Petition to the Medicines Patent Pool Foundation

Date: 13 October 2011

Source: KEIonline.org

Colleagues

I like many others hope our discussion and critique of the Medicines Patent Pool and the current state of affairs for access to medicines results in two things: a better and stronger patent pool and a better and stronger strategy to convinces developing countries to act proactively and collaboratively to ensure access to medicines by enacting maximum TRIPS flexibilities, using TRIPS flexibilities to reject weak patents and issuing compulsory licenses on needed medicines, and to resist TRIS plus patent, data, and enforcement rules.

That said, this analysis will mainly address the Petition/Letter to the MPP being circulated by some civil society groups that is highly critical of the Medicines Patent Pool and which fundamentally calls for a renegotiation of the Gilead license and a moratorium on further negotiations pending a top to bottom review of the MPP. Although in my view there are many positive features and analyses in the Petition, there are also some that I disagree with and others that I don't understand and that I hope constructive engagement will help to resolve. In sum, I think it is important to respond to the Petition rigorously and with candor and respect.

After stating its initial demands, the Petition lists eight major substantive concerns.

In point 1, it critiques the MPP/Gilead licenses as having been built on the template or earlier Gilead voluntary licenses with Indian generic companies. Although the Petition does not list all of the similarities, there are indeed many: both licenses do not allow sales in many middle income countries, Gilead exercises control over the sourcing and sale of active pharmaceutical ingredients, and Gilead tightly controls the country of production (India). On the other hand, there are difference as well, including differences advocated for by access-to-medicines activists: licensees may challenge patents, produce and export to satisfy compulsory licenses, and the licenses on different Gilead medicines are unbundled, meaning that licenses can reject a license on tenofovir, but still accept licenses on pipeline products. Point 1 further suggests that the MPP should have developed a

standard license with community input, a suggestion echoed by KEI, and with which I agree. Point 1 further implies that such a license should have had a non-negotiable term that all low- and middle-income countries must be included or that no license would issue (more on this below). There is community disagreement about the plausibility/winnability of such a non-negotiable term.

In point 2, the Petition reiterates its concern about the exclusion of many middle-income countries from the MPP/Gilead license both for tenofovir and pipeline medicines. This is the Petition's most powerful critique and one that has been echoed by essentially all commentators, and indeed one that was expressed by the MPP itself. The Petition correctly points out that the additional countries added to the pre-existing licenses add only 1% to the number of PWAs covered by earlier Gilead licenses on TDF, and that 12% remain excluded. Although this is mainly a critique of Gilead's intransigence, it is also an implicit critique of the MPP's effort and acquiescence. It is here that civil society activists disagree - some are convinced that the MPP could have accomplished total developing country inclusion if it held firm and others believe that the MPP had relatively little bargaining power to force Gilead into a voluntary license that included territories where companies are desperate to maintain their monopoly rights. There's no way to decide this issue empirically or conclusively. We have evidence of an NIH licenses that covers all low- and middle-income territories and we have a principle of non-discrimination between developing countries in the scope of work of the MPP, but we also have no example of a voluntary licenses or even a tiered-pricing policy by any proprietary company that has covered all middle-income countries. For some, the risk of no license in the MPP is preferable to licenses that differentiate between any developing countries. For others, expanding territories and gaining somewhat better terms on compulsory licenses, co-formulation, and unbundling is superior to having no license whatsoever. These seem to be legitimate differences of opinion that we should continue to explore and debate.

