts of other patients that could be entitled to access these medicines free of patent barriers.

Introducing a Global Patent System Through the Back Door:

In the licenses, Gilead insists on referring to its rights over TDF as 'proprietary'. This is so even though it appears that within the licensed territories Gilead only has a granted patent in Indonesia.

Given the barren patent landscape for TDF in these countries, we do not understand why the MPP agreed to royalties (other than for Indonesia) to be paid to Gilead. The MPP should have made this a non-negotiable term as part of the amended licenses and for any new licensees. Instead, the licenses state that if the TDF patents are eventually granted in India, the royalty rate ***will go up from 3% of net sales in the licensed TDF territory to 5%***.

By agreeing to such terms, the MPP has not only agreed to royalties where there are no patents, it has also agreed for royalties on any new uses e.g. HBV for TDF as well as allowing an increase in the rate should the TDF patents be granted in India. Equally worrying, the MPP has acted in conflict with a long-held position of the access to medicines movement, that patents are territorial rights and not global rights and

[8] Application No. 7260/DELNP/2008 – originating from WO2007/103934

should be treated as such. The consequence of facilitating such terms in the license is that the MPP has essentially endorsed a global patent system.

Middle Income Countries are Excluded:

The licenses fall short of covering the geographical territories where there are high burden HIV populations. Most of the key middle-income territories are missing, including Brazil, which has rejected the TDF patents.[9] We fully support the frustration of the Latin-American civil society groups and the Thai Network of People Living with HIV & AIDS for being excluded from the licensed territories, among other concerns.

We note that the licenses have been praised for expanding the licensing territory for TDF from the 95 countries in the original licenses to 111 countries under the MPP one. While the additional 92,000 patients (according to the MPP Q&A) that might be served through the expanded territories is welcome, on closer inspection at least half of these countries are small islands like Palau, Nauru and the British Virgin Islands, where there are neither patents nor a high burden HIV population.

Based on the list of licensed territories, the belief that the MPP's model of bringing in more licensees will improve access and bring prices down is built on a faulty premise. We have already seen with the existing TDF licenses granted in 2006 that of the 13 licensees only 4 are producing TDF (not including CIPLA).

One of the reasons for this is that in a limited market space, many generic companies are not able to enter and compete with the bigger generic players. What is needed are bigger markets, namely the middle-income territories so that there is room for other

[9] Countries missing from the licensed territories according to Act-Up Paris include:

For TDF: Asia: Malaysia, North Korea, China, and the Philippines; in Latin America: Argentina, Brazil, Chile,Colombia, Paraguay, Peru, Uruguay, and Venezuela; in Central America: Costa Rica, Mexico, and Panama; in Middle East: Iran, Iraq, Lebanon, and Jordan; in Eastern Europe and the Baltics: Albania, Azerbaijan, Belarus, Bulgaria, Croatia, Czech Rep, Estonia, Hungary, Latvia, Lithuania, Montenegro, Poland, Republic of Kosovo, Republic of Macedonia, Romania, Russia, Serbia, Slovak Rep, Turkey, and Ukraine; in Africa: Algeria, Egypt, Morocco, Tunisia, and Libya; in Island Nations: Marshall Islands, and Micronesia.

For EVG/COBI/Quad: Asia: Malaysia, North Korea, China, the Philippines, Kazakhstan, Sri Lanka, Thailand, Turkmenistan, and Indonesia; in Latin America: Argentina, Brazil, Chile, Colombia, Paraguay, Peru, Uruguay, Venezuela, Ecuador, and El Salvador; in Central America: Costa Rica, Mexico, and Panama; in Middle East: Iran, Iraq, Lebanon, and Jordan; in Eastern Europe and Baltics: Albania, Azerbaijan, Belarus, Bulgaria, Croatia, Czech Rep, Estonia, Hungary, Latvia, Lithuania, Montenegro, Poland, Republic of Kosovo, Republic of Macedonia, Romania, Russia, Serbia, Slovak Rep, Turkey, and Ukraine; in Africa: Algeria, Egypt, Morocco, Tunisia, Libya, Botswana, and Namibia; in Island Nations: Marshall Islands, and Micronesia.

licensees to enter the picture and truly help drive prices down. As the licenses stand, Gilead, with the agreement of the MPP, is still keeping the main markets to itself.

