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A newsletter from Lawyers Collective HIV/AIDS Unit

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PATENT POOL: LEGITIMISING BIG PHARMA'S PRACTICES?

July 2011 witnessed the announcement by Medicines Patent Pool Foundation (MPPF) of its first commercial voluntary licence signed with a multinational pharmaceutical company aimed at increasing access to medicines for persons living with HIV (PLHIV). This announcement was welcomed by some, yet criticised by others. The criticism came from treatment activists from Asia, Latin America and North Africa and several other non-governmental organisations. So, why did a move designed to increase access to medicines for PLHIV attract criticism from several actors, including several PLHIV themselves?

In this newsletter, we briefly explain what the patent pool is and publish our concerns about its impact on access to medicines.

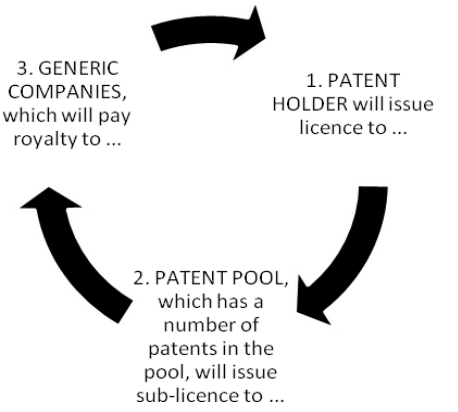
What is a patent pool?

As we all know, a patent on a medicine allows the patent holder to prevent others from manufacturing the patented medicine. It creates a monopoly and allows the patent holder to:

- Prevent other pharmaceutical companies from making the patented medicine and also from developing combinations and formulations of patented medicines. [In case of a product patent, no one else can make the medicine without the patent holder's consent. In case of a process patent, no one else can make the medicine using the patented process without the patent holder's consent.]; and
- Charge exorbitant, monopolistic prices on medicines.

When the patent holder consents to allow someone else to make the patented medicine, it does so by issuing a voluntary licence. The patent holder is known as the licensor and the other party who is licensed is known as the licensee.

The patent pool is a mechanism whereby patent holders agree to license one or more of their patents (for instance on anti-retrovirals) to the patent pool, an administrative mechanism, which, in turn, will issue a sub-license to generic companies.



By doing this, theoretically, a patent pool would help increase access to medicines by facilitating:

- Making of new fixed dose combinations and new paediatric formulations of medicines whose patents are held by different companies;
- Reduction of prices of medicines through competition amongst sub-licensees; and
- Reduction of cost of licensing and sublicensing.

In the 2000s, the proposal of a patent pool was theoretically mooted at various fora. Subsequently, the proposal to establish such a patent pool mechanism for antiretrovirals (ARVs) was taken up by UNITAID, the international drug purchase facility set up by the Governments of Brazil, Chile, France, Norway and United Kingdom.

Medicines Patent Pool: Its Origin (2006–2009)	
2006	Proposal put forth to UNITAID to establish Medicines Patent Pool.
July 2008	UNITAID Executive Board (EB) agreed in principle to establish a voluntary patent pool for HIV medicines.
Latter part of 2009	In response to news that the UNITAID EB would further consider the implementation of the patent pool at its December 2009 meeting, several civil society actors wrote to the UNITAID EB to express concerns about the proposed model.

In the latter part of 2009, when the Executive Board (EB) of UNITAID was scheduled to consider the proposal to establish a patent pool for anti-retrovirals (ARVs), several civil society and public health groups wrote to the UNITAID EB expressing their concerns. This included civil society groups from India and Thailand, Asia Pacific Network of People Living with HIV/AIDS, People's Health Movement and Lawyers Collective HIV/AIDS Unit.

By this time, there was reason to believe that the 2006 Gilead voluntary licence on *tenofovir disoproxil fumarate* (TDF) was being considered as a good example along the lines of which the proposed patent pool would operate. It may be recalled that, in 2006, Gilead Sciences, Inc. (Gilead), a multinational pharmaceutical company based in the United States, entered into commercial voluntary licences for TDF with at least one South African and several Indian generic companies, though it had not yet obtained a patent in India. Back in 2006, these licences had been criticised for excluding several developing countries, requiring generic companies to refrain from challenging Gilead's patent applications and including several anti-competitive clauses that would, in the long run, thwart generic competition.

As lawyers representing networks of persons living with HIV in litigation opposing patent applications and patents, Lawyers Collective HIV/AIDS Unit, too, wrote to the UNITAID EB (see Box below) expressing its concerns about the long-term impact of such licensing practices on access to medicines, generic competition and the flexibilities available to countries under the *Agreement on Trade Related Aspects of Intellectual Property Rights*.

In response, Lawyers Collective HIV/AIDS Unit received a letter from the UNITAID EB stating that many of the concerns raised had been discussed at its 11th session and that the Patent Pool would not "inhibit in any way countries' abilities to use TRIPS flexibilities" and that the aim of the Patent Pool would be "to provide benefits to all low- and middle-income countries".

10 December 2009

To
The Chair, UNITAID Board
Dr. Philippe Douste-Blazy
Special Adviser on Innovative Financing for Development
UN Under-Secretary General.

Sub: Concerns regarding the UNITAID Patent Pool Implementation Plan

Dear Dr. Douste-Blazy,

Greetings from Lawyers Collective HIV/AIDS Unit, India!

Lawyers Collective HIV/AIDS Unit (the Unit) was set up in 1998 premised on a realisation that law, policy and judicial action based on the human rights framework had a central role to play in effectively containing the HIV epidemic. The Unit provides free legal services to persons living with/ affected by HIV/AIDS and is involved in advocacy and policy research on legal and human rights issues related to HIV/AIDS. The Affordable Medicines and Treatment Campaign (AMTC) was launched in 2001 by the Unit, as the inequity in access to lifesaving AIDS treatment was becoming an issue of growing global outrage.

In 2005, given its obligations under the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property (TRIPS), the Indian Parliament enacted the Patents (Amendment) Act of 2005, introducing product patent protection for pharmaceuticals. With this Act, the ability of the Indian pharmaceutical industry to continue providing affordable medicines in India and throughout the developing world was placed in jeopardy. The Indian Parliament, mindful of the impact of patents on access to medicines, made use of TRIPS flexibilities to retain and introduce key public health safeguards in India's patent law. These included:

- **Patent Oppositions** allowing civil society and patients groups to challenge patent applications and granted patents;
- A prohibition on **evergreening** (Section 3d) by recognising that new forms, uses, combinations of existing medicines do not deserve patents; and
- Expansive **compulsory licensing** provisions.

