MPP Response to ITPC-I-MAK Briefing Paper on Gilead and MPP Licenses

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To the Boards of Directors of the International Treatment Preparedness Coalition (ITPC) and Initiative for Medicines, Access and Knowledge (I-MAK):

Earlier this week, we became aware of the joint briefing paper issued by ITPC and I-MAK on the recent licence agreement between Gilead Sciences and the Medicines Patent Pool. We very much welcome analysis and comments from

various stakeholders, as this helps to improve our work. However, we cannot let the factual inaccuracies and misleading statements in the paper go unchallenged. It is important that analysis of this agreement be firmly grounded in facts. In our view, the licences are a significant improvement upon the status quo, but also have important shortcomings. The Pool is committed to working to improve the terms and conditions in future licences, and relies upon the support of all stakeholders to make this happen. (Further details are available in the Q&A that was issued when the licence was first announced, and available here [1]). A general response to the various commentaries issued on the licences has also been widely circulated and is annexed to this letter.

Because of the serious inaccuracies and misinterpretations of the licence presented in the ITPC/I-MAK briefing paper, we feel obligated to respond to a number of the points.

Field of use and second use patents

The licence does not restrict sale of TDF for HIV only (as in previous TDF voluntary licences), but rather expands the field of use for TDF into hepatitis B (HBV). This is positive for access to medicines and public health. The field of use that is defined under a patent licence agreement is a completely separate issue from that of new use patents. It is incorrect to suggest that limiting the field of use to HIV would somehow make the manufacture and sale of the same medicine for treatment of HBV royalty-free.

If a patent licence for a compound that has known therapeutic benefit for both HIV and HBV limited the field of use only to HIV, that would mean that it would be a contractual violation for a generic company to market that medicine for the treatment for HBV. This would mean that generic companies would be prohibited from supplying the same drug to the millions of people who are living with HBV, and also reduce the scope for greater economies of scale that is created by a larger potential market for that drug. There are no patents for new uses covered under the licence agreement. Expanding the field of use in a licence agreement does not in any way validate patents on new uses, which many jurisdictions do not allow, consistent with flexibilities contained in the TRIPS Agreement.

Severability of the licences

An important feature of the agreement is that it is severable on a product-by product basis (the licence is not 'bundled'). This feature was specifically negotiated into the licence by the Patent Pool, particularly in light of the patent situation of TDF in India and elsewhere. This means that a generic company that has developed a non-infringing process to make TDF in India can opt-out of the TDF portion of the licence and be free of any obligation to pay royalties for its sale of TDF. Based on the information that has been made publicly available on our website in the Patents Status Database for Selected HIV Medicines, it would appear that opting out of the TDF licence would mean that licensees are free to supply TDF to a number of countries outside the licensed territory where Gilead does not hold a patent, including Argentina, Brazil, Chile, Colombia, Malaysia, Peru, the Philippines, the Ukraine and Uruguay (and possibly others). Moreover, because the licences are severable on a product-by-product basis, the licensee is free to terminate the licence on a product upon the expiration of what it deems to be the strongest patent (e.g., a patent covering the active compound) without any further obligation to pay royalties on what it deems to be weak patents or those that it can design-around. The licensee is also free to challenge the validity of any of the patents under applicable national law. The licences negotiated through the Patent Pool expressly allows for both things to happen. It is, therefore, inaccurate to claim that these licences somehow introduce a "global patent system" or allow royalties to be paid "in perpetuity."

Right of licensee to supply in the event of a compulsory licence

The Medicines Patent Pool supports the use of TRIPS flexibilities by countries, and is mandated under its Statutes to ensure that the licence agreements that it negotiates are consistent with the use of such flexibilities. As such, the licence agreement expressly allows for a licensee to supply a country outside the territory in the event of a compulsory licence. Further, as Professor Brook Baker's analysis [2] explains, Indian law relating to compulsory licensing for export can potentially be interpreted and implemented in a manner that overcomes many of the difficulties with the use of the WTO 30 August decision.

Transfer of know-how

The Medicines Patent Pool has consulted extensively with generic companies regarding a number of issues, including the necessity and desirability of a knowhow transfer in a patent licence agreement. Although some companies declared it unnecessary, others felt that it could potentially be of use. Therefore, the Medicines Patent Pool agreed to a know-how transfer, but ensured that no further obligations independent of the patent licences came with the transfer of knowhow. Under the previous Gilead licences, a licensee could potentially be obligated to pay royalties on a product even after some or all of the patents on a product were declared invalid as a result of the know-how transfer. The licensees are now free to terminate the licence for any reason with 30 days notice.