In point 3, several subissues are raised. Subpoint 3(a) states that the MPP/Gilead license undermines "the free and full use of TRIPS flexibilities by countries" by "circumventing the 2016 TRIPS deadline for LDCs by allowing royalties on medicines supplied to them, even though these countries do not have to impose patents on essential medicines until 2016." Certainly, it true that LDCs do not have to grant patents until 2016 and that they are free to rescind any premature pharmaceutical patent laws that they may have ill-advisedly adopted earlier (unfortunately, many LDCs have failed to rescind existing pharmaceutical patent legislation, potentially undermining a future

request for a further extension of the 2016 transition period). However, the fact that there are not patents in the importing LDC does not fully answer the question under TRIPS of whether there are royalties due on sales of generic versions of innovator products if those products must be imported from another country where a patent claim exists. Thus, if there is a patent in India, a compulsory license (or a voluntary license) must be issued in India allowing use of the patent. If export-allowing CLs are issued in the exporting country, a royalty will be due regardless of the patent status of the medicine in the importing country. This is a fundamental feature of the international patent regime, TRIPS Art. 31, that has been set up. Many of us think it is wrong. Many of us think that countries with insufficient manufacturing capacity where patent bars do not exist should be able to import without a royalty from an exporting country even if the exporting country has a patent on the medicine. We think that a royalty should not be paid because the real territory of commercialization and use is the importing country where a patent is not in force. Unfortunately, TRIPS has not been set up as we would like - one has to consider the patent status of a medicine both in country of production/export and the country of import/use - if there is a patent in either country, adequate compensation must be paid pursuant to Art. 31. Accordingly, the claim in Point 3(A) seems misguided to me. Despite this conclusion, if there is no plausible/defensible patent claim on the medicine being produced in India - as I believe there isn't for TDF - then the generic manufacturer should reject (unbundle) the license for TDF and supply TDF products without royalty to countries where there is no patent (in this case 110 out of 111 of the licensed territories). However, if a patent claim in India is plausible and if the sublicensee "accepts" the Gilead license on TDF or a pipeline product, it will be obligated to pay a royalty (based on the patent status in India) despite the absence of patent protection in an LDC.

Subpoint 3(b) claims that there are restrictions on the use of compulsory licenses by requiring the "prior permission of Gilead." This claim, which would benefit from greater clarification and elaboration, has some merit, at least with respect to a colorable risk of bad faith in practice were Gilead to try to undermine generics from producing pursuant to CLs. Nonetheless, it is important to clarify that the license does not actually require "prior permission" by Gilead, it merely requires agreement that about the "requirements of such [CL] law, rule or regulation and its "affect" on the agreement, with a further obligation that "agreement [to CL]" "not be unreasonably withheld." I actually think that it would have been preferable for this clause in the license to be excluded because Gilead might conceivably do some mischief under it, but I don't think that the questioned clause actually puts Gilead in a veto position with respect to whether a compulsory license is "permissible" or valid, and think it would

be a mistake to argue that it can or should be interpreted that way.

Subpoint 3(c) asserts that the MPP/Gilead license blocks excluded countries right to parallel import generic medicines [presumably those produced under license either from India or from an importing country] by allowing Gilead to directly intervene and cancel generic companies' distribution agreements if product diversions occur. This claim is certainly true, but it is also a central feature of the license that Gilead is trying to maintain market hegemony over excluded territories. If parallel importation of licenses were permitted to excluded territories, those potential territories would not just be excluded middle-income countries, but might also include upper-income countries that also adopt (now or in the future) international exhaustion. By my understanding, there is simply no circumstance in which an innovator company would voluntarily give up its rights in its most lucrative markets. Accordingly, whereas it's true that the license does restrict product diversion to non-territories, that is the central logic of territorial restrictions isn't it?

Subpoint 3(d) argues that the MPP/Gilead license undermines patent opposition work by requiring royalty payments until all patent claims and appeals have been exhausted. Again, this critique is true as far as it goes. If a generic company takes a sublicense because of putative patent claims, even though it thinks those claims might be proved unfounded in post-grant oppositions or in patent validity/non-infringement challenges, then the generic company will have to pay royalties. However, the decision to pay royalties does not interfere with generic's or other actors' rights to engage in pre- and post-grant opposition or to reject the offered sublicenses and roll the dice that the patent will eventually be found to be invalid. On the other hand, it is true, as the claim suggests, that obtaining voluntary sublicense rights reduces the market incentives of generics to oppose patents because they get to pursue sales in relatively large markets without having to pay lawyers fees. However, it is important that sublicensees retain the right to oppose and challenge the patents even as they are making licensed sales.