Since 2005, the Unit has represented several patients' groups in utilising these critical public health safeguards. Our work includes successfully opposing Novartis' patent application for *imatinib mesylate (Gleevec)* and the consequent constitutional challenge to section 3(d). We have also represented patients' groups, both Indian and from other Global South countries, in opposing patent applications relating to key HIV/AIDS drugs, including *tenofovir*.

Over the past five years, Indian groups have taken the battle for access to medicines to the multinational pharmaceutical companies by filing oppositions, resisting legal challenges to undermine India's public health safeguards or impose TRIPS-plus provisions and, in the process, demonstrated quite effectively the cracks and faults in the global intellectual property system. It is in the context of this battle for a more equitable global paradigm for access to medicines that we write to express our grave concerns about the outcome of the Patent Pool Implementation Plan. Though we do not have a copy of the proposed Implementation Plan, we have come to know through various reports of certain key elements of the proposed Implementation Plan, in respect of which we want to express our concerns.

We understand that the UNITAID Executive Board meets early next week to discuss this Plan. Our experience of opposing patent applications and granted patents and the actions of multinational pharmaceutical companies make us very wary of the impact of the UNITAID Patent Pool in ensuring access to medicines for all those in the Global South who need them. We are of the view that voluntary licences, which the UNITAID Patent Pool reportedly seeks to encourage, without adequate public health safeguards and public scrutiny, can actually encourage and strengthen the abuse of the patent system by multinational pharmaceutical companies and allow them to profit at the cost of millions of lives of people across the developing countries. We would like to voice our concerns by using the example of Gilead's voluntary licences on *tenofovir*, a pre-1995 drug which should not be patented in developing countries, and its patenting practices.

We choose the Gilead voluntary licences to discuss as these have been much touted as good examples of licensing. However, we believe picking the best of the worst practices is hardly a standard to aspire to in promoting global health equity.

As you are aware, *tenofovir* is a crucial antiretroviral for the treatment of persons living with HIV. The World Health Organization (WHO) now recommends the use of *tenofovir* for use in first line drug regimens in resource-poor settings.[i] The WHO is also recommending early start of treatment, thus increasing considerably the needs in developing countries for this

medicine. *Tenofovir* is commonly prescribed and widely available to persons living with HIV in the United States and Europe. However, *tenofovir* remained largely unavailable in developing countries until generic production was commenced by Indian pharmaceutical companies.

Recognising the importance of access to this crucial medicine in developing countries, Indian patients' groups filed challenges to Gilead's patent applications in 2006. Earlier this year, the Indian Patent Office rejected two patent applications relating to *tenofovir* (*tenofovir disoproxil* and *tenofovir disoproxil fumarate*) on several grounds, including that the claims in these applications did not satisfy the patentability criteria of inventive step and section 3(d) of the Indian patent law. The Brazilian Patent Office, too, had rejected similar patent applications relating to *tenofovir*.

As you may have just read, Gilead has now challenged these decisions of the Indian Patent Office.

In 2006, in a matter of days after the patent oppositions to *tenofovir* were filed, Gilead offered voluntary licenses to 11 Indian generic companies, several of whom had also filed pre-grant oppositions against Gilead's multiple patent applications. Subsequently, as a condition of the voluntary licences, they withdrew their pre-grant oppositions. The only patent oppositions that survived were those filed by patients' groups and Indian generic companies, who had not entered into voluntary licences with Gilead. Thus, in India, Gilead used the voluntary licences to restrict opposition to its patent applications and the exercise of pre-grant oppositions, a recognised procedural TRIPS-flexibility. It is important to note that, in 2006, Indian generic companies were well on their way to producing generic *tenofovir*, and there are no patent barriers in India with respect to *tenofovir* till date. Statements reportedly attributing the increase in competition to the voluntary licences issued by Gilead therefore do not present the entire picture on generic *tenofovir*.

Despite India being included in the voluntary licence, patient groups, however, persisted in their oppositions. As one of them noted, this was because, "*We know that the battles we are fighting in India are not just for us but for patients across the developing and least developed world who are entitled to access the best treatment options without discrimination*."[ii]

The decisions of the Indian and Brazilian Patent Offices on these patent applications only serve to underscore how the adoption of strict patentability criteria would actually ensure that only truly new and inventive medicines are patented and thus obviate the need for voluntary licences. However, through the voluntary licences, Gilead profited from the mere filing of patent applications, which have subsequently been rejected. This battle is, however, far from over. Civil society groups have now discovered divisional applications filed by Gilead in both India and Brazil, which are under examination. The divisional patent applications and appeals are obviously a strategy employed by Gilead to hold on to its royalty revenue stream from the voluntary licences entered into with several Indian generic companies on patents that do not even exist and to attempt to charge exorbitant prices from the Brazilian healthcare system.

Further, the voluntary licences entered into by Gilead included the least developing countries (LDCs), which are not even required to grant patents on pharmaceutical products until 2016. In 97 of the 99 licensed countries to which *tenofovir* can be exported on payment of royalty by the Indian generic companies, Gilead had not even filed patent applications relating to *tenofovir*.[iii] It should be noted that LDCs have until 2016 to comply with the TRIPS deadline for granting patents on pharmaceutical products. Gilead's voluntary licence, thus, takes away from such LDCs the benefits of the 2016 deadline to comply with the TRIPS Agreement.

It is also important to note that Gilead excluded several developing countries, including Argentina, Brazil, Bulgaria, Chile, China, Colombia, Cost Rica, Ecuador, El Salvador, Fiji, Malaysia, Mexico, Paraguay, Peru, Philippines, Sri Lanka, Uruguay and Venezuela.[iv] Thus, the products manufactured by Indian generic companies under the voluntary licences cannot be exported to these countries. It is apparent that the list excludes several developing countries, who have an immediate and huge need for access to *tenofovir*. The exclusion allows Gilead to continue to charge high prices in these countries. The most striking example is that of Brazil. In Brazil, Gilead sells *tenofovir* for USD 1,387[v] per patient per year; in comparison, the cheapest available generic version manufactured in India costs only USD 99[vi] per patient per year. We apprehend that similar exclusions will be placed by the vested interests of the multinational pharmaceutical companies in the licences negotiated by the Patent Pool to the detriment of patients in developing countries.