Maintaining Control of API:

As with the previous TDF licenses, Gilead has chosen to maintain control over the production of active pharmaceutical ingredients (API) for the licensed drugs. Moreover, the licenses restrict the production of API and products to Indian generic companies located in India. Licensees wishing to make products can only purchase API from a licensed Gilead supplier or Indian licensee.

This leaves several capable producers from countries like China, Brazil and Thailand out of the picture, including any Indian companies that may have manufacturing sites in other countries, e.g. CIPLA in Uganda. It also goes against the objective of TRIPS, to encourage north-south transfer of technology across the board.

Licensees Right to Supply Under a Compulsory License:

While the new MPP licenses make one improvement over the existing TDF licenses -- allowing Indian licensees to supply API or product outside of the licensed territories should a compulsory license be issued – this clause contains restrictions.

For this clause of the license to work:

a) the government of the country seeking to import has to issue a compulsory license for the importation of the API or product; or

b) the Government of India issues a compulsory license allowing for export of API or product from India into such country, provided that there are no patents preventing such use, import, sale of the API or product - or the importing country has issued a compulsory license.

It is important to note, however, that in both cases the licensee and Gilead have to be in agreement (which should not be unreasonably withheld by Gilead) regarding the existence, scope and content of the compulsory license, including the requirements of the law that govern its use.[10]

On paper, this reads as a reasonable concession by Gilead and a safeguard that the MPP has managed to bring into the licenses.

However, as we all know from the past experiences of countries issuing compulsory licenses, e.g. Thailand and Brazil, whether under the August 30 Decision or

[10] For example, section 92A of the Indian Patent Act.

otherwise, the process is not straightforward and often ends in failure.[11] While this clause may be seen as the MPP setting up the possibility of a flurry of compulsory licenses, the reality is likely to be different. Moreover, the license clearly states that the licensee and Gilead must be in reasonable agreement over the issuance of the compulsory license. Therefore, should a compulsory license be issued, Gilead could still prevent the export/import if it believes the requirements of the law have not been met. It can still legally challenge any issuance of compulsory license at the Indian patent office and more easily lean on the licensee not to step up as a producer under the compulsory license. After all, settlements between generics and originator companies are well known. The term could also be interpreted as Gilead now having the ability to control some of compulsory licensing process, especially amongst its licensees.

Licenses Do not Preclude Licensees from Challenging Gilead's Patents:

The MPP claims that another improvement in the new licenses over the existing TDF licenses is that licensees will not be prevented from challenging any of Gilead's licensed patents.

The issue with the non-patent challenge clause in the original TDF licenses was first raised in an analysis of the early licenses by I-MAK in 2006.[12] Following concerns raised by civil society and a decision in the U.S. Supreme Court case *MedImmune v Genentech (2006)*, which ruled that licensees could challenge a licensor's patent, Gilead issued a letter to Knowledge Ecology International (KEI) in 2008 recognising the concerns of the clause and that it would delete it from the Ranbaxy license (and presumably other licenses).[13]

In light of this, it would be fair to say that Gilead had already conceded this issue even before negotiations commenced with the MPP.

It is also worth noting, as will be discussed in the next section, that the lack of a non-patent challenge clause makes little difference to Gilead. This is because Gilead will

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[11] The August 30 Decision was introduced into TRIPS on 30 August 2003 to help those countries without drug manufacturing capacity to receive access to affordable medicines. Under the system, a country with manufacturing capacity can issue a compulsory license in order to export a medicine to a country that does not have capacity to produce its own. Almost eight years since its introduction, the August 30 system has only been successfully used once due to the number of hurdles that have to be overcome to make it work.