Subpoint 3(e) claims that the MPP licenses poor quality patents thereby legitimizing or endorsing weak patents. Many prior patent pools have had expert committees that analyze the strength of patents in the pool to avoid forced payments on presumptively invalid patents. To my understanding, these experts have historically been very cautious, however, in assessing patents because rejecting a patent doesn't necessarily mean that

licensees can use the patented technologies or processes without fear of litigation and/or damages. Moreover, I don't think the MPP is actually "endorsing" weak patents: the granting of patents is left to the sovereign authority of patent offices and hopefully the Indian Patent Office will get better and stronger over time in applying India's high patentability standards and stringent exclusions. (Thus far, the evidence on this is quite mixed.) In addition, activists, patient groups, and generics all have standing to oppose weak patents pre- and post-grant and to otherwise seek invalidation. A constructive campaign would continue to prioritize enforcement of the highest patent standards, which ultimately reduces the need for voluntary or compulsory licenses.

Point 4 criticizes the MPP for collecting royalties even in countries where patents do not exist and even before patents have been granted. As I said with respect to Point 3(a) this critique seems to ignore the unfortunate truth that royalties may be due because of patents in the country of production/export. In the ordinary course of events it is unlikely that medicines will be marketed before patents are issued (though this certainly has been a feature of India's post-mailbox period during which patents collected 1995-2005 are still being processed.) Even so, a generic company could conceivably make a medicine at some risk before the patent is granted or the final appeal prosecuted, subject to its own assessments about the strengths/weaknesses of the pending claims. In essence, what point 4 critiques is that generic producers generally prefer to produce under the immunity of a license rather than risk costly enforcement litigation or face product withdrawal if a patent is ultimately granted and survives appeals. This may undermine generic companies' incentives to engage in patent oppositions, though pre-grant and post-grant opposition procedures are themselves imperfect mechanisms to ensuring access to medicines.

Point 5 is 100% spot on - it is outrageous that Gilead has not only insisted in controlling the API market but also, at least in this first round, limited licensees to Indian manufacturers. Other regions need to development pharmaceutical capacity and have a development right to do so without being frozen out of lucrative, aggregated developing country markets. The MPP stated its preference for open licenses to all qualified generics regardless of territorial location, and it is indeed unfortunate and hopefully reversible that these API/manufacturing territorial rules have been adopted.

Point 6 accuses the MPP of falsely championing its "unbundling" provision instead of negotiating four difference licenses. This seems like a distinction without a difference. The unbundling provision in essence allows licensees to pick and choose which API licenses they want and thus to treat each API differently.

Point 7 asserts that the MPP has failed to explain to the public the consequences of severing (or unbundling) the TDF license with respect to its ability to produce emtricibitine. The relevant provision, section 5.3 says: "Gilead covenants and agrees that it shall not, at any time during the term of this Agreement, bring any claim or proceeding of any kind or nature against MPP in relation to any of the pending and issued patents identified in Appendix 3 hereto (the 'Emtricitabine Patents') to the extent that MPP remains in compliance with the terms and conditions set forth in this Agreement and each Sublicense Agreement." It is probably true that this clause does not expressly extend Gilead's covenant-not-to-sue to non-licensees, but the language does actually permit production of emtricibitine by sublicensees, including presumably those who take licenses on the pipeline products. In any event, many generic producers will prefer to produce TDF co-formulated with 3TC, which is therapeutically equivalent to FTC but significantly cheaper.

Point 8 raises the critique that the MPP has incomprehensibly waived its legal standing and right to enforce the provisions of the license, leaving such disputes to Gilead and the sub-licensee. I agree with so much of the critique suggests that this reduces the prospects of CS engagement with the implementation of the licenses and of the MPP's ability to influence the norms of implementation over time. On the other hand, policing the agreement draws on scarce resources in what is now a very lean and poorly resourced entity. Nonetheless, I think the MPP should maintain some standing in contract enforcement.