Gilead's voluntary licence serves as an indicator of how the Patent Pool is likely to work to the disadvantage of patients in the Global South. It provides several critical lessons, which we hope the Executive Board will take into account while discussing the proposed Implementation Plan. It shows how companies use voluntary licences to divide up developing countries based purely on considerations of profits and isolate patients in those developing countries unfortunate enough to meet some artificial economic criteria that is not reflective of their actual treatment needs.

The insistence by certain multinational pharmaceutical companies of excluding certain developing countries and requiring additional negotiations or the creation of conditions and incentives for their inclusion in the Pool is actually a ploy to leave certain countries out of the Pool. We are gravely concerned that such exclusionary practices would run counter to the objective of increasing access to medicines to those who require it.

We further note with concern that the "Statement on Patent Pool Scope" issued on 8 December 2009 merely states that "*the Patent Pool plan **aims** to enable both low- and middle-income countries to benefit from the work of the Patent Pool*", but stops short of an assurance that all developing countries would be included and benefit from the Patent Pool.

It is also our belief that the impact of voluntary licenses from the Patent Pool on patent oppositions will be similar to what happened in the case of *tenofovir*, *regardless* of whether this is a term of the Patent Pool licences or not. For us, the question then becomes whether the Patent pool mechanism will promote abusive patenting practices by companies filing multiple applications to create multiple and extended monopolies on medicines whose patents they contribute to the pool.

The lack of consultation and transparency in the drafting and finalisation of the UNITAID Patent Pool Implementation Plan further lends to our misgivings about the Patent Pool.

We would therefore urge the Executive Board to ensure that the Patent Pool Implementation Plan does not in any manner compromise the manner in which countries are able to utilise the TRIPS flexibilities—including that of stricter patentability criteria, oppositions and compulsory licensing. Accountability to patients and transparency should guide the work of international aid agencies committed to ensuring access to medicines for patients. Further, if the proposed Implementation Plan is to gain any measure of legitimacy, the finalisation of Patent Pool Implementation Plan ought to be done in a transparent manner based on consultations with stakeholders, most importantly patients' groups and civil society from the Global South.

It is indeed appropriate that we write this letter to the UNITAID Executive Board on the occasion of World Human Rights Day. Lawyers Collective HIV/AIDS Unit is dedicated to the spirit of the late activist Dominic D'Souza, who said, "*I live in the hope of a world that will be, if not free of disease, free of fear and discrimination.*" We firmly believe that the right to health and to access medicines is a right that must be enjoyed by all persons in all developing countries without exclusion or discrimination. We trust that the UNITAID Executive Board will examine and hold consultations on the Patent Pool Implementation Plan from this critical perspective of human rights.

In solidarity,

Julie George,
For Lawyers Collective HIV/AIDS Unit

[i] "New HIV recommendations to improve health, reduce infections and save lives", 20 November 2009, *available at* http://www.who.int/mediacentre/news/releases/2009/world_aids_20091130/en/index.html.

[ii] Neville Selhore of Sahara, (a co-petitioner with the Brazilian groups in a pre-grant opposition to one of Gilead's tenofovir patent applications in India) quoted in "Patent Denied in India", ABIA Press release, 4 September 2009.

[iii] "Knowledge Ecology International request for investigation into anticompetitive aspects of Gilead Voluntary Licences for patents on Tenofovir and Emtricitabine", 12 February 2007, at page 13–15.

[iv] "Knowledge Ecology International request for investigation into anticompetitive aspects of Gilead Voluntary Licences for patents on Tenofovir and Emtricitabine", 12 February 2007, at page 12.

[v] "Patent Denied in India", ABIA press release, 4 September 2009.

[vi] Clinton Foundation, Antiretroviral (ARV) Price List, 2009, *available at* http://www.clintonfoundation.org/files/chaiarvpricelistaugust2009english.pdf.

UNTIAD's Green Signal to MPPF

Despite the concerns expressed by civil society and public health groups in 2009, the UNITAID EB, at its meeting held in December 2009, approved the establishment of a patent pool. At its next meeting in June 2010, it decided to establish Medicines Patent Pool Foundation (MPPF) and proposed that it be set up as a Swiss not-for-profit organisation

In June 2010, MPPF was set up as a not-for-profit organisation under the laws of Switzerland.

At the XVIII International AIDS Conference held at Vienna in July 2010, Lawyers Collective HIV/AIDS Unit publicly raised concerns about the medicines patent pool at a satellite meeting organised by it.

Medicines Patent Pool: Its Realisation (2009–2010)	
December 2009	UNITAID EB agreed to proceed to next stage and approved setting up of patent pool in 2010.
June 2010	• UNITAID EB decided to establish MPPF as a Swiss not-for-profit organisation. • Immediate goals: 3 drugs out of 20 identified drugs to be taken on licence and sub-licensed.
July 2010	MPPF is registered as a Swiss not-for-profit organisation.
September 2010	Memorandum of Understanding signed between MPPF and UNITAID.

Almost a year after its establishment, on 12 July 2011, MPPF announced its first commercial voluntary licence with a pharmaceutical company. Perhaps, not surprisingly, the first commercial licence announced was with Gilead, the very same company whose 2006 voluntary licences had been criticised. MPPF announced that this first licence covered four drugs—*tenofovir* (TDF), *emtricitabine* (FTC), *elvitegravir* (EVG) and *cobcistat* (COBI) (the latter two being drugs under development) and QUAD, a combination of these four drugs. As per the announcement, interested generic companies from India (Gilead appears to have refused to allow any non-Indian generic sub-licensee) could sign a tripartite agreement with Gilead and MPPF and obtain a licence to these drugs. After having signed the sub-licence, Indian companies could choose to terminate the licence on a drug-by-drug basis. So, if an Indian generic company was of the opinion that it did not want the licence on TDF, it could terminate the licence for TDF but continue the licence for the other drugs.

On the same day as MPPF's announcement in London, Gilead and four other Indian generic companies held a press conference in India and announced that they had signed voluntary licences covering the same four drugs.

Civil society responds

MPPF's announcement was met with immediate welcoming statements by several health groups, mainly those based in the Global North. But, a perusal of the licences, which were published by MPPF on its website, sobered the euphoria. PLHIV in North Africa and Latin America realised that they had been left out of the licence. Realising that the MPPF-Gilead licence was, in fact, almost identical to the widely-criticised Gilead's 2006 voluntary licences, other civil society groups such as Third World Network and International Treatment Preparedness Coalition (ITPC) and Initiative for Medicines Access and Knowledge, too, released critiques of the MPPF-Gilead licence.