[12] See I-MAK Memorandum on TDF Voluntary Licenses , 17 September 2006, available at: http://www.i-mak.org/storage/IMAK%20Analysis%20of%20Gileads%20example%20licence%20LPPD%20Advisor.pdf

[13] Amendment to the Gilead-Ranbaxy License Agreement, KEI, 9 June 2008, available at http://keionline.org/node/77

still extract royalties, likely for years, even where no patents exist. ***The license allows Gilead to receive royalties on a drug until every possible legal avenue is exhausted, and the highest legal authority has rejected the patent.*** To illustrate, in India, despite the fact that there is no TDF patent, Gilead will receive royalties while the case is heard by the Appeals Board, High Court, and Supreme Court – a process that could take some years.

Potential for Royalties in Perpetuity Based on Non-Granted Patents:

In the MPP Q&A, the MPP has highlighted that, "*where a patent is no longer valid in India and in the country of sale, the licensee no longer has an obligation to pay royalties*."

However, on closer reading, the clause states that if all patents (on a particular product/product-by-product basis) containing a claim covering the manufacture, use, import, offer for sale or sale of API or product in India or in a licensed territory have been held invalid or unenforceable beyond the possibility of appeal, then no royalties will be due.

This clause raises a few issues for us:

a) First, if as is expected, Gilead continues to fight against the refusal of its TDF product patents in India (or any other patent that it has licensed), it could be some years before the matter is resolved. As a result, licensees will have to continue paying royalties and by that effect, ***Gilead will have achieved the objective of extracting a rent from a right it did not have. It also means that Gilead has managed to circumvent the very flexibilities India implemented in its Patent Laws to address patent quality issues.***

b) Second, the clause states that "if all" patents containing a valid claim over the manufacture, use, import or offer for sale of the API or product have been held invalid or unenforceable beyond appeal, then there will no royalties owed. The term "if all" could be interpreted as meaning that even if Gilead only has a granted process patent for TDF in India (which is does) then royalties will be due. This is so even if licensees maybe using their own process. If Gilead files new patent applications which cover the API or products of the license, that in itself could be interpreted as a valid claim over the manufacture, use etc for the sale of API or product until the patent is either finally refused or granted. More worrying, with respect to the issue of new use patents discussed above, Gilead could continue to extract royalties so long as such patent applications are pending or granted.[14]

[14] The licenses define patents to include "*patents listed in Appendix 2* ***and*** *any other patents and patent applications (and resulting patents therefrom)..*"

In light of these issues, it seems that this clause is another way to ensure Gilead has the ability to extort rents in India even where they have been legitimately and lawfully refused.

Transfer of Know-How and Technology:

Gilead has been praised for its royalty free, one-time technology transfer of know-how to licensees. In particular the MPP has said that the know-how transfer is a *"significant improvement over existing licenses"* because it provides for licensees to be able enable manufacture of the API and products licensed at commercial scale quantities.

However, a review of an existing license for TDF, shows that the wording in the previous license is identical to the 'significantly improved' terms in the new licenses. As such, we remain unconvinced that the technology transfer in these licenses will be better, given that that some of the earlier TDF licensees at the time stated that none of the know-how was proprietary and still required their own work to come to market.

It is also worth noting that any know-how transfer for EVG, COBI and the Quad will only take place after they receive FDA approval (on a product-by-product basis). While this is not an unreasonable term, it means that unless licensees have already worked on their own technologies for these drugs, it will be some time before they will be able to come to market.

Royalty Free Licenses for Gilead for Improvements by Licensees:

The license requires generic companies to give non-exclusive royalty free licenses to any improvements to API or product made by the generic companies. Such requirement will remain after the license expires. If the licensee terminates the agreement with respect to any API or product then the requirement will be limited to any improvements relating to the terminated API or product first developed by the licensee prior to the API termination date.

It is worth noting that Article 40 of TRIPS allows Members from including in their legislation licensing practices or conditions that may constitute an abuse of IP rights having an adverse effect on competition. As such Members may include measures in their laws to prevent or control practices such as grant back licenses negotiated between Gilead and the MPP.