Grant-back obligations

The licence agreement grants Gilead a non-exclusive, royalty-free licence back to Gilead for any improvements developed by the licensee. TRIPS, Article 40 allows countries to take measures against licensing practices that are deemed to be anticompetitive, such as exclusive grant-back provisions. The type of nonexclusive grant back provision included in the Gilead licences, however, are not considered to be controversial under competition law. Finally, we disagree with the ITPC/I-MAK briefing paper that this obligation will prevent the Indian generic industry from remaining far more competitive than originators in manufacturing quality medicines in high volumes at low cost. This is demonstrated in MSF's Untangling the Web data for TDF [3], which shows that several Indian companies are selling TDF for less than half of Gilead's reported at-cost price, and at five times less then when the first generic version of TDF was introduced.

Expert Advisory Group

The Medicines Patent Pool's Governance Board is in the process of formally convening an Expert Advisory Group (EAG). As specified in the Patent Pool's Statutes, the members of the EAG shall have a broad range of expertise, including IP expertise and public health in developing countries. The list of EAG members will be made public when the EAG is formally convened. For the Gilead licence, an ad hoc group of experts was consulted, which presented its recommendations for final decision by the Patent Pool Board.

Administrative fee

UNITAID has mandated that the Pool assess paths to self-sustainability, including the possibility of charging a commission to licensees for services rendered through the standard licensing agreements. The Statutes of the Medicines Patent Pool, which are publicly available on the Patent Pool website, expressly contemplate the possibility of the Patent Pool receiving a portion of royalty payments, where it states, "At all times, the majority of the Foundation's funding from third parties (excluding royalty payments, if any) shall come from sources of public and/or non-profit nature." The Statutes also mandate that, "The revenues that may be realised by the Foundation shall be used exclusively in furtherance of the Foundation's public utility aim." The proportion of royalties payable to the Patent Pool under the Gilead licence is 5% of the 3-5% royalty that Gilead itself receives -- in other words, the commission is 0.15% to 0.25% of the generic price. (The ITPC/I-MAK briefing paper is incorrect in asserting this as 5% of the generic price). Based on the market size and growth projections, the Pool has estimated the total revenue to the Pool from this royalty stream as ranging from $1,500 to $30,000 in 2011-2012, an amount that comprises less than 1% of the Pool?s annual operating costs. These amounts do not increase the royalty level (3-5%) or total amounts payable by generic firms to Gilead; rather, they are a portion of the royalty stream.

We reject the assertion that these amounts create ‘a serious conflict of interest’ and reaffirm the commitment of the Pool to the mission for which it was created, to improve access to medicines and public health in low- and middle-income countries.

Transparency

A key point that needs to be highlighted is the unprecedented transparency of the licences issued by the Pool. This is in stark contrast to the common practice in the pharmaceutical field, where voluntary licences, including those issued or obtained by public research organisations on HIV medicines, have been kept confidential. This may be why voluntary licences between companies and generic manufacturers have not received the same level of public attention, despite being significantly more restrictive than the licences negotiated by the Pool. Gilead and other companies that enter into the Pool know the licences will be made public and that as a result will face greater scrutiny due to the public nature of the licence. We hope that this process will become the accepted norm as we believe such transparency leads to stronger public health protections in the licences. We also hope that misleading comments and inaccurate criticisms such as those found in parts of the briefing paper will not discourage others from taking this route.

As ITPC/I-MAK noted, Gilead negotiated 'semi-exclusive' licences with four Indian generic firms and also negotiated a licence with the Pool. The terms and conditions of the semi-exclusive licences have not been publicly disclosed; therefore, it is not possible to assess their contents since they are kept confidential. As noted above, the Pool licences are publicly available, open to scrutiny, and contain a number of public health safeguards. Very concretely, the Pool license will enable increased production capacity, more robust competition and security of supply – all needed to put 15 million people on ART by 2015.

Since the licence was announced, ITPC and members of the World Community Advisory Board convened by ITPC have been briefed on the licence and discussions were held with members of the Pool several times over the last weeks including proactive invitations from the Pool to provide briefings. Discussions included extensive dialogue on the licence, on the terms and conditions and on the implications for access to the products. Immediately prior to the announcement, various members of ITPC and of WCAB were briefed on the workings of the Pool in various settings. At no time during all such meetings were most of the concerns raised in the briefing paper, factual or otherwise, presented so that any misunderstandings could be cleared up. We remain available and indeed invite continued dialogue so that going forward we can continue to work together to support our

common goal of access to safe and affordable medicines for all and more access-friendly licensing of HIV medicines.

Keywords: MPP Licenses / ITPC-I-MAK / Briefing Paper / Gilead