It was also belatedly realised that the two press announcements—in London and Hyderabad—were not related to each other. The announcement in India was that of another set of voluntary licences negotiated between Gilead and the Indian generic companies, with no involvement of MPPF at all. Gilead had, in effect, signed separate side deals with Indian generic companies, taking away MPPF's potential sub-licensees.

A brief comparison of the various licences is provided below.

ITPC then called for a meeting in Geneva in October 2011 to allow civil society, especially their constituents, from across the world to raise their concerns with representatives of MPPF. Towards the end of this meeting, the represenatives of the community organisations demanded that (i) the MPPF-Gilead licence be reviewed or cancelled, (ii) a moratorium be placed on all further negotiations until standard terms and conditions had been drawn up, as required by MPPF's Memorandum of Understanding with UNITAID, and (iii) MPPF's current structure be reviewed. After the meeting, a letter signed by several community organisations and civil society groups was sent to MPPF and UNITAID setting out the unresolved concerns and demands.

	2006 Gilead voluntary licences	**2011 MPPF-Gilead licence (July 2011)**	**2011 Gilead voluntary licences (July 2011)**	**2011 MPPF-Gilead-generic company sub-licences (Post July 2011)**
Parties to licence	Gilead and South African and Indian generic companies	MPPF and Gilead	Gilead and Indian generic companies[1]	MPPF, Indian generic company[2] AND Gilead
Drugs and countries covered	TDF(95 countries)	• TDF (112 countries) • EVG-QUAD (100 countries) • COBI (103 countries)	• TDF (112 countries) • EVG-QUAD (100+9 countries)[3] • COBI (103+9 countries)[3]	• TDF (112 countries) • EVG-QUAD (100 countries) • COBI (103 countries)
In case of dispute, who can raise a dispute? Who can enforce licence?	Gilead and generic company	MPPF and Gilead[4]	Gilead and generic company	Gilead and generic company[5]

1 *Hetero Labs Ltd., Matrix Laboratories Ltd., Ranbaxy Laboratories Ltd. and Strides Acrolab Ltd.*
2 *As of February 2012, MPPF had three Indian sub-licensees: Medchem, Aurobindo Pharma Limited and Emcure Pharmaceuticals Limited.*
3 *These additional nine countries are divided among the four generic companies so that they each have a semi-exclusive market.*
4 *MPPF can seek enforcement only (i) if Gilead refuses to sign a sub-licence with an Indian generic company that MPPF has identified, or (ii) if Gilead defaults on paying MPPF its fee.*
5 *MPPF cannot enforce the licence, except to obtain its fee from Gilead or to enforce it indemnification rights. MPPF has waived its standing in disputes between Gilead and generic company.*

Community Demands (October 2011)

At the conclusion of the meeting held on 2 October 2011 in Geneva, the representatives of community organisations, put forth three demands. They asked that the MPPF, in conjunction with UNITAID, its founding partner, should:

- Substantially revise or terminate the MPPF-brokered licence agreement with Gilead, including any potential or pending agreements with sub-licensees, given Gilead's bad faith and the controversial terms of the MPPF-Gilead agreement;
- Institute an immediate moratorium on negotiations of any new licence agreements, including any new or pending agreements with Indian generic producers (potential sub-licensees to the MPPF-Gilead agreement) or with other multinational drug companies (potential new licensors) until such time as standard terms and conditions or a model agreement is agreed to; and
- Re-evaluate the current structure of the MPPF, including its governance and administration, goals and mission, and implement comprehensive reforms designed to enhance its transparency, accountability and adherence to core principles of health equity.

Key Concerns of Community (October 2011)

The following are some of the concerns expressed by the community and civil society. Several of these were set out in letter sent to MPPF and UNITAID by several community organisations after the meeting held at Geneva in October 2011. The full text of the letter is available on the website of International Treatment Preparedness Coalition [http://www.itpcglobal.org/].

- The MPPF-Gilead licence is based on the previously-criticised 2006 Gilead voluntary licences and not on standard terms and conditions that were to be developed by MPPF
- The MPPF-Gilead licence excludes several developing countries. For instance, MPPF sub-licensees (i.e. Indian generic companies) cannot supply *tenofovir* to over 500,000 PLHIV in more than 43 countries (including Brazil, China, Russia and countries in Eastern Europe and North Africa). The number of PLHIV and countries excluded for the other medicines under development is larger (including Botswana and Namibia).
- The MPPF-Gilead licence allows Gilead to control the production and supply of active pharmaceutical ingredients (APIs). The sub-licensees cannot buy APIs from anyone who is not approved by Gilead. If the sub-licensee manufactures the API itself, it cannot sell the API to anyone, except Gilead or a company who is authorised by Gilead.
- The sub-licences are available only to Indian generic companies and not to non-Indian government or generic producers, thereby limiting local generic production in other parts of the world.
- Under the licence, Gilead can control the distribution of finished products by the sub-licensee. If it is found that the products have been diverted to other countries (that Gilead has excluded in the licence), even through use of TRIPS flexibilities such as parallel importation, Gilead can cancel the distribution agreement between the sub-licensee and its distributor.
- The MPPF-Gilead licence claims to include a safeguard for compulsory licensing. Under this, a sub-licensee can supply the medicines if a compulsory licence (CL) is issued.
  - This safeguard can be used only by the countries that are excluded. Even if included countries with local manufacturing capacity issue a CL, the generic sub-licensees cannot supply the API to them under the CL safeguard.
  - Even after a CL is issued, the generic sub-licensee requires consent from Gilead in as much as both sides have to be in agreement about the existence, scope and content of the CL.
- The MPPF-Gilead licence undermines the work of patent oppositions (where patients' groups file cases in the patent office to oppose the grant of patents or challenge the grant of patents) by requiring royalties to be paid on patent applications, even where Gilead has no patent, so long as even one patent application survives, and until all avenues of appeal have been exhausted.
- The MPPF-Gilead licence places restrictions on development of paediatric formulations (only liquid or dispersible tablets can be developed). Other formulations, such as sprinklers, cannot be developed.
- Having signed a tripartite sub-licence involving Gilead, the generic sub-licensee and MPPF (instead of a sub-licence involving only the generic sub-licensee and MPPF), MPPF waives its standing to raise a dispute and to enforce the provisions of the MPPF sub-licence. So, if Gilead violates the agreement or in case of a dispute between the sub-licensee and Gilead, MPPF cannot file a case or even be a party in a case between the sub-licensee and Gilead.
- Process and governance:
  - PLHIV were not effectively involved. Key organisations working on access to medicines were under-represented.
  - There was and continues to remain lack of transparency around the ad-hoc expert advisory group (EAG) constituted to advise MPPF on MPPF-Gilead licence.
  - MPPF continues to refuse to disclose the contents of the advice given by ad-hoc EAG.
  - In the MPPF-Gilead licence, MPPF agreed to receive a fee of 5 percent from Gilead's royalties on the licences, subject to a yearly cap of USD 1 million. This raises issues of conflict of interest.
  - There is lack of clarity over the parameters that govern MPPF's decision to enter into an agreement.
  - MPPF has refused to call Gilead out on its bad faith in signing separate side deals with four Indian generic companies, taking away potential MPPF sub-licensees.