After this eight-point list of substantive concerns about the MPP/Gilead license, the Petition also addresses six key concerns with respect to process and principles.

Concern 1 references a lack of transparency about the ad-hoc Expert Advisory Group. I agree that this lack of transparency is and has been problematic, that there should be some mechanisms of input on licenses at some point in the process, that EAG terms of reference, etc. should be more transparent, and that there must be stronger consultative mechanisms in the MPP. At the same time, I also understand that the degree of non-

communication have been exaggerated and that requests from UNITAID and MPP for input and consultation with CS has not always been responded to.

Concern 2 addresses transparency of the EAG's assessment of the Gilead license. On the one side, such transparency is appealing both for democratic input and possible improvements to the licenses. On the other hand, transparency could also detrimentally expose certain strategic considerations and proposals concerning future negotiations with the licensing company or with other potential licensors. Confidentiality with respect to professional advice (from lawyers, doctors, etc.) has a long tradition, but I frankly don't know exactly how that tradition intersects with the need for some degree of CS oversight over the EAG activities. The Global Fund has opened up portions of its technical reference group activities and asked it to produce public reports and reflections. Some undertakings might also be considered at the MPP and/or it might produce redacted versions of EAG deliberations.

Concern 3 asks for clarity about the process for the ultimate assessment of whether licenses improve the health of people in low- and middle-income countries or not. This also seems desirable, though the MPP will never be able to define a precise science through evaluation criteria or otherwise. Nonetheless, we often expect written justifications for decisions from other decision-makers and it seems appropriate that it be done here as well. That said, the MPP did provide written descriptions of what it considered to be the strengths and weaknesses of the Gilead license so it did provide important evidence of its internal weighing of different factors.

Concern 4 address apparent an conflict of interest from collecting a 5% fee on a 3-5% royalty. I think collecting fees for licensing services based on sales does not render the arrangement inherently conflicted, but I also note that the MPP has already indicated flexibility on this point. It seems important to note, however, that each additional dollar that UNITAID or other donors must spend to subsidizes the MPP's operational costs is a dollar that is not spent on purchasing commodities or building universal access.

Concern 5 alleges a confusing and misleading public relations strategy particularly with reference to the separate licenses that Gilead entered into unilaterally with four preferred generic companies - Ranbaxy, Hetero, Matrix and Strides Arcolab. Concern 5 continues by asserting that the separate agreements "completely undermined the

MPP/Gilead agreement. The recent MPP licenses with Aurobindo undercuts that claim that there has been a "total" undermining of the Pool license, but it is true that Gilead has succeeded in creating three classes of generics: highly favoured, moderately favoured (India companies only), and unfavor (generics from all other countries). As stated previously, this is highly undesirable. However, the blame lies primarily with Gilead and only secondarily with the MPP. Concern 5 suggests that the MPP should have criticized Gilead for acting in bad faith and that UNITAID and MPP should also have criticized Gilead for extracting higher royalties on sales in selected countries excluded from the MPP/Gilead license. I'm all in favor of the MPP and UNITAID being critical of Pharma overreaching, but I think CS could have and should have been much more active in critiquing Gilead's role in the license outcomes. Frankly, the MPP needed to develop a little positive media spin for itself and not come out of the box castigating the first Pharma company to grant it a license.

Concern 6 says that MPP publicity and supportive statements by others are misleading and damaging and that they are lulling originators and decision-makers to be complacent and satisfied with imperfect results and to hold the false belief that the MPP will solve all problems. I certainly agree that it is a mistake for anyone to present the MPP as the only game in town or that it is going to solve all or even manyaccess-to-medicines problems. I actually don't think the MPP has been promoting that idea, but inadvertently, I think we are collectively falling into a counter-productive all-or-nothing analyses.