We believe that by requiring licensees to always grant back improvements, licensees will never be able to become more competitive than Gilead in the market place, e.g. by developing a more efficient way to manufacture API or a better product. This raises potential competition issues.

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Understanding the Broader Impact of the Licenses on Access and the IP Landscape

In sum, despite the introduction of Gilead's pipeline drugs into the licenses, the licenses agreed between Gilead and MPP are not a significant improvement over the status quo. Not only do the licenses erode the many TRIPS flexibilities that civil society and developing countries had used to pressure pharmaceutical companies (e.g. patent oppositions and no patent rights for new use patents), they also fail to deliver for middle-income countries that have a high HIV/AIDS burden. Essentially, the licenses amount to a 'patent rights for drugs exchange'.

The terms agreed by the MPP support and validate what we, and many others, regard as a flawed patent system for medicines. While the MPP can argue that the licenses do not affect the ability of countries to use TRIPS flexibilities, the reality is that they have opened the door to a proliferation of patents, which will result in increased barriers to access in the long term.

A failure to be critical of the licenses would also send the wrong message to developing country governments who may decide to relax their standards on patentability criteria and/or not bother with legislative provisions that permit pre-grant oppositions. If anything, the agreed licenses could spell the end of the upward 'patent counter-harmonisation' effort of countries like India and the Philippines.

Equally of concern is how the MPP will be able to improve on these licenses with Gilead, given that it is widely acknowledged that Gilead has been one of the more receptive companies in the access debate. We fear that the terms agreed with Gilead are likely to now be the standard for any future agreement and possibly worse.

In this analysis we have set out why we do not think the licenses are an improvement and what the implications are. If the MPP is to work with or represent the public and PLHIVs, then there has to be a broad technical consultation with affected communities and public interest lawyers who represent their interests.

In view of these serious issues, we demand:

1. The Patent Pool Governance Board and EAG censure these licenses and places a moratorium on current negotiations with Bristol Myers Squibb and Boehringer-Ingelheim until a broad technical consultation is held with representatives for the affected communities to discuss the future and reform of the MPP's mandate. We note that the Patent Pool Governance Board is due to convene an Expert Advisory Group (EAG) in September to provide advice as to whether the negotiated licenses represent a significant improvement over the status quo.

2. The EAG should comprise civil society lawyers with expertise in IP issues and PLHIVs who act in the interests of patients on issues of access to medicines.

3. In the spirit of meaningful transparency and accountability, regular updates of negotiations and all draft license agreements are to be shared with interested civil society for comment and consensus building before any license can be signed off. We believe that including patient's voices (and concerns) from all countries is essential going forward.

4. An explanation from the MPP on the conflict of interest issues with respect to the $1million 'agent fee' that the MPP has agreed with Gilead. PLHIVs should be provided with a clear explanation of how this does not represent a conflict of interest. Moreover, a clear explanation is required as to how the MPP intends to use this money and what its future licensing plans are in light of the fact that it has assumed negotiating power at a global level on behalf of PLHIVs in a manner which directly benefits itself.

5. The MPP should not be permitted to take a commission for any licenses entered into, whether for identifying potential licensees on behalf of licensors, administrating licenses entered into or from any licensees.

6. An explanation from UNITAID as to why it has permitted the MPP to accept a fee from Gilead despite it conflicting with the UNITAID Patent Pool Initiative Implementation Plan (2009) to fully subsidise the pool, which was approved by the Board. In addition, a policy directive in this respect needs to be developed by UNITAID.

7. In light of the analysis provided here and by other groups, an explanation from the MPP and UNITAID as to how the licenses comply with the requirement of the Memorandum of Understanding agreed between the parties "*that the terms and conditions of the licenses and sub-licenses respect the different patentability criteria across jurisdictions.*"[15]

8. An explanation from the MPP and UNITAID as to whether the MPP was time pressured and influenced to enter into the license with Gilead in order to meet its performance requirements and secure its future funding under the Medicines Patent Pool Foundation Memorandum of Understanding.[16]

[15] See Article 6.2 of the Medicines Patent Pool Foundation, Memorandum Of Understanding.
[16] Article 6.1