Pursuant to this meeting and taking into account some of the concerns raised, MPPF and Gilead amended two clauses of the licence, one relating to compulsory licensing and the other relating to unbundling of licences. However, several other important concerns remain unaddressed.

CHANGES MADE TO THE MPPF-GILEAD LICENCE

	Original Licence (July 2011)	Revised Licence (November 2011)
Compulsory Licences (CL) For a generic sub-licensee to be able to supply under a CL, a CL has to be issued by India and / or excluded country.	• After a CL is issued, a generic sub-licensee still cannot supply under the CL until there is agreement between generic sub-licensee and Gilead about existence, scope and content of licence. • No clarity whether generic sub-licensee can apply for a CL.	• Requirement of consent from Gilead dropped. • Still no clarity whether generic licensee can apply for a CL.
Gilead's non-assert on *emtricitabine* (FTC) patent and Unbundling of TDF licence *Note: TDF and FTC are sold as a combination in several countries.*	• During the term of the agreement, Gilead will not sue generic sub-licensees for making, using, selling, etc products containing FTC for infringement of FTC patents. • However, a generic sub-licensee could be sued for infringement of FTC patents if it terminated the licence for any of the medicines, including TDF.	• Clarification added that, if sub-licensee terminates TDF licence, Gilead will not sue generic sub-licensee for making, using, selling, etc products containing TDF and FTC. • However, Gilead can sue the generic sub-licensee for selling such products in the excluded territory.

In December 2011, when the UNITAID EB was scheduled to meet to discuss MPPF's Business Plan for the next four years, Lawyers Collective HIV/AIDS Unit sent another letter, exactly two years after its 2009 letter (see Box below). We set out our concerns in detail and asked the UNITAID EB not to sanction the Plan unless certain conditions, including the setting of standard terms and conditions, were met. We understand that the UNITAID EB approved MPPF's four-year Business Plan for a reported approximately USD 27 million dollars. We have not yet received a response to this letter.

10 December 2011

To
The Chairperson
UNITAID Executive Board

Dear Dr. Philippe Douste-Blazy,

Greetings from Lawyers Collective HIV/AIDS Unit, India!

We write to you again on World Human Rights Day, two years after our earlier letter on the then proposed patent pool. [Copy of Letter dated 10 December 2009 attached]

You may recall that on 10 December 2009, on the eve of the meeting of the UNITAID Executive Board, we had written to you expressing our concerns about UNITAID's proposal to establish a patent pool based on the model of the 2006 voluntary licences issued by Gilead Sciences, Inc (Gilead) for *tenofovir*. We had highlighted the inherent problems of the voluntary licensing model of Gilead's 2006 licences on *tenofovir* and urged that the UNITAID Executive Board ensure that the Patent Pool Implementation Plan does not in any manner compromise the manner in which countries are able to utilise TRIPS flexibilities, including that of stricter patentability criteria, oppositions and compulsory licences.

As you meet again this year to consider the Business Plan of Medicines Patent Pool Foundation (MPPF) for the next four years, we are compelled to draw your attention to a few facts.

It is with great disappointment that we note that the first voluntary licence with a pharmaceutical company announced by the MPPF is almost identical to the 2006 Gilead voluntary licence that we had warned against.

The MPPF-Gilead licence claims to be an improvement over the "status quo" by including newer medicines that are yet to be approved for marketing (*elvitegravir*, *cobicistat* and its combinations), newer countries for the medicines (112 countries for *tenofovir*, 102 countries for *cobicistat* and 99 countries for *elvitegravir* and QUAD), allowing generic licensees to unbundle the medicines (or terminate the licence for any of the active pharmaceutical ingredients (APIs)) and allowing generic licensees to supply to excluded countries if they issue a compulsory licence.

The 2006 Gilead voluntary licences bore the marks of a purely commercial licence with the exclusion of countries and market segmentation, controlled competition by controlling API supply and product distribution, and restriction of the use of flexibilities available to countries under the TRIPS Agreement such as patent oppositions and compulsory licences.

After close analysis, we find that the MPPF licence closely resembles the 2006 Gilead voluntary licences. Amongst the several areas of concern, the MPPF-Gilead licence too excludes countries, controls competition through the control of APIs and restricts the use of TRIPS flexibilities.

I. MPPF-Gilead licence is in violation of MPPF's mandate

The MPPF-Gilead licence, in fact, is contrary to the Statutes of MPPF of June 2010 as well as the Memorandum of Understanding signed between UNITAID and MPPF (UNITAID-MPPF MoU) in September 2010. The points below (which are by no means exhaustive as there are several other concerns with the licence) illustrate this.