Thus, it is at this point that I would like to turn to an argument that it is up to us as civil society not only to strive to make the MPP better but also to raise the stakes for Pharma and to provoke developing country decision-makers to act more decisively to protect the interests of their own patients. I think we should engage collaboratively to articulate a strategic approach about how we can work collectively to both strengthen CS/developing country campaigns for compulsory licenses, IP reform, extension of the LDC waiver, etc. and to improve and deepen the MPP. I don't think that the pool (or UNITAID) is going to accept a moratorium and/or revoke the Gilead license, but I do think there's plenty of scope to try to figure out how it might do better and be much more transparent and participatory in the process.

At this point, I think suggesting that it's all about supporting the pool only or all about the pool shutting down is counterproductive. I don't know that "yelling" at the MPP gives it more power in negotiations (not that that's all that critics are doing) or that the access movement is better off relying solely on voluntary licenses or actions of developing countries to get their act together (most haven't even amended their IP law to maximize TRIPS-compliant flexibilities, let alone used even the flexibilities they have). As stated previously, civil society still has internal disagreement about relative value, if any, of what the MPP has and reasonably can be expected to accomplish. I personally think it is an institution that has relatively weak negotiating power and that it faced an intransigent opponent intent on protecting middle-income markets and controlling API sourcing. We can all stand on the side and say that the MPP should have swung harder, but Big Pharma still has the fast ball, and we have to bring more players into the game.

Ultimately, the question some are posing is whether we would be better off with only the NIH license and waiting until developing countries get their act together to amend and use TRIPS compliant flexibilities in a coordinated way that will actually aggregate 150+ developing countries into a viable market for robust generic competition. Africa and LDCs have pretty much been treated with kid gloves in their access to first-generation generic ARVs, but it isn't as true for second and third generation medicines and it hasn't been true for middle-income countries, few of which have issued any compulsory licenses let alone coordinated their activities. In essence, neither the MPP or developing countries are doing good enough.

Even if my analysis above is wrong in whole or in part, there is still the question of how to move forward - whether it should be based solely on back-and-forths about what was and wasn't achieved or on simultaneously exploring concrete steps for taking complementary campaigns forward. My sense is that the MPP will only swing harder and that the access-to-medicine team will win when real pressure is put on drug companies about the consequences they will face when they exclude countries and/or fail to join the MPP. In any event, shutting the Pool down and insisting that it achieve near-perfect licenses will only succeed if there is some pressure on companies to accede to terms they don't want. If the Pool were to enter a moratorium and suspend the Gilead license, then what? Try again to get what it didn't get the first time with the most willing company?

As an example of a proactive campaign, there are efforts underway to launch a global Kaletra campaign, or more importantly, a global ritonavir campaign to enable production of other boosted PI products. Shouldn't at least part of our collective discussion be about how to work together on this proactive strategy?

In sum, I think we should be trying to strategize exactly how to achieve better licenses, which I don't think will be achieved simply by having more consultative processes (though I think we should have them) or by having more critical voices in the technical review group (though this should probably happen too). I think actual political campaigns in the real world that force developing countries to act and that shame Big Pharma are necessary prerequisites to better MPP licenses in the short and middle-term. Right now, focusing most of the criticism on the MPP and very little publicly on Pharma and developing countries seems to be letting the entities with real power standing on the sidelines laughing at our internecine disputes. Developing countries should not be lulled into thinking that the MPP is the only game in town or that it is going to do all the heavy lifting for them. We in civil society are the ones who can ensure that that message is sent.

All this said, I still think a robust, but less accusatory, discussion about the issues raised in the Petition needs take place, where every disagreement with the critics' analysis is not met with counterclaims of impertinence and arrogance and where every defense of an MPP term is not met with under-explained "it's a difference of opinion" and "it's all that could be achieved."

I have already received what I consider to be useful and constructive feedback on some arguments I have made, including about a possibly erroneous assertion that Gilead's pipeline products are likely to be patentable as new chemical entities and about a perhaps overly optimistic interpretation of section 92A of the India Patents Act. I may have made similar (or worse!) mistakes here, but let's be gentle with each other.

Brook K. Baker

P.s This analysis is mine; it is not Health GAP's official policy.

Keywords: Petition / Medicines / Patent Pool