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UN Secretary General High-Level Panel

on Access to Medicines

Ruth Dreifuss, Co-Chair

Festus Mogae, Co-Chair

18 April 2016

Dear Madam Dreifuss,

Dear Mr Mogae,

As a follow-up to the London Hearing of the UN High Level Panel on Access to Medicines in which I had the opportunity to explain some of the key elements of our submission, and the subsequent dialogues in London and Johannesburg, I would hereby like to submit some supplementary information that may be of interest to the Panel and Expert Advisory Group. These points respond or supplement some of the questions and comments made during the Hearing and the Dialogues and should help to clarify and provide additional information with respect to these issues.

Patent transparency

The challenges around identifying the patent status of different medicines across countries, and in particular in developing countries, was discussed during the London Dialogue. We agree that this remains a major challenge for public health organizations, which has direct consequences on decisions relating to the procurement, supply or production of medicines as well as on policy analysis and decision-making.

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Since its establishment, the Medicines Patent Pool (MPP) has been devoting significant efforts and resources to collecting the patent information needed to carry out its work, often with the support of patent offices, the World Intellectual Property Organization (WIPO), patent holders and local civil society groups. In April 2011, we took the decision to make this information publicly available in an on-line database, which has been regularly updated since, and today includes information on the patent status of 24 HIV medicines in 89 countries (see: http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/).
The database is now a key resource that is regularly used by a wide range of stakeholders including the leading procurement agencies involved in the purchase of HIV medicines.

With the expansion of the MPP's mandate to Hepatitis C and tuberculosis, the database is now under revision in order to include patented medicines needed for the treatment of these two conditions. In addition, the database will be expanded to include information on licences, and will include a number of additional new features that will make it more user friendly, including through more regular updates of the data.

In addition to the information contained in the database, the MPP licences with patent holders also disclose the patent status of the licensed products in a large number of countries including, in some cases, countries outside of the licensed territory, such as high-income countries. Disclosure of patent information by patent holders (e.g through the licences with the MPP as well as through public disclosures) is welcome and also contributes to improving patent transparency. It is important to bear in mind that patent status is not static and needs to be regularly checked and updated at national level.

Despite the above, and beyond HIV, HCV and TB, significant challenges remain in understanding patent status of medicines in many countries and it would be important that the UN High Level Panel consider highlighting this challenge and the need to improve patent transparency as an integral part of a functional patent system.

Middle Income Countries in MPP Licences:

In the course of discussions at the UNHLP dialogues, a few interventions alluded to the geographical scope of MPP licences and the extent to which middle-income

countries (MICs) were included. The table below indicates the number of MICs included in each one of the MPP licences negotiated to date, out of a total of 104 MICs.

Product(s) Licensed	Lower Middle Income Countries	Upper Middle Income Countries	Total MICs
Abacavir (paediatric)	53	31	**84**
Atazanavir	46	29	**75**
Cobicistat	42	18	**60**
Daclatasvir	46	30	**76**
Dolutegravir (paediatric)	53	31	**84**
Dolutegravir	34	6	**40**
Elvitegravir	42	17	**59**
Lopinavir/Ritonavir (paediatric)	50	19	**69**
Lopinavir/Ritonavir (Africa)	17	10	**27**
Raltegravir (paediatric)	50	9	**59**
Tenofovir disoproxil fumarate	46	23	**69**
Tenofovir alafenamide	46	23	**69**

It is worth noting that in addition to the MICs listed above, several other MICs are able to procure generic versions of MPP-licensed products in light of specific provisions included in the MPP licences. For example, the MPP-ViiV licence on dolutegravir (DTG) includes provisions that enable countries in which DTG is not patented to procure generic versions of the adult formulation, even if the product were to be granted in the country of manufacture (e.g. India). As a result, approximately 50 additional MICs will be able to benefit from the MPP licence on adult formulations of DTG.[1]

The UN HLP may also wish to consider whether any specific incentives may be suitable in order to enable additional MICs to also benefit from voluntary licensing.

[1] Further explanation available at: MPP, *Progress and Achievement of the Medicines Patent Pool*, 2010-2015, page 4.

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Terms and Conditions in MPP Licences

As indicated in the MPP submission to the UN High Level Panel, the MPP works with IP holders to include terms and conditions in its licences that are important from a public health perspective and that promote policy coherence between the right to health, the rights of inventors and trade rules. While a number of examples are mentioned in the submission, I hereby wanted to highlight one that is directly relevant to some of the discussions that took place during the Dialogues, and namely whether the licences restrict the use by countries of certain TRIPS flexibilities, such as compulsory licences.

In relation to this, I would like to stress that while the MPP's role is to solely work on voluntary licences, all MPP licences provide flexibility to licensees to sell outside the licensed territory to countries that have issued compulsory licences in accordance with the TRIPS Agreement. These provisions have been specifically negotiated by the MPP, and agreed by patent holders. Summaries of the key features of the MPP licences are available at: http://www.medicinespatentpool.org/summaries-of-licensing-agreements/ with links to the full text of the licences, which are all publicly available.

Trends in Licensing

While until recently voluntary licensing enabling the sale of generic products in developing countries was limited to HIV, this has begun to change. Recent licences on HCV medicines, including the licence on daclatasvir by the MPP, and the recent announcement by GSK of its intention to license all its patented medicines for lower middle-income countries, will hopefully contribute to making voluntary licences for developing countries more common in other disease areas and enable availability of more affordable generics sooner in more countries. The UNHLP may wish to welcome this trend and recommend that this continue in the future in order to ensure that access-oriented licences do not remain limited to one or two diseases.

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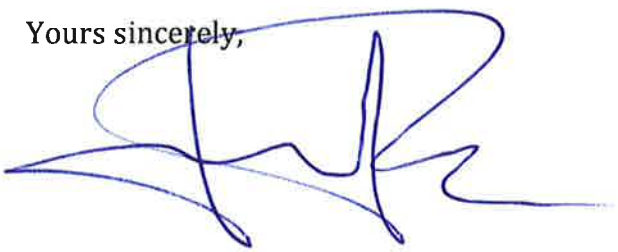
Addressing access holistically

Addressing IP issues remains a key issue in access to medicines, particularly in relation to accessing new, patented breakthrough treatments in developing countries. It is also important to highlight other access issues that also need to be addressed, including problems with healthcare systems, limited public healthcare expenditure, under financing of R&D particularly in relation to addressing specific developing country needs, problems of regulatory under capacity and market authorization delays and lack of accessible and affordable point-of-care diagnostic tools. Country graduation out of global funding will likely also have a major impact on access in certain countries, particularly among certain vulnerable groups. Finally, lack of treatment funding beyond those diseases for which global funding is available remains a major challenge for many countries. It is important that the Panel recognises the need for a holistic approach to creating solutions in access to medicines. Indeed much of the work of the MPP in creating major opportunities for accessing new breakthrough treatments for people in developing countries can only be maximized if other areas are also addressed.

I am grateful to the Panel for this opportunity to submit supplementary information and hope that these comments can contribute to your analysis. We remain available to provide any additional clarification that may be needed and very much look forward to reading the final report once it is finalized in June.

Yours sincerely,



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