- The UNITAID-MPPF MoU requires all developing countries to be included in the scope of the Pool. However, the MPPF-Gilead licence excludes several developing countries, including those in conflict, those negotiating free trade agreements and countries in Eastern Europe facing rising HIV epidemics. Not even Africa was non-negotiable for MPPF as all of North Africa is excluded (Egypt, Libya, Morocco, Algeria and Tunisia). For the newer medicines, even sub-Saharan Africa is not sacrosanct with the exclusion of Botswana and Namibia.
- The MPPF Statutes and the UNITAID-MPPF MoU require that MPPF make available the sub-licenses to all interested parties. However, under the MPPF-Gilead licence, only generic companies based in India can be sub-licensees. This excludes government producers in developing countries such as Brazil and Thailand and other developing countries with domestic manufacturing capacity.
- The UNITAID-MPPF MoU requires MPPF to enhance competition. However, by allowing Gilead to control the production and supply of API and restricting sub-licences to Indian companies only, the MPPF-Gilead licence actually impedes competition, and is anti-competitive.
- The MPPF Statutes and the UNITAID-MPPF MoU require MPPF to facilitate newer fixed dose combinations and paediatric formulations. However, the MPPF-Gilead licence restricts the development of fixed dose combinations only to the specifically licensed medicines and places limitations on the development of fixed dose combinations of other medicines over which other companies may hold intellectual property. Further, it places restrictions on the development of paediatric formulations by specifying that the sub-licensee may only develop liquid or dispersible tablets formulations.
- The UNITAID-MPPF MoU requires MPPF to use all reasonable measures to develop standard terms and conditions. However, the first MPPF licence was negotiated without any such standard terms and conditions. Till date, MPPF has not released the standard terms and conditions that would set out its non-negotiable position nor has it given any indication that it intends to draft and make public its standard terms and conditions.
- The MPPF Statutes specifically gives MPPF the power to enforce licences. It also requires MPPF to assist in dispute resolution between licensors and licensees and requires the alternative dispute resolution mechanism to be actionable by all signatories to the licence agreements. However, MPPF has waived all rights to its standing in case of a dispute between Gilead and a sub-licensee. The licence is actionable by MPPF only when Gilead refuses to sign a sub-licence with an Indian generic manufacturer or to enforce the payment of five percent of the royalties by Gilead to MPPF as the MPPF's fee or to enforce the MPPF's indemnity under the licences. There has been absolutely no explanation as to why this right was waived by MPPF. The argument that generic companies will look after their own interests does not answer at all the question of who will look after the public interest in case of a dispute between Gilead and the sub-licensee over this agreement which has been negotiated with public money and advocacy.

All these show that MPPF has clearly acted in violation of its mandate.

II. Legitimisation of "evergreening" and abusive patenting practices

Pertinently, the MPPF-Gilead licence legitimises weak patents and "evergreening"—the practice of pharmaceutical companies to establish or maintain monopolies by seeking patents with claims that cover minor improvements of known medicines, combinations of known medicines and new uses of known medicines. For instance, on *tenofovir* (a pre-1995 medicine), it legitimises Gilead's claim to royalties for patents on new forms of *tenofovir* (*tenofovir disoproxil* and *tenofovir fumarate*) [*sic*]. In India, its patent applications for *tenofovir disoproxil* and *tenofovir disoproxil fumarate* having been rejected, Gilead only owns a weak process patent on *tenofovir*. Yet, the MPPF-licence allows Gilead to charge royalties on the basis of this weak process patent. Further, if Gilead filed a patent application or obtained a patent on new use of *tenofovir* to treat Hepatitis B, royalty would be payable to Gilead even after the patent with claims on the basic molecule expired.

Similarly, the list of patents or patent applications on *elvitegravir* demonstrates how Gilead would continue to obtain royalties beyond the patent term of the basic patent on *elvitegravir* by filing staggered patent applications for new forms and processes.

Finally, one of the so-called products that is part of the licence is nothing more than a combination product of the other four medicines included in the licence. QUAD is a combination of *tenofovir*, *emtricitabine*, *elvitegravir* and *cobicistat* (TDF+FTC+EVG+COBI). It is unclear why this is mentioned as a separate medicine in the licence as the licence on all the other products allows for them to be made in combination anyway. The patents on QUAD are simply patents on a combination of known medicines.

It may be argued that the sub-licensee could terminate the licence once the blocking patent expires or is revoked. However, the reality of commercial interests that may be at work for the medicines under development, if they do secure marketing approval, would likely deter a sub-licensee from terminating its strategic alliance with its multinational business partner until all such "evergreening" patents expire.

Faced with multiple patents and patent applications on each medicine, patients' groups in India, Brazil and other developing countries are opposing blocking patent applications or patents so as to ensure that generic competition is not compromised. However, if the sub-licencee is to supply generic medicines to an excluded country, the MPPF-Gilead licence would require that patients' groups now oppose every single patent application and every patent to ensure that no patent with a valid claim in the importing or exporting country —whether process or product, whether for use or combination, whether it blocks production or not—is granted or subsists before supply can take place. In addition, Gilead must be allowed to exhaust every avenue of appeal under the laws of both countries before supply is allowed.

The MPPF-Gilead licence also allows royalties to be claimed by Gilead even when it has not been granted a patent i.e. during the pendency of a patent application . The definition of "Patents" in the MPPF-Gilead licence includes patent applications allowing Gilead to collect royalties just for filing applications. In India and Brazil, for instance, Gilead has filed multiple patent applications and divisional patent applications relating to *tenofovir*. This provides an incentive to Gilead to pursue abusive patenting practices such as multiple and divisional patent applications, even if these have no chance of succeeding.

III. Compromises use of compulsory licences

While the MPPF-Gilead licence claims that it has a safeguard that would allow sub-licensees to supply the medicines on issuance of a compulsory licence, even this clause compromises the ability of countries to use the TRIPS flexibility of compulsory licences. In the first version of this clause on compulsory licencing, Gilead's agreement was required before supply under a compulsory licence would be possible. A recent amendment removes this additional hurdle but still contains restrictions that are of concern.

- Firstly, this safeguard is available only to countries that are excluded and is not available to included countries who might want to issue a compulsory licence despite the existence of the present voluntary licence if, for instance the countries within the "territory" would like to obtain supply of the API for their own local production.
- Secondly, if there is no blocking patent in an excluded country that wants to import the generic medicines under the MPPF licence, but there are other patents related to the medicine that would not otherwise block import, under normal circumstances, only India would have to issue the compulsory licence for export (if there were a blocking patent). However, under the MPPF-Gilead licence, even if there is a single patent with a valid claim, whether it is blocking or not, the importing country would be forced to issue a compulsory licence to meet the requirements of the provisions of the MPPF-Gilead licence.
- Thirdly, the sub-licensees are still tied in by the MPPF-Gilead licence even while a patent application is pending though a patent may not have been issued. It is not possible to issue a compulsory licence on a patent application.

- Fourthly, the MPPF-Gilead licence does not clarify that the action of a sub-licensee in filing an application for a compulsory licence in India or the excluded territory would not constitute a ground on which Gilead would terminate the licence or raise a dispute.

