To: consultation@medicinespatentpool.org.
Date: August 28, 2015
Re: Comments by James Love on behalf of KEI for the consultation regarding the MPP mandate to expand into HCV (and other diseases).

KEI has submitted joint comments with UAEM in this consultation. Here on behalf of KEI I make a few additional points.

1. We think it is important to acknowledge and appreciate the talented and highly regarded persons who collectively run the Medicines Patent Pool. The Governance Board is chaired by Charles Clift, a perceptive policy analyst and diplomat with a long history of advocacy for more equitable and inclusive access to medicines. His contributions to the UK Commission on Intellectual Property Rights, the WHO Commission on Intellectual Property Rights and Development (CIPIH), and the WHO Consultative Expert Working Group (CEWG) were enormously important. Every member who has served on the MPP Governance Board has come with a long and highly regarded record of public service. The MPP expert advisory board is chaired by Maximiliano Santa Cruz of the National Institute of Industrial Property, Chile, and includes eleven other members with deep expertise in health and intellectual property rights. The diverse membership of the expert advisory board includes many names that will be familiar to activists and policy makers in the area of health and development.

    - Achal Prabhala (Researcher and Writer, India)
    - Alexandra Calmy (Hopitaux Universitaires de Geneve, Switzerland)
    - Carlos Correa (Center for Interdisciplinary Studies, University of Buenos Aires, Argentina)
    - Eun-Joo Min (World Intellectual Property Organization, Korea)
    - Gracia Violeta Ross (Bolivian Network of Positive People, Bolivia)
    - Jonathan Berger (Advocate, Johannesburg Bar, South Africa)
    - Labeeb Abboud (International AIDS Vaccine Initiative, USA)
    - Lita Nelsen (Technology Licensing Office, Massachusetts Institute of Technology, USA)
    - Maximiliano Santa Cruz (National Institute of Industrial Property, Chile)
    - Nelson Juma Otwoma (National Empowerment Network of People Living with HIV/AIDS (NEPHAK), Kenya)
    - Shing Chang (Pharmaceutical R&D Expert, USA)
    - Wim Vandevelde (HIV and TB Treatment Advocate, Belgium)

    We would be hard pressed to name a better expert advisory board.

The MPP Executive Director Greg Perry manages a highly qualified and staff, and they have accomplished a lot. Nearly every company with significant patent rights for HIV/AIDS drugs has entered into negotiations with the MPP, and the licenses include a very impressive set of drugs, making treatment much more sustainable and effective in the developing countries. The MPP has developed excellent relationships with donors, generic and brand name companies, and many others. It is ironic that the success of the MPP in building productive relationships with patent holders is used against by the MPP by some critics, because without these relationships, few if any licenses would have been forthcoming. One could imagine a world where governments pressured companies to license to the MPP, but that would be an imaginary world. There is almost no pressure at from developing country governments to license patents to the MPP.

2. The criticism that the MPP has not achieved coverage of a larger set of countries in the licenses would be more persuasive if there had ever been any licenses negotiated for a larger set of countries, by anyone else, for any medicine patents of economic significance.

3. None of the people who argue that voluntary licenses undermine compulsory licensing efforts appear to have had experience in obtaining compulsory licenses. I have extensive experience in compulsory licensing efforts. We are involved in compulsory licensing efforts, for HCV, right now.

   Most compulsory licenses in developing countries are done pursuant to the rules of Article 31 of the WTO TRIPS agreement. This article has a general requirement that non-voluntary uses of patents:

   > "may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."

   The WTO provides for exceptions to this requirement, for public non-commercial use or emergencies, but in many national laws, the prior negotiation is required by statute. When it is not required by statute, it is often required by practice, sometimes in response to pressure from the US or the EU.

   When the MPP was first proposed, we thought that one important role for the MPP would be to ask for voluntary licenses, in order to satisfy the prior negotiation requirement. The MPP licenses also provide another important benefit -- they establish benchmarks for "reasonable commercial terms and conditions."

   It is true that if a voluntary license is forthcoming, there is no need for a compulsory license. But that's normally an advantage, because the country wants to avoid being

known for granting compulsory licenses, and it often takes a significant mobilization to get a government to act, and even with such mobilizations, few governments act, or they act rarely. We have seen just one compulsory license from India and one from Brazil. Only a handful of countries in the entire global south have issued compulsory licenses, and outside of drugs for HIV/AIDS, very few compulsory licenses have been issued at all. We wish compulsory licenses were the standard response to high prices. Today, that is not true. That is not true at all. Note that we raise money to undertake compulsory licensing efforts, and we are involved in compulsory licensing projects, year in and year out, and if anyone has money to support compulsory licensing efforts, please send some our way. We think compulsory licensing is important, even though it will not work for all drugs, all countries or all patients. Among other things, compulsory license establish an option that empowers governments and patients to challenge high prices. Compulsory licenses also encourage voluntary licensing.

4. There are some opportunities to block patents or eliminate or modify issued patents, including through pre and post grant administrative process, or litigation. This is a technically challenging and potentially expensive process. It can and will work some of the time, in some countries for some patents. It will not work all of the time, it will not work for all patents, and it will not work for all countries. It will also take time. In some countries, blocking a patent for an extended time has a perverse effect, if there is a chance the patent will eventually be granted, with retroactive liability for infringement. This is not to say that patent challenges are unimportant. When they are feasible and effective, patent challenges have large benefits regarding access, and the freedom to use inventions. But, like compulsory licensing, it is difficult to scale challenges to address all cases or the needs of all patients.

5. The subset of countries, patents and drugs where you can rely upon compulsory license or challenges to patents is unfortunately small relative to the number of patents, drugs, countries and patients that matter. In the absence of more transformative reforms, such as delinkage, voluntary licenses are a life saving mechanism that we need, and we need to manage well.

6. It is extremely difficult to create, manage and sustain an institution like the MPP, and I don't think it makes sense to limit the MPP to a single disease when you can justify broader voluntary licensing efforts for so many more diseases. How many governance structures do we want to monitor, and how much money can we raise to do this type of activity? There is a reason the leading software/computing licensing agencies manage so many different patent pools. There are large economies of scale and scope in this type of activity.

7. Rather than spending time trying to marginalize the MPP, time will be better spend seriously engaging the MPP to make more formal its accountability to the public health

community, and working with the MPP constructively to improve its negotiating objectives, practices and policies.

8. Efforts to expand access to medicines will necessarily involve many different strategies, including compulsory licensing, voluntary licensing, patent challenges, price negotiations, smarter procurement, parallel trade, and both radical and incremental reforms. If this was an academic exercise, we could be purists, favoring our preferred method. But this is not a theoretical issue, it is one where people, including many low income persons and marginalized populations, live or die, depending upon how effective are those strategies. We need to use everything that works, when it works. Voluntary licenses can be implemented poorly, lead to cartel like activity, fall short of opportunities, or have other flaws. The challenge is to obtain pro-competitive licenses that make patients better off, and avoid pitfalls. We want the MPP to expand its mandate to HCV and other diseases, including cancer, and also to develop a longer run more sustainable system of accountability with the public health community that will give the process more legitimacy and accountability.