It should be noted that Gilead does not covenant that it will not oppose an application for compulsory licence if it is filed or a compulsory licence that may be issued. This is particularly of concern given the evidence in India of multinational pharmaceutical companies opposing compulsory licence applications of anti-cancer medicines, including compulsory licence for export to countries with little or no manufacturing capacity (under section 92A of the Indian patent law which incorporates para 6 of Doha Declaration). These concerns hold true even for the amended clause.

IV. Unbundling

In an earlier civil society letter of October 2011 to which we were a signatory, we had raised the concern about the unbundling clause which has been touted as one of the improvements on "status quo". Firstly, we still fail to understand why the MPPF-Gilead licence bundles all the medicines together in a single licence and then leaves it to the sub-licensee to terminate it on a medicine-by-medicine basis. Secondly, we are still concerned about the implications of a sub-licensee terminating the licence for *tenofovir*. Pursuant to the letter of October 2011, MPPF announced an amendment to the MPPF-Gilead licence and clarified that if a sub-licensee were to terminate the licence for *tenofovir*, Gilead would not sue the sub-licensee if it were to manufacture and sell the combinations of *tenofovir* and *emtricitabine* in the licensed territories. However, there is still no clarity whether the sub-licensee who terminates the *tenofovir* licence would not be able to make other fixed dose combinations containing *emtricitabine*. Thirdly, it is also unclear why the clarification sought through the amendment is limited only to the unbundling of *tenofovir* and does not extend to the other medicines.

V. Conflict of interest

Under the MPPF-Gilead licence, MPPF is entitled to five percent of the royalties obtained by Gilead up to a maximum amount of USD 1,000,000 per year. MPPF's acceptance of a fee from Gilead gives rise to a conflict of interest. MPPF has acknowledged that it would raise this issue with the UNITAID Executive Board. We hope that the Executive Board would consider this issue. Given that the licence negotiated is not a good licence, either from the point of view of access or ensuring competition, the presence of an avoidable conflict of interest only complicates issues further.

VI. Imprimatur on bad licensing

Effectively, Gilead's 2006 voluntary licence now bears the imprimatur of MPPF even as Gilead exhibited bad faith by signing secret side agreements with four major Indian generic companies at the same time as they signed the MPPF licence thereby taking away MPPF's potential sub-licensees. We understand that these 2011 Gilead voluntary licences not only cover the same medicines but also grant monopolies to these Indian licensees in the 12 countries that left have been left out by the MPPF-licence for *elvitegravir*, *cobicistat* and QUAD in return for royalty rates of 10–15 percent. The manipulation of public relations announcements to time the press releases of the announcement of both the MPPF-Gilead licence and the Gilead-Indian generic companies 2011 voluntary licences on the same day (12 July 2011) allowed Gilead to walk away with applause for its act of taking away potential MPPF sub-licensees. Yet, neither MPPF nor UNITAID has made any public statement against this exhibition of bad faith. Of further concern is the presence of the President of the United States-India Business Council (USIBC) celebrating the announcement of Gilead's 2011 voluntary licences. As you may be aware, the USIBC actively advocates against the use of TRIPS flexibilities by India such as section 3(d) of its patent law to prevent evergreening and compulsory licences.

VII. Process and governance

We also have concerns about the process and governance of MPPF. We understand that MPPF constituted an ad-hoc Expert Advisory Group (EAG) to advise it on its first voluntary licence. We further understand that the said ad-hoc EAG did not meet in person even once. It remains unclear whether they even had joint tele-conferences to discuss concerns in depth.

We had specifically asked about the views of the ad-hoc EAG members and whether they had been followed or ignored but were informed that the views of the ad-hoc EAG are confidential and cannot be shared with the public.

While the composition may have left something to be desired, it is alarming that a shroud of confidentiality has been thrown over the views of the members of the ad-hoc EAG and whether the MPPF acted in accordance with or contrary to the views of the members of the ad-hoc EAG. Since the licence is now public, this refusal, to make public the deliberations (if any) or individual advice and inputs of the ad-hoc advisory group, is not only baffling, it can only fuel greater distrust of the process followed in the negotiation of this licence. We believe it is vital that all information and documents related to the ad-hoc EAG be made public immediately.

VIII. Conclusion

A voluntary patent pool suffers from some inherent weaknesses. Primarily, it lacks negotiating power when negotiating as a not-for-profit entity with multinational pharmaceutical companies, the very same companies whose profit-motivated actions were the cause of extended ill-health and death of thousands of persons living with HIV in the earlier years of the treatment access movement. Given the vast resources of some NGOs and community groups that have gone into advocacy on the Patent Pool and the resultant licence still leaving out hundreds of thousands presently in need of treatment, this weakness has not been resolved. It is unclear what the premise is for further calls for community groups already struggling to survive to put in more time, money and energy advocating for the Patent Pool and how this pressure will have a different outcome the next time around. We reiterate that geographical scope is only one of the problems with this licence. An improved geographical scope with the same restriction and control of competition will be extremely detrimental for the future of generic production and for those countries who continue to be excluded from the Patent Pool.

We would request the UNITAID Executive Board to consider closely the implications if all future licences of MPPF follow more or less the content of the MPPF-Gilead licence and if all companies are given the green light to tie up key generic producers in side deals, thereby offering MPPF an even more limited scope of operation. While community groups will have to determine for themselves whether their priorities will focus on ensuring government action to increase access or advocating with companies instead, we would ask the UNITAID Executive Board to realistically analyse the limited negotiating power of the MPPF and compare this with its far greater (and demonstrated) ability at generating positive public relations outcomes for companies negotiating with it. This alone seems to give companies a public relations boost that money cannot buy while they, in fact, continue with most, if not all, of their bad licensing practices. We highlight the fact that the public relations boost is being funded by public money collected (or to be collected) through taxes by the various UNITAID Executive Board members including developing country Board members some of whom find themselves excluded from the Pool as well.

With MPPF insisting that geographical scope and the restriction to Indian generic companies are the only key concerns with the MPPF-Gilead licence and the repeated denials of the licence undermining TRIPS flexibilities, MPPF is effectively providing its imprimatur on these bad licencing practices. To be clear, the critiques do not state that the MPPF-Gilead licence changes country laws. Obviously it does not. However, the MPPF-Gilead licence works in a way that either undermines or makes useless the use of these TRIPS flexibilities. The impact of the agreement on compulsory licencing, patent oppositions and evergreening discussed above are clear examples of this. As is the case of parallel imports where Gilead's ability to directly cancel distribution agreements means that, for countries excluded from the licence whose laws would allow the parallel imports of these generics, the MPPF-Gilead licence essentially removes any chance of using these laws. Of course, these may be demands made by companies but glossing over these demands or refusing to acknowledge that they undermine the use of flexibilities is creating an extremely fraught situation between groups working on operationalising TRIPS flexibilities and MPPF.

Time and again, we have decried the attempts of pharmaceutical companies to obtain and establish and maintain monopolies over what they term "incremental innovation" and what we term as "evergreening" because they deny access to medicines and compromise the right to health. In the same spirit, we decry the imprimatur of MPPF and ostensibly that of UNITAID over the MPPF-Gilead licence that offers minor "improvements in status quo" over existing commercial licences that enable a few pharmaceutical companies to deny access to medicines for people living with HIV, establish and maintain oligopolies, and threaten "real competition" amongst generic players from several countries and the development of local production. After closely examining the MPPF Statutes and the UNITAID-MPPF MoU, it is unclear to us as to when "improvement in status quo" became the standard for MPPF to meet rather than the clear parameters within which it was to deliver a licence.

The long-term harm of allowing companies to collude in this manner under the cover of a public health oriented institution must be a matter of serious discussion. The implications for the future of treatment not just for HIV but for all treatment are grave. Already, MPPF has waded into the world of Hepatitis B through the MPPF-Gilead licence and, by all accounts, has done little due diligence to understand the scope, nature and extent of Hepatitis B or the countries where generic treatment for Hepatitis B may be required the most.

Therefore, we call upon you:

1. To ask MPPF to terminate the MPPF-Gilead licence, including any potential or pending agreements with sub-licensees, given Gilead's bad faith and the controversial terms of the MPPF-Gilead licence;
2. To ask MPPF to institute an immediate moratorium on negotiations of any new licence , including any new or pending agreements with Indian generic producers (potential sub-licensees to the MPPF-Gilead licence) or with other multinational pharmaceutical companies (potential new licensors) until such time as standard terms and conditions or a model agreement is agreed to;

3. To re-evaluate the current structure of MPPF, including its governance and administration, goals and mission, and implement comprehensive reforms designed to enhance its transparency, accountability and adherence to core principles of health equity.

4. To defer the consideration of the Business Plan of MPPF until such time as may be appropriate. The work of many groups like ours in ensuring access to medicines is being impacted in a negative manner by such bad licencing practices and the approval of the four year business plan of MPPF cannot be regarded as a mere project proposal.

As we had asked two years ago, we ask again on Human Rights Day that the UNITAID Executive Board examine and hold consultations on MPPF and the voluntary licence it has produced from the critical perspective of human rights. Lawyers Collective HIV/AIDS Unit is dedicated to the spirit of the late Indian HIV activist Dominic D'souza, who said, "I live in the hope of a world that will be, if not free of disease, free of fear and discrimination." Access to anti-HIV medicines has been instrumental in reducing the fear and discrimination around HIV and in enabling persons living with HIV to living lives with dignity. We firmly believe that the right to health and to access medicines must be enjoyed by all persons in all developing countries without exclusion or discrimination.

In solidarity,
Lawyers Collective HIV/AIDS Unit

MPPF: A protective shield for Big Pharma's bad licensing practices?

Back in 1999 and the early 2000s, civil society, in one voice, decried the bad practices of Big Pharma, which were responsible for the denial of access to medicines for thousands and thousands of PLHIV. Big Pharma's reputation took a hit. At the same time, Indian generic companies were able to step in and, through unhindered competition, offer anti-HIV medicines at lower prices, thereby enabling countries to scale up access to medicines for PLHIV.

Today, Big Pharma is in a position to earn brownie points, at least through calculated media advocacy, by signing onto voluntary licences with MPPF. And, through the voluntary licences, it can also dictate the terms and conditions under which generic companies can provide access to medicines to the rest of the developing world, thereby jeopardising "real" competition.

The voluntariness inherent in the mechanism means that MPPF has no bargaining power when its sits across the table from Big Pharma. Therefore, the voluntary licences it negotiates are set in the paradigm of already existing purely commercial voluntary licences.

Though an independent not-for-profit entity, MPPF has placed itself in a position of negotiating the terms and conditions for access to medicines for millions of PLHIV in the developing world. Yet, there is no indication of what MPPF considers as non-negotiables when it negotiates with pharmaceutical companies to decide which countries get access to medicines and on what terms. MPPF representatives have not responded to calls to hold a meeting to discuss and set standard terms and conditions. The UNITAID-MPPF Memorandum of Understanding, which forms the basis of UNITAID's funding of MPPF, requires MPPF to use all reasonable measures to develop standard terms and conditions. MPPF's continued reluctance to draw up standard terms and conditions is a cause of grave concern.

MPPF has, thus far, refused to acknowledge the shortcomings in the MPPF-Gilead licence, except for the exclusion of developing countries and Gilead's refusal to issue sub-licences to non-Indian actors. But, MPPF has also indicated that it would not be possible to include all developing countries even in the future licences. Apart from this, MPPF has effectively legitimised the bad patenting and bad licensing practices of Big Pharma in its first commercial voluntary licence.

Announcements of refusal by Big Pharma entities to negotiate with MPPF are now met with calls of actions against them. But, should Big Pharma entities now be rebuked only if they do not enter into negotiations with MPPF, negotiations to enter into licences that will eventually leave out several developing countries and allow them to control competition? Or should they be criticised even for their bad licensing practices? For the latter, it is important that MPPF acknowledge the shortcomings. Until MPPF does so, MPPF provides Big Pharma with immunity to criticisms from civil society of their bad practices.

Contributor: Julie George

Address

Registered Office: Lawyers Collective, Jalaram Jyot, Fourth Floor, 63, Janmabhoomi Marg, Fort, Mumbai 400 001.
Tel: 022 43411600 / 22875482/3 Fax: 022 22821724 Email: aidslaw@lawyerscollective.org

Delhi : First Floor, 63/2, Masjid Road, Jangpura, New Delhi 110 014.
Tel: 011 46805555 / 24377101/2 Fax: 011 24372236 Email: aidslaw1@lawyerscollective.org

Website: www.lawyerscollective.org